Rules and Regulations of the State of Georgia

Department 111 RULES OF DEPARTMENT OF COMMUNITY HEALTH

Current through Rules and Regulations filed through November 2, 2022

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Rule 111-8-40-.24. Imaging and Therapeutic Radiology Services.
Rule 111-8-40-.25. Laboratory Services.
Rule 111-8-40-.26. Respiratory/Pulmonary Services.
Rule 111-8-40-.27. Organ, Tissue, and Eye Procurement and Transplantation.
Rule 111-8-40-.28. Surgical Services.
Rule 111-8-40-.29. Anesthesia Services.
Rule 111-8-40-.30. Nuclear Medicine Services.
Rule 111-8-40-.31. Emergency Services.
Rule 111-8-40-.32. Outpatient Services.
Rule 111-8-40-.33. Rehabilitation Services.

Rule 111-8-40-.34. Maternal and Newborn Services.
Rule 111-8-40-.35. Pediatric Services.
Rule 111-8-40-.36. Dialysis Services.
Rule 111-8-40-.37. Psychiatric and Substance Abuse Services.
Rule 111-8-40-.38. Special Requirements for Critical Access Hospitals.
Rule 111-8-40-.39. Special Requirements for Rural Free Standing Emergency Departments.
Rule 111-8-40-.40. Physical Plant Design and Construction.
Rule 111-8-40-.41. Requests for Waiver or Variance.
Rule 111-8-40-.42. Enforcement of Rules and Regulations.
Rule 111-8-40-.43. Severability of These Rules.
Subject 111-8-41. RULES AND REGULATIONS FOR HOSPITAL TRANSPARENCY.
Rule 111-8-41-.01. Legal Authority.
Rule 111-8-41-.02. Applicability.
Rule 111-8-41-.03. Definitions.
Rule 111-8-41-.04. Required Documentation.
Rule 111-8-41-.05. Posting Requirements.
Rule 111-8-41-.06. Enforcement.
Subject 111-8-47. INTERMEDIATE CARE HOMES.
Rule 111-8-47-.01. Definitions.
Rule 111-8-47-.02. Governing Body.
Rule 111-8-47-.03. Administration.
Rule 111-8-47-.04. Personal Care Services.
Rule 111-8-47-.05. Professional Service.
Rule 111-8-47-.06. Dietary Service.
Rule 111-8-47-.07. Social Service.
Rule 111-8-47-.08. Medications.
Rule 111-8-47-.09. Physical Therapy Service.
Rule 111-8-47-.10. Resident Care.
Rule 111-8-47-.11. Records.
Rule 111-8-47-.12. Equipment.
Rule 111-8-47-.13. Safety.
Rule 111-8-47-.14. Environmental Sanitation and Housekeeping.
Rule 111-8-47-.15. Health of Employees.
Rule 111-8-47-.16. Recreation.
Rule 111-8-47-.17. Resident Capacity.
Rule 111-8-47-.18. Physical Plant Standards.
Rule 111-8-47-.19. Application for Permit.

Rule 111-8-47-.20. Permits.
Rule 111-8-47-.21. Provisional Permits.
Rule 111-8-47-.22. Inspections.
Rule 111-8-47-.23. New Construction.
Rule 111-8-47-.24. Enforcement.
Subject 111-8-50. LONG-TERM CARE FACILITIES: RESIDENTS' BILL OF RIGHTS.
Rule 111-8-50-.01. Definitions.
Rule 111-8-50-.02. Administration.
Rule 111-8-50-.03. Notification of Rights.
Rule 111-8-50-.04. Citizenship and Personal Choice.
Rule 111-8-50-.05. Privacy.
Rule 111-8-50-.06. Management of Personal Property and Financial Affairs.
Rule 111-8-50-.07. Residential Care and Treatment.
Rule 111-8-50-.08. Refusal of Medical Treatment, Dietary Restrictions and Medications.
Rule 111-8-50-.09. Use of Restraints, Isolation and Restrictions.
Rule 111-8-50-.10. Temporary Suspension of Rights.
Rule 111-8-50-.11. Transfer and Discharge.
Rule 111-8-50-.12. Contributions to the Facility.
Rule 111-8-50-.13. Nondiscrimination.
Rule 111-8-50-.14. Grievance Procedure.
Rule 111-8-50-.15. Administrative Hearing.
Rule 111-8-50-.16. Enforcement.
Subject 111-8-53. RULES AND REGULATIONS FOR NARCOTIC TREATMENT PROGRAMS.
Rule 111-8-53-.01. Legal Authority.
Rule 111-8-53-.02. Title and Purpose.
Rule 111-8-53-.03. Definitions.
Rule 111-8-53-.04. Governing Body.
Rule 111-8-53-.05. Licenses.
Rule 111-8-53-.06. Provisional Licenses.
Rule 111-8-53-.07. Applications.
Rule 111-8-53-.08. Inspections and Plans of Correction.
Rule 111-8-53-.09. Administration.
Rule 111-8-53-.10. Staffing.
Rule 111-8-53-.11. Physical Plant and Safety.
Rule 111-8-53-.12. Patient Screening, Assessment, and Admission.
Rule 111-8-53-.13. Individual Treatment Plan.

Rule 111-8-53-.14. Discharge and Aftercare Plans.
Rule 111-8-53-.15. Narcotic Drugs.
Rule 111-8-53-.16. Drug-Screen Tests.
Rule 111-8-53-.17. Quality Improvement.
Rule 111-8-53-.18. Patient Rights, Responsibilities, and Complaints.
Rule 111-8-53-.19. Central Registry.
Rule 111-8-53-.20. Reporting to the Department.
Rule 111-8-53-.21. Enforcement and Penalties.
Rule 111-8-53-.22. Variance and Waiver.
Rule 111-8-53-.23. Severability.
Subject 111-8-56. NURSING HOMES.
Rule 111-8-56-.01. Definitions.
Rule 111-8-56-.02. Governing Body.
Rule 111-8-56-.03. Administration.
Rule 111-8-56-.04. Nursing Services.
Rule 111-8-56-.05. Professional Service.
Rule 111-8-56-.06. Dietary Service.
Rule 111-8-56-.07. Social Service.
Rule 111-8-56-.08. Pharmacy Management and Administration.
Rule 111-8-56-.09. Physical Therapy Service.
Rule 111-8-56-.10. Medical, Dental and Nursing Care.
Rule 111-8-56-.11. Records.
Rule 111-8-56-.12. Equipment.
Rule 111-8-56-.13. Safety.
Rule 111-8-56-.14. Environmental Sanitation and Housekeeping.
Rule 111-8-56-.15. Health of Employees.
Rule 111-8-56-.16. Recreation.
Rule 111-8-56-.17. Patient Capacity.
Rule 111-8-56-.18. Physical Plant Standards.
Rule 111-8-56-.19. Application for Permit.
Rule 111-8-56-.20. Permits.
Rule 111-8-56-.21. Provisional Permits.
Rule 111-8-56-.22. Inspections.
Rule 111-8-56-.23. New Construction.
Rule 111-8-56-.24. Enforcement.
Rule 111-8-56-.25. Dining Assistants.
Rule 111-8-56-.26. Background Screening and Employees.
Rule 111-8-56-.27. Vaccines.

Subject 111-8-62. PERSONAL CARE HOMES.
Rule 111-8-62-.01. Authority.
Rule 111-8-62-.02. Purposes.
Rule 111-8-62-.03. Definitions.
Rule 111-8-62-.04. Applicability of Rules and Exemptions.
Rule 111-8-62-.05. Application for Permit.
Rule 111-8-62-.06. Permits.
Rule 111-8-62-.07. Governing Body.
Rule 111-8-62-.08. Administration.
Rule 111-8-62-.09. Workforce Qualifications and Training.
Rule 111-8-62-.10. Staffing.
Rule 111-8-62-.11. Home Accountability and Inspections.
Rule 111-8-62-.12. Home Design Requirements.
Rule 111-8-62-.13. Physical Plant Health and Safety Standards.
Rule 111-8-62-.14. Furnishings and Fixtures.
Rule 111-8-62-.15. Admission.
Rule 111-8-62-.16. Admission Agreement.
Rule 111-8-62-.17. Services.
Rule 111-8-62-.18. Precautions for Residents at Risk of Elopement.
Rule 111-8-62-.19. Additional Requirements for Certified Memory Care Centers.
Rule 111-8-62-.20. Medications.
Rule 111-8-62-.21. Nutrition.
Rule 111-8-62-.22. Temperature Conditions.
Rule 111-8-62-.23. Infection Control, Sanitation and Supplies.
Rule 111-8-62-.24. Resident Files.
Rule 111-8-62-.25. Supporting Residents' Rights.
Rule 111-8-62-.26. Procedures for Change in Resident Condition.
Rule 111-8-62-.27. Death of a Resident.
Rule 111-8-62-.28. Immediate Transfer of Residents.
Rule 111-8-62-.29. Discharge or Transfer of Residents.
Rule 111-8-62-.30. Reporting.
Rule 111-8-62-.31. Deemed Status.
Rule 111-8-62-.32. Variance and Waiver.
Rule 111-8-62-.33. Enforcement and Penalties.
Rule 111-8-62-.34. Severability.
Subject 111-8-63. RULES AND REGULATIONS FOR ASSISTED LIVING COMMUNITIES.
Rule 111-8-63-.01. Authority.

Rule 111-8-63-.02. Purpose.
Rule 111-8-63-.03. Definitions.
Rule 111-8-63-.04. Exemptions.
Rule 111-8-63-.05. Application for Permit.
Rule 111-8-63-.06. Permits.
Rule 111-8-63-.07. Owner Governance.
Rule 111-8-63-.08. Community Leadership.
Rule 111-8-63-.09. Workforce Qualifications, Training and Staffing.
Rule 111-8-63-.10. Community Accountability.
Rule 111-8-63-.11. Community Design and Use Requirements.
Rule 111-8-63-.12. Community Furnishings.
Rule 111-8-63-.13. Community Safety Precautions.
Rule 111-8-63-.14. Emergency Preparedness.
Rule 111-8-63-.15. Admission and Resident Retention.
Rule 111-8-63-.16. Admission Agreements.
Rule 111-8-63-.17. Services in the Community.
Rule 111-8-63-.18. Precautions for Residents at Risk of Elopement.
Rule 111-8-63-.19. Additional Requirements for Certified Memory Care Centers.
Rule 111-8-63-.20. Medications.
Rule 111-8-63-.21. Nutrition and Food Preparation.
Rule 111-8-63-.22. Temperature Control.
Rule 111-8-63-.23. Infection Control, Sanitation and Supplies.
Rule 111-8-63-.24. Residents' Files.
Rule 111-8-63-.25. Supporting Residents Rights and Obtaining Feedback.
Rule 111-8-63-.26. Procedures for Change in Resident's Condition.
Rule 111-8-63-.27. Death of a Resident.
Rule 111-8-63-.28. Immediate Transfers of Residents.
Rule 111-8-63-.29. Discharge or Transfer of Residents.
Rule 111-8-63-.30. Reports to the Department.
Rule 111-8-63-.31. Deemed Status.
Rule 111-8-63-.32. Variances and Waivers.
Rule 111-8-63-.33. Enforcement of Licensing Requirements.
Rule 111-8-63-.34. Severability.
Subject 111-8-65. RULES AND REGULATIONS FOR PRIVATE HOME CARE PROVIDERS.
Rule 111-8-65-.01. Legal Authority.
Rule 111-8-65-.02. Title and Purposes.
Rule 111-8-65-.03. Definitions.

Rule 111-8-65-.04. Governing Body.
Rule 111-8-65-.05. Licenses.
Rule 111-8-65-.06. Applications.
Rule 111-8-65-.07. Exemptions.
Rule 111-8-65-.08. Inspections and Plans of Correction.
Rule 111-8-65-.09. Administration and Organization.
Rule 111-8-65-.10. Private Home Care Provider Services.
Rule 111-8-65-.11. Service Plans.
Rule 111-8-65-.12. Client Rights, Responsibilities, and Complaints.
Rule 111-8-65-.13. Enforcement and Penalties.
Rule 111-8-65-.14. Waivers and Variances.
Rule 111-8-65-.15. Severability.
Subject 111-8-68. RULES AND REGULATIONS FOR RESIDENTIAL MENTAL HEALTH FACILITIES FOR CHILDREN AND YOUTH.
Rule 111-8-68-.01. Legal Authority.
Rule 111-8-68-.02. Title and Purposes.
Rule 111-8-68-.03. Definitions.
Rule 111-8-68-.04. General Policies.
Rule 111-8-68-.05. Organization and Administration.
Rule 111-8-68-.06. Facilities.
Rule 111-8-68-.07. Services.
Rule 111-8-68-.08. Behavior Management and Emergency Safety Interventions.
Rule 111-8-68-.09. Waivers and Variances.
Rule 111-8-68-.10. Enforcement and Penalties.
Rule 111-8-68-.11. Severability.
Subject 111-8-71. TRAUMATIC BRAIN INJURY FACILITIES.
Rule 111-8-71-.01. Legal Authority.
Rule 111-8-71-.02. Purpose.
Rule 111-8-71-.03. Definitions.
Rule 111-8-71-.04. Governing Body.
Rule 111-8-71-.05. Permits.
Rule 111-8-71-.06. Applications.
Rule 111-8-71-.07. Inspections.
Rule 111-8-71-.08. Admissions.
Rule 111-8-71-.09. Client Assessment and Individual Program Planning.
Rule 111-8-71-.10. Recordkeeping.
Rule 111-8-71-.11. Treatment and Rehabilitative Care.
Rule 111-8-71-.12. Physical Environment and Safety.

Rule 111-8-71-.13. Disaster Preparedness.
Rule 111-8-71-.14. Dining and Food Service.
Rule 111-8-71-.15. Variances and Waivers.
Rule 111-8-71-.16. Enforcement.
Rule 111-8-71-.17. Severability.
Subject 111-8-90. RULES AND REGULATIONS FOR X-RAY.
Rule 111-8-90-.01. General Provisions.
Rule 111-8-90-.02. Registration.
Rule 111-8-90-.03. Standards for Protection against Radiation.
Rule 111-8-90-.04. X-Rays in the Healing Arts.
Rule 111-8-90-.05. Radiation Safety Requirements for Particle Accelerators.
Rule 111-8-90-.06. Radiation Safety Requirements for the Use of Non-Medical X-Ray.
Rule 111-8-90-.07. Records, Reports and Notifications.
Rule 111-8-90-.08. Penalties.
Rule 111-8-90-.09. Enforcement.
Subject 111-8-91. RULES AND REGULATIONS FOR LASER RADIATION.
Rule 111-8-91-.01. Definitions.
Rule 111-8-91-.02. Registration.
Rule 111-8-91-.03. Injury Reporting.
Rule 111-8-91-.04. Report of Discontinuance.
Rule 111-8-91-.05. Laser System Exempt from Registration.
Rule 111-8-91-.06. Enforcement.
Subject 111-8-100. RULES AND REGULATIONS FOR PROXY CAREGIVERS USED IN LICENSED HEALTHCARE FACILITIES.
Rule 111-8-100-.01. Legal Authority.
Rule 111-8-100-.02. Title and Purpose.
Rule 111-8-100-.03. Definitions.
Rule 111-8-100-.04. Use of Proxy Caregivers and Informed Consent.
Rule 111-8-100-.05. Training and Other Requirements for Proxy Caregivers.
Rule 111-8-100-.06. Variances and Waivers.
Rule 111-8-100-.07. Enforcement.
Rule 111-8-100-.08. Severability.
Chapter 111-9. PUBLIC HEALTH.
Subject 111-9-1. REPEALED.
Rule 111-9-1-.01. Legal Authority.
Rule 111-9-1-.02. Title and Purpose.
Rule 111-9-1-.03. Definitions.

Rule 111-9-1-.04. Purpose and Administration.
Rule 111-9-1-.05. Vendor Terms and Conditions.
Rule 111-9-1-.06. Vendor Administrative Review, Hearings and Appeals.

ADMINISTRATIVE HISTORY

The **Administrative History** following each Rule gives the date on which the Rule was originally filed and its effective date, as well as the date on which any amendment or repeal was filed and its effective date. Principal abbreviations used in the Administrative History are as follows:

f. - filed

eff. - effective

R. - Rule (Abbreviated only at the beginning of the control number)

Ch. - Chapter (Abbreviated only at the beginning of the control number)

ER. - Emergency Rule

Rev. - Revised

Note: Emergency Rules are listed in each Rule's Administrative History by Emergency Rule number, date filed and effective date. The Emergency Rule will be in effect for 120 days or until the effective date of a permanent Rule covering the same subject matter superseding this Emergency Rule is adopted, as specified by the Agency.

Chapter 111-1-2 entitled "Vendor Relationships" has been adopted. Filed January 21, 2004; effective February 10, 2004.

Chapter 111-3-8 entitled "Estate Recovery" has been adopted. Filed July 16, 2004; effective August 5, 2004.

Rules 111-3-8-.01 to .04, and .08 have been amended. Filed August 17, 2004; effective September 6, 2004.

Chapters 111-2-1 entitled "Administration", 111-2-2 entitled "Certificate of Need", 111-2-3 entitled "Patient's Right to Independent Review", and 111-2-4 entitled "Rural Hospital Assistance Act" have been adopted. Filed December 16, 2004; effective January 5, 2005.

Rule 111-2-2-.21 has been amended. Chapter 111-4-1 entitled "State Health Benefit Plan" has been adopted. Filed April 18, 2005; effective May 8, 2005.

Emergency Rule 111-4-1-0.1-.03 and .06 adopted. Filed June 13, 2005; effective June 16, 2005, as specified by the Agency, to be in effect for 120 days or until the effective date of a permanent Rule covering the same subject matter superseding this Emergency rule is adopted, as specified by the Agency. This Emergency Rule was adopted to insure all subscribers were aware of the requirement to reenroll electronically for the State Health Insurance Plan. (This Emergency Rule will not be published; copies may be obtained from the Agency.)

Rule 111-3-8-.07 has been amended. Rules 111-4-1-.03 and .06 have been amended superseding Emergency Rule 111-4-1-0.1-.03 and .06. Filed September 15, 2005; effective October 5, 2005.

Rules 111-2-2-.36 and .43 has been adopted. Filed November 17, 2005; effective December 7, 2005.

Chapter 111-3-6 entitled "Indigent Care Trust Fund" has been adopted. Filed May 31, 2006; effective June 20, 2006.

Chapter 111-5-1 entitled "Georgia Volunteer Health Care Program" has been adopted. Filed June 13, 2006; effective July 3, 2006.

Rules 111-2-2-.06 and .10 have been amended. Filed August 28, 2006; effective September 17, 2006.

Rules 111-4-1-.02, and .07 have been amended. Filed September 26, 2006; effective October 16, 2006.

Chapter 111-3-8 has been amended. Filed October 19, 2006; effective November 8, 2006.

Rules 111-2-2-.26, .34 to .36 have been amended. Filed November 22, 2006; effective December 12, 2006.

Chapter 111-4-1 has been repealed and a new Chapter adopted. Filed January 22, 2007; effective February 11, 2007.

Rules 111-4-1-.02, 111-4-1-.04 to 111-4-1-.06 have been amended. Filed May 25, 2007; effective June 14, 2007.

Rule 111-4-1-.10 has been amended. Filed September 28, 2007; effective October 18, 2007.

Rule 111-4-1-.01 has been amended. Rule 111-4-1-.13 has been adopted. Filed October 15, 2007; effective November 4, 2007.

Rules 111-2-2-.07, .09, .33, and .34 have been amended. Filed November 13, 2007; effective December 3, 2007.

Rules 111-2-2-.11 and .40 have been amended. Filed December 14, 2007; effective January 3, 2008.

Rules 111-3-6-.01 and .03 have been amended. Filed March 3, 2008; effective March 23, 2008.

Rules 111-2-2-.41 and .42 have been repealed and new Rules adopted. Rule 111-2-2-.43 has been repealed. Filed May 13, 2008; effective June 2, 2008.

Rules 111-4-1-.02, .04, and .10 have been amended. Filed August 20, 2008; effective September 9, 2008.

Rule 111-2-1-.01, .02, 111-2-2-.01, .03 to .11, .20, .21, .24, .31, .33, .34, and .40 have been amended. Filed September 11, 2008; effective October 1, 2008.

Rules 111-2-2-.10 and .20 have been amended. Filed November 14, 2008; effective December 4, 2008.

Rule 111-2-2-.07 has been amended. Filed January 21, 2009; effective February 10, 2009.

Rules 111-2-2-.03 and 111-4-1-.06 have been amended. Filed May 1, 2009; effective May 21, 2009.

Rules 111-5-1-.01, .02, .04 to .06, and .14 have been amended. Filed August 26, 2009; effective September 15, 2009.

Rule 111-4-1-.06 has been amended. Filed October 16, 2009; effective November 5, 2009.

Chapter 111-8-62 entitled "Personal Care Homes" has been adopted. Filed November 19, 2009; effective December 9, 2009.

Rule 111-2-2-.32 has been repealed and a new Rule adopted. Filed February 16, 2010; effective March 8, 2010.

Chapter 111-8-25 entitled "Enforcement of Licensing Requirements" has been adopted. Filed March 17, 2010; effective April 6, 2010.

Rules 111-4-1-.01, .02, .10, and .11 have been repealed and new Rules adopted. Chapter 111-9-1 entitled "The Special Supplemental Nutrition Program for Women, Infants and Children (WIC)" has been adopted. Filed April 14, 2010; effective May 4, 2010.

Chapter 111-8-25 entitled "General Licensing and Enforcement Requirements" containing Rules 111-5-25-.01, .02, .03, .05, and .06 have been repealed and new Rules and titles adopted. Chapter 111-8-68 entitled "Rules and Regulations for Residential Mental Health Facilities for Children and Youth" has been adopted. Filed July 14, 2010; effective August 3, 2010.

Rules 111-4-1-.01, 111-4-1-.02, 111-4-1-.04, 111-4-1-.05, and 111-4-1-.09 amended. F. Jan. 26, 2011; eff. Feb. 16, 2011.

Chapter 111-9-2 adopted. F. Jun. 10, 2011; eff. Jun. 30, 2011.

Chapter 111-8-100 adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.

Chapters 111-8 and 111-8-63 adopted. F. Dec. 13, 2011; eff. Jan. 2, 2012.

Rules 111-4-1-.01, .02, .04, .05, and .09 amended. F. Jan. 26, 2012; eff. Feb. 16, 2012.

Chapter 111-9-2 repealed (see Chapter 511-9-2). F. Dec. 14, 2011; eff. Jan. 3, 2012.

Chapter 111-9-1 repealed (see Chapter 511-8-1). F. Jan. 4, 2012; eff. Jan. 24, 2012.

Rules 111-4-1-.01, .02, .04, .06 amended. F. Jan. 17, 2012; eff. Feb. 6, 2012.

Rule 111-8-25-.03 amended. F. Aug. 22, 2012; eff. Sep. 11, 2012.

Rules 111-8-62-.01 through 111-8-62-.34 amended. F. Dec. 19, 2012; eff. Jan. 8, 2013.

Chapters 111-8-4, 111-8-5, 111-8-9, 111-8-10, 111-8-22, 111-8-28, 111-8-31, 111-8-40, 111-8-50, 111-8-56, 111-8-65 adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Chapters 111-3-9 and 111-3-10 adopted. F. May 13, 2013; eff. Jun. 2, 2013.

Chapters 111-8-16, 111-8-19, 111-8-53, 111-8-71 adopted. F. Sep. 9, 2013; eff. Sep. 29, 2013.

Chapter 111-5-1 repealed (see Chapter 511-7-1). F. Sep. 20, 2013; eff. Oct. 10, 2013.

Chapter 111-8-1 adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Chapter 111-8-37 adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-65-.03 amended. F. Mar. 17, 2016; eff. Apr. 6, 2016.

Chapter 111-8-47 entitled "Intermediate Care Homes" adopted. Rules 111-8-10-.03, .06, 111-8-56-.03, .19, 111-8-63-.24 amended. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rules 111-8-22-.09, .11, .12, .14 amended. F. May 9, 2017; eff. May 29, 2017.

Rules 111-8-53-.03, .05, .07 through .17, .19, .20 amended; Rule 111-8-53-.22 repealed and new rule adopted; Rule 111-8-53-.23 adopted. F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rules 111-8-10-.03, 111-8-16-.01 through .03, 111-8-37-.18, 111-8-56-.10 amended. F. Mar. 19, 2018; eff. Apr. 8, 2018.

Note: Correction of typographical error in Rules 111-8-63-.03, .14, .16 History on SOS Rules and Regulations website. In accordance with *Official Compilation Rules and Regulations of the Stare of Georgia*, eff. Jan. 2, 2012, original filed date, "Dec. 13, 2012", corrected to "Dec. 13, 2011." Effective May 6, 2018.

Rules 111-8-62-.03, .08, .16; 111-8-63-.03, .14, .16; 111-8-100-.03, .04, .05 amended. F. Apr. 16, 2018; eff. May 6, 2018.

Rules 111-2-2-.01, .03 amended. F. Oct. 19, 2018; eff. Nov. 8, 2018.

Subject 111-8-12 entitled "Rules and Regulations for Criminal Background Checks" adopted. F. Aug. 14, 2019; eff. Sep. 3, 2019.

Subject 111-8-41 entitled "Rules and Regulations for Hospital Transparency" adopted. F. Dec. 12, 2019; eff. Jan. 1, 2020.

Rules 111-8-37-.07, .08, .11, .13, .21; 111-8-62-.03, .09, .11; 111-8-63-.03, .09, .10, .20 amended. F. Feb. 28, 2020; eff. Mar. 19, 2020.

Rules 111-3-8-.01 through .08 amended. F. Mar. 27, 2020; eff. Apr. 16, 2020.

Chapter 111-4, adoption of the title "State Health Benefit Plan," as filed by Agency after discovery that title was omitted in original filing. "Subjects 111-3-12 entitled "Rules and Regulations for Hospital Care for the Indigent," 111-8-7 entitled "Rules and Regulations for Birth Centers," 111-8-29 entitled "Rules and Regulations for Health Maintenance Organizations," 111-8-90 entitled "Rules and Regulations for X-Ray," 111-8-91 entitled "Rules and Regulations for Laser Radiation" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rules 111-8-16-.01, .02, .04 through .10 amended, Rule 111-8-16-.11 adopted. F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rules 111-8-25-.02, .03, .05 amended. F. Apr. 16, 2021; eff. May 6, 2021.

Rules 111-8-62-.07 through .10, .13, .15, .17 through .20, .23; 111-8-63-.03, .05, .07 through .10, .17 through .19, .23, amended. F. Aug. 24, 2021; eff. Sep. 13, 2021.

Subject 111-8-13 entitled "Rules and Regulations for the Georgia Caregiver Registry" adopted. F. Nov. 30, 2021; eff. Dec. 20, 2021.

Rules 111-8-56-.01, .03, .04 amended. F. Dec. 29, 2021; eff. Jan. 18, 2022.

Subjects 111-2-1, 111-2-2 amended. F. Mar. 11, 2022; eff. Mar. 31, 2022.

Subject 111-3-11 entitled "Hospital Directed Payment Program" adopted. F. July 20, 2022; eff. Aug. 9, 2022.

Subject 111-3-14 entitled "Ambulance Provider Matching Payment Program" adopted. F. Aug. 15, 2022; eff. Sep. 4, 2022.

Rules 111-2-2-.07, 111-8-4-.24, 111-8-7-.22 amended. F. Oct. 14, 2022; eff. Nov. 3, 2022.

Chapter 111-1. ADMINISTRATION.

Subject 111-1-2. VENDOR RELATIONSHIPS.

Rule 111-1-2-.01. Definitions.

(1) "Lobbyist" shall have the meaning given in O.C.G.A. § 21-5-70(6) as it presently exists or as it may hereafter be amended. In addition, for the purpose of these regulations, the term shall also be deemed to include:

(a) any person who, for compensation, either individually or as an employee of another person, corporation, or association, undertakes to influence a public employee or state agency in the selection of a vendor to supply any goods or services to any state agency where the total value of any single contract, including authorized or anticipated renewals, exceeds $50,000 in value or where the total value of all contracts the lobbyist promotes or opposes, including authorized or anticipated renewals, exceeds $100,000 in a calendar year, but does not include a person solely on the basis that such person participated in preparing a written bid, written proposal, bid protest, or other document relating to a potential involvement with or sale to the Department; or

(b) any natural person who makes expenditures totaling more than $250.00 in a calendar year, not including the person's own travel, food, and lodging expenses, or informational material, to promote or oppose the awarding of any contract to a particular vendor or vendors by the Department where the total value of any single contract, including authorized or anticipated renewals, exceeds $50,000 in value or where the total value of all contracts the lobbyist promotes or opposes, including authorized or anticipated renewals, exceeds $100,000 in a calendar year.

(2) "Department" means the Department of Community Health, any division, section, or unit of the Department, and any agency attached to the Department for administrative purposes.

(3) "Public employee" shall have the meaning given in O.C.G.A. § 45-1-6(a)(4) as it presently exists or as it may hereafter be amended. In addition, for the purpose of these

regulations, the term shall also be deemed to include all persons holding a state elective office.

(4) "Vendor" shall have the meaning given in O.C.G.A. § 45-1-6(a)(5) as it presently exists or as it may hereafter be amended. For the purpose of these regulations, a person seeking or opposing a certificate of need shall also be deemed to be a vendor.

(5) "Contract" shall mean any agreement, written or verbal, by which the Department agrees to purchase goods and/or services from a vendor. For the purpose of these regulations, the term shall also be deemed to include a certificate of need.

(6) "Certificate of need" shall have the meaning given in Article 3 of Chapter 6 of Title 31 of the Official Code of Georgia Annotated as it presently exists or as it may hereafter be amended. The term shall further include the determination by the Department that a project is exempt from the requirements of Article 3 of Chapter 6 of Title 31 of the Official Code of Georgia Annotated.

(7) "Person" shall mean an individual, partnership, committee, association, corporation, labor organization, or any other organization or group of persons.

Cite as Ga. Comp. R. & Regs. R. 111-1-2-.01
Authority: O.C.G.A. Secs. 21-5-70*et seq.*, 45-1-6.
History. Original Rule entitled "Definitions" adopted. F. Jan. 21, 2004; eff. Feb. 10, 2004.

Rule 111-1-2-.02. Registration Requirements.

(1) All current or prospective vendors who employ, retain, or associate one or more lobbyists shall require such lobbyists to register with the State Ethics Commission in accordance with the provisions of Article 4 of Chapter 5 of Title 21 of the Official Code of Georgia Annotated.

(2) All current or prospective vendors who employ, retain, or associate one or more lobbyists shall require such lobbyists to file the disclosures required by Article 4 of Chapter 5 of Title 21 of the Official Code of Georgia Annotated.

(3) In addition to the disclosures required by Article 4 of Chapter 5 of Title 21 of the Official Code of Georgia Annotated, such lobbyists shall further disclose:

   (a) the name of any vendor(s) by which the lobbyist is employed, retained, or associated;

   (b) an identification of the contract(s) regarding which the lobbyist is lobbying, including the contract or procurement number, if one has been assigned by the Department; and

(c) a good faith estimate of the total amounts of all income to the lobbyist from the vendor (or from any other person on behalf of the vendor) other than income for matters unrelated to lobbying.

(4) The disclosures made to the State Ethics Commission pursuant to this Chapter shall be considered to be "information voluntarily supplied" pursuant to O.C.G.A. § 21-5-6(b)(3).

(5) The registrations and disclosures to the State Ethics Commission pursuant to this Chapter shall be cumulative of, and shall not supplant or substitute for, any reports required to be made by O.C.G.A. § 45-1-6.

Cite as Ga. Comp. R. & Regs. R. 111-1-2-.02
Authority: O.C.G.A. Secs. 21-5-70*et seq.*, 45-1-6.
History. Original Rule entitled "Registration Requirements" adopted. F. Jan. 21, 2004; eff. Feb. 10, 2004.

Rule 111-1-2-.03. Certification Requirements.

(1) All current or prospective vendors who submit a bid, response to request for proposals, or any response to any other procurement method, shall certify:

(a) that the vendor has not employed, retained, or associated one or more lobbyists required to register with the State Ethics Commission in accordance with these regulations; or

(b) that any lobbyist employed, retained, or associated by the vendor has registered with the State Ethics Commission and made the disclosures required by law and by these regulations.

(2) Any vendor who submits an application for a certificate of need, confirmation of status, letter of non-reviewability, or opposition to any such application or letter, shall certify:

(a) that the vendor has not employed, retained, or associated one or more lobbyists required to register with the State Ethics Commission in accordance with these regulations; or

(b) that any lobbyist employed, retained, or associated by the vendor has registered with the State Ethics Commission and made the disclosures required by law and by these regulations.

Cite as Ga. Comp. R. & Regs. R. 111-1-2-.03
Authority: O.C.G.A. Sec. 21-5-70*et seq.*
History. Original Rule entitled "Certification Requirements" adopted. F. Jan. 21, 2004; eff. Feb. 10, 2004.

Rule 111-1-2-.04. Forms.

(1) The registration of lobbyists as required by these regulations shall be made on forms prescribed by and in the manner prescribed by the State Ethics Commission.

(2) The disclosures required of lobbyists by these regulations shall be made on forms prescribed by and in the manner prescribed by the State Ethics Commission.

(3) The certifications required of vendors by these regulations shall be made on forms prescribed by and in the manner prescribed by the Department.

(4) The Department will not execute any contract with any vendor that fails to make the certifications required by these regulations, and may rescind any previously executed contract upon a determination that any certification contained misrepresentations or falsehoods. Such misrepresentations or falsehoods may, in the sole discretion of the Department, be deemed to be a material breach of the contract by the vendor.

Cite as Ga. Comp. R. & Regs. R. 111-1-2-.04
Authority: O.C.G.A. Secs. 21-5-70*et seq.*,45-1-6, 45-12-130 *et seq.*
History. Original Rule entitled "Forms" adopted. F. Jan. 21, 2004; eff. Feb. 10, 2004.

Chapter 111-2. HEALTH PLANNING.

Subject 111-2-1. ADMINISTRATION.

Rule 111-2-1-.01. Definitions.

(1) "Board" means the Board of Community Health, the body created under O.C.G.A. § 31-2-3, appointed by the Governor, that establishes the general policy to be followed by the Department of Community Health.

(2) "Certificate of Need Appeal Panel" or "appeal panel" means the panel of independent hearing officers created pursuant to O.C.G.A. § 31-6-44 to conduct appeal hearings.

(3) "Commissioner" means the commissioner of community health established under O.C.G.A. § 31-2-6.

(4) "Department" means the Department of Community Health established under O.C.G.A. § 31-2-4.

(5) "Health Strategies Council" or "Council" means the body created by this chapter to advise the Department of Community Health.

Cite as Ga. Comp. R. & Regs. R. 111-2-1-.01
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Definitions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-1-.02. Health Planning Functions of the Department.

(1) The Department is authorized to administer the health planning and Certificate of Need programs established under O.C.G.A. § 31-6*et seq.* and a state health plan approved by the Board. The Department shall provide by rule for procedures to administer its functions. As appropriate, the Commissioner may delegate the authority to administer any function or duty prescribed by law or these Rules to one or more authorized designees in the Office of Health Planning and the Office of General Counsel.

(2) The functions of the Department shall be:

(a) to conduct the health planning activities of the State and, within appropriations made available by the General Assembly and consistent with the laws of the State of Georgia, to implement such parts of the State Health Plan as may relate to State government;

(b) to prepare and revise a draft State Health Plan with recommendations from technical advisory committees;

(c) to seek advice, at its discretion, from technical advisory committees;

(d) to adopt, promulgate, and implement rules and procedures necessary to carry out the provisions of O.C.G.A. § 31-6*et seq.* in accordance with O.C.G.A. § 50-13*et seq.*, the Georgia Administrative Procedure Act.

(e) to define the form, content, schedules, fees, and procedures for submission of applications for Certificates of Need, other determinations and periodic reports;

(f) to establish time periods and procedures consistent with O.C.G.A. § 31-6*et seq.* to hold hearings and to obtain the viewpoints of interested persons prior to issuance or denial of a Certificate of Need;

(g) to provide for such payment as may be necessary to share the costs of preparing the record for Certificate of Need appeals before the Certificate of Need Appeal Panel;

(h) to provide for a reasonable and equitable fee schedule for Certificate of Need applications; provided, however, that a Certificate of Need application filed by or on behalf of a hospital in a rural county shall be exempt from any such fee;

(i) to grant, deny, suspend, rescind, cancel, or revoke a Certificate of Need as applied for or as amended;

(j) to impose civil penalties as permitted or required by law for violation of these Rules and O.C.G.A. § 31-6*et seq.*; and

(k) to study the amount of uncompensated indigent and charity care provided by each type of health care facility, recommend requirements for the levels of uncompensated indigent and charity care required to be performed by each health care facility type and develop standardized reporting requirements for the Department to accurately track the amount of uncompensated indigent and charity care provided by each health care facility.

(3) The Commissioner shall have the power to establish and abolish technical advisory committees as he or she deems necessary, in consultation with the board, to inform effective strategy development and execution.

Cite as Ga. Comp. R. & Regs. R. 111-2-1-.02
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Health Planning Functions of the Department" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Subject 111-2-2. CERTIFICATE OF NEED.

Rule 111-2-2-.01. Definitions.

As used in these Rules, the term:

(1) "Acquisition of an existing health care facility" means to come into possession or control of a health care facility by purchase, gift, merger of corporations, lease, purchase of stock, inheritance, or by any other legal means.

(2) "Acquisition of diagnostic or therapeutic equipment":

(a) as it relates to a diagnostic, treatment, or rehabilitation center, means to come into possession, or control of, or to otherwise use diagnostic or therapeutic equipment by purchase, gift, donation, lease, transfer, or by any other legal means by or on behalf of the diagnostic, treatment, or rehabilitation center; and

(b) as it relates to a health care facility, means to come into possession or control of diagnostic or therapeutic equipment by purchase or lease by or on behalf of the health care facility.

(3) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services ("CMS"), by the Georgia Division of Medical Assistance ("DMA"), by the State Health Benefit Plans, or by any successor entities as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed 24 hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(4) "Ambulatory surgical or obstetrical facility", as defined at O.C.G.A. § 31-6-2(1), means a public or private facility, not a part of a hospital, which provides surgical or obstetrical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization.

(5) "Applicant" means the owner or lessee of an existing health care facility or the person who would be the owner or lessee of a proposed facility, as named in the application. An applicant may also be multiple owners or lessees of existing health care facilities who share common ownership or corporate affiliation and wish to submit an application to the Department for a single Certificate of Need for certain non-clinical health services, for example, but not limited to, parking decks, infrastructure improvement or replacement, and capital renovation expenditures.

(6) "Application", as defined at O.C.G.A. § 31-6-2(2), means a written request for a Certificate of Need made to the Department, containing such documentation and information as the Department may require.

(7) "Approved date" means the date that the Department issues a Certificate of Need to an applicant.

(8) "Associated with and simultaneously developed or proposed" means that if the Department determines that a single project or the substantial equivalent of a single project is divided into separate components which are associated and which are developed or planned simultaneously, so that the project or the substantial equivalent of a project or any component thereof does not require a total capital expenditure in excess of the capital expenditure or diagnostic or therapeutic equipment threshold, the Department shall combine the components for purposes of computing the amount of the total capital expenditure or expense and shall treat the combined components as a single project or substantial equivalent of a project. The Department shall include items and expenditures which are related and which occur simultaneously in computing an applicable threshold regardless of whether the items or expenditures individually may otherwise be below the threshold or may be otherwise unreviewable exclusive of the items exempted from review by 111-2-2-.03(1) - (3) and 111-2-2-.03(5) - (19);

(a) The Department may determine that activities, services, expenditures, and items are associated if they share a relationship or association based on law, regulation, definition, function, procedure, or process; and

(b) The Department shall determine that expenditures related to activities, services, and items are simultaneously developed or planned if such expenditures occur within a 6-month period. The 6-month period shall run from operation of the activity, service or item to initial capital expenditure on the second activity or item or from operation of the activity or item to operation of the second activity or item. For services, the date of operation shall be the date that the service is actually offered. If applicable, for facilities, the date of operation shall be the date a Certificate of Occupancy is issued.

(9) **Reserved.**

(10) "Basic perinatal services" means providing basic inpatient care for pregnant women and newborns without complications; managing perinatal emergencies; consulting with and referring to specialty and subspecialty hospitals; identifying high-risk pregnancies; providing follow-up care for new mothers and infants; and providing public/community education on perinatal health.

(11) "Bed capacity", as defined at O.C.G.A. § 31-6-2(4), means space used exclusively for inpatient care, including space designed or remodeled for inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by Rules of the Department, except that single beds in single rooms shall be counted even if the room contains inadequate square footage.

(12) "By or on behalf of" means any expenditures made by a health care facility, a political subdivision of the State, a diagnostic, treatment, or rehabilitation center, or a hospital authority, itself as well as capital expenditures made by other persons or related entities to assist the facility, subdivision, center, or authority, directly or indirectly, to offer services to its patients or residents. Related entities include entities that are associated or affiliated with, have control over or are controlled by, or have any direct financial interest in, the health care facility, political subdivision of the State, diagnostic, treatment, or rehabilitation center, or hospital authority, including, without limitation, an underwriter, guarantor, parent organization, sister organization, subsidiary or sub-entity, foreign corporation, joint venturer, partner, general partner, or building lessor, as applicable.

(13) "Capital expenditure" in relation to a proposed modification, renovation, or addition to a health care facility or to a diagnostic, treatment, or rehabilitation center, or acquisition of equipment, means an expenditure by or on behalf of a health care facility or diagnostic, treatment, or rehabilitation center that, under generally accepted accounting principles, is not properly chargeable as an expense of operation or maintenance. Any series of capital expenditures, each less than a threshold, but which when taken together are in excess of a threshold, directed toward the accomplishment of a single project, requires a Certificate of Need. Any series of capital expenditures, which are associated and simultaneously developed or proposed, will be presumed to be a single project. In

calculating the capital expenditure for modifications, additions, or renovations "capital expenditure" is the amount per construction bid or total amount of invoices or purchase orders for the single project excluding diagnostic, therapeutic, or other imaging equipment.

(14) "Certificate of Need" or "CON", as defined at O.C.G.A. § 31-6-2(6), means an official finding by the Department, evidenced by certification issued pursuant to an application, that the action proposed in the application satisfies and complies with the criteria contained in the Statute and Rules promulgated thereto.

(15) **Reserved.**

(16) "Clinical health services", as defined at O.C.G.A. § 31-6-2(8), means diagnostic, treatment, or rehabilitative services provided in a health care facility and includes, but is not limited to, the following: radiology and diagnostic imaging, such as magnetic resonance imaging and positron emission tomography (PET); radiation therapy; biliary lithotripsy; surgery; intensive care; coronary care; pediatrics; gynecology; obstetrics; general medical care; inpatient nursing care, whether intermediate, skilled or extended care; cardiac catheterization; open heart surgery; inpatient rehabilitation; and alcohol, drug abuse, and mental health services.

(17) "Consumer", as defined at O.C.G.A. § 31-6-2(10), means a person who is not employed by any health care facility or provider and who has no financial or fiduciary interest in any health care facility or provider.

(18) "Cost estimate" means an estimate of the total cost of a project's development and construction prepared by a licensed architect or engineer within sixty days prior to the date of submittal of an application.

(19) "Defined location," as it relates to the approved location of a project or substantial equivalent of a project, means the address of the project, or in the case of a health care facility or diagnostic, treatment, or rehabilitation center with multiple addresses, the campus of such health care facility or diagnostic, treatment, or rehabilitation center. However, in no case shall a campus be considered a single defined location if varying locations and facilities of such campus are more than 3 miles apart or within more than one county.

(20) "Destination cancer hospital" means an institution with a licensed bed capacity of fifty (50) or less which provides diagnostic, therapeutic, treatment, and rehabilitative care services to cancer inpatients and outpatients, by or under the supervision of physicians, and whose proposed annual patient base is composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia.

(21) "Develop", as defined at O.C.G.A. § 31-6-2(14), with reference to a project, means constructing, remodeling, installing, or proceeding with a project, or any part of a project, or a capital expenditure project, the cost estimate which exceeds $10 million. Notwithstanding the provisions of this paragraph, the expenditure or commitment or

incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications, or working drawings, or to acquire, develop, or prepare sites shall not be considered to be the developing of a project.

(22) "Diagnostic imaging" means magnetic resonance imaging, computed tomography (CT) scanning, positron emission tomography (PET) scanning, positron emission tomography/computed tomography, and other advanced imaging services as defined by the Department by rule, but such term shall not include X-rays, fluoroscopy, or ultrasound services.

(23) "Diagnostic, treatment, or rehabilitation center", as defined at O.C.G.A. § 31-6-2(16), means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting which is not part of a hospital; provided, however, that any such diagnostic, treatment, or rehabilitation center that offers or proposes to offer surgery in an operating room environment and to allow patients to remain more than twenty-three (23) hours shall be considered a hospital for purposes of O.C.G.A. § 31-6, et seq.

(24) "Effective date" means:

(a) for approved projects that have not been appealed pursuant to the appeal provisions of the Rules of the Certificate of Need Appeal Panel, the approved date;

(b) for projects, which are appealed pursuant to the appeal provisions of the Rules of the Certificate of Need Appeal Panel, the date of the final resolution of any such administrative appeal if the resolution results in the approval of the project; or

(c) for projects which undergo judicial review, the effective date shall be the date referenced in (b) above, unless the Department, pursuant to Ga. Comp. R & Regs. r. 111-2-2-.07(2)(h), or the reviewing court stays the effective date of the project pending the outcome of the judicial review. If the Department or the reviewing court stays the effective date, the effective date shall be the date of the final resolution of any such judicial review if the resolution results in approval of the project.

(25) "Expiration date" is the date upon which a Certificate of Need expires and becomes null and void.

(26) "Functionally related diagnostic or therapeutic equipment" means that pieces of diagnostic, therapeutic, or other imaging equipment are interdependent to the extent that one piece of equipment is unable to function in the absence of or without the functioning piece or equipment, or that pieces of equipment are normally used together in the provision of a single health care facility or diagnostic, treatment, or rehabilitation center service.

(27) "General cancer hospital" means an institution which was an existing and approved destination cancer hospital as of January 1, 2019; has obtained final Certificate of Need approval for conversion from a destination cancer hospital to a general cancer hospital in accordance with O.C.G.A. § 31-6-40.3; and offers inpatient and outpatient diagnostic, therapeutic, treatments, and rehabilitative cancer care service or other services to diagnose or treat co-morbid medical conditions or diseases of cancer patients so long as such services do not result in the offering of any new or expanded clinical health service that would require a Certificate of Need under this chapter unless a Certificate of Need or letter of determination has been obtained for such new or expanded services.

(28) "Health care facility", as defined at O.C.G.A. § 31-6-2(17), means hospitals; destination cancer hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes; ambulatory surgical or obstetrical facilities; freestanding emergency departments or facilities not located on a hospital's primary campus; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitation centers, but only to the extent that O.C.G.A. § 31-6-40(a)(3) or (7) or both are applicable thereto.

(29) "Health maintenance organization", as defined at O.C.G.A. § 31-6-2(18), means a public or private organization organized under the laws of this state which:

(a) provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physicians' services, hospitalization, laboratory, X-ray, emergency and preventive services, and out-of-area coverage;

(b) is compensated, except for co-payments, for the provision of the basic health care services listed in subparagraph (a) of this paragraph to enrolled participants on a predetermined periodic rate basis; and

(c) provides physicians' services primarily:

1. directly through physicians who are either employees or partners of such organization; or

2. through arrangements with individual physicians organized on a group practice or individual practice basis.

(30) "Home health agency", as defined at O.C.G.A. § 31-6-2(20), means a public agency or private organization, or a subdivision of such an agency or organization, which is primarily engaged in providing to individuals who are under a written plan of care of a physician, on a visiting basis in the places of residence used as such individuals' homes, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the following services:

(a) physical therapy;

(b) occupational therapy;

(c) speech therapy;

(d) medical social services under the direction of a physician; or

(e) part-time or intermittent services of a home health aide.

(31) "Hospital", as defined at O.C.G.A. § 31-6-2(21), means an institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. Such term includes public, private, psychiatric, rehabilitative, geriatric, osteopathic, micro-hospitals, general cancer hospitals, and other specialty hospitals.

(32) "Incur a financial obligation", in relation to the offering of a new institutional health service, means that, within time periods described in Ga. Comp. R. & Regs. r. 111-2-2-.02(5) and (6) of these Rules, the applicant has fulfilled the following performance requirements.

(a) With regard to new construction or renovation:

1. has acquired title, an option to purchase or a leasehold to an appropriate site;

2. has filed with the Department the complete set of plans, drawings, and specifications for the project in the electronic format designated by the Department;

3. has obtained a firm commitment for adequate capital financing; and

4. has entered into a construction contract that provides for a specific date for commencement, and completion of construction within a reasonable time span.

With regard to equipment not associated with a construction project;

1. a purchase or lease agreement has been entered into or, if acquired by a comparable arrangement, the applicant has possession of the equipment.

(33) **Reserved.**

(34) "Intermediate care facility", as defined at O.C.G.A. § 31-6-2(22), means an institution which provides, on a regular basis, health related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but who, because of their mental or physical condition, require health related care and services beyond the provision of room and board.

(35) "Joined applications" means two or more applications which involve similar projects in the same service area or overlapping service areas all of which have been declared complete within thirty days of the date the first application was declared complete, and whose time limits are scheduled to run from the latest date that any one of the joined applications was declared complete for review.

(36) "Joint venture ambulatory surgical center" means a freestanding ambulatory surgical center that is jointly owned by a hospital in the same county as the center or a hospital in a contiguous county if there is no hospital in the same county as the center and a single group of physicians practicing in the center and that provides surgery in a single specialty as defined by the Department; provided, however, that general surgery, a group practice which includes one or more physiatrists who perform services that are reasonably related to the surgical procedures performed in the center, and a group practice in orthopedics which includes hand surgeons with a certificate of added qualifications in Surgery of the Hand from the American Board of Plastic and Reconstructive Surgery shall be considered a single specialty. The ownership interest of the hospital shall be no less than thirty percent (30%) and the collective ownership of the physicians or group of physicians shall be no less than thirty percent (30%).

(37) "Life plan community" means an organization, whether operated for profit or not, whose owner or operator undertakes to provide shelter, food, and either nursing care or personal services, whether such nursing care or personal services are provided in the facility or in another setting, and other services, as designated by agreement, to an individual not related by consanguinity or affinity to such owner or operator providing such care pursuant to an agreement for a fixed or variable fee, or for any other remuneration of any type, whether fixed or variable, for the period of care, payable in a lump sum, lump sum and monthly maintenance charges or in installments. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party.

(38) "Medical use rights" means rights or interests in real property in which the owner of the property has agreed not to sell or lease such real property for identified medical uses or purposes.

(a) It shall be unlawful for any health care facility to purchase, renew, extend, lease, maintain, or hold medical use rights.

(39) "Micro-hospital" means a hospital in a rural county which has at least two and not more than seven inpatient beds and which provides emergency services seven days per week and 24 hours per day.

(40) "Mobile unit" means an object with the ability by structure, function or design to move or be moved from one site to another, such that upon arriving at a site the object is not permanently fixed but is temporarily secured for the purpose of providing a service to individuals.

(41) "New and emerging health care service" means a health care service or utilization of medical equipment which has been developed and has become acceptable or available for implementation or use but which has not yet been addressed under the Rules and regulations promulgated, adopted and included within and hereto.

(42) "New institutional health service", as defined at O.C.G.A. § 31-6-40(a) means:

(a) the construction, development, or other establishment of a new, expanded, or relocated health care facility, except as otherwise provided in O.C.G.A. § 31-6-47;

(b) any expenditure by or on behalf of a health care facility in excess of $10 million, which amount shall be adjusted annually as provided by law, and which, under generally accepted accounting principles consistently applied, is a capital expenditure, except expenditures for acquisition of an existing health care facility. See the definition of "threshold" below for expenditures that shall be counted to calculate the threshold;

(c) any increase in the bed capacity of a health care facility, regardless of whether a capital expenditure is made, which increases the total bed capacity. An exception to this Rule will be made in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.03(14);

(d) clinical health services that are offered in or through a health care facility, which were not offered on a regular basis in or through such health care facility within the twelve (12) month period prior to the time such services would be offered;

(e) any conversion or upgrading of any general acute care hospital to a specialty hospital or of a facility such that it is converted from a type of facility not covered by these Rules to any of the types of health care facilities which are covered by these Rules;

(f) the purchase or lease by or on behalf of a health care facility of diagnostic or therapeutic equipment except as otherwise provided in O.C.G.A. § 31-6-47 and Ga. Comp. R. & Regs. r. 111-2-2-.03 and Ga. Comp. R. & Regs. r. 111-2-2-.10;

(g) clinical health services which are offered in or through a diagnostic, treatment, or rehabilitation center which were not offered on a regular basis in or through that center within the twelve (12) month period to the time such services would be offered, but only if the clinical health services are any of the following:

1. Radiation therapy;

2. Biliary lithotripsy;

3. Surgery in an operating room environment, including but not limited to ambulatory surgery; and

4. Cardiac catheterization.

(h) The conversion of a destination cancer hospital to a general cancer hospital.

(43) "Nonclinical health services", as defined at O.C.G.A. § 31-6-2(25), means services or functions provided or performed by a health care facility, and the parts of the physical plant where they are located in a health care facility that are not diagnostic, therapeutic, or rehabilitative services to patients and are not clinical health services as defined in this chapter.

(44) "Offer", as defined at O.C.G.A. § 31-6-2(26), means that the health care facility is open for the acceptance of patients or performance of services and has qualified personnel, equipment, and supplies necessary to provide specified clinical health services.

(45) "Operating room environment", as defined at O.C.G.A. § 31-6-2(27), means an environment which meets the minimum physical plant and operational standards specified in the applicable administrative rules of the state which shall consider and use the design and construction specifications as set forth in the Guidelines for Design and Construction of Health Care Facilities published by the American Institute of Architects.

(46) "Pediatric cardiac catheterization" means the performance of angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization on children fourteen (14) years of age or younger.

(47) "Person", as defined at O.C.G.A. § 31-6-2(29), means any individual, trust, or estate, partnership, limited liability company or partnership, corporation (including associations, joint-stock companies and insurance companies), state, political subdivision, hospital authority, or instrumentality (including a municipal corporation) of a state as defined in the laws of this State. This term shall include all related parties, including individuals, business corporations, general partnerships, limited partnerships, limited liability companies, limited liability partnerships, joint ventures, nonprofit corporations, or any other for profit or not for profit entity that owns or controls, is owned or controlled by, or operates under common ownership or control with a person.

(48) "Personal Care Home", as defined at O.C.G.A. § 31-6-2(30), means a residential facility that is certified as a provider of medical assistance for Medicaid purposes pursuant to Article 7 of Chapter 4 of Title 49 having at least twenty-five (25) beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal

care homes including those facilities which monitor daily residents' functioning and location, have the capability for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

(a) Old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

(b) Boarding facilities that do not provide personal care.

(49) "Primary campus" means the building at which the majority of a hospital's or a remote location of a hospital's licensed and operational inpatient hospital beds are located, and includes the health care facilities of such hospital within 1,000 yards of such building. Any health care facility operated under a hospital's license prior to July 1, 2019, but not on the hospital's primary campus shall remain part of such hospital but shall not constitute such hospital's primary campus unless otherwise meeting the requirements of this paragraph.

(50) Project", as defined at O.C.G.A. § 31-6-2(31), means a proposal to take an action for which Certificate of Need review is required under these Rules. A project or proposed project may refer to the proposal from its earliest planning stages up through the point at which the new institutional health service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed", the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, unless expressly not included by other provisions of these Rules, which are determined by the Department to be associated with one another, to be a single project.

(51) "Remote location of a hospital" means a hospital facility or organization that is either created by, or acquired by, a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider.

(52) "Rural county" means a county having a population of less than 50,000 according to the United States decennial census of 2010 or any future such census.

(53) "Service-specific Rule" means those rules that are part of Ga. Comp. R. & Regs. r. 111-2-2 that regard specific clinical health care services as outlined at Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq.

(54) "Single specialty ambulatory surgical center" means an ambulatory surgical center where surgery is performed in the offices of an individual private physician or single group practice of private physicians if such surgery is performed in a facility that is owned, operated, and utilized by such physicians who are also of a single specialty; provided, however, that general surgery, a group practice which includes one or more physiatrists who perform services that are reasonably related to the surgical procedures

performed in the center, and a group practice in orthopedics which includes plastic hand surgeons with a certificate of added qualifications in Surgery of the Hand from the American Board of Plastic and Reconstructive Surgery shall be considered a single specialty.

(55) "Skilled nursing facility", as defined at O.C.G.A. § 31-6-2(34), means a public or private institution or a distinct part of an institution which is primarily engaged in providing inpatient skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(56) "Specialty hospital" means a hospital that is primarily or exclusively engaged in the care and treatment of one of the following: patients with a cardiac condition, patients with an orthopedic condition, patients receiving a surgical procedure, or patients receiving any other specialized category of services defined elsewhere in these Rules. A "specialty hospital" does not include a destination cancer hospital or a general cancer hospital.

(57) "State health plan", as defined at O.C.G.A. § 31-6-2(36), means a comprehensive program based on recommendations by the Health Strategies Council and the board, approved by the Governor, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the State. The State Health Plan is divided into a series of component plans modified from time to time as needed.

(58) "Substantial equivalent of a project" means a proposal to take an action for which a letter of determination is sought under these Rules. A substantial equivalent of a project may refer to the proposal from its earliest planning stages up through the point at which the service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed", the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, unless expressly not included by other provisions of these Rules, which are determined by the Department to be associated with one another, to be a single substantial equivalent of a project.

(59) "Threshold" means the dollar amount of capital expenditures for which, when exceeded, a Certificate of Need is required.

(a) In calculating the dollar amounts of a proposed project for purposes of 111-2-2 .01(42)(b) and (42)(f), and 111-2-2-.01(54) and (36) of these Rules, the capital costs of all items subject to review by these Rules and items not subject to review by these Rules associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(b) The following threshold amounts are effective as of July 1, 2019:

1. The capital expenditure threshold of Ga. Comp. R. & Regs. r. 111-2-2.01(42)(b), is $10 million;

2. The equipment threshold of Ga. Comp. R. & Regs. r. 111-2-2.03(30) is $3 million;

3. The physician-owned, single-specialty, office-based ambulatory surgery center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(54) is $2.5 million;

4. The joint venture ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(36) is $5 million;

With respect to (b)1., above, beginning on July 1, 2019, and with respect to (b)3., and 4. above, beginning on July 1, 2009, the Department shall update or adjust this CON threshold amount by the annual percentage of change in an appropriate composite price index that, in the judgment of the Department, represents national construction prices for the preceding calendar year such as those published by the Department of Commerce of the United States government or other government agency;

With respect to (b)2. above, beginning on July 1, 2010, the Department shall update or adjust this CON threshold amount by the annual percentage of change in an appropriate consumer price index, or its successor or appropriate replacement index, for the preceding calendar year, such as those published by the United States Department of Labor or other United States government agency. However, diagnostic or other imaging services that are not offered in a hospital or in the offices of an individual private physician or single group practice of physicians exclusively for use on patients of that physician or group practice shall be deemed to be a new institutional health service regardless of the cost of the equipment. Also, however, this amount or threshold figure shall not include build out costs, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(c), but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five (5) years.

(c) For purposes of computing the capital expenditure threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(b) and Ga. Comp. R. & Regs. r. 111-2-2-.01(21) and the physician-owned, single specialty ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(21) and the joint venture ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(22), the Department shall include, but not be limited to, the following guidelines:

1. Pursuant to the definition of "associated with and simultaneously developed or proposed", the total cost of all associated capital expenditures for items to be obligated for or purchased within a six (6) month period for a single program, service, plan, or project, regardless of whether or not the cost of any individual item is in excess of the capital expenditure threshold and regardless of whether or not the expenditure or item is otherwise reviewable under these Rules or the CON Statute, is included in the computation;

2. The cost of depreciable equipment that is not used for diagnosis or treatment, such as office equipment, usual business equipment, and office and waiting room furniture, is included in the computation, if such items are associated with and simultaneously developed or proposed with the project. If such furnishing and equipment are used, the cost that shall be used in calculating the threshold shall be the depreciated value or current market value of the furnishings or equipment, whichever is greater;

3. The cost of normal inventories of supplies, such as glassware, chemicals, drugs, linens, and paper, is exempt from the computation as an operating expense;

4. The value of the facilities to be acquired by lease, gift, donation or other means is based on a current (within six (6) months) appraisal of the facility, except that the value of newly constructed facilities shall be based on the actual square footage cost to construct the facility;

5. For facilities that are acquired by lease, the computation of value shall be based on the rentable square footage of the facility and not the useable square footage. Notwithstanding this Rule, lease payments shall be considered to be operating expenses for leases other than capital leases;

6. For facilities that are only partly occupied by a person, the computation shall include a pro-rata share of the value of the common space, unless the rentable square footage is provided as required by 5. above and that rentable square footage already includes an allocation for common space, as documented by the lease agreement; and

7. In the case of a gift or donation, the value of equipment, furnishings or facilities is the fair market value of the equipment, furnishings, or facilities;

(d) For purposes of computing the equipment threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(59)(b)(2) and Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(f), the Department shall include, but not be limited to, the following guidelines:

1. The cost of diagnostic, therapeutic, or other imaging equipment includes all capital costs, expenditures, charges, fees and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended, including but not limited to the following expenses:

   (i) Any expense incurred for the purchase of a warranty on the diagnostic, therapeutic, or other imaging equipment from the manufacturer or vendor for the first five years of operation;

   (ii) Any expense incurred for operator training;

   (iii) Any expense incurred for installation and assembly of the equipment;

   (iv) Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

   (v) Any expense incurred for functionally related diagnostic, therapeutic or other imaging equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.

   (vi) Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

   (vii) Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

   (viii) Any dollar amount attributable to service contracts for the first five (5) years of operation;

   (ix) Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of determination by the manufacturer or vendor of the equipment;

   (x) For mobile units of equipment, expenditures and values associated with the motor coach, trailer, van, rig, or other form of modular or transitional housing shall be included in the computation of the threshold;

2. The acquisition by whatever means of one or more items of functionally related diagnostic, therapeutic, other imaging equipment shall be considered as one project. The acquisition of functionally related

accessories shall also be counted. Pursuant to the definition of "functionally related diagnostic, therapeutic, or other imaging equipment", any individual components or pieces of diagnostic, therapeutic, or other imaging equipment, which depend on one another in order to function and that are purchased within a six (6) month period, shall be considered in the aggregate in calculating the threshold;

3. Diagnostic, therapeutic, or other imaging equipment shall include single and multiple units of equipment, if such units are associated with and simultaneously developed or proposed with one another. Pursuant to the definition of "associated with and simultaneously developed or proposed", the Department may determine that individual pieces or units of diagnostic, therapeutic, or other imaging equipment are associated with one another if such pieces or units of equipment are used for the same or similar health services and if such pieces or units of equipment are developed, proposed, or acquired simultaneously. Such associated and simultaneous units purchased within a six (6) month period shall be aggregated to calculate the threshold;

4. Purchase or lease shall include purchases, contracts, encumbrances of funds, lease arrangements, conditional sales or a comparable arrangements that purport to be a transfer of ownership in whole or in part;

5. In the case of a lease, loan, or gift, the value of the diagnostic, therapeutic, or other imaging equipment is the fair market value of the diagnostic, therapeutic, or other imaging equipment, as evidenced by documentation from a reputable vendor or manufacturer.

(60) "Uncompensated indigent or charity care" means the dollar amount of "net uncompensated indigent or charity care after direct and indirect (all) compensation" as defined by, and calculated in accordance with, the Department's Hospital Financial Survey and related instructions.

(61) "Urban county" means a county having a population equal to or greater than 50,000 according to the United States decennial census of 2010 or any future such census.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.01
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq*.
History. Original Rule entitled "Definitions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Oct. 19, 2018; eff. Nov. 8, 2018.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.02. Nature of Certificate of Need.

(1) **Purpose**. The purpose of the Certificate of Need evaluation process is to ensure that adequate health care services and facilities are developed in an orderly and economical manner and are made available to all Georgians and that only those health care services that are found to be in the public interest shall be provided in the State. The goals are to:

(a) Review proposed health care services;

(b) Contain health costs;

(c) Promote economic value;

(d) Ensure compatibility of health care services with the needs of various areas and populations of Georgia; and

(e) Prevent unnecessary duplication or services.

(2) **Contents.** The certificate, or attachments, shall specify, but not be limited to:

(a) the scope of the project;

(b) the defined location of the project;

(c) the person to whom the certificate was issued;

(d) the maximum capital expenditure, if any, which may be obligated under the certificate;

(e) the service area of the project;

(f) the valid dates;

(g) the schedule of time periods to be followed in making the service or equipment available or in completing the project;

(h) the services or units of services, which have been approved; and

(i) when the progress reporting requirements under Ga.Comp. R. & Regs. r. 111-2-2-.04(2) and Ga. Comp. R. & Regs. r. 111-2-2-.02(5) are due.

(3) **Validity.** A Certificate of Need shall be valid only for the defined scope, physical location, cost, service area, and person named in the application as the applicant.

(4) **Non-transferability.** A Certificate of Need shall not be transferable or assignable, nor shall a project for which a Certificate of Need has been issued be transferred from or assigned by one person to another, except under the following circumstances:

(a) the death of the holder of the Certificate, provided the transfer is solely from the estate of the holder to his or her heirs; or

(b) an existing licensed health care facility to which a Certificate has been issued is acquired by another person, in which instance the Certificate shall be valid for the person who acquires the facility and for the scope, location, cost, and service area previously approved by the Department.

(5) **Effective Period.** Unless otherwise provided by a service-specific rule, or unless the Department in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.02(7) has extended the effective period, the effective period of a Certificate of Need shall be as follows:

(a) Certificates involving neither construction nor equipment acquisition shall be effective for twelve (12) months;

(b) Certificates solely involving acquisition of equipment shall be effective for twelve (12) months, by which date the applicant must be in possession of the equipment; and

(c) Certificates for projects involving construction shall be effective based on a reasonable, phased timetable presented in the application, which may be amended during the review cycle, as planned, developed, proposed, and submitted by the applicant. In determining the reasonableness of the proposed phases and time periods, the Department will be guided by the applicable horizon year for the project. However, in appropriate circumstance, the Department may approve an effective period in excess of the applicable horizon year. The approved and valid phases and effective period shall be included in the Certificate of Need. When the Department extends the effective period pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.02(7) or when, due to an appeal of a project, a project's effective date is not the approved date, the Department will update the effective period, including the horizon year, of the project accordingly.

(6) **Initial 12-month Implementation Period for Projects Involving Construction.** Unless otherwise provided in a service-specific rule or unless the Department in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.02(7) has extended the initial 12-month implementation period, all projects involving construction regardless of the dollar amount must, within twelve (12) months of the effective date of the certificate, demonstrate, as evidenced by a progress report (as described at Ga. Comp. R. & Regs. r. 111-2-2-.04(2)) and supporting documentation, substantial performance in beginning the project. Substantial performance shall be demonstrated by the following:

(a) The construction plans have been approved by the Department's Architect;

(b) The construction contract has been signed and specifically indicates beginning and completion dates; and

(c) Construction materials and equipment are on site.

(7) Extension of Time Periods. The Department may, upon written request of the certificate holder, grant an extension of the effective period of a Certificate of Need or of the initial 12-month implementation period if the applicant's request is received by the Department 30 days prior to expiration of the Certificate of Need or of the initial 12-month implementation period, as applicable.

(a) A request for an extension of the initial 12-month implementation period, or any extension thereof, shall demonstrate:

1. that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the initial 12-month implementation period may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences. Ordinarily, lack of adequate or accurate planning, uncertainty as to reimbursement and/or financial difficulties will not justify an extension of the implementation period;

2. that the certificate holder has made substantial and timely progress in implementing the project. In order to show substantial and timely progress in implementing the project, the certificate holder must show that the project was on schedule and could reasonably have been implemented during the initial 12-month implementation period or extension thereof, but for the occurrence or circumstance beyond the certificate holder's control;

(b) A request for an extension of the effective period of a Certificate of Need, or any phase or extension thereof, shall:

1. demonstrate that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the effective period, or any phase or extension thereof, may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences.

2. demonstrate that but for the circumstance beyond the control of the certificate holder, the project, or phase thereof, would have been completed within the effective period;

3. demonstrate that the certificate holder has made substantial and timely progress in completing the project, or phase thereof;

4. indicate the expected completion date of the project, or phase thereof, as applicable; and

5. affirm that the project, or phase thereof, will be completed within the requested extension period.

(c) The length of an extension of the effective period or of the initial 12-month implementation period of a Certificate of Need shall be determined by the Department and shall be reasonable and consistent with the circumstances. In no case, shall the Department extend the initial 12-month implementation period of a Certificate of Need beyond an additional 12 months.

(d) In circumstances where the certificate holder is precluded from normal progression due to litigation involving the Certificate or where the method of financing is precluded by litigation, the Department may, at its discretion, suspend any or all of the time periods specified herein until the litigation has been resolved.

(8) **Expiration and Cancellation**. If, within the effective period specified in Ga. Comp. R. & Regs. r. 111-2-2-.02(5) and initial 12-month implementation period specified in Ga. Comp. R. & Regs. r. 111-2-2-.02(6), as applicable, the required performance standards are not met, the Certificate will be deemed to have expired unless an extension has been obtained from the Department pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.02(7). Unless the certificate holder demonstrated good cause not to deem the Certificate to have expired, which shall be determined by the Department, the Certificate will be canceled and notifications of same issued to the applicant, local governing authorities, Regional Development Center, and a newspaper of general circulation in the area where the application originated. An applicant whose Certificate has expired may not resubmit an application for the same or a substantially similar project until at least 120 days after expiration of the Certificate.

(9) **Modification by Operation of Law of Certificate for Failure to Complete**. Upon expiration of the effective period, if a certificate holder has not completed all activities or has not implemented all services or units of services granted in the Certificate of Need issued on the approved date (or if appealed, the effective date), the Certificate shall be modified upon such expiration to include and be valid for only those activities, services, or units of services, which have been completed and implemented as of the date of expiration.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.02
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Nature of Certificate of Need" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.03. Exemptions from Review.

The following shall not be subject to Certificate of Need review and shall be exempted from the provisions of these Rules regarding Certificate of Need Review except as otherwise provided:

(1) infirmaries operated by educational institutions for the sole and exclusive benefit of students, faculty members, officers, or employees thereof;

(2) infirmaries or facilities operated by businesses for the sole and exclusive benefit of officers or employees thereof, provided that such infirmaries or facilities make no provision for overnight stay by persons receiving their services;

(3) institutions operated exclusively by the federal government or by any of its agencies;

(4) offices of private physicians or dentists, as determined in the sole discretion of the Department, whether for individual or group practice except as otherwise provided in Ga. Comp. R. & Regs. r .111-2-2-.01(54) and Ga. Comp. R. & Regs. r .111-2-2-.01(42)(f). Simple ownership of a facility by a practitioner or a group of practitioners of the healing arts does not, in and of itself, exempt such facility from the scope of these Rules. Seeking licensure of a place, building, or facility as a health care institution is inconsistent with an assertion that such place, building, or facility is being occupied exclusively as the office of private physicians or dentists. Therefore, any person who seeks licensure as a health care facility must secure a Certificate of Need if a new institutional health service is being offered or developed;

(5) Religious, nonmedical health care institutions as defined in 42 U.S.C. Section 1395x(ss)(1), listed and certified by a national accrediting organization;

(6) site acquisitions for health care facilities or preparation or development costs for such sites prior to filing a Certificate of Need application**;**

(7) expenditures related to adequate preparation and development of an application for a Certificate of Need;

(8) the commitment of funds conditioned upon the obtaining of a Certificate of Need;

(9) transfers from one health care facility to another such facility of major medical equipment previously approved under or exempted from Certificate of Need review, except where such transfer results in the institution of a new clinical health service for which a Certificate of Need is required in the facility acquiring said equipment, provided that such transfers are recorded at net book value of the medical equipment as recorded on the books of the transferring facility;

(10) expenditures for the restructuring or acquisition of existing health care facilities by stock or asset purchase, merger, consolidation, or other lawful means;

(11) the purchase of a closing hospital or of a hospital that has been closed for no more than twelve (12) months by a hospital in a contiguous county to repurpose the facility as a micro-hospital;

(12) capital expenditures otherwise covered by this Chapter required solely to eliminate or prevent safety hazards as defined by federal, state or local fire, building, environmental

occupational health, or life safety codes of regulations, to comply with licensing requirements of the Healthcare Facility Regulation Division, or to comply with accreditation standards of the Joint Commission or another nationally recognized health care accreditation body;

(13) except as otherwise provided in this subsection, all cost overruns are excluded from prior Certificate of Need review and approval. For purposes of this subsection, a cost overrun that is subject to prior Certificate of Need review and approval (i.e., a reviewable cost overrun) is defined as meaning any cost overrun which is in excess of the current capital or diagnostic, therapeutic, or other imaging equipment threshold, or in excess of ten percent (10%) of the approved capital expenditure amount, whichever is less. However, in no event shall an additional expenditure of less than $300,000 be deemed a reviewable cost overrun. Reviewable cost overruns will be reviewed by the Department in accordance with the following provisions:

(a) A reviewable cost overrun associated with ongoing construction or renovation activity which has not been incurred prior to a Certificate of Need approval and is solely related to an unanticipated engineering, major fixed equipment or other construction problem, or federal, state or local fire requirements which were adopted or became effective after the issuance of the Certificate of Need but prior to the completion of construction or renovation, will receive favorable review consideration if the applicant demonstrates that the overrun will have no impact or a minimal impact on costs and/or charges per patient day or procedure; and

(b) A reviewable cost overrun which is the result of subsequent project bidding prior to any contractual obligation for construction and/or renovation work will not receive favorable review consideration by the Department but will require the entire project to be reviewed as an entirely new project subject to all the applicable criteria, standards and plans; and

(c) A reviewable cost overrun which is due to delays of project construction and/or renovation activity resulting from an appeal proceeding, when such delay has been in excess of one year, and where the Department has suspended the time periods until the issues are resolved, will be given favorable consideration as long as the project has not changed in scope, square footage, services or number of new beds proposed.

(d) For projects involving either construction or renovation, but not both, a reviewable cost overrun which increases the square footage beyond five percent (5%) of the originally approved project's total new square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(e) For projects involving construction and renovation, a reviewable cost overrun which increases the square footage beyond five percent (5%) of the sum of the new construction square footage and renovated square footage will require the

entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(f) Regardless of cost, during implementation of the project, any increase in the scope of the original project or any change in the number of beds (i.e., the subtraction, addition, replacement or conversion of different number of beds than authorized in the original Certificate of Need) will invalidate the original project and the Department will deem the original project to have been withdrawn unless prior written approval is obtained from the Department;

(14) increases in the bed capacity of a hospital up to ten beds or ten percent (10%) of capacity, whichever is greater, in any consecutive two-year period, in a hospital that has maintained an overall occupancy rate greater than seventy-five percent (75%) (exclusive of any skilled nursing units or comprehensive inpatient rehabilitation units) for the previous twelve (12) month period;

(15) expenditures of less than $870,000.00 for any minor or major repair or replacement of equipment by a health care facility that is not owned by a group practice of physicians or a hospital and that provides diagnostic imaging services if such facility received a letter of non-reviewability from the Department prior to July 1, 2008. This paragraph shall not apply to such facilities in rural counties;

(16) except as provided in paragraph (15) of this subsection, expenditures for the minor or major repair of a health care facility or a facility that is exempt from the requirements of these Rules, parts thereof or services provided or equipment used therein; or the replacement of equipment, including but not limited to CT scanners, magnetic resonance imaging, positron emission tomography (PET), and positron emission tomography/computed tomography previously approved for a Certificate of Need.

(a) To qualify for this exemption, the replaced equipment must have received prior CON review and approval, or have been grandfathered, and the replaced equipment must be removed entirely from the premises and not be used in tandem with the replacement equipment, unless authorized in writing by the Department. Replacement equipment must be placed in the same defined location as the replaced equipment.

1. The Department may authorize in writing the retention of certain functionality of the equipment to be replaced if such retained functionality is not used in tandem with the replacement equipment and if the retained functionality would not otherwise result in the provision of a new institutional health service. The fair market value of the retained functionality must not exceed the applicable equipment threshold at the time of replacement.

(b) Expenditures associated with activities essential to acquiring and making operational the replacement equipment shall also be exempted from review.

"Activities essential to acquiring and making operational the replacement equipment" means those activities that are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

(c) Replacement equipment shall be comparable diagnostic or therapeutic equipment in relation to the replaced equipment. "Comparable diagnostic or therapeutic equipment" means equipment which is functionally similar and which is used for the same or similar diagnostic or treatment purposes. Replacement equipment is comparable to the equipment being replaced if it is functionally similar and is used for the same or similar diagnostic, therapeutic, or treatment purposes as the equipment currently in use and is not used to provide a new health service;

(17) new institutional health services offered by or on behalf of a Health Maintenance Organization, or a health facility controlled, directly or indirectly, by a Health Maintenance Organization or a combination of Health Maintenance Organizations, provided specific and detailed documentation is provided to the Department that one of the following conditions are met:

(a) that seventy-five percent (75%) of the patients who can reasonably be expected to use the service will be individuals enrolled in a Health Maintenance Organization certified by the State of Georgia;

(b) that the service is needed by the Health Maintenance Organization in order to operate efficiently and economically and that it is not otherwise readily accessible to the Health Maintenance Organization because:

1. existing similar services are not available under a contract of reasonable duration;

2. full and equal staff privileges are not available in existing facilities; or

3. arrangements with existing facilities are not administratively feasible;

(18) capital expenditures for a project otherwise requiring a Certificate of Need if those expenditures are for a project to remodel, renovate, replace, or any combination thereof, a medical-surgical hospital and all the following conditions are met:

(a) the hospital has a bed capacity of not more than fifty (50) beds;

(b) the hospital is located in a county in which no other medical-surgical hospital is located;

(c) the hospital has at any time been designated as a disproportionate share hospital by the Department;

(d) the hospital has at least forty-five percent (45%) of its patient revenues derived from Medicare, Medicaid, or any combination thereof, for the immediately preceding three years;

(e) the project has at least eighty percent (80%) of its capital expenditures financed by proceeds of a special purpose county sales and use tax imposed pursuant to Article 3 of Chapter 8 of Title 48;

(f) the proposed replacement hospital is located within a three (3) mile radius of and within the same county as the hospital's existing facility; and

(g) the project does not result in any of the following:

1. the offering of any new clinical health services;

2. any increase in bed capacity;

3. any redistribution of existing beds among existing clinical health services; and

4. any increase in the capacity of existing clinical health services;

(19) Expenditures for nonclinical projects, including parking lots, parking decks, and other parking facilities; computer systems, software, and other information technology; medical office buildings; administrative office space; conference rooms; education facilities; lobbies; common spaces; clinical staff lounges and sleep areas; waiting rooms; bathrooms; cafeterias; hallways; engineering facilities; mechanical systems; roofs; grounds; signage; family meeting or lounge areas; other nonclinical physical plant renovations or upgrades that do not result in new or expanded clinical health services; and state mental health facilities;

(20) Life plan communities, provided that the skilled nursing component of the facility is for the exclusive use of residents of the life plan community and that a written exemption is obtained from the Department; provided, however, that new sheltered nursing home beds may be used on a limited basis by persons who are not residents of the life plan community for a period up to five years after the date of issuance of the initial nursing home license, but such beds shall not be eligible for Medicaid reimbursement. For the first year, the life plan community sheltered nursing facility may utilize not more than fifty percent (50%) of its licensed beds for patients who are not residents of the life plan community. In the second year of operation, the life plan community shall allow not more than forty percent (40%) of its licensed beds for new patients who are not residents of the life plan community. In the third year of operation, the life plan community shall allow not more than thirty percent (30%) of its licensed beds for new patients who are not residents of the life plan community. In the fourth year of operation, the life plan community shall allow not more than twenty percent (20%) of its licensed beds for new patients who are not residents of the life plan community. In the fifth year of operation,

the life plan community shall allow not more than ten percent (10%) of its licensed beds for new patients who are not residents of the life plan community. At no time during the first five (5) years shall the life plan community sheltered nursing facility occupy more than fifty percent (50%) of its licensed beds with patients who are not residents under contract with the life plan community. At the end of the five (5) year period, the life plan community sheltered nursing facility shall be utilized exclusively by residents of the life plan community and at no time shall a resident of a life plan community be denied access to the sheltered nursing facility. At no time shall any existing patient be forced to leave the life plan community to comply with this paragraph. The Department is authorized to promulgate rules and regulations regarding the use and definition of "sheltered nursing facility" in a manner consistent with this Code section. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party;

(21) Any single specialty ambulatory surgical center that:

(a)

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health services which do not exceed $2.5 million; or

2. Is the only single specialty ambulatory surgical center in the county owned by the group practice and has two (2) or fewer operating rooms; provided, however, that a center exempt pursuant to this paragraph shall be required to obtain a certificated of need in order to add any additional operating rooms;

(b) Has a hospital affiliation agreement with a hospital within a reasonable distance from the facility or the medical staff at the center has admitting privileges or other acceptable documented arrangements with such hospital to ensure the necessary backup for the center for medical complications. The center shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the facility with adequate emergency room services. Hospitals shall not unreasonably deny a transfer agreement or affiliation agreement to the center;

(c)

1. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the center is not a participant in Medicaid or the PeachCare for Kids® Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both

in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; provided, however, single specialty ambulatory surgical centers owned by physicians in the practice of ophthalmology shall not be required to comply with this subparagraph; and

(d) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70.

Noncompliance with any condition of this paragraph shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index. In calculating the dollar amounts of a proposed project for purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with an simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(22) Any joint venture ambulatory surgical center that:

(a) Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5 million;

(b)

1. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the center is not a participant in Medicaid or the PeachCare for Kids® Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare

for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

(c) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70. Noncompliance with any condition of this paragraph shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index. In calculating the dollar amounts of a proposed project for purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(23) Expansion of services by an imaging center based on a population needs methodology taking into consideration whether the population residing in the area served by the imaging center has a need for expanded services, as determined by the Department in accordance with its rules and regulations, if such imaging center:

(a) Was in existence and operational in this state on January 1, 2008;

(b) Is owned by a hospital or by a physician or a group of physicians comprising at least eighty percent (80%) ownership who are currently board certified in radiology;

(c) Provides three (3) or more diagnostic and other imaging services;

(d) Accepts all patients regardless of ability to pay; and

(e) Provides uncompensated indigent and charity care in an amount equal to or greater than the amount of such care provided by the geographically closest

general acute care hospital; provided, however, this paragraph shall not apply to an imaging center in a rural county;

(24) Diagnostic cardiac catheterization in a hospital setting on patients fifteen (15) years of age and older;

(25) Therapeutic cardiac catheterization in hospitals selected by the Department prior to July 1, 2008, to participate in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Study and therapeutic cardiac catheterization in hospitals that, as determined by the Department on an annual basis, meet the criteria to participate in the C-PORT Study but have not been selected for participation; provided, however, that if the criteria requires a transfer agreement to another hospital, no hospital shall unreasonably deny a transfer agreement to another hospital;

(a) The standards for therapeutic cardiac catheterization, pursuant to the exemption in subsection (24) for hospitals who have not been selected for participation in the C-PORT Study shall be as follows:

A hospital that wishes to receive authorization to perform therapeutic cardiac catheterization procedures must:

1. submit a request for a letter of determination on the required form with the proper filing fee between May 1 and May 15 of each year, beginning with calendar year 2009; the sufficiency of the information submitted in the request shall be determined within the administrative discretion of the Department;

2. provide documentation which demonstrates it can perform a minimum of two hundred (200) percutaneous cardiac interventions (PCI) per year by the beginning of the third year of operation of a program, including both elective and primary PCI, with a minimum of thirty-six (36) primary PCI per year beginning the third year of operation;

3. provide documentation to support the criteria referenced in subsection 2 above that includes substantive information on the number of diagnostic cardiac catheterization procedures performed at the hospital, or referred to existing PCI providers by the hospital, in or out of the state of Georgia, in the two (2) calendar years immediately preceding the request;

4. provide documentation that it will have, prior to beginning a PCI program, on active medical staff, at least one (1) interventional cardiologist who will meet the American College of Cardiology (ACC) and American Heart Association (AHA) competency standards, including the performance of at least seventy-five (75) PCI procedures per year;

5. provide documentation that the interventional cardiologist is board certified, or is in the process at the time of the request, of obtaining board certification in Interventional Cardiology from the American Board of Internal Medicine;

6. provide documentation of access to at least one (1) other interventional cardiologist who meets the criteria of subsections 4. and 5. above, to participate in its program on an as-needed basis as determined by the hospital;

7. agree to report annually the data on number of PCI procedures, type, and outcomes to the National Cardiovascular Data Registry Cath/PCI registry;

8. provide documentation to show that one (1) or more interventional cardiologist(s), as qualified in subsections 4., 5. and 6. above, are available to perform primary PCI procedures twenty-four (24) hours a day, seven (7) days a week, three hundred sixty-five (365) days a year;

9. provide documentation one (1) or more interventional cardiologist(s) are required to respond to a call, within the calendar availability specified in subsection 8. above, within sixty (60) minutes;

10. provide documentation that competent and trained nursing and technical cardiac catheterization staff are available at all times and are required to respond in a manner determined by the hospital in conjunction with the interventional cardiologists;

11. provide documentation of a transfer agreement with a tertiary medical facility that has an open heart surgery service to which a patient can be transferred when necessary within a period of sixty (60) minutes, by any means of transportation as chosen by the hospital, from the time the need for transfer is identified;

    (i) if the provider of an open heart surgery service within the travel time parameters of this subsection refuses to enter into a transfer agreement with the requesting hospital, the hospital may submit documentation on the reasons given for the denial, and the Department may consider these reasons;

    (ii) the Department may allow a requesting hospital to submit a transfer agreement with a provider of an open heart surgery service that is beyond the travel time parameters in this subsection if the reasons given for the denial of a transfer agreement by the tertiary provider are determined by the Department to be unreasonable;

(iii) if the Department determines the reasons for the denial of a transfer agreement by the tertiary provider within the time travel parameters in this subsection are reasonable, the Department may require the requesting hospital to address the reasons for the denial and enter into further negotiations for a transfer agreement prior to receiving a favorable determination from the Department;

12. provide documentation of an agreement with an ambulance service capable of advanced life support and intra aortic balloon pump services and that guarantees a thirty (30) minute or less response time;

13. agree to provide accurate and timely data, including outcomes analysis and formal periodic external and internal case review as required by the Department;

14. provide documentation to show that guidelines for determining patients appropriate for PCI procedures in a setting without on-site open heart backup consistent with C-PORT and ACC standards will be developed and maintained;

15. provide documentation to show the cardiac catheterization laboratory(s) at the requesting hospital is equipped in a manner consistent with C-PORT and ACC guidelines;

16. agree to participate in an elective and primary PCI Development Program at its expense, the successful completion of which will be verified by the Department through the use of an identified third-party; and

17. affirmatively agree authorization to begin a therapeutic cardiac catheterization program is expressly contingent upon successful completion of the development program as referenced in subsection 16. above.

(b) Any hospital approved to perform therapeutic cardiac catheterization procedures as a result of a request submitted between May 1 and May 15 of any calendar year after the adoption of this rule, must, between May 1 and May 15, of each subsequent year, submit a request which documents its compliance with the standards of this Rule, and the Department must re-affirm the hospital's current compliance in writing in order for the hospital to continue its therapeutic cardiac catheterization program.

(c) Any administrative proceeding held pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.10(6), in opposition to a Department approval of a request from a hospital to perform therapeutic cardiac catheterization procedures in accordance with the

standards established in this section, or in opposition to a Department decision to deny a hospital request to perform therapeutic cardiac catheterization procedures, shall not conduct a de novo review of the Department decision, and such decision shall only be reversed by an administrative hearing officer upon a showing the Department's action was without reason, arbitrary, or capricious;

(26) Infirmaries of facilities operated by, on behalf of, or under contract with the Department of Corrections or the Department of Juvenile Justice for the sole and exclusive purpose of providing health care services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution, including correctional institutions operated by private entities in this state which house inmates under the Department of Corrections or the Department of Juvenile Justice;

(27) The relocation of any skilled nursing facility, intermediate care facility, or micro-hospital within the same county, any other health care facility in a rural county within the same county, and any other health care facility in an urban county within a three-mile radius of the existing facility so long as the facility does not propose to offer any new or expanded clinical health services at the new location;

(28) Facilities which are devoted to the provision of treatment and rehabilitative care for periods continuing for twenty-four (24) hours or longer for persons who have traumatic brain injury, as defined in O.C.G.A. § 37-3-1;

(29) The renovation, remodeling, refurbishment, or upgrading of a health care facility, so long as the project does not result in any of the following:

(a) The offering of any new or expanded clinical health services;

(b) Any increase in inpatient bed capacity;

(c) Any redistribution of existing beds among existing clinical health services; or

(d) A capital expenditure exceeding the threshold contained in paragraph (2) of subsection (a) of O.C.G.A. § 31-6-40;

(30) Other than for equipment used to provide positron emission tomography (PET) services, the acquisition of diagnostic, therapeutic, or other imaging equipment with a value of $3,000,000.00 or less, by or on behalf of:

(a) A hospital; or

(b) An individual private physician or single group practice of physicians exclusively for use on patients of such private physician or single group practice of physicians and such private physician or member of such single group practice of physicians is physically present at the practice location where the diagnostic or

other imaging equipment is located at least seventy-five percent (75%) of the time that the equipment is in use.

The amount specified in this paragraph shall not include build-out costs, as defined by the Department, but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five years. The acquisition of one or more items of functionally related diagnostic or therapeutic equipment shall be considered as one project. The dollar amount specified in this paragraph and in paragraph (15) of this subsection shall be adjusted annually by an amount calculated by multiplying such dollar amounts (as adjusted for the preceding year) by the annual percentage of change in the consumer price index, or its successor or appropriate replacement index, if any, published by the United States Department of Labor for the preceding calendar year, commencing on July 1, 2010; and

(31) A capital expenditure of $10 million or less by a hospital at such hospital's primary campus for:

(a) The expansion or addition of the following clinical health services: operating rooms, other than dedicated outpatient operating rooms; medical-surgical services; gynecology; procedure rooms; intensive care; pharmaceutical services; pediatrics; cardiac care or other general hospital services; provided, however, that such expenditure does not include the expansion or addition of inpatient beds or the conversion of one type of inpatient bed to another type of inpatient bed; or

(b) The movement of clinical health services from one location on the hospital's primary campus to another location on such hospital's primary campus.

Pursuant to O.C.G.A. § 31-6-40(c)(1), any person who had a valid exemption granted or approved by the former Health Planning Agency or the Department of Community Health prior to July 1, 2008, shall not be required to obtain a Certificate of Need in order to continue to offer those previously offered services.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.03
Authority: O.C.G.A. §§ 31-2*et seq*., 31-6 *et seq*.
History. Original Rule entitled "Exemptions from Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. May 1, 2009; eff. May 21, 2009.
Amended: F. Oct. 19, 2018; eff. Nov. 8, 2018.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.04. Periodic Reports.

The availability of accurate, current data is critical for adequate health planning and for the review process. Therefore, all inpatient and outpatient health care facilities and services subject to Certificate of Need review will be required to provide complete and accurate data, in a timely manner, as required by the Department. Pursuant to O.C.G.A. § 31-6-70(a), this reporting requirement shall also apply, beginning July 1, 2008, to all ambulatory surgical centers and imaging centers, whether or not exempt from obtaining a Certificate of Need under O.C.G.A. § 31-6 et seq. and these Rules.

(1) **Annual and Special Questionnaires.**

(a) All CON-regulated facilities and services, as well as all ambulatory surgical centers and imaging centers, whether or not exempt from obtaining a Certificate of Need under these Rules, shall complete and submit certain surveys annually and periodically to the Department, as deemed necessary by the Department.

(b) Any facility offering ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2; any diagnostic, treatment, or rehabilitation center offering diagnostic imaging or other imaging services in operation and exempt prior to July 1, 2008; or any facility operating pursuant to a letter of non-reviewability and offering diagnostic imaging services prior to July 1, 2008, shall:

1. Provide notice to the Department of the name, ownership, location, single specialty, and services provided in the exempt facility; and

2. Beginning on January 1, 2009, provide annual reports in the same manner and in accordance with the provisions of this Rule.

(c) The Department shall publish a notice giving a date when the information responsive to subsection (b)1. of this Rule by December 30, 2008, or the Department does not receive the annual report referenced in subsection (a), and subsection (b)2., of this Rule from a health care facility requiring a Certificate of Need or an ambulatory surgical center or imaging center, whether or not exempt from obtaining a Certificate of Need under these Rules, on or before the date such report is due or receives a timely but incomplete report, the Department shall notify the health care facility or center regarding the deficiencies and shall be authorized to fine such health care facility or center an amount not to exceed $500.00 per day for every day up to thirty (30) days and $1,000.00 per day for every day over thirty (30) days for every day the Department has not received a report or an incomplete report has not been sufficiently corrected based on the Department's notice of deficiencies.

(d) Survey notices will be mailed or electronically transmitted by the Department to each such facility. The accurately and fully completed survey, covering the report period indicated, shall be filed with the Department within the time frame specific in the notice. The Survey shall be filed with the Department in the electronic

format designated by the Department in the Survey Notice or on the Department's website. The survey shall include an electronic signature as authorized by law, of the chief executive officer or principal administrator of the facility, who shall attest to the accuracy and completeness of the information provided.

(e) Reporting requirements shall also apply to new health facilities and services approved through Certificate of Need review. Generally, new facilities and services will be required to report if approved for operation or occupancy for sixty (60) days or more of the report period.

(f) Surveys submitted to the Department pursuant to these Rules and any service-specific Rules shall not be available for public review until after the deadline for submission for all surveys of that type;

(g) Required surveys submitted for a given period of time may not be revised by the facility or service after the survey filing deadline unless the request for revision is approved by the Department at its sole discretion.

(h) If the Department does not receive an annual report from a health care facility within one hundred eighty (180) days following the date such report was due or receives a timely but incomplete report which is not sufficiently completed within such one hundred eighty (180) days, the Department shall be authorized to revoke the Certificate of Need of the health care facility in accordance with O.C.G.A. § 31-6-45 and Ga. Comp. R. & Regs. r. 111-2-2-.05.

(i) The Department shall make publicly available all annual reports submitted pursuant to O.C.G.A. § 31-6-70 on the Department website. The Department shall also provide a copy of such annual reports to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the chairpersons of the House Committee on Health and Human Services and the Senate Health and Human Services Committee.

(j) All health care facilities, ambulatory surgical centers, and imaging centers required to submit an annual report pursuant to O.C.G.A. § 31-6-70(a) shall make such annual reports publicly available on their websites.

(2) **Post-Approval Reporting.**

(a) All entities receiving a Certificate of Need shall maintain a valid and accurate mailing and electronic mail address with the Department. Any notification, notice, or letter required by these Rules is deemed to be received by the certificate holder when the Department sends such notification, notice, or letter to the mailing or electronic mail address on file with the Department.

(b) Persons holding Certificates for construction projects shall, within twelve (12) months of the effective date of the Certificate, i.e., at the end of the

implementation period, provide a progress report to the Department including documentation of the following:

1. that the construction plans have been approved by the Department;

2. that a construction contract has been signed, specifically indicating beginning and completion dates;

3. that construction materials and equipment are on the site and construction of the project has actually begun.

(c) The Department shall monitor the Certificate of Need holder's progress in completing the project and phases thereof, as applicable, within the effective period as specified at Ga. Comp. R. & Regs. r. 111-2-2-.02(5). Each Certificate of Need issued requires a regular reporting of the different stages of development to completion. All projects approved as presented with phases shall submit a progress report within forty-five (45) days of the completion of each phase. All Certificate of Need projects must satisfy the pertinent reporting requirements or the Certificate shall be subject to revocation. These reports shall include information as to the total dollar amount of capital expenditures that have been obligated under the certificate, and any changes in amounts of proposed or previously obligated capital expenditures or changes to the timing of phases, if approved by the Department in advance. These reports will be made on a form provided by the Department on its website and will be due on the date or dates indicated by the Department on attachments to the Certificate of Need and in subsequent correspondence.

(d) The Department may also request additional reports as often as necessary in order to determine:

1. if the timetable specified in the certificate is being met;

2. if the scope of the project is being completed as described on the certificate and in the application for the Certificate of Need;

3. if the amount of the capital expenditure or expenditures obligated under the certificate has exceeded or can be expected to exceed the maximum under the certificate; and

4. if the condition(s) of approval, if any, have been satisfactorily met.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.04
Authority: O.C.G.A. Secs. 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Periodic Reports" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.05. Enforcement.

(1) Revocation

(a) In the event that the Department has cause to consider revocation of a Certificate, in whole or in part, the Department shall provide notice to the holder of the Certificate and shall hold a hearing to determine whether the holder has:

1. Intentionally provided false information to the Department;

2. Failed to incur a financial obligation in accordance with the Certificate as granted;

3. Failed to implement the project in accordance with the specific purpose(s) for which the certificate was granted or failed to meet the initial twelve (12) month performance standards or failed to request an extension of such standards. For certificates issued on or after July 1, 2008, failed to implement the services or units of services for which the Certificate of Need was issued, and that were outlined in or on the certificate granted, in a timely manner as also outlined in or on the certificate granted, as provided by O.C.G.A. § 31-6-45(a.1);

4. Transferred controlling ownership in the facility before completion of the project without prior written approval of the Department, except as authorized by Ga. Comp. R. & Regs. r. 111-2-2-.02(4);

6. Changed the defined location of the project except as allowed by O.C.G.A. § 31-6-45(a) authorizing change in location under certain conditions;

7. Failed to comply with any and all requirements or conditions of the Certificate;

8. Failed to submit a timely or complete periodic report within 180 days following the date the report is due pursuant to O.C.G.A. § 31-6-70 and as otherwise required by Ga. Comp. R. & Regs. r. 111-2-2-.04;

9. Failed repeatedly to pay any fines or moneys due to the Department;

10. Failed to maintain minimum quality of care standards that are outlined within the Certificate as granted; or

11. Failed to participate as a provider of medical assistance for Medicaid purposes if made a condition of the Certificate as granted pursuant to O.C.G.A. § 31-6-45.2(a).

(b) In the event that there is sufficient evidence to justify revocation of a Certificate, the Department shall provide written notification to the holder, which shall be

effective as of the postmark date on the notification letter. Notice shall also be provided to the public, to the county or municipal authority and to the appropriate Regional Development Center. Any person whose Certificate is revoked under this Rule is entitled to judicial review, pursuant to O.C.G.A. § 50-13 et seq.

(c) A person whose Certificate of Need has been revoked or denied may not reapply for a Certificate of Need for the same or substantially similar project for at least one hundred twenty (120) days from the date that the revocation or denial becomes final, at which time the person may submit a new application. For purposes of this subparagraph, a decision revoking or denying a Certificate of Need shall become final when the time for appealing that decision expires without an appeal of such decision having been timely filed. If an appeal is timely filed, the decision is not final until the resolution of the administrative appeal, if any.

(d) A person holding a Certificate of Need may voluntarily request revocation of the Certificate without prejudice by submitting such request to the Department in writing.

(e) A health care facility which has a Certificate of Need or is otherwise authorized to operate pursuant to this chapter shall have such Certificates of Need or authority to operate automatically revoked by operation of law without any action by the Department when that facility's permit to operate pursuant to O.C.G.A. § 31-7-4 is finally revoked by order of the Healthcare Facility Regulation Division. For purposes of this subsection, the date of such final revocation shall be as follows:

1. When there is no appeal of the order pursuant to O.C.G.A. § 31-5, the one hundred and eightieth (180th) day after the date upon which expires the time for appealing the revocation order without such an appeal being filed; or

2. When there is an appeal of the order pursuant to O.C.G.A. § 31-5, the date upon which expires the time to appeal the last administrative or judicial order affirming or approving the revocation or revocation order without such appeal being filed.

   The Department may become a party to any judicial proceeding to review a decision by the Healthcare Facility Regulation Division to revoke such a permit.

(f) A certificate shall be subject to revocation for the following failures, without limitation:

1. Failure to incur a project-specific capital expenditure, within the initial twelve (12) month implementation period specified at Ga. Comp. R. & Regs. r. 111-2-2-.02(6) and in the Certificate itself or within an extension implementation period granted by the Department, through initiation of

substantial project above-ground construction or lease or purchase of the proposed equipment;

2. Failure to file the required Progress Report(s);

3. Failure to meet the conditions on the face of the Certificate; or

4. Failure to pay any penalty assessed pursuant to O.C.G.A. § 31-6-40.1.

(2) **Sanctions.**

(a) Any health care facility offering a new institutional health service without having obtained a Certificate of Need and which has not been previously licensed as a health care facility shall be denied a license to operate by the Healthcare Facility Regulation Division.

(b) In the event that a new institutional health service is knowingly offered or developed without having obtained a Certificate of Need as required by O.C.G.A. § 31-6 et seq., or by these Rules, or the Certificate of Need for such service is revoked according to the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.05(1), a facility or person may be fined an amount not to exceed $5,000.00 per day up to thirty (30) days, $10,000.00 per day from thirty-one (31) days through sixty (60) days, and $25,000.00 per day after sixty (60) days for each day that the violation of these Rules and O.C.G.A. § 31-6 et seq. has existed and knowingly and willingly continues; provided however, that the expenditure or commitment of or incurring an obligation for the expenditure of funds to take or perform actions not subject to this chapter or to acquire, develop or prepare a health care facility site for which a Certificate of Need application is denied, shall not be a violation of this Chapter and shall not be subject to such a fine. The Commissioner or his designee shall determine, after notice and a hearing if requested, whether the fines provided in the Code section shall be levied.

(c) Any person who acquires a health care facility by stock or asset purchase, merger, consolidation, or other lawful means shall notify the Department of such acquisition, the date thereof, and the names and address of the acquiring person. Such notification shall be made in writing to the Commissioner or his designee within forty-five (45) days following the acquisition and the acquiring person may be fined by the Department in the amount of $500.00 for each day that such notification is late.

(d) The Department may require that any applicant for a Certificate of Need commit to provide a specified amount of clinical health services to indigent or charity, Medicare, Medicaid, PeachCare, and similar patients as a condition for the grant of a Certificate of Need. A grantee or successor in interest of a Certificate of Need or authorization to operate under O.C.G.A. § 31-6 et seq. which violates such an

agreement, whether made before or after July 1, 1991, shall be liable to the Department for a monetary penalty in the amount of the difference between the amount of services so agreed to be provided and the amount actually provided. Penalties authorized under this Code section shall be subject to the same notices and hearing for the levy of fines under Ga. Comp. R. & Regs. r. 111-2-2-.05(2)(b).

(e) All hearings under this Section shall be in accordance with the Georgia Administrative Procedure Act. Any person so penalized under this Rule is entitled to judicial review, pursuant to O.C.G.A. § 50-13 et seq.

(f) If the person assessed fails to pay the amount of the assessment to the Department within thirty (30) days after notice of assessment is postmarked to him, or within such longer period, not to exceed ninety (90) days, as the Department may specify, the Department may institute a civil action to recover the amount of the assessment or may revoke the Certificate of Need. The Department may add reasonable interest to the assessment.

(g) For purposes of this Rule, the State of Georgia, acting by and through the Department or any other interested person, shall have standing in any court of competent jurisdiction to maintain an action for injunctive or other appropriate relief to enforce the provisions of this Rule.

(3) **Department's Right to Inspect and Audit**. The Department or an authorized representative or employee designated by the Department shall have the right to inspect and audit any facility, site, location, book, document, paper, files, or other record of the holder of the Certificate of Need or letter of non-reviewability or other determination that is related to any project authorized by the Certificate of Need or letter of non-reviewability or other determination, in order to monitor and evaluate the person's compliance with the terms of issuance of the Certificate of Need or the letter of non-reviewability or other determination. The Department shall have the authority to make public or private investigations or examinations inside or outside of the state of Georgia to determine whether all provisions of O.C.G.A. § 31-6-2 et seq. or any other law, rule, regulation, or formal order relating to the provisions of O.C.G.A. § 31-6-40 in particular, has been violated. Such investigations may be initiated at any time in the discretion of the Department and may continue during the pendency of any action initiated by the Department pursuant to section (1)(a) of this Rule. For the purpose of conducting any investigation or inspection pursuant to this subsection, the Department shall have the authority, upon providing reasonable notice, to require the production of any books, records, or other information related to any Certificate of Need issue.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.05
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Enforcement" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.06. Application for Certificate of Need.

(1) **Letter of Intent.** Beginning July 15, 2008, all persons who wish to submit an application for a Certificate of Need for a new institutional health service or health care facility, as provided in O.C.G.A. § 31-6-40(a) and (b), must submit a letter of intent notifying the Department of their intent to do so at least thirty (30) days prior to submission of the Certificate of Need application. The notice must be in writing, must be submitted via the Department's web portal, and must contain the following information:

(a) Name and address of the legal applicant;

(b) Person to whom inquiries must be addressed;

(c) Name, address of facility, if different from legal applicant;

(d) Proposed project site location with specificity;

(e) Brief summary description of proposal;

(f) Proposed service area; and

(g) Cost of the project.

The Department will not accept any notices of intent submitted by either telephone, facsimile, or electronic mail, pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.06(6). Beginning with the date referenced above, no Certificate of Need application will be accepted without a previously filed letter of intent. The Certificate of Need application must be submitted no later than thirty (30) calendar days after the letter of intent has been received by the Department. In the event that the thirtieth (30th) calendar day falls either on a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. If a Certificate of Need application is not submitted as provided herein, it will not be accepted and an applicant filing an application beyond the time period specified will be required to submit a new letter of intent in the manner specified above.

(2) **Contents of Application.** Applications shall contain all relevant data, information and assurances required by the Department. The Department will provide application forms on request, and all applications must be on the form supplied by the Department or a copy thereof, and comply with the content requirements specified thereon. Applications shall provide information including, but not necessarily limited to, the following categories as they relate to the proposed projects:

(a) identification of the applicant;

(b) ownership;

(c) site identification;

(d) compliance with State and local codes and ordinances, including flood hazards;

(e) a detailed and complete description of proposed project;

(f) project justification, including specific documentation of the need (utilizing the Department's data and methodology) that the population to be served has for the project;

(g) staffing and operation;

(h) financial information, which shall include positive evidence of ability to obtain financing, the source of financing, and maximum interest rates, which will be paid to the lender. Applications submitted for or on behalf of a health care institution shall include one copy of the latest audit report (or internal financial statement for investor-owned facilities). Also submitted shall be all pro forma financial data requested in the application;

(i) cost containment and quality of care considerations;

(j) project design and construction schedule including as applicable:

1. Schematic Design Documents meeting the standards defined by the American Institute of Architects in section 2.4.2 of the Standard AIA Contract Language. These Schematic Design Documents shall establish the conceptual design of the Project illustrating the scale and relationship of the Project components. The Schematic Design Documents shall also include a conceptual site plan, if appropriate, and preliminary building plans, sections and elevations. Preliminary selections of major building systems and construction materials shall be noted on the drawings or described in writing;

2. A written summary of the Architect's evaluation and planning findings and recommendations meeting the standards defined by the American Institute of Architects in section 2.3 of the Standard AIA Contract Language. This summary shall include, as applicable, an evaluation of the Applicant's program and schedule requirements and budget for the Cost of the Work, each in terms of the other, a preliminary evaluation of the Applicant's site for the Project based on the information provided by the Applicant of site conditions, and the Applicant's program, schedule and budget for the Cost of the Work, and an evaluation of the applicant's proposed method of contracting for construction services; and

3. A detailed description of the proposed timeline and phases for project completion.

(k) a cost estimate prepared by a licensed architect or engineer within the sixty (60) days immediately preceding submission of the application;

(l) documentation from the Healthcare Facility Regulation Division of no uncorrected licensure operational standards in the applicant's facility, if applicable.

(3) **Submittal of Applications.**

(a) Using the Department's web portal, Applicants should submit one (1) copy of the application signed by the applicant or the legal representative of the applicant. Failure to do so will result in non-acceptance of the application.

(b) Applications received after 3:00 p.m. on any business day will be considered to have been received on the next business day. Receipt of the application will be acknowledged in writing by the Department.

(4) **Filing Fee Required.**

(a) Each application for a Certificate of Need review shall be accompanied by a fee, except for the provisions covered in Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(d) and Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(e), the amount of which shall be determined by the following schedule:

1. for applications with a total project cost from zero to $1,000,000.00, the fee shall be $1,000.00; and

2. for applications with a total project cost greater than $1,000,000.00, the fee shall be one-tenth of one percent (.001) of the total cost but not to exceed $50,000.00; and

3. for the review of cost overruns the fee shall be computed as shown above for the amount of the overrun only.

(b) For any project, which is to be accomplished by lease, gift or other means of acquisition, the dollar value for purposes of computing the fee will be based on the value of the major medical equipment or facilities to be acquired. The value of the major medical equipment is the expenditure, which would be required for purchase. The value of the facilities to be acquired is based on a current (within six (6) months of the submittal of the Certificate of Need application) appraisal of the property.

(c) Payment of the fee shall be by credit/debit card via the Department's website, certified check, or money order made payable to the State of Georgia and must be received by the Department before an application will be accepted for review. Failure to provide payment of the appropriate fee will result in non-acceptance of the application. Fee payments are collected as general State revenue.

(d) State-owned institutions shall be exempt from payment of a filing fee.

(e) The Department may waive payment of a filing fee, or any portion thereof, for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. A party requesting a waiver must make such request at the time the application is submitted to the Department.

(f) Subject to the Rules in (a) through (e) above, applicants shall submit an additional filing fee for additional information or amendments provided during the review period that increase the cost of the project. For such supplementary information which increases the cost of the project, the amount that shall be submitted is an amount equal to the difference between the calculation of the filing fee based on the total amended project costs as outlined in (a) and the filing fee paid at the time of application, except that in no case shall the amount submitted be less than $500.00. Should such supplementary information decrease the costs associated with a project, the filing fee shall not be reduced or refunded. The Department shall not issue decisions on applications for which such supplementary information has been provided where an applicant has not submitted the additional filing fee, as applicable.

(5) **Review for Completeness**.

(a) Upon receipt of an application, the Department shall determine whether the application is complete. No application shall be reviewed until it has been determined by the Department to be complete in accordance with information requirements specified in this Section.

(b) An application will be determined to be incomplete if any of the following were not either provided with the application or as may be specified in this Section, submitted previously to the Department:

1. all the required data, information and assurances provided on the correct forms, including but not limited to the following:

(i) detailed description of the proposed project as required by Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(e);

(ii) financial program to meet the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(h);

(iii) documentation of necessary financing for the project, such as a letter of credit, etc.;

(iv) financial pro forma to meet the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(h); and

(v) most recent audited financial statements, or personal financial statements if audited statements are not available (tax returns would meet this requirement for unaudited entities and individuals);

(vi) for projects invoking service-specific Rules, as outlined in Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq., the appropriate service-specific review considerations;

(vii) for projects involving construction, renovation, and/or expansion, schematic plans and cost estimates certified by an architect, engineer, or general contractor, as appropriate and as required by Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(j) and (k);

(viii) for projects involving the acquisition of equipment, purchase orders or invoices, as appropriate;

2. signature of the applicant;

3. payment of the filing fee, as described in Ga. Comp. R. & Regs. r. 111-2-2-.06(4);

4. the most recent three (3) years of all required surveys, as may be previously submitted to the Department, including the Annual Hospital Questionnaire, Annual Nursing Home Questionnaire, survey of home health agencies, or other data-gathering instruments required by the Department for any health care facilities and services owned or operated by the applicant, to include data requested pursuant to O.C.G.A. § 31-6-70. In order for an application to be deemed complete, such surveys and data-gathering instruments shall be complete and accurate, as determined by the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have submitted completed questionnaires with the Department;

5. written verification certifying entitlement to any necessary real estate property or leasehold as described by the applicant in the application. Verification of entitlement shall include, but not be limited to, deeds, contracts, lease arrangements, conditional sales agreements or a comparable arrangement that purports to be a transfer of ownership in whole or in part. If an unsigned lease arrangement is submitted, the Applicant shall also submit an original letter documenting both the lessor's and lessee's commitment to participate in the lease once the CON is approved;

6. authorization to conduct business, including but not limited to, as appropriate:

   (i) if the applicant is an entity requiring authorization by the Secretary of State to become a legal entity entitled to do business in the State of Georgia, such documentation;

   (ii) by-laws, articles of incorporation, or articles of organization; and

   (iii) if the applicant is an existing and licensed or permitted entity, a copy of such license or permit.

7. The applicant shall file one copy of the application with the office of the County Commissioner of the county in which the project exists or is proposed. The applicant shall submit with the application an exact copy of the letter addressed and submitted to the County Commission that accompanied the submittal of the application to the County Commission;

8. all post-approval reporting requirements as mandated at Ga. Comp. R. & Regs. r. 111-2-2-.04(2) for all previously approved projects, as may be previously submitted to the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have met the said post-approval reporting requirements for all previously approved projects with the Department;

9. the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2);

10. In order to be determined complete, an applicant must be current will all indigent and charity care commitments, if any, made to the Department as a condition or requirement for past approval of a project. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation are current with any and all indigent and charity care commitments made to the Department; and

11. In order to be determined complete, an applicant must be current with any and all fines, if any, levied by the Department for violation of these Rules.

12. No applicant for a new Certificate of Need, a modification to an existing Certificate of Need, or a conversion of a Certificate of Need that has any outstanding amounts owed to the state including fines, penalties, fees, or

other payments for noncompliance with any requirements contained in O.C.G.A. §§ 31-6-40.1, 31-6-45.2, 31-6-70, 31-7-280, or 31-8-179.2 shall be eligible to receive a new Certificate of Need or a modification to an existing Certificate of Need unless such applicant pays such outstanding amounts to the state. Any such fines, penalties, fees, or other payments for noncompliance shall be subject to the same notices and hearing for the levy of fines under O.C.G.A. § 31-6-45.

(c) The Department shall notify the applicant within ten (10) business days following receipt of the application that the application is complete as submitted or that additional information is required to complete the application. If additional information is required, the notice shall include a statement of the specific additional information required. Notice shall be effective the date it is sent electronically by the Department.

(d) The Department shall notify the applicant no later than ten business days following receipt of the additional information whether such information is sufficient to complete the application. If it is not sufficient, the notice shall include a specific statement of the information which needs clarification or which does not adequately respond to the original request.

(e) The Department will deem an application to be withdrawn if the applicant fails to provide the Department with information requested on a notice of incompleteness within two (2) calendar months after the date of the original letter notifying the applicant of the information necessary for completeness.

(f) In addition to the provisions of a paragraph (b) above, additional requirements shall be in effect where the application involves the acquisition of a hospital owned or operated by or on behalf of a political subdivision, any combination of such subdivisions, or by or on behalf of a hospital authority. These requirements shall be as follows:

1. in the event that a health care facility, which has been assisted at any time during the past twenty years through a grant of State funds, is proposed to be acquired by a non-grant-eligible entity, the Department, in accordance with O.C.G.A. §§ 31-7-53(c) and 31-7-57(d), is required to recover the funds granted by the State. A commitment regarding return to the State of such monies consistent with the Code should be forwarded to the Department no later than the end of the review period.

2. there shall be submitted a written agreement between the parties containing the following commitments:

   (i) that the purchaser or lessee will annually allocate funds for the purpose of providing indigent/charity care. The funds allocated will

be no less than three percent (3%) of the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare contractual adjustments have been deducted. The funds allocated will be based on the previous year's financial records, except the first year of operation following an acquisition the three percent (3%) will be based on the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare adjustments have been deducted. For purposes of this Rule; gross revenues will include all income derived from all sources;

(ii) that the purchaser will agree that no resident of the county in which the hospital resides will be denied emergency care (including emergency obstetrical care) due to inability to pay;

(iii) that the purchaser will participate in the Medicaid and Medicare programs and the State Health Benefit Plan, if authorized by the Department.

(6) **Submission of Information and Documents.**

For the purposes of meeting any deadlines imposed by either these Rules or O.C.G.A. § 31-6, the Department will not accept any information or documents that are submitted either via telephone or facsimile. In order to meet any of the above referenced deadlines, it will be necessary to submit the information or documents via the Department's web portal or as otherwise directed by these Rules. Except as otherwise provided, information and documents received after 5:00 p.m. on any business day will be considered to have been received on the next business day. Except as otherwise provided by these Rules, all documents required and described in these Rules, except for the periodic reports described in Ga. Comp. R. & Regs. r. 111-2-2-.04, including, but not limited to, applications, opposition letters, supplementary information, requests for determinations, and opposition to determinations, shall be submitted via the Department's web portal.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.06
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Application for Certificate of Need" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Aug. 28, 2006; eff. Sept. 17, 2006.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.07. Review Procedures.

(1) Beginning of Review Process.

(a) When an application is deemed by the Department to be complete, the Department shall provide written notice to the applicant of the completeness of the application and the schedule for review. The Department shall provide similar notice to a newspaper of general circulation in the county of the project, to the appropriate Regional Development Center, and to the chief elected official of the county and municipal government, if any, within whose boundaries the proposed project would be located. The date on the letter of notification shall be deemed to be the date of notification and the beginning date of the Certificate of Need review cycle.

(b) The Department will schedule reviews so that, unless joined with another application, no review shall, except as noted in (d) below, take longer than one hundred and twenty (120) days from the date of notification of the beginning of review until the date the decision to issue or not to issue a Certificate of Need is sent electronically to the applicant. Absent good cause, the Department generally will not issue a decision prior to the sixtieth (60th) day of the review cycle.

(c) In the event that, from the time an application is declared complete until thirty (30) days thereafter, one or more additional applications are declared complete which involve similar projects in the same or overlapping service areas, the Department may declare that such applications will be joined with the first application for review purposes. Following such joinder, none of the subsequent applications so joined may be considered as a first application for purposes of future joinder. The Department shall notify all applicants whose applications have been joined and shall set a new time parameter for Department actions. The one hundred and twenty (120) day final decision deadline shall run from the latest date that any one of the joined applications was declared complete for review. Except as otherwise provided in Ga. Comp. R. & Regs. r. 111-2-2-.08(1), such joinder shall be the sole method of comparative review for all applications filed after July 1, 2008.

(d) Where the Department determines that conditions exist which make it impractical to complete a review in one hundred and twenty (120) days, the Department may, on notification to the applicant, extend the time limit another thirty (30) days to one hundred and fifty (150) days. Conditions, including but not limited to the following, may constitute cause for extending the time:

1. The Department anticipates issuance of new demographic or utilization, data affecting the application;

2. The Department has received conflicting or contradictory information necessitating further investigation;

3. Results of impending legal action may have an effect on the application.

(e) For good cause shown, as shall be determined by the Department, a public hearing will be held at a time and location specified by the Department.

1. A request for a public hearing shall be signed by at least fifty (50) residents of the area where the project is located and must be received by the Department within twenty (20) days after the beginning date of the review cycle. The request shall include justification for the public hearing based on circumstances described in this paragraph.

2. To the extent possible, notification will be provided in a newspaper of general circulation in the area where the project is located approximately two weeks in advance of the hearing.

3. Any person desiring to offer testimony at the hearing will be given the opportunity to do so, but the providing of such testimony or evidence shall not confer upon the person or persons so testifying the status of "party" as that term is used in the Administrative Procedure Act.

4. Where distance and the nature of the project warrant, and within the budget constraints of the Department, the public hearing may be held by the Department in the area where the project is proposed to be located. Circumstances, which may indicate good cause for a hearing in the area, include but are not limited to:

   (i) Projects, which could have significant effect on access to frequently used services by a sizable population group;

   (ii) Projects generating strong conflicting viewpoints by the residents of an area;

   (iii) Projects with potential for unusually significant impact on existing services.

5. A summary report of the hearing will be prepared, a copy of which will be sent to the party requesting the hearing and to the applicant. Such report will be made a part of the master record regarding the project. The Department may charge a fee for the summary report.

(f) If during the first two (2) months of the review of the application the Department finds there are factors that create a potential for denial of the application, the Department shall, on or before the sixtieth (60th) day of the review period, provide the applicant an opportunity to meet with the Department. The problems with the application will be described and an opportunity offered to amend or to withdraw the application or to submit additional information. The sixty (60) day meeting with the applicant(s) is restricted to the Department and the applicant(s). Parties opposing an application(s) may not attend or participate in an applicant sixty (60) day meeting. Such addition information must be submitted prior to the seventy-fifth (75th) day of the review period.

1. "Additional information" is information and data submitted in response to a direct request from the Department at the meeting afforded an applicant after the first two (2) months of the review of the application or in response to issues and concerns raised by the Department in said meeting, or in the lack of such a meeting or request by the Department, information and data submitted consistent with the scope, physical location, cost, charges, service, and owners in the originally submitted application. Additional information must be submitted to the Department prior to the seventy-fifth (75th) day of the review period.

2. "Amendment" is a revision to the additional information or application as originally submitted that is submitted to the Department no later than the one hundred and tenth (110th) day of the review cycle and that constitutes a change in scope, physical location, cost, charge, service, or owner. The following changes in an application will qualify as an amendment:

   (i) A reduction or increase in the proposed physical space capacity; or

   (ii) A reduction or increase in the number of proposed beds or service units (e.g., operating rooms); or

   (iii) A change in the owners of the legal applicant entity, as long as the legal applicant entity remains the same; or

   (iv) A reduction or increase in a proposal's capital or operating costs; or

   (v) A change in site within three (3) miles of the site proposed in the original application or within the same service area as long as the population to be served and the service area to be served is not substantially different from that originally proposed as long as the proposed change does not require the application of a new need study or different rules; or

   (vi) A reduction or subtraction in the scope of the original application; or

   (vii) A change in the amount of commitment to indigent or charity care, projected utilization, financial information or patient charges that do not alter the basic financing or operations of the proposed project.

(g) The Department shall be notified with either a new application or written amendment to the current completed application when there are changes in the scope, physical location, cost, charges, service or owners of the applicant entity. Any revisions that constitute a total change in or addition to the scope of an application, in the location (except for the exemption in Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(f) 2.(v)), or in the legal applicant that would require the submission

of a new application. If the Department determines that the amendment constitutes a total change in either the scope, location, or legal applicant, the original application will be considered to be withdrawn and the applicant will be so notified. An application may be amended by the applicant at any time up to the one hundred and tenth (110th) day of the review cycle. (g.1) No party may oppose an application for a Certificate of Need for a proposed project unless:

1. Such party offers substantially similar services as proposed within a 35-mile radius, in Georgia, of the proposed project, or has a service area in Georgia that overlaps the applicant's proposed service area; or

2. Such party has submitted a competing application in the same batching cycle and is proposing to establish in Georgia the same type of facility proposed or offers, in Georgia, substantially similar services as proposed and has a service area located in Georgiathat overlaps the applicant's proposed service area.

(h) Any party, pursuant to O.C.G.A. § 31-6-43(d)(2), who is permitted to oppose an application, or an application(s) joined for review, must submit a notice of opposition, on the form provided by the Department, no later than the sixtieth (60th) day of the review cycle. The notice must contain the information specified by the form. The notice of opposition form submission shall also include one signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2). The notice of opposition must not contain the substantive arguments against a particular application.

1. Those parties who are opposed to an application will be given an opportunity to meet with the Department at a time and place specified by the Department after a review of the opposition notices. The opposition meeting provided for by O.C.G.A. § 31-6-43(h), shall be held no earlier than the ninetieth (90th) day of the review cycle. The applicant(s) shall be entitled to attend the opposition meeting. Only one designated person on behalf of each party opposed to a particular application will be allowed to speak on behalf of the opposition to said application at the opposition meeting. The time period provided for the opposition spokesperson shall be determined in the sole discretion of the Department. The applicant(s) will not be allowed to speak in rebuttal of the opposition remarks at the opposition meeting. The Department shall make no formal substantive comments regarding the review of the application(s) at the opposition meeting. The opposition parties shall submit via the Department's web portal, substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must provide one copy of the substantive opposition comments to the applicant at the opposition meeting. In order for an opposing party to have standing to appeal an adverse decision pursuant to O.C.G.A. § 31-6-44, such party must

attend and participate in an opposition meeting. Substantive opposition comments must pertain to only one application and one applicant. In no case shall the Department accept substantive opposition comments that concern multiple applicants or applications.

2. Letters of support for a particular application must be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6) via the Department's web portal and can be submitted no later than the one hundredth (100th) day of the review cycle.

3. Applicants shall be given the opportunity to respond to the substantive opposition comments made orally and submitted in writing at the opposition meeting. The last day for the applicant(s) to submit final amendments to the application and/or to respond to the opposition meeting comments shall be the one hundred and tenth (110th) day of the review cycle. The Department reserves the right, but is not required to, ask the applicant(s) for information in response to the substantive opposition comments. If the Department asks the applicant for information as a result of the comments provided at the opposition meeting, the applicant must submit the information requested no later than the one hundred and tenth (110th) day of the review cycle.

4. The Department shall provide written notification of its decision to issue or deny a Certificate of Need no later than the one hundred and twentieth (120th) day of the review cycle, or, if the project was extended, no later than the one hundred and fiftieth (150th) day of the review cycle.

(i) The Department, in accordance with the provisions of subsections (k)-(m) below, will give special expedited consideration to emergency expenditures required solely to cope with a situation posing an immediate threat to the health and safety of patients, visitors, or staff. The General Counsel, or his designee, upon a showing that a proposed replacement facility is critical to the welfare, health and stability of the immediate community as evidenced by written support from the local, county and state governing bodies may, authorize an expenditure based on a request by telephone, with written documentation to be provided later. In the event that the authorized emergency expenditure requires an application to replace an existing health care facility, the application will not be subject to joinder.

"Emergency expenditures" as set forth in this subparagraph (i) shall include but not be limited to expenditures necessitated by circumstances arising from an authorized hazardous condemnation as well as from acts of God including but not limited to earthquakes, hurricanes, tornados or floods.

(j) The Department will decline to review through Certificate of Need application capital expenditures that do not reach the dollar threshold as required under the

Certificate of Need program, provided the person proposing such expenditure receives from the Department a prior written authorization for the expenditure. Where a proposal is considered to meet the language of this subsection, a letter describing the reasons for the expenditure, the cost and the anticipated date the expenditure is proposed to be made should be submitted to the Department, in accordance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.10, prior to the obligation of such funds. If, in the opinion of the Department, the expenditure is consistent with those expenditures not subject to review the Department will issue a confirmation to the requestor, which shall serve as authorization for the expenditure.

(k) Pursuant to the provisions of O.C.G.A. § 31-6-43(g), the Department shall conduct an expedited review with a review period of no longer than (30) thirty days for those projects deemed an emergency. When the Governor has declared a state of emergency in a region of the state, existing health care facilities in the affected region may seek emergency approval from the Department to make expenditures in excess of the capital expenditure threshold or to offer services that may otherwise require a Certificate of Need. The Department shall give special expedited consideration to such requests and may authorize such requests for good cause. Once the state of emergency has been lifted, any services offered by an affected health care facility under this subsection shall cease to be offered until such time as the health care facility that received the emergency authorization has requested and received a Certificate of Need. For purposes of this subsection, "good cause" means that authorization of the request shall directly resolve a situation posing an immediate threat to the health and safety of the public.

(l) The Department shall issue a decision on applications for a Certificate of Need for emergency projects as provided in subsection (k) above, no later than thirty (30) days after the application has been deemed complete for review; failure to issue the decision on or before the thirtieth (30th) day after it has been deemed complete for review shall result in an automatic approval of the application, subject to subsection (n) below; the decision issued by the Department shall be a summary statement of the findings during the review of the project;

(m) If, during the course of the review period, the Department finds that there are factors that create the potential for denial of the application, the Department shall immediately discontinue its emergency review, notify the applicant in writing of that decision, and review the application in accordance with the applicable non-emergency review procedures set forth in Ga. Comp. R. & Regs. r. 111-2-2-.07.

(n) The review of such projects as outlined in subsections (k) - (m) above shall be governed by the emergency provisions of the referenced subsections and not the provisions of subsections (a) - (h) above.

(o) The filing fee for applications of the type specifically listed in subsections (k) - (n) above shall be $1,000.00, notwithstanding the filing fee provisions of Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(a).

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.07
Authority: O.C.G.A. § 31-6-43(d).
History. Original Rule entitled "Review Procedures" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Nov. 13, 2007; eff. Dec. 3, 2007.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
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Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.
Amended: F. Oct. 14, 2022; eff. Nov. 3, 2022.

Rule 111-2-2-.08. Alternative Application and Review Procedures.

(1) **Batching Review Process**

(a) Pursuant to O.C.G.A. § 31-6-43(e), the Department may limit the time periods during which it will accept applications for the following health care facilities and/or services: skilled nursing facilities; intermediate care facilities; home health agencies, open heart surgical services, pediatric cardiac catheterization and open heart services, perinatal services, freestanding birthing centers, psychiatric and substance abuse services, comprehensive inpatient physical rehabilitation services, ambulatory surgical services, positron emission tomography services, and megavoltage radiation therapy services. Limitation of the time periods shall be to only such times after the Department has determined there is an unmet need for such facilities and/or services, or will accept applications pursuant to any service-specific need standard exceptions. The Department shall make a determination as to whether or not there is an unmet need for each type of facility at least every six (6) months and shall notify those requesting such notification of that determination. No application for the services listed above will be accepted for review by the Department except as provided for pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1). For purposes of batching only, the applications entered into the one hundred twenty (120) day review period shall be evaluated according to the data used to publish the unmet need, or to accept applications pursuant to any service-specific need standard exceptions, for the particular service at issue, for those services listed above, and not the latest available data at the time of decision, as is the case with all non-batched applications.

(b) Upon the determination of an unmet need for a particular facility/service in a given service area, the Department shall provide notice indicating which applications will be considered in that particular batching cycle to all interested parties requesting notice of that determination. It shall be the sole and exclusive responsibility of the interested party to notify the Department in writing of that

party's desire to be informed of the Department's unmet need determination(s) for batching purposes. The Department's notice shall contain the unmet need for the type of facility/service in the given service area(s) and shall also contain the pertinent time frames and deadlines for submission of notices of intent to apply, for submission of applications, and the review of such applications.

(c) All parties interested in applying for the particular unmet need in a given service area must notify the Department of that party's intent to apply.

1. The notice must be in writing, submitted via the Department's web portal, and must address specifically the type of unmet need and service area(s) for which the applicant intends to apply.

2. The notice of intent must be received by the Department no later than the close of business on the thirtieth (30th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the thirtieth (30th) calendar day falls on either a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday.

3. Notwithstanding any other relevant provisions within this Rule, the notice of intent to apply must be received by the Department either before or simultaneously with the submission of the actual application in accordance with the notice of intent deadline.

4. In the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party shall be disqualified automatically from applying during that batching cycle.

(d) Subject to the proper submission of a notice of intent to apply, any interested party shall use the Department's web portal to submit an application no later than 12:00 P.M. on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. For purposes of batching only, all properly submitted applications will be deemed received on the sixtieth (60th) day, regardless of the actual date of submission.

(e) For the purposes of batching only, an application which has been deemed received according to (d) above, will only be deemed properly submitted and complete if the following requirements, in addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(5), are met:

1. The appropriate Certification Statement (an applicable service-specific related checklist) is submitted simultaneously with the original application; and

2. All of the items addressed in the Certification Statement are provided, as certified, with the original application.

(f) In the event that an application is deemed in receipt by (d) above, but is not deemed to be properly submitted and complete by (e) above by 12:00 PM on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need (in the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday), the application will be disqualified from the batching review.

(g) The batching review cycle will be conducted in the following manner:

1. The batching review cycle shall be one hundred and twenty (120) days in duration. As a result, no party participating in the batching review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day.

2. The first day of the batching review cycle shall be the day upon which all properly submitted applications are deemed to be received. [See Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(d) above.]

3. On or before the sixtieth (60th) day of the batching review cycle, the Department shall provide the applicant(s) an opportunity to meet with the Department. The Department will describe any issues with the application and provide an opportunity to the applicant(s) to amend or withdraw the application or to submit additional information. Any and all additional information must be submitted on or before the seventy-fifth (75th) day of the batching review cycle. The sixty (60) day meeting with the applicant(s) is restricted to the Department and the applicant(s). Parties opposing an application(s) may not attend or participate in an applicant sixty (60) day meeting.

4. Any party who is opposed to one or more applications submitted during a batching cycle must submit a notice of opposition via the Department's web portal, on the form provided by the Department, no later than the sixtieth (60th) day of the batching review cycle. The notice must contain the information specified by the form. The notice of opposition form submission shall also include one signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2).

The notice of opposition must not contain the substantive arguments against a particular application.

Those parties who are opposed to an application will be given an opportunity to meet with the Department at a time and place specified by the Department after a review of the opposition notices. The opposition meeting, provided for by O.C.G.A. § 31-6-43(h), shall be held no earlier than the ninetieth (90th) day of the batching review cycle. The applicant(s) shall be entitled to attend the opposition meeting. Only one designated person on behalf of each party opposed to a particular application will be allowed to speak on behalf of the opposition to said application at the opposition meeting. The time period provided for that opposition spokesperson shall be determined in the sole discretion of the Department. The applicant(s) will not be allowed to speak in rebuttal of the opposition remarks at the opposition meeting. The Department shall make no formal substantive comments regarding the review of the application(s) at the opposition meeting. The opposition parties shall submit via the Department's web portal, substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must provide one copy of the substantive opposition comments to the applicant at the opposition meeting. In order for an opposing party to have standing to appeal an adverse decision pursuant to O.C.G.A. § 31-6-44, such party must attend and participate in an opposition meeting. Substantive opposition comments must pertain to only one application and one applicant. In no case shall the Department accept substantive opposition comments that concerns multiple applicants or applications.

Letters of support for a particular application must be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6) via the Department's web portal and can be submitted no later than the one hundredth (100th) day of the batching review cycle.

5. Applicants shall be given the opportunity to respond to the substantive opposition comments made orally and submitted in writing at the opposition meeting. The last day for the applicant(s) to submit final amendments to the application and/or to respond to the opposition meeting comments, shall be the one hundred and tenth (110th) day of the batching review cycle. The Department reserves the right, but is not required to, ask the applicant(s) for information in response to the substantive opposition comments. If the Department asks the applicant for information as a result of the comments provided at the opposition meeting, the applicant must submit the information requested no later than the one hundred and tenth (110th) day of the batching review cycle.

6. No later than the one hundred and twentieth (120th) day of the batching review cycle, the Department shall provide written notification of its decision to issue or deny a Certificate of Need to the pertinent applicant(s).

(h) In evaluating batched applications, if any or all of the batched applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. The past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. Specific services to be offered;

3. Appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. Demonstrated readiness to implement the project, including commitment of financing;

5. Patterns of past performance, if any, of the applicants in implementing previously approved projects in a timely fashion;

6. Past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. Evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care; and

8. Past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments.

(i) In the event of a favorable decision, the Department's notification letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter of the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the batching review cycle, whichever is applicable. The effective date of the Certificate shall be the decision or approval date if not appealed. If administratively appealed in a timely fashion, the effective date of the Certificate

shall be the date of final resolution of any administrative hearing. The Department may stay the effective date of a project appealed through judicial process at the request of any party to such appeal or upon the Department's own initiative. Any determination by the Department to stay the effective date will be based upon sound health planning principles. If the Department stays the effective date of a project appealed through judicial process, the effective date shall be the date of final resolution of any judicial appeal.

(j) The decision letter shall contain at least the following:

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

2. Information pertaining to the availability of an appeal hearing.

(k) A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Department's decision shall be subject to the provisions of the Open Records Act.

(l) Appeals of the Decision of the Department shall be in accordance with the Rules promulgated by the Certificate of Need Appeal Panel found in Ga. Comp. R. & Regs. Chapter 274.

(2) **Alternative Healthcare Models**

(a) **Applicability**.

1. For Certificate of Need purposes, Alternative Healthcare Models are defined as new and/or innovative models of providing new or existing institutional health services delivered in a proposed or existing healthcare facility.

2. For Certificate of Need purposes, the applicant for an Alternative Healthcare Model CON will be as follows:

(i) If the service(s) will be provided within a single healthcare facility, the owner of that facility will be the applicant;

(ii) If the service(s) will be provided within two or more healthcare facilities that are part of a healthcare services network, the owner(s) of the facility(ies) in which the service(s) will be provided will be the co-applicant(s).

3. The Department shall evaluate the performance of the Alternative Healthcare Model according to the scope as defined by the Department

decision and the standards set forth in these Rules. If after a review the Department determines that the Alternative Healthcare Model does not meet the defined scope or expected standards, the Department may either immediately revoke the Certificate of Need or grant a specified time period during which the Alternative Healthcare Model must meet the defined scope and the expected standards or lose its Certificate of Need.

(b) **Definitions**

1. "Alternative healthcare model" means a new and/or innovative model of providing new or existing institutional health service(s) delivered in or through a healthcare facility(ies) and/or healthcare services networks.

2. "Authorized service" means a Department sanctioned Alternative Healthcare Model, which is either existing or approved. An existing service is an authorized service, which has become operational, and an approved service is an authorized service, which has not yet become operational.

3. "Board" means the Board of Community Health.

4. "Health care facility", as defined at O.C.G.A. § 31-6-2(17), means hospitals; destination cancer hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes of at least twenty-five (25) beds; ambulatory surgical or obstetrical facilities; freestanding emergency departments or facilities not located on a hospital's primary campus; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitative centers, but only to the extent that O.C.G.A. § 31-6-40(a)(3) or (7) or both are applicable thereto.

5. "Healthcare services network" means a collaborative arrangement that consists of at least one healthcare facility plus one or more physician groups and/or one or more third party payers, or a collaborative arrangement that includes at least two or more healthcare facilities.

6. "Most recent year" means the most recent calendar year prior to submission of an application.

7. "Official inventory" means the inventory of all authorized Alternative Healthcare Models maintained by the Department based on CON approval and official Department records.

8. "Official state component plan" means the most recent document(s) that is/are most closely related to those services being provided by the

Alternative Healthcare Model. The most recent document(s) will have been developed by the Department and approved by the Board.

9. "State health policies" means the most recent policies developed by the Board, which provide a framework for the service-specific policies included within each component of the State Health Plan. These state health policies include health promotion, financial accessibility, least restrictive care, regionalization, cost containment, health planning and citizen participation, healthcare personnel, and healthcare data and information networks.

(c) **Requests for Proposals**

1. Within the period of April 1 through May 31 of each year, the Board may accept abstracts describing potential Alternative Healthcare Models, based on the recommendation of the Department. The Board will review these abstracts, if any are solicited for that year, by August 31 of that year and select a list of those categories for which Alternative Healthcare Model Certificate of Need applications may be submitted.

2. Within thirty (30) days of the determination by the Board of the particular categories under which Alternative Healthcare Model Certificate of Need applications may be submitted, the Department shall provide notice of these categories to all interested parties. The notice shall contain:

   (i) the listing of category(ies) related goals and desired outcomes and the probable scope of services;

   (ii) the pertinent time frames and deadlines for submission of notices of intent to apply for Alternative Healthcare Model Certificate of Need;

   (iii) the pertinent time frames and deadlines for submission of CON applications; and

   (iv) the pertinent time frames and deadlines for the review of such applications, and any related criteria for review.

(d) **Intent to Apply**

1. All parties wanting to apply for Alternative Healthcare Model Certificates of Need under the selected categories must notify the Department of that party's intent to apply.

2. This notice must be:

(i) in writing, submitted via the Department's web portal, and must address specifically the particular category under which the applicant intends to apply;

(ii) received by the Department no later than the close of business on the sixtieth (60th) calendar day following the date that the Department publishes the notice of the selected categories. In the event that the sixtieth (60th) calendar day falls on either a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday;

(iii) must be received by the Department either before or simultaneously with the submission of the actual application; and

(iv) in the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party automatically shall be disqualified from applying during that particular review cycle.

(e) **Application Process**

1. Certificate of Need applications pertaining to the selected categories will be submitted via the Department's web portal on or before 3:00 p.m. June 1 of the year following the year in which the categories were selected by the Board. (Although applications may be submitted prior to 3:00 p.m. June 1, all application will be deemed received on June 1.) In the event that June 1 falls either on a weekend or a legal holiday, the day of submission shall become automatically the next business day that is neither a weekend nor a legal holiday;

2. Alternative Healthcare Model Certificate of Need applications must comply with the requirements in Ga. Comp. R. & Regs. r. 111-2-2-.06(2) and (3).

3. For the purposes of Alternative Healthcare Model Certificate of Need applications, an application will be deemed properly submitted if the following requirements are met:

   (i) a summary of the Certificate of Need application is included to be used as information for the Board and general public;

   (ii) a Certification Statement of Completeness is included designating under which category the application is being submitted; and

(iii) all items addressed in the Certification Statement of Completeness are provided with the application.

(f) **The Review Cycle**

1. The review cycle shall be automatically one hundred and twenty (120) days in duration. As a result, no party participating in the review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day;

2. The first day of the review cycle shall be the day upon which all properly submitted applications are deemed to be received as specified in Ga. Comp. R. & Regs. r. 111-2-2-.08(2)(e)3.

3. No later than the thirtieth (30th) day of the review cycle, the Department shall, if deemed necessary, submit a written request to any and all pertinent applicants for clarifying and/or supplemental information. This written request may be distributed within a meeting of the applicant(s). The purpose of the request for clarifying and/or supplemental information shall be to obtain information from the applicant(s) that clarifies or supplements the initial information submitted with the original application.

4. No later than the forty-fifth (45th) day of the review cycle, the applicant(s) shall, if deemed necessary by the Department, submit their clarifying and/or supplemental information. Failure to submit the required clarifying and/or supplemental information by the forty-fifth (45th) day may be grounds for denial of the application.

5. If, by the forty-fifth (45th) day, the review indicates potential for denial of the application(s), the Department, on or before the sixtieth (60th) day of the review cycle, shall provide the applicant(s) an opportunity to meet with the Department. The problems with the application(s) will be described and an opportunity offered to amend or withdraw the application or to submit additional information. Any and all additional information and amendments must be submitted on or before the seventy-fifth (75th) day of the review cycle.

6. The last day for interested parties (including, but not limited to, competing applicant(s) and/or existing competing health care facilities) to submit letters of support or opposition addressing the underlying merits, or lack thereof, of any pending application(s) shall be the eighty-fifth (85th) day of the review cycle and must be submitted via the Department's web portal. Any letters of support and/or opposition that are received after the eighty-fifth (85th) day of the review cycle shall not be considered by the Department in its review

of the pertinent application(s) and the letter(s) shall not become part of the master file compiled for the pertinent application(s).

7. The last day for applicant(s) to submit final amendments and responses to letters of opposition shall be the one hundred and tenth (110th) day of the review cycle.

8. No later than the one hundred and twentieth (120th) day of the review cycle, the Department shall provide a written letter notifying the applicant of their decision to issue or deny a Certificate of Need to the pertinent applicant(s).

9. In the event of a favorable decision, this letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter from the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the review cycle, whichever is applicable.

10. The decision letter shall contain at least the following:

    (i) a detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

    (ii) information pertaining to the availability of an appeal hearing.

11. A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Department's decision shall be subject to the provisions of the Open Records Act.

12. Appeals of the decision of the Department shall be in accordance with the Rules promulgated by the Certificate of Need Appeal Panel.

(g) **Standards**

1. An Alternative Healthcare Model must be consistent with the State Health Policies adopted by the Board.

2. An Alternative Healthcare Model must clearly define its target population/community.

3. An Alternative Healthcare Model must:

    (i) include a hypothesis(es) to be tested within a time-limited period not to exceed five (5) years;

(ii) demonstrate, as applicable, how it will support research, new service development, health professional education and training, and/or affiliation with an academic center of higher learning; and

(iii) demonstrate that the community supports the Alternative Healthcare Model.

4. An applicant for an Alternative Healthcare Model CON shall demonstrate the feasibility of operating the Alternative Healthcare Model in Georgia, based on a review of the experience in other states including the impact on health professionals of other healthcare programs or facilities and how the project is impacted by payers and regulatory entities.

5. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to reduce healthcare costs to consumers, third party payors and the system as a whole.

6. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to maintain or improve the standards of healthcare quality in some measurable fashion.

7. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to provide increased choices or access for consumers to a continuum of services within the target community.

8. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to meet existing or emerging health status and/or health system needs.

9. For any applicant that meets the requirements of this Rule the Department may waive all or part of otherwise applicable service-specific Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.08
Authority: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Alternative Application and Review Procedures" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.09. General Review Considerations.

(1) **General Considerations**. The burden of proof for producing information and evidence that an application is consistent with the applicable considerations and review policies, which follow, shall be on the applicant. In conducting review and making findings for Certificates of Need, the Department will consider whether:

(a) the proposed new institutional health services is reasonably consistent with the relevant general goals and objectives of the State Health Plan. The goals and objectives related to issues and addressed in the State Health Plan, which are relevant to the Certificate of Need proposal, will be considered in the review. It should be recognized that the goals of the State Health Plan express the ideal and, in some respects, may be incompatible with the concept of cost containment. The statutes and Rules represent the final authority for review decisions and the content of the Plan, or any component thereof shall not supersede the Rules in such determination;

(b) the population residing in the area served, or to be served, by the new institutional health service has a need for such services;

1. Population projections used by the Department will be resident population figures prepared or approved by the Office of Planning and Budget or other official figures that may be applicable as determined by the Department.

2. Updated resident population projections will be utilized upon the official effective date as stated by the Department, pursuant to these Rules, replacing and superseding the older data.

3. The projection period or horizon year for need determinations will be five years for hospital services and three years for all other services, unless otherwise provided by the Rules for the specified service. The projection period or horizon year will be advanced to the next projection year or horizon year on or about April 1 of each year.

4. Inpatient facilities will be inventoried on the basis of bed capacity approved, grandfathered, or authorized through the Certificate of Need process regardless of the number of beds in operation at any given time or which may be licensed by the Healthcare Facility Regulation Division.

5. Data sources to be utilized by the Department to evaluate need, population characteristics, referral patterns, seasonal variations, utilization patterns, financial feasibility, and future trends will include, but not be limited to, the following:

(i) any surveys required by the Department, including but not limited to those for hospitals, nursing facilities, home health agencies, specialized services, and ambulatory surgery facilities;

(ii) Cost reports submitted to fiscal intermediaries and the Department;

(iii) periodic special studies or surveys, as produced or formally adopted or used by the Department;

(iv) the United States Census and other studies conducted by the Census and other Federal and State agencies and bureaus, including but not limited to, the Department of Labor; and

(v) such other data sources utilized by the Department for measurement of community health status. Such data may include information submitted by the applicant pursuant to Ga. Comp. R. & Regs. 111-2-2-.06(2)(f), which may be necessary for the Department to ensure that the project is consistent with applicable general consideration provisions.

6. All data used by the Department in a Certificate of Need review will be available to the applicant on request, in accordance with Department policies on requested information. The most recent data reported and validated will be used in the analysis of a proposal.

(c) existing alternatives for providing services in the service area the same as the new institutional health service proposed are neither currently available, implemented, similarly utilized, nor capable of providing a less costly alternative, or no Certificate of Need to provide such alternative services has been issued by the Department and is currently valid

1. The Department supports the concept of regionalization of those services for which a service-specific Rule exists.

2. The Department shall consider economies of scale where need exists for additional services or facilities.

3. Utilization of existing facilities and services similar to a proposal to initiate services shall be evaluated to assure that unnecessary duplication of services is avoided. Where there exists significant unused capacity, initiating a similar service in another health care facility would require strong justification under other criteria.

(d) the project can be financed adequately and is in the immediate and long term, financially feasible;

(e) the effects of the new institutional health service on payors for health services, including governmental payors, are reasonable;

(f) the costs and methods of a proposed construction project, including the costs and methods of energy provision and conservation, are reasonable and adequate for quality health care. Construction plans will be reviewed in detail to assure that space is designed economically. Space shelled-in for some future use will not be accepted unless the applicant demonstrates that the shelled-in space will not be directly related to the provision of any clinical health service;

(g) the new institutional health service proposed is reasonably financially and physically accessible to the residents of the proposed service area and will not discriminate by virtue of race, age, sex, handicap, color, creed or ethnic affiliation;

1. In accordance with the provision found in O.C.G.A. § 31-6-42(7), the Department will evaluate the extent to which each applicant applying for a Certificate of Need participates in a reasonable share of the total community burden of care for those unable to pay. This provision shall not apply to applicants for life plan communities, skilled nursing facilities or units, and to projects that are reviewed by the Department on an emergency basis in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(k). In all other instances, the following indicators will be evaluated:

   (i) administrative policies and directives related to acceptance of indigent, medically indigent, and Medicaid patients;

   (ii) policies relating medical staff privileges, if applicable, to reasonable acceptance of emergency referrals of Medicaid and PeachCare patients and all other patients who are unable to pay all or a portion of the cost of care;

   (iii) evidence of specific informational efforts targeted toward patients regarding arrangements for satisfying charges;

   (iv) documented records of refunds, if any, received from the Federal, State, county, city, philanthropic agencies, donations, and any other source of funds other than from direct operations, such as indigent care trust fund distributions and disproportionate share payments, if applicable;

   (v) the applicant's commitment to participate in the Medicare/Medicaid and PeachCare programs; to provide legitimate emergency care, if applicable, regardless of ability to pay; and to provide indigent and charity care; and

   (vi) documented records of care provided to patients unable to pay, Medicare and Medicaid contractual adjustment, Hill-Burton payments (if applicable), other indigent care, and other itemized deductions from revenue including bad debt. Such records shall

demonstrate that the levels of care provided correspond to a reasonable proportion of those persons who are medically or financially indigent and those who are eligible for Medicare or Medicaid within the service area.

2. The evaluation in 1. above is in addition to satisfaction of a minimum indigent and charity care commitment required by prior CON(s), if any.

(h) the proposed new institutional health service has a positive relationship to the existing health care delivery system in the service area;

(i) the proposed new institutional health service encourages more efficient utilization of the health care facility proposing such service;

(j) the proposed new institutional health service provides, or would provide a substantial portion of its services to individuals not residing in its defined service area or the adjacent service area;

(k) the proposed new institutional health service conducts biomedical or behavioral research projects or new service development that is designed to meet a national, regional, or statewide need;

(l) the proposed new institutional health service meets the clinical needs of health professional training programs;

(m) the proposed new institutional health service fosters improvements or innovations in the financing or delivery of health services; promotes health care quality assurance that can be documented with outcomes greater than those which are generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations; promotes cost effectiveness; or fosters improvements or innovations in the financing or delivery of health services; or fosters competition that is shown to result in lower patient costs without a significant deterioration in the quality of care;

(n) the proposed new institutional health service fosters the special needs and circumstances of Health Maintenance Organizations;

(o) the proposed new institutional health service meets the Department's minimum quality standards, including, but not limited to, standards relating to accreditation, minimum volumes, quality improvements, assurance practices, and utilization review procedures;

(p) the proposed new institutional health service can obtain the necessary resources, including health care management personnel; and

(q) the proposed new institutional health service is an underrepresented health service, as determined annually by the Department. The Department shall, by rule, provide for an advantage to equally qualified applicants that agree to provide an underrepresented service in addition to the services for which the application was originally submitted.

(2) **Destination Cancer Hospitals**. In the case of Certificate of Need applications for the construction, development, or establishment of a destination cancer hospital, the applicable general considerations as to the need for such service shall not include paragraphs (a), (b), (c), (g), (h), (j), (k), and (n) of Section (1) of Ga. Comp. R. & Regs. r. 111-2-2-.09, but shall include:

(a) Paragraphs (d), (e), (f), (i), (l), (m), (o), (p), and (q) of Section (1) of Ga. Comp. R. & Regs. r. 111-2-2-.09;

(b) That the proposed new destination cancer hospital can demonstrate, based on historical data from the applicant or its affiliated entities, that its annual patient base shall be composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia;

(c) The proposed new destination cancer hospital states its intent to provide uncompensated indigent and charity care which shall meet or exceed three percent (3%) of its adjusted gross revenues and provide care to Medicaid beneficiaries;

(d) That the proposed new destination cancer hospital shall conduct biomedical or behavioral research projects or service development which is designed to meet a national or regional need;

(e) That the proposed new destination cancer hospital shall be reasonable financially and physically accessible;

(f) That the proposed new destination cancer hospital shall have a positive relationship to the existing health care delivery system on a regional basis;

1. That the proposed new destination cancer hospital shall enter into a hospital transfer agreement with one or more hospitals within a reasonable distance from the destination cancer hospital or the medical staff at the destination cancer hospital has admitting privileges or other acceptable documented arrangements with such hospital or hospitals to ensure necessary backup for the destination cancer hospital for medical complications. The destination cancer hospital shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the destination cancer hospital with adequate emergency room services. Hospitals shall not unreasonable deny a transfer agreement with the destination cancer hospital. In the event that a destination cancer hospital and another hospital cannot agree to the terms of a transfer agreement as required by this paragraph, the Department

shall mediate between such parties for a period of no more than forty-five (45) days. If an agreement is still not reached within such forty-five (45) day period, the parties shall enter into binding arbitration conducted by the Department.

(g) That an applicant for a new destination cancer hospital shall document in its application that the new facility is not predicted to be detrimental to existing hospitals within the planning area. Such demonstration shall be made by providing an analysis in such application that compares current and projected changes in market share and payor mix for such applicant and such existing hospitals within the planning area. Impact on an existing hospital shall be determined to be adverse if, based on the utilization projected by the applicant, such existing hospital would have a total decrease of ten percent (10%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data; and

(h) That the destination cancer hospital shall express its intent to participate in medical staffing work force development activities.

(3) **General Cancer Hospital**

(a) On and after July 1, 2019, a destination cancer hospital may apply for a letter of determination in accordance with O.C.G.A. § 31-6-40(a)(8).

(b) Upon its receipt of a complete application for a destination cancer hospital to convert to a general cancer hospital, the Department shall issue such determination within 60 days.

(c) Upon the conversion of a destination cancer hospital to a general cancer hospital:

1. The general cancer hospital may continue to provide all institutional health care services and other services it provided as of the date of such conversion, including but not limited to inpatient beds, outpatient services, surgery, radiation therapy, imaging, and positron emission tomography (PET) scanning, without any further approval from the Department;

2. The destination cancer hospital shall be classified as a general cancer hospital under this chapter and shall be subject to all requirements and conditions applicable to hospitals under this article, including but not limited to, indigent and charity care and inventories and methodologies to determine need for additional providers or services; and

3. The hospital's inpatient beds, operating rooms, radiation therapy equipment, and imaging equipment existing on the date of conversion shall not be counted in the inventory by the Department for purposes of determining

need for additional providers or services, except that any inpatient beds, operating rooms, radiation therapy equipment, and imaging equipment added after the date of conversion shall be counted in accordance with the Department's rules and regulations.

(d) In the event that a destination cancer hospital does not convert to a general cancer hospital, it shall remain subject to all requirements and conditions applicable to destination cancer hospitals under this article.

(4) In the case of applications for basic perinatal services in counties where:

(a) Only one civilian health care facility or health system is currently providing basic perinatal services; and

(b) There are not at least three (3) different health care facilities in a contiguous county providing basic perinatal services, the Department shall not apply the consideration contained in paragraph (b) of section (1) of this Rule.

(5) **Osteopathic Considerations**. When an application is made for a Certificate of Need to develop or offer a new institutional health service or health care facility for osteopathic medicine, the need for such facility shall be determined on the basis of the need and availability in the community for osteopathic services and facilities. Nothing in this Chapter shall, however, be construed as recognizing any distinction between allopathic and osteopathic medicine.

(6) **Minority-Administered Hospital Considerations**. If the denial of an application for a Certificate of Need for a new institutional health service proposed to be offered or developed by a minority-administered hospital serving a socially and economically disadvantaged minority population in an urban setting, or by a minority-administered hospital utilized for the training of minority medical practitioners, would adversely impact upon the facility and population served by said facility, the special needs of such hospital facility and the population to be served by said facility for the new institutional health service shall be given extraordinary consideration by the Department in making its determination of need. The term "minority-administered" means a hospital controlled or operated by a governing body or administrative staff composed predominantly of members of a minority race. The Department shall have the authority to vary or modify strict adherence to the provisions of Code Chapter 31-6-42(c) and this Chapter in considering the special needs of said facility and its population served and to avoid an adverse impact on the facility and the population served thereby.

(7) **Considerations for Joined Applications**.

(a) In evaluating joined applications, if the services proposed are found to be needed, and if any or all applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. the past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. specific services to be offered;

3. appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. demonstrated readiness to implement the project, including commitment of financing;

5. patterns of past performance, if any, of the applicants in implementing previously approved projects in timely fashion;

6. past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care;

8. past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments;

9. hospital and physician collaborations that promote greater cost efficiency to patients, ensure greater quality assurance outcomes and foster positive relationships within the existing healthcare delivery network which benefits both providers and members within the impacted service area population; and

10. proposed services that include or involve a clinical healthcare service that is or has been underrepresented in the proposed service area for more than twelve (12) months as evidenced by geographical barriers to the service, insufficient staffing to provide the service and/or recent termination of the service in the proposed planning area.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.09
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "General Review Considerations" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
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Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.10. Determinations.

(1) **General Provisions Relating to Determinations**

(a) Determinations are conclusions of the Department that are based on specific facts and are limited to the specific issues addressed in the request for determination, as applicable. Therefore, the conclusions of a specific determination shall have no binding precedent in relation to parties not subject to the request and to other facts or factual situations that are not presented in the request.

(b) This Rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need.

(c) A person requesting a determination shall make such a request in writing and shall specify in detail all relevant facts, which relate to the proposed action or course of conduct. The request shall be directed to the General Counsel or his designee. The General Counsel or his designee shall respond to the request in writing. The request shall include, at a minimum, the following components:

1. a statement citing by appropriate reference the statutory provision or other authority under which the request is to be granted by the Department.

2. the exact legal name of each person whose rights are affected and who is requesting a determination and the address or principal place of business of each such person. A request may be submitted by an attorney or other party on behalf of such person, but the request must include the information required by this subsection relating to the person whose rights are affected;

3. The name, title, address, telephone number, facsimile telephone number and electronic mail address of the attorney or other person, if any, to whom correspondence or communications in regard to the request shall be addressed; and

4. An explanation of any unusual circumstances involved in the request which the Department will be expected to direct its particular attention, including the existence of emergency conditions.

(d) Requests for determination shall address only one matter per request.

(e) Requests for determination shall be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6). Such requests shall also include one

signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2).

(f) Requests for determination shall include payment of a request fee. Payment of the fee shall be by credit/debit card via the Department's website, certified check, or money order made payable to the State of Georgia Department of Community Health and must be received by the Department before a determination request will be reviewed. Failure to provide payment of the appropriate fee will result in non-acceptance of the request.

1. The request fee for determination shall be $250.00;

2. State-owned institutions shall be exempt from payment of these fees; and

3. The Department may waive payment of these fees for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. Such requests for waiver must be received at the time of the initial request.

(2) **Letters of Determination**. Pursuant to O.C.G.A. § 31-6-47, if a person believes or has reason to believe that the application of a Department Rule or statutory provision may directly affect or impair the legal rights of that person as to some proposed action or course of conduct being considered by that person, including, but not limited to, determinations regarding reviewability, grandfathering decisions, and relocation or replacement determinations, such person may request a written determination from the Department regarding the application of such Department Rule or statutory provision upon that person's proposed action or course of conduct. A determination request is distinguished from a general question as a determination does not address general issues relating to policy and procedure.

Any person proposing an activity that would make it a health care facility unless exempted from prior CON review and approval pursuant to O.C.G.A. § 31-6-47, or any other part of the CON statute at O.C.G.A. § 31-6 et seq. shall be required to, pursuant to O.C.G.A. § 31-6-47.1, submit a request for a letter of determination from the Department. The Department's written response which confirms that the proposed activity is exempt from review shall act as the official confirmation of exemption provided in this Code section. A party is not authorized to commence or undertake the activity in question which it believes to fall within any one or more of the statutory exemptions in O.C.G.A. § 31-6-47 until written approval is issued by the Department in response to a request for a letter of determination as provided in this Rule.

In reviewing a determination request pursuant to this Rule to relocate all or a portion of an existing skilled nursing facility, intermediate care facility, or intermingled nursing facility, pursuant to O.C.G.A. § 31-6-47(a)(24) and Ga. Comp. R. & Regs. r. 111-2-2-

.03(27), the Department may allow such facility to divide into two or more such facilities if the Department determines that the proposed division is financially feasible and would be consistent with quality patient care. Under no circumstances will the Department allow, via a favorable determination, a facility as listed above to relocate as one facility, or divide into more than one facility, with more than the total number of beds authorized in the facility's location prior to any relocation and/or division.

(a) No person shall be entitled to request a determination that relates to an actual or proposed action or course of conduct which has been taken or which would be taken by a third party; and

(b) In addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.10(1), a determination request shall include a concise and explicit iteration of the facts on which the Department is expected to rely in granting the determination.

(c) The Department shall establish timeframes, forms, and criteria to request a letter of determination that an activity is properly exempt or excluded under this chapter prior to its implementation.

1. If no objection to a request for determination is filed within 30 days of the Department's receipt of such request for Determination, the Department shall have 60 days from the date of the Department's receipt of such request to review the request and issue a letter of determination.

2. Where conditions exist which make it impractical to complete a review in 60 days, the Department may, on notification to the requester, extend the time limit another 30 days to 90 days.

(d) The Department shall publish notice of all requests for letters of determination regarding exempt activity and opposition to such request.

(e) In addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.10(1) and pursuant to the meaning of threshold as defined at Ga. Comp. R. & Regs. r. 111-2-2-.01(59), the Department applies the following Rules as they concern requests for determinations that the value of certain diagnostic, therapeutic, or other imaging equipment does not exceed the Department's equipment threshold, pursuant to O.C.G.A. § 31-6-47(a)(28) and therefore that such equipment is not subject to prior CON review and approval.

1. The party who requests the letter of determination must submit a manufacturer's or vendor's price quotation or purchase order for the diagnostic, therapeutic, or other imaging equipment. This requirement applies even if the equipment is to be leased.

2. The party who requests the letter of determination must submit a sworn affidavit affirmed by a person capable of making a binding commitment on

behalf of the manufacturer or vendor of the diagnostic, therapeutic, or other imaging equipment for which a determination containing the following affirmations:

(i) that the affiant is capable of making a binding commitment on behalf of the manufacturer or vendor; and

(ii) that the price shown on the price quotation or purchase order is the total expense the requesting party is incurring for the equipment shown and the total dollar amount that the manufacturer or vendor is receiving for the exact unit shown on the quotation or purchase order; or

(iii) In the case of a lease or other means of acquisition, that the price shown is the total dollar amount that would have been expended had the equipment been purchased.

(3) **Requests for Letters of Determination for Below Threshold Diagnostic, Therapeutic, or Other Imaging Equipment**. A party requesting a letter of determination for the acquisition of diagnostic, therapeutic, or other imaging equipment with a value below the equipment threshold must submit with the request a sworn affidavit from a person capable of making a binding commitment on behalf of the party containing the following affirmations:

(a) that the affiant is:

1. a hospital; or

2. an individual private physician or single group practice of physicians and is

   (i) acquiring the equipment exclusively for use on patients of such private physician or single group practice of physicians; and

   (ii) such private physician or member of such single group practice of physicians is physically present at the practice location where the diagnostic or other imaging equipment is located at least seventy-five percent (75%) of the time that the equipment is in use.

3. that the affiant is capable of making a binding commitment on behalf of the party;

4. that no acquisition of additional items not listed on a Line Item Valuation Sheets or the Aggregate Valuation Sheet, to be added to or used with the operational configuration of the particular diagnostic, therapeutic, or other imaging equipment at issue to include functionally related equipment, will

be made or will take place for a period of six (6) months from the date of installation of the equipment that would put the total expenditure incurred on the diagnostic, therapeutic, other imaging equipment or its operational configuration over the Department's equipment threshold;

5. that no acquisition of additional equipment reasonably related to or associated with the general type of service provided by the equipment to be acquired not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet will occur within a period of six (6) months, that is that such expenditure for associated, but not functionally related equipment, regardless of modality, shall occur simultaneously;

6. that no construction not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet that can reasonably be determined to be associated with the equipment to be acquired will occur within a period of six (6) months;

7. that the Line-Item Valuation Sheets and the Aggregate Valuation Sheet included in the request are accurate, reflect all of the expenses required by Ga. Comp. R. & Regs. r. 111-2-2-.10(2)(e), and reflects the true cost of acquiring the exact same equipment and any and all associated and simultaneous items and activities; and

8. that the price shown on the price quotation(s) or purchase order(s) reflects the exact amount of the total expense that will be incurred and paid to the manufacturer or vendor for the exact same equipment listed on the price quotation or purchase order; or

9. in the case of a lease or other acquisition, that the price shown on the purchase order(s) or quote(s) is the total dollar amount that would have been expended had the equipment been purchased.

(b) The request for a letter of determination must include an Equipment Line-Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to each category listed below of items the Department will evaluate for purposes of determining if the value of the diagnostic, therapeutic, or other imaging equipment is below the equipment threshold dollar amount. If an item is not applicable, the requesting party should include the item on the Line-Item Valuation Sheet and indicate the dollar amount as $0. For each simultaneous and associated unit of equipment, as outlined at Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(e) below, a separate line-item valuation sheet must be submitted.

1. The dollar amount of the base price of the unit before adding any of the following items;

2. Any expense incurred for the purchase of a warranty on the diagnostic, therapeutic, or other imaging equipment from the manufacturer or vendor for the first five (5) years of operation;

3. Any expense incurred for operator training;

4. Any expense incurred for installation and assembly of the equipment;

5. Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

6. Any expense incurred for functionally related diagnostic, therapeutic or other imaging equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.;

7. Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

8. Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

9. Any dollar amount attributable to service contracts for the first five (5) years of operation;

10. Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of determination by the manufacturer or vendor of the equipment;

11. For mobile equipment, any expense incurred for a mobile coach, trailer, or van in which the equipment will be operated; and

12. The final line of the Line Item Valuation Sheet should reflect the total of the preceding eleven (11) items.

(c) The value of diagnostic, therapeutic, or other imaging equipment for which a letter of determination is requested shall not include build out costs. Build out costs are defined as expenditures made for items such as electrical, plumbing, masonry such as concrete pads, construction of modular buildings, and renovation of the space that will actually house the equipment, such as the room where an MRI unit would be used. Build out costs shall also include expenditures for new construction for a building to house the equipment or to renovate a building or structure to house the equipment, or expenditures for administrative office space unrelated to the actual functionality of the equipment, related equipment, or software necessary to operate the equipment.

(d) A party acquiring functionally related equipment or items, including those items and expenses listed in Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(b) within a six (6) month period, which when added to the values of the items submitted for approval would exceed the threshold applicable at the time of approval, will be considered to be offering a new institutional health service without Certificate of Need authorization;

(e) All simultaneously acquired and associated diagnostic, therapeutic, and other imaging equipment regardless of modality shall be aggregated. See the definition of "associated with and simultaneously developed or proposed." If additional diagnostic, therapeutic, and other imaging equipment is to be acquired, the party must submit price quotations for each piece of simultaneously acquired diagnostic, therapeutic, and other imaging equipment;

(f) A letter of determination for the acquisition of diagnostic, therapeutic, or other imaging equipment shall be valid only for the defined equipment, physical location, cost, and entity or person named in the request as the acquirer and operator of the equipment and only to the pertinent facts that were disclosed in the request, except that cost may exceed the amount approved by the Department as long as the actual final expenditures do not exceed the equipment threshold. Such letters are non-transferable and may not be acquired. If the facts pertinent to the letter of determination change in any way, the letter is no longer valid;

(g) Upon completion of the acquisition of the equipment, the party requesting a determination shall submit a final statement of the total costs of the equipment. In addition, if the if the equipment and associated activities are not completed within one hundred and eighty (180) days of the issuance of the determination, the party requesting a determination shall submit an interim statement within two weeks of the end of that one hundred and eighty (180) day period and within two weeks of the end of each succeeding ninety (90) day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the expenses incurred to date, and any good faith estimates of the percentage of completion and the amount of costs expected to be incurred to complete. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a determination. Failure to comply with the provisions of this subsection may result in the rescission of the determination issued.

(4) **Requests for Letters of Determination for Exempt Single Specialty or Joint Venture Ambulatory Surgical Centers**.

(a) When the Department receives a request for a letter of determination for the establishment of a physician-owned, single specialty, office-based ambulatory surgery facility, or a joint venture ambulatory surgical center, pursuant to

O.C.G.A. § 31-6-2(33), (23), and O.C.G.A. § 31-6-47(a)(18), (19), the party requesting such a letter must comply with the following:

1. Identify the name and address of the proposed ambulatory surgery facility, including the principal business address of the sole physician or group practice that will own the facility.

2. Identify the individual private physician, or all owners (e.g. stockholders, partners, members) of the single group practice of private physicians who are also on the same single specialty, that will own, operate, and utilize the proposed facility. All members of the single group practice must be of the same specified surgical specialty. Physicians who perform procedures within the single specialty ambulatory surgical center must own at least eighty-five percent (85%) of the group practice and the surgery center. The Department will issue a determination, if all other criteria are met, to a single group practice which utilized the services of employee physicians of the same specialty in the surgery center if these employee physicians are not a member or employee of any other medical practice. All employee physicians must be identified, and an affirmative statement with regard to their practice affiliation must be included. The Department will allow no more than fifteen percent (15%) non-physician ownership in the physician(s) practice requesting a determination, and/or the surgery center in a single specialty ambulatory surgical center. Evidence of non-physician ownership, including the percentage of such ownership, must be provided with the determination request. For a joint venture ambulatory surgical center, the ownership interest of the hospital shall be no less than thirty percent (30%) and the collective ownership of the physicians or group of physicians shall be no less than thirty percent (30%). Any evidence of non-hospital or non-physician or group of physician's ownership in a joint venture ambulatory surgical center must be provided with the determination request.

3. All physicians must be licensed to practice in the state of Georgia, and must submit a copy of such license; should any physician members of a single group practice perform procedures in the ambulatory surgery facility created by the issuance of a determination lose their license to practice medicine in Georgia, the determination shall be revoked, unless within sixty (60) days of such physician losing their license, the group practice submits new evidence documenting that the physician ownership of the facility by the group practice does not include the physician who lost their license.

4. Submit evidence of the sole physician professional corporation or the entity comprising the single group practice of private physicians, to include authorizing and governing documents such as articles of incorporation, by-laws, operating agreements, partnership agreements, etc. Submit a sworn

affidavit, signed by the owners, which lists all owners of the sole or group practice and the proposed surgery facility.

5. The physician(s) must show evidence of ownership by warranty deed or lease of the space housing the ambulatory surgery facility including the clinical office space.

6. Provide a detailed description of the proximity of the physician's or the group practice's clinical offices to the ambulatory surgery facility. The Department will only grant a determination to those proposed ambulatory surgical facilities, which are deemed to be in reasonable proximity to the clinical offices of the sole physician or single group practice that will own the proposed facility. Reasonable proximity will be determined on a case-by-case basis. Example of reasonable proximity include those ambulatory surgical facilities on the same floor and physically attached to the clinical offices; surgical suites on a different floor of the same building as the clinical offices with one public entrance to the proposed facility.

7. State the number of operating rooms in the proposed ambulatory surgery facility.

8. State the total square footage in the proposed ambulatory surgery facility. This total includes the square footage associated with all operating suites, reception and waiting areas, business offices, pre and post-operation areas, all building common areas including a pro rata share of the common areas of buildings utilized by multiple tenants, which are new and/or renovated and involve expenditures to be incurred in the development, construction and establishment of the proposed surgery facility.

9. List costs attributable to new construction or renovation of the total area comprising the ambulatory surgery facility. Documentation of the total costs of constructing, developing, and establishing the proposed ambulatory surgical facility, and the costs of all items associated with or simultaneously developed with the project, including, but not limited to, fixed equipment not included in the construction contract, moveable equipment, architectural and engineering fees, legal and administrative fees, interim financing (interest during construction), and underwriting costs. The documentation of construction and renovation costs must be in the form of a letter from a licensed Georgia architect verifying the estimated construction costs of the proposed ambulatory surgery facility. With regard to the construction of a new building (or a new wing including space devoted to services other than the surgery center) to house an ambulatory surgery facility, a pro-rata portion of the building shell costs, including all building common areas, must be allocated to the costs of the proposed ambulatory surgery facility. Other costs to be included are:

(i) The cost of new space (even if the space will be leased) based on the construction cost of the new space. Appropriate documentation from an architect licensed in Georgia must be submitted. A copy of all leases must be submitted;

(ii) The cost of all equipment (medical and non-medical) purchases for the ambulatory surgery facility.

(iii) The present value of any equipment to be leased for the surgery facility.

(iv) The Department must have a line item breakdown of all amounts attributable to new construction, renovation, furnishings, leases, and items of equipment in accordance with the provisions outlined above, including new expenditures for furnishings for non-patient care areas such as waiting areas, reception areas, and business offices.

The Department will require a sworn affidavit that no party associated with the practice or physicians requesting a determination, by virtue of ownership or employment, has incurred any expenditure for equipment of any kind to be utilized in the surgery center that has been subsequently donated to the practice for use in the surgery center and the cost of that equipment, whether purchased or leased, was not included in the dollar threshold applicable to the surgery center.

10. A schematic floor plan must be provided to the Department. This documentation must be clear and readable. The floor plan must clearly show all areas of the proposed ambulatory surgery facility.

11. Pursuant to O.C.G.A. § 31-6-2(14), list the cost of all other items, regardless whether they are independently subject to Certificate of Need review, that are associated and to be simultaneously developed with the proposed ambulatory surgery facility, except for the expenditure or commitment of funds to develop studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites.

12. The Department will not issue a determination to any sole physician or single specialty group practice of physicians proposing to bill a professional fee through a larger multi-specialty group practice in which the single specialty group practice requesting the determination remains a part of. For purposes of these Rules, this provision does not preclude the issuance of a determination to a physician(s), which utilizes a larger group

practice for the sole purpose of billing services under the provider number of the sole physician or single group practice.

13. The Department will not issue a determination to any physician(s) who is a member of more than one single group practice, pursuant to O.C.G.A. § 43-1B-3(5) of the Georgia Patient Self-Referral Law.

14. The Department will not issue a determination to any group practice of physicians if any members of that group practice are also members of a multi-specialty clinical practice. For purposes of these Rules a multi-specialty clinical group practice does not mean any volume purchasing association or managed care network whose function is managed care contracting in which the physician or group practice participates.

15. The Department will not issue a determination to any party proposing to share operating rooms or common space in a proposed ambulatory surgical facility between more than one group practice of the same specialty or between more than one surgical group practice of different specialties, or between more than one sole physician of the same or different specialties who are not members of the same medical practice.

16. Provide a sworn affidavit, signed by the physician(s) owners, that the party requesting a determination will not incur any additional capital expenditures involving new construction or renovation of physical space or the addition or replacement of equipment within three (3) years after the issuance of the determination, which, when coupled with prior expenditures, would exceed the threshold amount applicable to the statutory exemption for this type of facility unless it first secures a Certificate of Need. A party holding a determination issued by the Department may request, in writing, a waiver from this provision for expenditures for equipment involving newly recognized and innovative medical technologies (FDA approved) present in the marketplace. Any such expenditure will be applied to the original threshold amount unless the written consent of the Department is obtained prior to the expenditure.

17. Upon completion of construction of the ambulatory surgery facility, the party requesting a determination shall submit a final statement of the total costs of the facility, including a separate line item completed project cost sheet with the same detail and documentation as required in subsection (4)(a)11. above. In addition, if the proposed ambulatory surgery facility is not completed within one hundred and eighty (180) days of the issuance of a determination, the party requesting a determination shall submit an interim statement within two weeks of the end of that one hundred and eighty (180) day period and within two weeks of the end of each succeeding ninety (90) day period until the final statement is submitted

upon completion of the facility. Each of the interim statements shall disclose the cost of the facility incurred to date, and any good faith estimates of the percentage of completion of the facility and the amount of costs expected to be incurred to complete the facility. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a determination and from the general contractor. Failure to comply with the provisions of this subsection may result in the rescission of the determination issued.

18. The determination is not transferable to a purchaser of the sole physician or single group practice, which originally received a determination. This provision is not intended to limit the transferability of a sole physician practice or a group practice but is intended to put the new physician owners on notice that they must request a new determination as new owners of that practice. Such a new request will be evaluated based on the determination criteria applicable at the time of the new request, and the acquisition costs of the practice will not be a part of the applicable capital expenditure threshold.

(b) A single specialty ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $2,500,000.00; or

2. Is the only single specialty ambulatory surgical center in the county owned by the group practice and has two or fewer operating rooms; provided, however, that a center exempt pursuant to this provision shall be required to obtain a Certificate of Need in order to add any additional operating rooms;

3. Has a hospital affiliation agreement with a hospital within a reasonable distance from the facility or the medical staff at the center has admitting privileges or other acceptable documented arrangements with such hospital to ensure the necessary backup for the center for medical complications. The center shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the facility with adequate emergency room services. A party requesting a letter of determination must provide documentation to support an assertion that a hospital, pursuant to this requirement, has unreasonable denied a transfer agreement or affiliation agreement to the center;

4. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

5. If the center is not a participant in Medicaid or the PeachCare for KidsT Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; provided, however, single specialty ambulatory surgical centers owned by physicians in the practice of ophthalmology shall not be required to comply with this subparagraph; and

6. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

   Noncompliance with any condition of subsections 4. and 5. of Section (4)(b) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 6. of section (4)(b) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(c) Any joint venture ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5,000,000.00;

2. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries and

provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

3. If the center is not a participant in Medicaid or the PeachCare for KidsT Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

4. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

   Noncompliance with any condition of subsections 2. and 3. of section (4)(c) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 4. of section (4)(c) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(c) Any joint venture ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5,000,000.00;

2. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

3. If the center is not a participant in Medicaid or the PeachCare for KidsT Program, provides uncompensated care to Medicaid beneficiaries and, if the

facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

4. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

Noncompliance with any condition of subsections 2. and 3. of section (4)(c) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 4. of section (4)(c) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(5) **Requirements Applicable to Valid Holders of Ambulatory Surgery or Diagnostic or Therapeutic Equipment Exemptions Prior to July 1, 2008.**

(a) Any facility offering ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2; any diagnostic, treatment, or rehabilitation center offering diagnostic imaging or other imaging services in operation and exempt prior to July 1, 2008; or any facility operating pursuant to a letter of nonreviewability and offering diagnostic imaging services prior to July 1, 2008, shall:

1. Provide notice to the department of the name, ownership, location, single specialty, and services provided in the exempt facility in accordance with the provisions of Rule 111-2-2-.04(1)(b)1.;

2. Beginning on January 1, 2009, provide annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and in accordance with the provisions of Rule 111-2-2-.04(1)(b)2.

(b) If, on or after July 1, 2008, any facility referenced in subsection (5)(a) above that, makes a capital expenditure associated with the construction, development,

expansion, or other establishment of a clinical health service of the acquisition or replacement of diagnostic or therapeutic equipment with a value in excess of $800,000.00 over a two-year period; builds a new operating room; or chooses to relocate in accordance with Rule 111-2-2-.03, it shall:

1. Provide care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for KidsT beneficiaries and provide uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the facility is not a participant in Medicaid or the PeachCare for KidsT Program, provide uncompensated care for Medicaid beneficiaries and, if the facility provides medical care and treatment to children, for PeachCare for KidsT beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue.

   Noncompliance with any condition of subsection (b)1. and 2. above shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the department for repeated failure to pay any fees or monies due to the department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the consumer price index, or its successor or appropriate replacement index, if any, published by the United States Department of Labor for the preceding calendar year, commencing on July 1, 2009. In calculating the dollar amounts of a proposed project for the purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop certificate of need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites. Subsections (b)1. and 2. of section (5) of this rule, shall not apply to facilities offering ophthalmic ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2 that are owned by physicians in the practice of ophthalmology.

(6) **Administrative Remedies for Adverse Determinations**.

When the Department makes a determination or decision pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.10(1) through (5) of this Rule or any other determination or decision over which the Certificate of Need Appeal Panel lacks subject matter jurisdiction, the person who requests and receives the determination or decision may appeal to the Commissioner or his designee for an administrative hearing pursuant to the Administrative Procedures Act if such person is aggrieved by the Department's determination or decision. Such request for a hearing must be made in writing and must be received by the Department within thirty (30) days of the date of the Department's determination or decision. If such written request is not received by the Department within thirty (30) days, the Department's determination or decision shall become final upon the thirty-first (31st) day. The Department shall publish notice of all requests for letters of determination regarding exempt activity and opposition to such request, whether pursuant to O.C.G.A. § 31-6-47 or any other provision of Code Section 31-6 and these Rules. Persons opposing a request for approval of an exempt activity, whether pursuant to an express statutory exemption or any other provision of the health planning statute or these Rules, shall be entitled to file a written objection with the Department and the Department shall consider any filed objection when determining whether an activity is exempt. A person who wishes to file a written objection to an exemption determination request, including requests for letters of determination for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center, must do so no later than thirty (30) days after the date of Department receipt of the initial request for the exemption determination. Such written opposition should be submitted via the Department's web portal. The opposition shall be submitted in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6).

If no objection to a request for determination is filed within 30 days of the Department's receipt of such request for Determination, the Department shall have 60 days from the date of the Department's receipt of such request to review the request and issue a letter of determination. The Department may adopt rules for deciding when it is not practicable to provide a determination in 60 days and may extend the review period upon written notice to the requestor but only for an extended period of no longer than an additional 30 days. After the issuance of an approval to a response to the request for an exemption determination, including requests for letters of determination for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center, a person in opposition that has complied with the provisions outlined above, shall have the right to a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act, and judicial review of a final decision in the same manner and under the same provisions as in O.C.G.A. § 31-6-44.1 and Ga. Comp. R. & Regs. r. 274-1 et seq. A person who requested and received the exemption determination shall have automatic standing to participate in any such administrative proceeding to defend the approved exemption determination. The Department may also participate to defend its decision. A person who opposes an exemption determination request that is denied, and who has complied with the written opposition submission requirements provided above, shall have standing to participate in any administrative proceeding requested by the person denied an approved exemption determination. If the written opposition is not submitted in

accordance with the provisions outlined above, the Department shall not consider the opposition, and the rights to an administrative hearing, and/or any participation in any proceeding as outlined above, will not adhere to the opposing person.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.10
Authority: O.C.G.A. §§. 31-2 *et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Determinations and Letters of Non-Reviewability" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Aug. 28, 2006; eff. Sept. 17, 2006.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Nov. 14, 2008; eff. Dec. 4, 2008.
Amended: New title, "Determinations." F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.11. Service-Specific Review Considerations Generally.

(1) The Department has adopted the following service-specific requirements and review considerations:

(a) Acute Care and Acute Care-Related Rules:

1. Short-Stay General Hospital Services, Ga. Comp. R. & Regs. r .111-2-2-.20;

2. Adult Cardiac Catheterization Services, Ga. Comp. R. & Regs. r. 111-2-2-.21;

3. Open Heart Surgical Services, Ga. Comp. R. & Regs. r. 111-2-2-.22;

4. Pediatric Cardiac Catheterization and Open Heart Services, Ga. Comp. R. & Regs. r. 111-2-2-.23;

5. Perinatal Services, Ga. Comp. R. & Regs. r. 111-2-2-.24;

6. Freestanding Birthing Center Services, Ga. Comp. R. & Regs. r. 111-2-2-.25; and

7. Psychiatric and Substance Abuse Inpatient Services, Ga. Comp. R. & Regs. r. 111-2-2-.26;

(b) Long-Term Care Rules:

1. Skilled Nursing and Intermediate Care Facility Services, Ga. Comp. R. & Regs. r. 111-2-2-.30;

2. Personal Care Home Services, Ga. Comp. R. & Regs. r. 111-2-2-.31;

3. Home Health Services, Ga. Comp. R. & Regs. r. 111-2-2-.32;

4. Life Plan Community ("LPC") Sheltered Nursing Facilities, Ga. Comp. R. & Regs. r. 111-2-2-.33;

5. Traumatic Brain Injury Services, Ga. Comp. R. & Regs. r. 111-2-2-.34; and

6. Comprehensive Inpatient Physical Rehabilitation Services, Ga. Comp. R. & Regs. r. 111-2-2-.35;

7. Long Term Care Hospitals, Ga. Comp. R. & Reg. R. 111-2-2-.36

(c) Special and Other Health Services:

1. Ambulatory Surgical Services, Ga. Comp. R. & Regs. r. 111-2-2-.40;

2. Positron Emission Tomography, Ga. Comp. R. & Regs. r. 111-2-2-.41; and

3. Radiation Therapy Services, Ga. Comp. R. & Regs. r. 111-2-2-.42.

(2) The review considerations and standards that are promulgated in service-specific rules are considerations and standards that apply to specific services in addition to the general considerations in Ga. Comp. R. & Regs. r. 111-2-2-.09. Any conflict between the meaning or application of a service-specific requirement and the general considerations shall be interpreted in favor of the service-specific consideration, unless a general consideration specifically indicates that it supersedes any and all service-specific considerations.

(3) The meaning of words as they are defined in a particular service-specific rule only applies to that service-specific rule, unless a specific citation is made to another service-specific rule.

(4) Numerical Need Calculations.

(a) The numerical need calculations, which shall apply to an application for a clinical health service for which service-specific rules exist, shall be the calculated need in effect on the date the application is deemed complete for review less any subsequently approved units and services during the review period. This provision does not apply to batching reviews as the need applicable to batching decisions is the need stated in the batching notice.

(b) In the instance of joined projects where one project is reviewed as an exception based on utilization and the other is reviewed as need-based, the approval of the utilization exception shall not preclude an approval based on a numerical need projection should, prior to the approval of any of the joined projects, the numerical need projection indicates a need for the clinical health service.

(c) Approved projects that affect service-specific numerical need calculations shall be added to the Department's service-specific inventories and the numerical need projections shall be adjusted as of the approved date of the project.

(d) Approved projects that are reversed through administrative and/or judicial appeal final resolution shall be subtracted from the Department's service-specific inventories and the numerical need projections shall be adjusted as of the date of such final resolution.

(5) Service-specific component plans provide general background on specific considerations that were undertaken in developing service-specific rules. The service-specific rules shall supersede a component plan.

(6) If any provision of these service-specific rules, or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the particular service-specific rule in question or of the service-specific rules in general which can be given effect without the invalid provision or application, and to this end the provisions of these service-specific rules are severable.

(7) The commissioner shall be authorized, with the approval of the board, to place a temporary moratorium of up to six (6) months on the issuance of certificates of need for new and emerging health care services. Any such moratorium placed shall be for the purpose of promulgating service-specific rules and regulations regarding such new and emerging health care services. A moratorium may be extended one time for an additional three (3) months if circumstances warrant, as approved by the board. In the event that final service-specific rules and regulations are not promulgated within the time period allowed by the moratorium, any applications received by the Department for a new and emerging health care service shall be reviewed under existing general statutes and regulations relating to certificates of need. Upon the identification by the Department of a new and emerging health care service as defined by Ga. Comp. R. & Regs. r. 111-2-2-.01(41), and the request for and receipt of approval by the board of a moratorium as provided in this subsection, the Department shall publish notice of the moratorium and the identified service in a manner used in the normal course for other Certificate of Need information and announcements.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.11
Authority: O.C.G.A. Secs. 31-2*et seq*., 31-6 *et seq*.
History. Original Rule entitled "Service-Specific Review Considerations Generally" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Dec. 14, 2007; eff. Jan. 3, 2008.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.12. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.12

Rule 111-2-2-.13. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.13

Rule 111-2-2-.14. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.14

Rule 111-2-2-.15. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.15

Rule 111-2-2-.16. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.16

Rule 111-2-2-.17. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.17

Rule 111-2-2-.18. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.18

Rule 111-2-2-.19. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.19

Rule 111-2-2-.20. Specific Review Considerations for Short-Stay General Hospital Beds.

(1) **Applicability.**

(a) A Certificate of Need will be required prior to the establishment of a new hospital, replacement of an existing hospital, or expansion of an existing hospital.

(b) The provisions in these Rules do not apply to the following situations:

1. bed replacements in existing hospital facilities which do not require a capital or equipment expenditure over the applicable dollar threshold; or

2. changing the physical location of existing beds within an existing facility regardless of cost; provided, however, that any project in excess of the

applicable capital expenditure or equipment dollar threshold must be reviewed in accordance with the review considerations set forth in Ga. Comp. R. & Regs. r. 111-2-2-.09; or

3. projects that are otherwise exempt from review pursuant to O.C.G.A. § 31-6-47(a)(15).

(c) An existing hospital seeking an expansion to be used for new institutional health services, including perinatal services, rehabilitation services, or psychiatric and substance abuse services, must meet the applicable service-specific Rules found in this Chapter and, as a threshold matter, meet the need standards set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b)(3) but shall not be required to meet the other requirements in Ga. Comp. R. & Regs. r. 111-2-2-.20.

(d) A hospital that has been approved through the Certificate of Need process to use a certain number of short-stay hospital beds for long-term acute care ("LTAC") beds shall have such LTAC beds removed from the official inventory of available short-stay beds once the LTAC is certified by Medicare; provided, however, that such beds will revert to the hospital's official inventory of available short-stay beds at any point that the LTAC ceases operation or is no longer certified by Medicare. An application to use existing short-stay hospital beds for LTAC beds shall not be subject to the guidelines in Ga. Comp. R. & Regs. r. 111-2-2-.20.

(2) **Definitions.**

(a) "Age cohorts" for purposes of these Rules refers to the following age groups: persons zero (0) to seventeen (17); persons eighteen (18) to sixty-four (64); and persons sixty-five (65) and older.

(b) "Available beds" or "CON approved beds" means the total number of beds authorized for use by a hospital or group of hospitals based on capacity approved or authorized through the Certificate of Need process.

(c) "Children's hospital" means a hospital in which ninety percent (90%) or more of the patients served by the hospital are seventeen (17) or less years of age.

(d) "Critical Access Hospital" means a hospital designated as a critical access hospital pursuant to the state's rural health plan and the guidelines of the Medicare Rural Hospital Flexibility Program authorized by section 4201 of the Balanced Budget Act of 1997.

(e) "Destination cancer hospital" means an institution with a licensed bed capacity of fifty (50) or less which provides diagnostic, therapeutic, treatment, and rehabilitative care services to cancer inpatients and outpatients, by or under the supervision of physicians, and whose proposed annual patient base is composed of

a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia.

(f) "Expansion" means the addition of available beds or CON approved beds for an existing hospital.

(g) "Health planning area" or "planning area" means the twelve (12) state service delivery regions as defined in O.C.G.A. § 50-4-7.

(h) "Horizon year" means the last year of a five (5) year projection period for need determinations.

(i) "Optimal Occupancy Rate" means a target or expected level of use of available beds as calculated based on the annual patient days divided by the available beds multiplied by three hundred sixty-five (365). The optimal occupancy rate is variable based on the following:

1. for hospitals located in a rural county, sixty-five percent (65%);

2. for hospitals located in a non-rural county, seventy-five percent (75%); and

3. for teaching or children's hospitals, seventy percent (70%).

(j) "Patient days" means the number of days of inpatient services based on the most recent full year of hospital discharge data or the annual hospital questionnaire.

(k) "Replacement" means new construction to substitute another facility for an existing facility. New construction may be considered a replacement only if the replacement site is located three (3) miles or less from the facility being replaced or, in the case of the facility proposing a replacement site beyond the three (3) mile limit, if the replacement site is located within the same county and would serve substantially the same patient population, based on patient origin by zip code and payer mix, as the existing facility.

(l) "Rural county" means a county with a population of 35,000 or less based on the most recent decennial census, as defined in O.C.G.A. § 31-7-94.1(c)(3).

(m) "Safety net hospital" is defined as a hospital that meets at least two (2) of following criteria:

1. the hospital is a children's hospital or a teaching hospital;

2. the hospital is designated by the Healthcare Facility Regulation Division as a trauma center;

3. Medicaid and Peach Care inpatient admissions constitute twenty percent (20%) or more of the total hospital inpatient admissions;

4. Uncompensated charges for indigent patients constitute six percent (6%) or more of hospital adjusted gross revenue; or

5. Uncompensated charges for indigent and charity patients constitute ten percent (10%) or more of hospital adjusted gross revenue.

(n) "Short stay hospital" or "hospital" is defined as a facility with an average length of stay of less than thirty (30) days.

(o) "Target service area population" means the total populations of all counties, which are in part or in whole, within a ten (10) mile radius of the planned location of a new, expanded, or replacement hospital.

(p) "Teaching hospital" means a hospital designated as a teaching hospital by the Georgia Board for Physician Workforce, which serves as a sponsoring or major participating hospital for a program of graduate medical education accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) and maintains a written affiliation agreement with an accredited medical school located in Georgia or is owned and operated by an accredited medical school in Georgia.

(3) **Standards.**

(a) A new hospital must be at least fifty (50) beds in size if located in a rural county and at least one hundred (100) beds in size if located in a county other than a rural county.

(b) The need for a new, replacement or expanded hospital shall be determined through application of an appropriate numerical need methodology designed to assess need for the specific purpose sought in the application.

1. The numerical need for a new hospital shall be determined through application of a demand-based forecasting model. The model is outlined in the steps below:

(i) Calculate the use rate for current hospital services in the target service area population by dividing the patients days for each age cohort by the population for each age cohort for same year as patient days were calculated.

(ii) Project the horizon year use rate for hospital services in the target service area population by multiplying the use rate for current hospital services by age cohort by the horizon year population by age cohort.

(iii) Divide the results of the calculations in Step (ii) by 365 and sum these numbers to determine a baseline bed need.

(iv) Adjust the baseline bed need by adding a factor to account for use of the hospital services located within the target service area population by persons from out of state. The factor shall be determined by calculating the patient days for the hospitals in the target service area that may be attributed to persons from out of state as a percentage of total patient days, and then dividing that percentage into the baseline bed need. In addition, if the target service area population includes any county or counties outside the state of Georgia, the projected bed need of the out-of-state counties should be calculated by applying the projected rate of beds needed per 1,000 for in-state counties in the target service area population to the prorated portion of population in out-of-state counties.

(v) Divide the baseline bed need by the optimal occupancy rate, as determined by the size of the proposed new facility, to project the total number of beds needed for the target service area population.

(vi) Calculate the number of available beds for the target service area population by adding all of the short stay beds located in the counties, including those outside of Georgia if applicable, which are in part or in whole within a ten (10) mile radius of the planned location of the new hospital.

(vii) Subtract the number of available beds from the total number of beds needed for the target service area population to determine the net number of beds needed.

2. A new hospital shall be approved only if the total target service area population is at least 50,000 persons.

3. The numerical need for a replacement or expanded hospital shall be determined through application of a demand-based forecasting model. The model is outlined in the steps below:

(i) Calculate the county use rate for the current hospital's services by dividing the patients days for Georgia residents by county within each age cohort by the population by county for each age cohort for the same year as patient days were calculated.

(ii) Project the horizon year use rate for the hospital's services by multiplying each county use rate by age cohort by the horizon year population of each county by age cohort.

(iii) Sum the number of patients resulting from Step (ii) and divide by three hundred and sixty-five (365) to determine a baseline bed need rate.

(iv) Adjust the baseline bed need rate by adding a factor to account for use of the hospital's services by persons from out of state. The factor shall be determined by calculating the patient days for the hospital that may be attributed to persons from out of state as a percentage of total patient days, and then dividing that number into the baseline bed need.

(v) Divide by optimal occupancy rate, as determined by the size of the proposed facility, to project the total number of beds needed for the replacement or expanded hospital.

(vi) Compare the results of Step (v) with the number of beds requested for the replacement or expanded hospital and, if appropriate, the number of available beds to determine whether the proposed replacement or expanded hospital meets the need standards.

(c) The Department may allow an exception to need and adverse impact standards outlined in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b) and (d) for a facility meeting any one of the following criteria:

1. The facility is an existing facility designated by the Department of Public Health as a trauma center;

2. The facility is an existing teaching hospital;

3. The facility is a sole community provider and more than twenty percent (20%) of the capital cost of any new, replacement or expanded facility is financed by the county governing authority, as defined in O.C.G.A. § 1-3-3(7), of the home county or the county governing authorities of a group of counties; or

4. The facility is a designated critical access hospital and is seeking replacement of its existing facility at a size not to exceed twenty-five (25) CON approved beds.

(d)

1. An applicant for a new, replacement or expanded hospital shall demonstrate the expected effects of the proposed services on other hospitals within the target service area population, including how any enhanced competition will have a positive impact upon the cost, quality, and access to the services proposed; and in the case of applications for a new, replacement or expanded hospital where competition between providers will not have a favorable impact on cost, quality and access, the applicant shall be required to document that its application will not have an adverse impact.

2. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to safety net hospitals within the planning area. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any safety net hospitals. Impact on an existing safety net hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing safety net hospital would have a total decrease of ten percent (10%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

3. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to any teaching hospitals in the state. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any teaching hospitals. Impact on an existing teaching hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing teaching hospital would have a total decrease of five percent (5%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

(e) In considering applications joined for review, the Department may give favorable consideration to whichever of the applicants historically has provided the higher annual percentage of unreimbursed care to indigent and charity patients and the higher annual percentage of services to Medicare, Medicaid and Peach Care patients.

(f) An applicant for a new, replacement or expanded hospital shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard that meets or exceeds three percent (3%) of annual, adjusted gross revenues for the hospital;

3. providing a written commitment to participate in the Medicare, Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the hospital is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(g)

1. An applicant for a replacement or expanded hospital shall document that the hospital is fully accredited by the Joint Commission or another nationally recognized accrediting body, and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three (3) years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies. In the event that the hospital is not accredited by the Joint Commission or another nationally recognized health care accreditation body and relies solely on state licensure, the applicant should provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past five (5) years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

2. An applicant for a new, replacement or expanded hospital shall:

   (i) provide a written commitment that the applicant presently participates, or in the case of a new hospital, will participate, in a statewide or national external reporting and peer review process related to patient safety and control of medical errors;

   (ii) provide evidence of the availability of resources, including health care providers, management personnel and funds for capital and operating needs, for the provision of the hospital services; and

(iii) document a plan for obtaining and maintaining staff and service quality standards necessary to promote effective patient care and clinical outcomes.

(h)

1. An applicant for a new, replacement or expanded hospital shall document a plan to operate an emergency room licensed by the Healthcare Facility Regulation Division.

2. An applicant for a new, replacement or expanded hospital shall provide a description of the proposed service area for the hospital and document a community planning process that addresses primary care relationships and the range of transfer and referral activities across the range of care levels. The descriptions and community planning process should address:

   (i) Estimated geographic boundaries of primary and secondary service areas and the primary and outpatient providers in these areas;

   (ii) Demographic and income characteristics of the service area by age, gender and racial compositions;

   (iii) Anticipated payer sources by population totals and percentages to include public payers and indigent and charity care services;

   (iv) Patient access to the full continuum of care, including discharge planning and long-term care options;

   (v) The projected financial and economic impact that the project will have on the community;

   (vi) Strategies related to physician recruitment and medical staffing to include the hospital's plan to ensure that the care provided by physicians and other clinicians is made available to patients without regard for ability to pay;

   (vii) The manner in which the facility coordinates or will coordinate with the existing health care system;

   (viii) The manner(s) in which the hospital will make available the necessary ancillary and support services; and

   (ix) The manner in which the hospital will support the operation of any affiliated critical access hospitals, if applicable.

3. An applicant for a new, replacement or expanded hospital shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the hospital.

4. An applicant for a new, replacement or expanded hospital shall demonstrate that proposed charges for services shall compare favorably with charges for other similar hospital services in the planning area when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for hospital services, the Department may compare the applicant's history of charges if applicable, with other hospitals in the planning area(s) previously served by the applicant or its parent company.

(i)

1. To respond to changes in the health care delivery system and to promote improved efficiency, access and cost-containment, the Department may authorize the consolidation of two or more hospitals located in one rural county or in contiguous rural counties. A proposal to consolidate hospitals into a single, new consolidated hospital requires a Certificate of Need and must comply with the following criteria.

2. Two or more existing facilities, each of which are operational at the time of approval and each of which are located in the same rural county or in contiguous rural counties, may seek a consolidation to create a single consolidated facility at an existing site or a new site within the same rural county or one of the same rural counties. The applicant or applicants for such a consolidated facility must be able to meet the following conditions:

   (i) The available beds for the proposed consolidated facility must not exceed the total number of available beds of the existing facilities proposed for consolidation;

   (ii) The applicant(s) for the proposed consolidated facility must show, using patient origin data, that the proposed new facility and/or location is reasonably projected to continue to meet the utilization needs of those populations that historically utilized the existing facilities;

   (iii) The applicant(s) must explain the impact of consolidation on the service area's health care delivery system and show that any negative impacts on existing and approved providers will be outweighed by the benefits of the proposal;

(iv) The applicant must submit documentation demonstrating that the consolidation will promote the most efficient handling of patient needs; improve the ability to update medical technology infrastructure; maximize efficiency for capital and physical plant needs; and improve consumer access to enhanced quality and depth of services; and

(v) The applicant(s) must comply with all other provisions of this Rule with exception of the need and adverse impact standards set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b) and (d).

(j)

1. To respond to changes in the health care delivery system and to promote improved efficiency, access and cost-containment, the Department may authorize the consolidation of two or more hospitals located in one non-rural county. A proposal to consolidate hospitals into a single, new consolidated hospital requires a Certificate of Need and must comply with the following criteria.

2. Two or more existing facilities, each of which are operational at the time of approval and each of which are located in the same non-rural county, may seek a consolidation to create a single consolidated facility at an existing site or a new site within the same non-rural county. The consolidating facilities must apply as co-applicants. The applicant or applicants for such a consolidated facility must be able to meet the following conditions:

(i) The available beds sought for the proposed consolidated facility must not exceed the sum of the total number of beds for which each of the consolidating facilities would be authorized, at the time the application is filed, pursuant to the demand-based forecasting model for determining need set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b)3.

(ii) The applicant(s) for the proposed consolidated facility must show, using patient origin data by zip code, that the proposed new facility and/or location is reasonably projected to continue to meet the utilization needs of those populations that historically utilized the existing facilities;

(iii) The applicant(s) must explain the impact of consolidation on the facilities to be consolidated existing service area(s) health care delivery system and show that any negative impacts on existing and approved providers will be outweighed by the benefits of the proposal;

(iv) The applicant must submit documentation demonstrating that the consolidation will promote the most efficient handling of patient needs; improve the ability to update medical technology infrastructure; maximize efficiency for capital and physical plant needs; and improve consumer access to enhanced quality and depth of services; and

(v) The consolidating facilities must not seek to offer in a consolidation application any new clinical health service at the proposed new site not offered in each or all of the facilities to be consolidated.

(k)

1. A Certificate of Need will be issued to an applicant for a destination cancer hospital if it meets the following standards and under the following conditions.

2. An applicant for a destination cancer hospital must document that it meets the criteria described in the definition in Section (2)(e).

3. An applicant for a destination cancer hospital must:

   (i) Document that the destination cancer hospital itself and all affiliated facilities are within twenty-five (25) miles of a commercial airport in the State of Georgia with five (5) or more runways;

   (ii) Document that the services to be offered by the facility are solely related to the treatment of cancer patients;

   (iii) Document the services to be offered within and by the facility that would otherwise be considered a separate new institutional health service. Such services will not be required to obtain separate Certificate of Need authorization, or be reviewed under any service-specific need methodology or rules other than those for a destination cancer hospital if included in the initial Certificate of Need application reviewed under the Rules outlined in section (k) of these Rules;

   (iv) Document that the destination cancer hospital will not offer services that are not reasonable related to the diagnosis and treatment of cancer such as, but not limited to, open heart surgery, perinatal services, and cardiac catheterization;

(v) Document that at least sixty-five percent (65%) of its projected annual patient base will be composed of persons who reside outside of the State of Georgia;

(vi) Agree to provide uncompensated indigent and charity care for residents of the State of Georgia which meets or exceeds three percent (3%) of the applicant's adjusted gross revenue;

(vii) Agree to provide care to Medicaid beneficiaries;

(viii) Document that the applicant for a destination cancer hospital will comply with the criteria found in the General Review Considerations of these Ga. Comp. R. & Regs. r. at Section 111-2-2-.09(2).

4. A destination cancer hospital that does not meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia in a calendar year shall be fined $2,000,000.00 for the first year of noncompliance, $4,000,000.00 for the second consecutive year of noncompliance, and $6,000,000.00 for the third consecutive year of noncompliance. Such fine amount shall reset to $2,000,000.00 after any year of compliance. In the event that a destination cancer hospital does not meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia for three (3) calendar years in a five (5) year period, such hospital shall be fined an additional amount of $8,000,000.00. All revenues collected from any such fine may be dedicated and deposited by the Department into the Indigent Care Trust Fund created pursuant to O.C.G.A. § 31-8-152. The Department, pursuant to O.C.G.A. § 31-6-45(a)(7), may revoke the Certificate of Need of a destination cancer hospital, in whole, or in part, after notice and an opportunity for a hearing, for failure to meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia for three calendar years in any five-year period.

5. After commencing operations upon receipt of a Certificate of Need pursuant to these Rules, a destination cancer hospital seeking to add an additional new institutional health service, shall apply for and obtain an additional Certificate of Need under the applicable statutory provisions and the Rules in this section. Any such application shall only be granted if the patient base of the destination cancer hospital is composed of at least sixty-five percent (65%) of patients who reside outside of the State of Georgia for two consecutive years.

6. The Department may apply the Rules in section (k) of these Rules to an application from a destination cancer hospital for a Certificate of Need for services and equipment required for it to meet federal or state laws applicable to a hospital.

7. If a destination cancer hospital cannot show a patient base of a minimum of sixty-five percent (65%) of persons who reside outside of the State of Georgia, the application for a Certificate of Need for any new institutional health service shall be evaluated under the specific statutes and Rules applicable to that particular service.

8. If a destination cancer hospital applies for a Certificate of Need to add an additional new institutional health service before commencing operations or completing two (2) consecutive years of operation, the applicant may rely on historical data from its affiliated entities.

9. The number of beds, services, and equipment used in and by a destination cancer hospital shall not be counted as part of the Department's inventory when determining the need for those beds, services, or equipment for other providers in other Certificate of Need applications not involving destination cancer hospitals.

10. No person shall be issued more than one Certificate of Need for a destination cancer hospital.

11. The Department will not accept an application for a Certificate of Need for a destination cancer hospital on or after January 1, 2010; however, an existing destination cancer hospital may avail itself of all applicable Certificate of Need provisions regarding the upgrade, purchase, or replacement of diagnostic or therapeutic equipment.

12. An applicant for a destination cancer hospital shall agree to provide information related to the operation of and services provided by the facility in the time frame and manner requested by the Department. In addition, a destination cancer hospital shall submit an annual statement, in accordance with the timeframes and format specified by the Department, affirming that the hospital has met an annual patient based composed of a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia. The chief executive officer of the destination cancer hospital shall certify under penalty of perjury that the statement as prepared accurately reflects the composition of the annual patient base. The Department shall have the authority to inspect any books, records, papers, or other information of the destination cancer hospital to confirm the information provided on such statement or any other information required of the destination cancer hospital. The report required by this sub-section shall

not be construed to require the release of any information that would violate the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.20
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Short-Stay General Hospital Beds" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
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Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.21. Specific Review Considerations for Adult Cardiac Catheterization Services.

(1) **Applicability.**

(a) For Certificate of Need purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center ("DTRC"). A Certificate of Need will be required prior to the establishment of a new or expanded adult cardiac catheterization service, if not exempt as provided by O.C.G.A. § 31-6-47(a)(21) and Ga. Comp. R. & Regs. r. 111-2-2-.03(24).

(b) If the service will be provided within a licensed acute care hospital, the hospital shall be the applicant.

(c) If cardiac catheterization services will be provided in a DTRC, the organizational entity that develops the service shall be the applicant.

(d) Seeking and receiving approval from the Department under the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)3. shall neither be considered a new adult cardiac catheterization service nor an expanded service. Additionally, the issuance of such an approval shall not be construed to be anything other than a time-limited approval to participate in the particular medical research trial specified in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)(3).

(2) **Definitions.**

(a) "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a

patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively without the use of motorized vehicles.

(b) "Adult" means a person fifteen (15) years of age and over.

(c) "Authorized service" means an adult cardiac catheterization service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not yet become operational.

(d) "Capacity" means 1300 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. In the computation of the use rate (percent of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 procedure equivalent, each coronary angioplasty procedure shall equal 1.5 procedure equivalents, and each electrophysiological (EP) study shall equal 2.0 procedure equivalents. If pediatric catheterizations are performed in a room in which adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0 procedure equivalents.

(e) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(f) "Cardiac catheterization service" means an organized program which serves inpatients and/or outpatients of an acute care hospital or diagnostic, treatment and rehabilitation center (DTRC) with a room or a suite of rooms, with equipment to perform angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization procedures. An authorized adult cardiac catheterization service is prohibited from performing coronary angioplasty procedures unless the acute care hospital where the service is located meets the requirements identified in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f).

(g) "Coronary angioplasty" means a cardiac catheterization procedure to treat coronary artery disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(h) "Diagnostic cardiac catheterization" means the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heart structure, whether

congenital or acquired. Post-operative evaluation of the effectiveness of prostheses (e.g., heart valves or vein grafts) also can be accomplished through use of diagnostic cardiac catheterization.

(i) "Diagnostic, treatment, or rehabilitation center (DTRC)" means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting that is not part of a hospital.

(j) "Expanded Service" or "Expansion" means an adult cardiac catheterization service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the cardiac catheterization services are or will be offered, the cost of which exceeds the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of cardiac catheterization services; or that seeks the addition of a new catheterization laboratory or room regardless of cost. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such services is not an expansion for purposes of these Rules.

(k) "Horizon year" means the last year of a five-year projection period for need determinations for any adult cardiac catheterization services.

(l) "Official inventory" means the Department's inventory of all authorized hospital-based and diagnostic, treatment, or rehabilitation center (DTRC) adult cardiac catheterization laboratories or any other authorized laboratory approved for operation at the time of adoption of these Rules.

(m) "Official state component plan" means the document related to specialized cardiovascular services developed by the Department adopted by the Health Strategies Council and approved by the Board of Community Health.

(n) "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization.

(o) "Planning area" means each of the planning areas designated in the official State Component Plan.

(p) "Therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of ameliorating certain conditions that have been determined to exist in the heart or great arteries or veins of the heart.

(3) **Standards.**

(a) The need for new or expanded adult cardiac catheterization services shall be determined through application of a numerical need method and an analysis of

service demand based on an assessment of the aggregate utilization rate of existing services;

1. the numerical need for new or expanded adult cardiac catheterization services shall be determined by a population-based formula which includes current usage patterns and projected population as follows:

   (i) calculate the current state adult cardiac catheterization rate for the most recent year of reported survey or hospital and outpatient discharge data by dividing the total number of adult cardiac catheterizations performed on Georgia residents by the total state adult Resident population;

   (ii) determine the projected adult cardiac catheterization procedures for the horizon year by multiplying the state rate by the adult Resident population for the planning area for the horizon year;

   (iii) adjust the projected adult cardiac catheterization procedures for the planning area by adding the out-of-state hospital-based catheterizations for the most recent year based on the percentage of total procedures performed on out-of-state patients by hospitals in each planning area;

   (iv) convert projected adult cardiac catheterization procedures to procedure equivalents by multiplying the projected procedures by the statewide rate of equivalents per catheterization; and

   (v) determine the projected net surplus or deficit for adult cardiac catheterization capacity, expressed in terms of rooms/laboratories, in the planning area by subtracting the rooms/laboratories needed for the total projected procedure equivalents calculated in steps (i) through (iv) from the total capacity (1300 procedure equivalents per room/laboratory) based on the official inventory.

2. before a new or expanded adult cardiac catheterization service will be approved in any planning area, the aggregate utilization rate of all adult cardiac catheterization services in that planning area shall be eighty-five percent (85%) or more during the most recent year;

(b) 1. The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(a) in the following circumstances:

   (i) actual utilization in the applicant's existing service has exceeded ninety percent (90%) of capacity over the past two (2) years;

(ii) to remedy an atypical barrier to adult cardiac catheterization services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(I) An atypical barrier to services based on cost may include the failure of existing providers of adult cardiac catheterization services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state and/or planning area.

(II) An atypical barrier to services based on quality may include the failure of existing providers of adult cardiac catheterization services to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Cardiology, peer review programs and comparable state rates for similar populations.

(III) An atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing providers of services within the community to provide services to indigent, charity, and Medicaid patients.

(IV) An atypical barrier to services based on geographic accessibility may include a planning area which has an adult cardiac catheterization rate significantly less than the state rate (two or more standard deviations from the mean), a cardiovascular disease rate as projected through death and hospital discharge data which is significantly higher than the state rate (two or more standard deviations from the mean), and other demographic risk factors which can be documented through research and clinical studies.

(V) An applicant seeking approval for a new or expanded adult cardiac catheterization service solely for the purpose of providing cardiac electrophysiological studies may apply for consideration under the terms of an atypical barrier; provided, however, that any such applicant if approved shall be restricted to the provision of electrophysiological studies.

2. The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(a) and (3)(c) for any cardiac catheterization service seeking an expansion, other than the addition of another laboratory or room; provided the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(d), (e), (f), (g), (h), (j), (k) and (l).

(c) An applicant for a new or expanded adult cardiac catheterization service shall document that authorized cardiac catheterization services which could be adversely impacted by the establishment of the new or expanded service are not predicted to perform less than eighty percent (80%) of capacity as a result of the establishment of the new or expanded service. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application.

(d) An applicant for a new or expanded adult catheterization service shall demonstrate a plan whereby the service and its medical staff agree to provide a full array of cardiovascular services to the community, including, but not limited to, education and outreach, prevention and screening, diagnosis and treatment, and rehabilitation.

(e) An applicant for a new or expanded adult cardiac catheterization services shall:

1. demonstrate the ability to meet the optimal clinical and physical environment standards established in the most recent American College of Cardiology/American Heart Association's Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. These standards include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services;

2. document the availability of, or shall present a plan for recruiting, at least two board-certified cardiologists with training and qualification in cardiac catheterization, and, if applicable with training and qualification in coronary intervention, who will reside within one hour drive of the service site; and

3. document a plan for obtaining a sufficient number of clinical, professional and technical staff to safely and effectively operate the service.

(f) An authorized adult cardiac catheterization service shall not perform catheterization procedures requiring open heart surgery backup as part of its service unless the acute care hospital where the service is located:

1. operates an existing adult open heart surgery service;

2. has a Department approved written agreement for open heart surgery backup with an adjacent acute care hospital as defined by these Rules; or

3. has been accepted as a participant in a randomized medical research trial comparing patient outcomes after non-primary Percutaneous Coronary Intervention (PCI) in hospitals with and without cardiac surgery on-site, which also requires the performance of Primary PCI and has a parallel Primary PCI Registry, and which is coordinated by the Atlantic Cardiovascular-Patient Outcomes Research Team (Atlantic C-PORT). The authorized adult cardiac catheterization service must receive such Atlantic C-PORT acceptance and also must obtain written approval from the Department to perform such procedures, except that the Department may approve no more than ten (10) existing and authorized hospital services for participation, regardless of the number of such services that are accepted by Atlantic C-PORT.

   (i) Any request for such Departmental approval must be submitted to the Department no later than June 30, 2005 in writing on a form developed by the Department for such purposes. Prior to final approval to participate by the Department, the requesting authorized service must provide written proof it has been accepted by Atlantic C-PORT as a participant in said trial under all applicable protocols;

   (ii) In reviewing and approving such requests, the Department shall take into consideration such factors including, but not limited to, rural, suburban or urban location of the service, mix of patients to be treated, whether the service has the capability of performing a minimum of 100 PCIs (elective and primary combined) during the first year of such approval, 200 PCIs (elective and primary combined) during the second year of such approval unless a lower number, but not below 150 PCIs, is approved for specific reasons by both the Department and the trial chairperson, and 200 PCIs (elective and primary combined) during the third year of such approval, and whether the service has on its staff physicians and support staff with training and experience in both therapeutic and diagnostic cardiac catheterizations;

   (iii) The selection of an authorized service for participation pursuant to this Rule will be made at the sole discretion of the Department; however, the Department shall consult with medical experts in the fields of cardiology and percutaneous coronary intervention when making the decision to approve or not approve a particular service for participation in such trial;

(iv) Any approval obtained from the Department in this regard shall only be valid for as long as the health care facility receiving such approval is an active participant in the trial; however, in no case shall such approval continue to be valid upon Atlantic C-PORT declaring the trial concluded, or under no circumstance for a period in excess of three (3) years from the time the authorized service's first procedure is conducted under the authority of the Department's approval and Atlantic C-PORT's acceptance to begin active participation in the trial; whichever event occurs first; and

(v) As any such Departmental approval is conditioned on being an active participant in the trial, should an authorized service which has received approval under the provisions of this Rule be expelled or otherwise lose the approval of Atlantic C-PORT to continue participation, the Department's approval will be simultaneously withdrawn without said service's or facility's right to an appeal of the Department's withdrawal of its approval to participate in such trial.

(g) Catheterization procedures requiring open heart surgery backup include coronary angioplasty and the following:

1. catheter atherectomy;
2. catheter endomyocardial biopsy;
3. left ventricular puncture;
4. percutaneous transluminal coronary angioplasty;
5. percutaneous catheter balloon valvuloplasty; and
6. transeptal catheterization.

(h) An applicant for a new or expanded adult cardiac catheterization service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac catheterization services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

   (i) A clinical intervention program for all catheterization patients that shall provide for the following in a comprehensive, systematic way:

      (I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

      (II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

      (III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

   (ii) The program, if not operated by a facility with an existing Open Heart Surgical Service, shall submit a written affiliation agreement with at least one Open Heart Surgical Service that provides, at a minimum, for:

      (I) a plan to transplant and handle acute cardiac emergencies;

      (II) a plan to facilitate referral of patients for whom surgery or angioplasty may be indicated without unnecessarily repeating diagnostic studies; and

      (III) a plan for ongoing communications between representatives of the Open-Heart Surgical Service and the proposed applicant, to allow for review of pre-operative and post-operative processes and specific cases.

   (iii) The program shall provide for annual support and participation in at least three (3) professional education programs targeted to community-based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iv) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(i) An applicant for a new or expanded adult cardiac catheterization service must project and, if approved, shall document that the proposed service will be performing a minimum of 1,040 adult cardiac catheterization procedure equivalents within three (3) years of initiation of the service and annually thereafter within the authorized guidelines for such services. Such projections, at a minimum, shall include consideration of patient origin data for catheterization services, the use rate of existing services, referral data and market patterns for existing hospital and DTRC services in the community, and cardiovascular disease incidence rates and related health indicators. An applicant seeking approval solely for the purpose of providing electrophysiological (EP) studies shall not be required to document a projected performance minimum but shall be required to document compliance with guidelines for EP studies issued by the American College of Cardiology.

(j) An applicant for a new or expanded adult cardiac catheterization service shall provide documentation that the service is fully accredited by the Joint Commission or another nationally recognized health care accreditation body, in the case of an applicant proposing a new facility location, shall provide a written commitment to secure full accreditation by the Joint Commission or another nationally recognized health care accreditation body within eighteen (18) months of initiating operation.

(k) An applicant for a new or expanded adult cardiac catheterization service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(h), that such services shall be provided regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the adult cardiac catheterization service, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(l) An applicant for a new or expanded adult cardiac catheterization service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital or DTRC as well as a national, state or multi-program system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital or DTRC;

3. development of procedures to ensure that cardiologists and any other physicians providing care in the cardiac catheterization service or related services shall be required to accept Medicaid, PeachCare and Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(m) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.21
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Adult Cardiac Catheterization Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Apr. 18, 2005; eff. May 8, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.22. Specific Review Considerations for Adult Open Heart Surgery Services.

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or, subject to certain stipulations, expanded adult open heart surgical service.

(2) **Definitions.**

(a) "Adult" means persons 15 years of age and over.

(b) "Authorized service" means an adult open heart surgery service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not become operational.

(c) "Coronary Angioplasty" means a cardiac catheterization procedure to treat coronary heart disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(d) "Expanded Service" or "Expansion" means an adult open heart surgery service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the adult open heart surgery service is or will be offered, the costs of which exceed the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of open heart surgery services; or, for any service a full four (4) years or more following implementation of an approved Certificate of Need, that increases adult open heart surgery volume to a level resulting in a twenty-five percent (25%) or more increase in procedures being performed by the service over the higher annual number of procedures having been performed during the most recent prior two calendar years. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such service is not an expansion for purposes of these Rules.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung by-pass machine (extracorporeal pump) may be used to perform the work of the heart and lungs.

(g) "Open heart surgery service" means an organized surgical program that serves inpatients of a hospital that has a suitable operating room or suite of operating rooms, equipment, staff, intensive care unit, and all support services required to perform adult open-heart surgery. The adult open heart surgery service shall be located in an acute care hospital that has an authorized adult cardiac catheterization service.

(h) "Procedure" means an adult open heart surgery operation or combination of operations performed in a single session on a single patient who appears for open heart.

(3) **Standards.**

(a) 1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the preceding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the preceding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact; and

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to open heart surgery services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

   (i) An atypical barrier to services based on cost may include the failure of existing providers of open-heart surgical services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state.

   (ii) An atypical barrier to services based on quality may include the failure of existing providers of open-heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations.

   (iii) An atypical barrier to services based on financial access may include the repeated failure as exhibited by a documented pattern over two or more years prior to the submission of the application, of an existing provider or group of providers of open-heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b) 1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c), (d), (e), (g), (h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in Ga. Comp. R. & Regs. r. 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a Certificate of Need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application.

(c) An applicant requesting a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Document that the open-heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

   (i) repair and replacement of heart valves;

   (ii) cardiac revascularization;

   (iii) treatment of cardiac trauma;

   (iv) repair of congenital defects in adults; and

   (v) repair of acute aortic dissection.

2. Document that the applicant has available to the open-heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

   (i) medicine: cardiology, hematology, nephrology;

   (ii) radiology: diagnostic, nuclear medicine;

   (iii) surgery: cardiovascular, thoracic;

   (iv) pathology: anatomic, clinical, blood bank, coagulation laboratory;

   (v) anesthesiology: inhalation therapy; echocardiology in the operating room;

   (vi) neurology;

   (vii) special laboratories: cardiac catheter/angiographic;

(viii) clinical dietary;

(ix) cardiac surgical intensive care unit;

(x) pacemaker therapy;

(xi) cardiac rehabilitation services;

(xii) renal dialysis; and

(xiii) social services.

3. Document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives;

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and

(IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

(II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(III) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

(iv) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, disease management in clinical settings, and case finding and referral strategies.

(v) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

(3) **Standards.**

(a) 1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse

if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the preceding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the preceding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact; and

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to open heart surgery services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(i) An atypical barrier to services based on cost may include the failure of existing providers of open-heart surgical services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state.

(ii) An atypical barrier to services based on quality may include the failure of existing providers of open-heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations.

(iii) An atypical barrier to services based on financial access may include the repeated failure as exhibited by a documented pattern

over two or more years prior to the submission of the application, of an existing provider or group of providers of open-heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b)

1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in Ga. Comp. R. & Regs. r. 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a Certificate of Need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application.

(c) An applicant requesting a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Document that the open-heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

   (i) repair and replacement of heart valves;

   (ii) cardiac revascularization;

   (iii) treatment of cardiac trauma;

   (iv) repair of congenital defects in adults; and

   (v) repair of acute aortic dissection.

2. Document that the applicant has available to the open-heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

   (i) medicine: cardiology, hematology, nephrology;

   (ii) radiology: diagnostic, nuclear medicine;

   (iii) surgery: cardiovascular, thoracic;

   (iv) pathology: anatomic, clinical, blood bank, coagulation laboratory;

   (v) anesthesiology: inhalation therapy; echocardiology in the operating room;

   (vi) neurology;

   (vii) special laboratories: cardiac catheter/angiographic;

   (viii) clinical dietary;

   (ix) cardiac surgical intensive care unit;

   (x) pacemaker therapy;

   (xi) cardiac rehabilitation services;

   (xii) renal dialysis; and

   (xiii) social services.

3. Document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

   (i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

      (I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

      (II) Assessment of risk factors and referral for appropriate care in first-degree relatives;

      (III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and

      (IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

   (ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

      (I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

      (II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(III) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

(iv) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, disease management in clinical settings, and case finding and referral strategies.

(v) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(e) An applicant for a new or expanded adult open heart surgery service shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(d), that such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the adult open heart surgery service, or the applicant may request that the Department allow the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(f) In considering applications joined for review for new adult open heart surgery services, the Department may give favorable consideration to an applicant which historically has provided a higher annual percentage of unreimbursed services to indigent and charity patients and a higher annual percentage of services to Medicare and Medicaid patients.

(g) An applicant for a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Demonstrate the intent to achieve the optimal standards established by the American College of Surgeons and the Advisory Council for Cardiothoracic Surgery of the American College for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, support services, physical plant, and equipment.

2. Document the availability of; or shall present a plan for recruiting, a qualified surgeon certified by the American Board of Thoracic Surgery with special qualifications in cardiac surgery.

3. Document a plan for obtaining a sufficient number of professional and technical staff; including cardiac intensive care nurses, for the size of the adult open heart surgery program proposed and document that the operating room team necessary for an adult open heart surgical procedure shall be available, including a cardiovascular surgeon who is board certified by the American Board of Thoracic Surgery; a second physician who is a cardiovascular or thoracic surgeon or surgical resident; a board-certified anesthesiologist trained in open heart surgery; a circulating nurse or scrub nurse (RN); an operating room technician or registered nurse trained in cardiac procedures; and one or two pump technicians, with one being certified and one qualified.

(h) An applicant for a new or expanded adult open heart surgery service shall provide documentation that the hospital is fully accredited by the Joint Commission or another nationally recognized health care accreditation body, and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

(i) An applicant for a new adult open heart surgery service shall demonstrate that charges and/or reimbursement rates for the service shall compare favorably with charges and/or reimbursement rates in existing adult open heart surgery services in the state when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for adult open heart surgery procedures, the Department may compare the applicant's history of charges and/or reimbursement rates for cardiac catheterization procedures and other treatments and/or interventions for disorders of the circulatory system and for open heart procedures, if applicable, with such charges and/or reimbursement rates in other similar hospitals.

(j) An applicant for a new or expanded adult open heart surgery service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs; and

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national,

state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;

3. development of procedures to ensure that any surgeon authorized to perform open heart surgery for the hospital shall be required to perform at least 100 procedures on annual basis across his or her various practice settings, and shall be required to accept Medicaid or Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(k) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.22
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
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Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022

Rule 111-2-2-.23. Specific Review Considerations for Pediatric Cardiac Catheterization and Open-Heart Surgery.

(1) **Definitions.**

(a) "Authorized service" means a pediatric cardiac catheterization service or pediatric cardiac surgery service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not become operational.

(b) "Capacity" means:

1. for a pediatric catheterization service:

   (i) in considering applications for a new pediatric cardiac catheterization service, 750 procedures per year per authorized service regardless of the number of rooms used; or

   (ii) in considering applications for expansion of an existing service, 750 pediatric cardiac catheterization procedures per dedicated room per year in the existing service (3 per day per room, 5 days per week, 50 weeks per year) and for each multipurpose room in the existing service, 750 procedures (special procedures and pediatric cardiac catheterization procedures) per year. If adult and pediatric cardiac catheterization are performed in the same room in a service seeking to expand, the capacity of the room shall be equivalent to 750 pediatric procedures with adult procedures performed in the room weighted in proportion to pediatric procedures as being 0.50 for each adult cardiac catheterization or special procedure, except for each adult coronary angioplasty, which shall be 0.75, in order to determine the service's use rate; or

2. for a pediatric cardiac surgery service, the number of pediatric cardiac surgery procedures which could be performed annually as reported by each hospital with an authorized service and based on survey and other reported data. In determining capacity, a hospital must consider factors such as available operating rooms which can be used for pediatric cardiac surgery, cardiac surgical intensive care beds and other pediatric intensive care beds available for pediatric patients, general bed capacity, and any other factors which impact the determination.

(c) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(d) "Closed heart surgery" means an operation performed directly on the heart or its associated veins or arteries that does not require use of a heart and lung bypass machine (extracorporeal pump) to perform the work of the heart and lungs. Such operations often require the bypass machine to be available on standby for use if the surgery needs to be changed to open heart with the machine then performing the work of the heart and lungs.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department, established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung bypass machine (extracorporeal pump) is used to perform the work of the heart and lungs.

(g) "Pediatric" refers to children 14 years of age and under.

(h) "Pediatric cardiac catheterization service" means an organized program which serves pediatric patients of a hospital which has a room or suite of rooms with the equipment, staff, and all support services required to perform angiographic, physiologic, and, as appropriate, therapeutic cardiac catheterization procedures. The pediatric cardiac catheterization service shall be located in a pediatric tertiary hospital. Procedures may be performed in a room dedicated to cardiac catheterization and/or in a special procedures or multipurpose room not exclusively used for cardiac catheterization.

(i) "Pediatric cardiac surgery" means an operation performed directly on a pediatric patient's heart or its associated veins or arteries, including open heart and closed heart surgery procedures but excluding surgical procedures for the closure of neonatal patent ductus arteriosus.

(j) "Pediatric cardiac surgery service" means an organized surgical program which serves pediatric inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, and all support services required to perform closed heart and open-heart operations for pediatric patients. The pediatric cardiac surgery service shall be located in a pediatric tertiary hospital.

(k) "Pediatric tertiary hospital" means a teaching center, specialty medical or large community hospital characterized by serving pediatric patients from a large region or the entire state with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients.

(l) "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization or a pediatric open or closed heart operation or combination of operations performed in a single session on a single patient who appears for pediatric cardiac surgery.

(m) "Service area", for pediatric cardiac catheterization and pediatric cardiac surgery means the State of Georgia.

(2) **Standards**.

(a) An applicant for new pediatric cardiac catheterization and pediatric cardiac surgery services must be a pediatric tertiary hospital. Due to the highly specialized nature of pediatric cardiac catheterization and pediatric cardiac surgery services, applicants for these services must propose to provide both pediatric cardiac catheterization and pediatric cardiac surgery. Only those projects that meet all applicable standards for both services will be approved.

(b) New pediatric cardiac catheterization services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate for all existing and approved pediatric cardiac catheterization services in the state has been at or above eighty percent (80%) of capacity for the past two (2) years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of one-hundred fifty (150) procedures per year within three (3) years of initiation of the service in order to maintain and strengthen skills. Such projection at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac catheterization services that would be impacted by the establishment of the new service are not predicted to perform less than the minimum quality level of one-hundred fifty (150) procedures annually as a result of the establishment of the new service.

(c) An application for expansion of an existing pediatric cardiac catheterization service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least eighty percent (80%) of capacity for each of the past two (2) years and the applicant can project a minimum of one-hundred fifty (150) additional pediatric procedures per year within three (3) years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of Ga. Comp. R. & Regs. r. 111-2-2-.23(2)(f) through (o).

(d) New pediatric cardiac surgery services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate of all authorized pediatric cardiac surgery services in the state has been at or above eighty percent of (80%) capacity for the past two (2) years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of one hundred (100) pediatric cardiac surgery procedures per

year, of which at least fifty (50) are open heart operations, within three years of initiation of the service in order to maintain and strengthen skills. Such projections at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac surgery services which would be impacted by the establishment of the new services are not predicted to perform less than the minimum quality level of one hundred (100) procedures annually, of which at least fifty (50) are open heart operations, as a result of the establishment of the new service.

(e) An application for expansion of an existing pediatric cardiac surgery service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least eighty percent (80%) of capacity for each of the past two years and the applicant can project a minimum of one hundred 100 additional pediatric cardiac surgery procedures, of which at least fifty (50) are open heart operations, within three (3) years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of Ga. Comp. R. & Regs. r. 111-2-2-.23(2)(f) through (o).

(f) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult cardiac catheterization services, the hospital shall have support services and equipment necessary for the diagnosis and treatment of infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics.

(g) An applicant for a new or expanded pediatric cardiac surgery service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult open-heart surgery, the hospital shall have support services and equipment

necessary for surgery on infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers. This includes a complete pediatric cardiology unit, a neonatal intensive care unit, a pediatric intensive care unit, and a general pediatric unit with pediatric sub-specialists in hematology, endocrinology, pulmonary neurology, and radiology.

(h) An applicant for a new or expanded pediatric cardiac catheterization service or for a new or expanded pediatric cardiac surgery service shall document that the service shall be available for the performance of procedures as needed at least eight hours per day, five days per week, and shall document the capability to rapidly mobilize the surgical and medical support teams for emergency procedures 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(i) An applicant for a new or expanded pediatric cardiac catheterization service and/or pediatric cardiac surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

   (i) A clinical intervention program for all patients that shall provide for the following in a comprehensive, systematic way:

      (I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

      (II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

      (III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate

weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

(ii) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iii) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

3. propose a system of outcome monitoring and quality improvement and identify at least five (5) clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(j) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the pediatric cardiac catheterization and surgical services, or the applicant may request that the

Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid and PeachCare programs and to accept any Medicaid- and/or PeachCare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(k) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. demonstrate the intent to achieve the optimal standards established by the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac catheterization services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment;

2. document the availability of, or shall present a plan for recruiting, a qualified service director who is a physician, board-certified in pediatrics, with subspecialty training and board eligibility in pediatric cardiology and who is competent to perform physiologic and angiographic procedures or both; and

3. document a plan for obtaining a sufficient number of professional and technical staff for the size of the pediatric cardiac catheterization service proposed, including a pediatric nurse, radiologic technologist, cardiopulmonary technician, and darkroom technician and document that the staff required for most procedures shall be available, including two physicians, one nurse, and two technicians, with the nurse and technicians

cross trained to cover technical responsibility of the monitoring and recording technicians.

(l) An applicant for a new or expanded pediatric cardiac surgery service shall comply with the following three requirements:

1. Demonstrate the intent to achieve the optimal standards established by the Advisory Council for Cardiothoracic Surgery of the American College of Surgeons, and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment.

2. Document the availability of, or shall present a plan for recruiting, a qualified pediatric cardiac surgery director who is a pediatric cardiovascular surgeon, board-certified in thoracic surgery, with special emphasis and experience in surgery for congenital heart disease.

3. Document a plan for obtaining a sufficient number of professional and technical staff, including pediatric cardiac intensive care nurses, for the size of the pediatric cardiac surgery service proposed, including at least two board-qualified cardiac surgeons on the staff of the hospital and a cardiovascular surgical team which includes a neonatologist, a pediatric anesthesiologist, a pediatric radiologist, a pediatric cardiologist, a nurse clinician, and backup of medical social services.

(m) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall provide documentation that the hospital is fully accredited by the Joint Commission or another nationally recognized health care accreditation body and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and Medicaid certification deficiencies in the past three (3) years and has no outstanding licensure and Medicare and Medicaid certification deficiencies.

(n) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall demonstrate that the applicant's charges and/or reimbursement for pediatric cardiac catheterization and pediatric cardiac surgery services shall compare favorably with charges and/or reimbursement in existing pediatric cardiac catheterization and pediatric cardiac surgery services in the state, when adjusted for annual inflation.

(o) An applicant for new or expanded pediatric cardiac catheterization and/or pediatric cardiac surgery services must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;

3. development of procedures to ensure that any surgeon or cardiologists authorized to perform pediatric cardiac services for the hospital shall be required to accept Medicaid and PeachCare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(p) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.23
Authority: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Pediatric Cardiac Catheterization and Open Heart Surgery" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: New title, "Specific Review Considerations for Pediatric Cardiac Catheterization and Open-Heart Surgery." F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.24. Specific Review Considerations for Perinatal Services.

(1) **Applicability.** For Certificate of Need purposes, Basic Perinatal Services, Neonatal Intermediate Care Services (Specialty/Level II), and Neonatal Intensive Care Services (Subspecialty/Level III) shall be defined as new institutional health services.

(2) **Definitions.**

(a) "Basic Perinatal Services (Level I)" means providing basic inpatient care for pregnant women and newborns without complications; managing perinatal emergencies; consulting with and referring to specialty and subspecialty hospitals; identifying high-risk pregnancies; providing follow-up care for new mothers and infants; and providing public/community education on perinatal health.

(b) "Most recent year" means the most current twelve-month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. If the Department has conducted a survey within six (6) months of the date of completion of the first application when applications are joined, the Department may consider the most recent year to be the report period covered by the prior survey.

(c) "Neonatal Intensive Care Service (Subspecialty/Level III)" means a hospital service that meets the requirements for a Neonatal Newborn Care Service and meets the definition of a Subspecialty Perinatal Hospital Service as contained in the most recent edition of the Recommended Guidelines for Perinatal Care in Georgia, as published by the Council on Maternal & Infant Health.

(d) "Neonatal Intermediate Care Service (Specialty/Level II)" means a hospital service that meets the requirements for a Neonatal Newborn Care Service and meets the definition of a Specialty Perinatal Hospital Service as contained in the most recent edition of the Recommended Guidelines for Perinatal Care in Georgia, as published by the Council on Maternal & Infant Health.

(e) "Neonatal Newborn Care Service (Basic/Level I)" means a hospital service which meets the minimum standards contained in Chapter 111-8-40 of the Rules of the Healthcare Facility Regulation Division, such chapter being entitled "Newborn Service. Amended."

(f) "Obstetric Service" means a hospital service that meets the minimum standards contained in Chapter 111-8-40 of the Rules of the Healthcare Facility Regulation Division, such chapter being entitled "Maternity and Obstetric Service. Amended."

(g) "Official Inventory" means the inventory for each hospital of Basic Perinatal Service and Neonatal Intermediate and Intensive Care Service beds maintained by the Department based upon responses to the Annual Hospital Questionnaire (AHQ) and/or its Perinatal Addendum and any Certificate of Need approved beds after the period covered by the AHQ and with the following provisions:

1. the official inventory for each facility will remain unchanged for the year following the last day of the report period on each hospital's completed AHQ and/or its Perinatal Addendum unless the Department approves a change of bed capacity through the Certificate of Need process; and

2. the capacity of existing freestanding birthing centers will not be counted as part of the official inventory of available services when computing unmet numerical need for Basic Perinatal Services in a planning area.

(h) "Perinatal physician training program" refers to obstetrics and gynecology, family practice and pediatrics disciplines.

(i) "Planning Areas" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Perinatal Services.

(j) "Regional Perinatal Center" (RPC) means those hospitals designated by the Department of Public Health to serve a defined geographic area to provide the highest level of comprehensive perinatal health care services for pregnant women, their fetuses and neonates of all risk categories. The RPC accepts patients in need of these services from its region regardless of race, creed, religion, ability to pay, or funding source. The RPC provides consultation and transport for patients requiring special services; coordination and assurance of follow-up medical care for maternal and neonatal patients requiring special care; educational support to ensure quality care in institutions involved in perinatal health care; compilation, analysis, and evaluation of perinatal data from the center and referring hospitals and coordination of perinatal health care within the region.

(k) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) **Standards.**

(a) The need for a new or expanded Obstetric Service, Neonatal Intermediate Care Service and Neonatal Intensive Care Service shall be determined through application of a Numerical Need method and an assessment of the aggregate occupancy rate of existing services.

1. The numerical need for a new or expanded Obstetric Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the average obstetric utilization rate (UR) by dividing the obstetric days (OBDays) reported by hospitals for the two most

recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the female population ages 15 to 44 (FP) for the corresponding years:

$$UR = \frac{OBDays_1 + OBDays_2}{FP_{YR}1 + FP_{YR}2}$$

(ii) Multiply the obstetric utilization rate by the projected female population ages 15 to 44 (PFP) for the horizon year to determine the number of projected obstetric days (POBDays):

$$POBDays = URxPFP$$

(iii) Calculate the number of projected obstetric beds (POBBeds) by dividing the number of projected obstetric days by 273.75 (the result of 365 days multiplied by the occupancy standard of seventy-five percent (75%)) with any fraction rounded up to a whole bed:

$$POBBeds = \frac{POBDays}{273.75}$$

(iv) Determine the net numerical unmet need (UN) for new or additional obstetric beds by subtracting the number of beds in the Official Inventory (OI) from the number of projected obstetric beds:

$$UN = POBBeds - OI$$

2. The numerical need for a new or expanded Level II Neonatal Intermediate Care Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps below, and all data elements relate to each planning area:

(i) Calculate the average resident live-birth rate (ABR) using the sum of the resident live births (RB) for the three most recent calendar years available from the Department of Public Health or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

$$ABR = \frac{RB_1 + RB_2 + RB_3}{FP_{YR}1 + FP_{YR}2 + FP_{YR}3}$$

(ii) Determine the number of projected resident live births (PRB) for the horizon year by multiplying the average resident live-birth rate by the estimated female population ages 15 to 44 (PFP) for the horizon year:

$$PRB = ABRxPFP$$

(iii) Calculate the projected number of neonatal intermediate care patient days (PN2Days) in the horizon year by multiplying the average number of patient days (N2Days) in neonatal intermediate care beds reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the number of projected resident live births divided by the actual number of resident live births (RB) available from the Department of Public Health or other official source for the most recent calendar year:

$$PN2Days = N2Daysx\frac{PRB}{RB}$$

(iv) Project neonatal intermediate care bed need (N2Beds) into the horizon year by dividing the projected patient days for neonatal intermediate care services by 292 (the result of 365 days multiplied by the occupancy rate of eighty percent (80%)) with any fraction rounded up to a whole bed:

$$N2Beds = PN2\frac{Days}{292}$$

(v) To determine unmet numerical bed need (UN), subtract the official inventory (OI) from the projected neonatal intermediate care bed need:

$$UN = N2Beds - OI$$

3. The numerical need for a new or expanded Level III Neonatal Intensive Care Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps below, and all data elements relate to each planning area:

(i) Calculate the average resident live-birth rate (ABR) using the sum of the resident live births (RB) for the three most recent calendar years available from the Department of Public Health or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

$$ABR = \frac{RB_1 + RB_2 + RB_3}{FP_{YR}1 + FP_{YR}2 + FP_{YR}3}$$

(ii) Determine the number of projected resident live births (PRB) for the horizon year by multiplying the average resident live-birth rate by the estimated female population ages 15 to 44 (PFP) for the horizon year:

$$PRB = ABRxPFP$$

(iii) Calculate the projected number of neonatal intensive care patient days (PN2Days) in the horizon year by multiplying the average number of patient days (N2Days) in neonatal intensive care beds reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the number of projected resident live births divided by the actual number of resident live births (RB) available from the Department of Public Health or other official source for the most recent calendar year:

$$PN2Days = N2Daysx\frac{PRB}{RB}$$

(iv) Project neonatal intensive care bed need (N2Beds) into the horizon year by dividing the projected patient days for neonatal intensive care services by 292 (the result of 365 days multiplied by the occupancy rate of eighty percent (80)) with any fraction rounded up to a whole bed:

$$N2Beds = PN2\frac{Days}{292}$$

(v) To determine unmet numerical bed need (UN), subtract the official inventory (OI) from the projected neonatal intensive care bed need:

$$UN = N2Beds - OI$$

4. Prior to approval of a new or expanded Obstetric Service, Neonatal Intermediate Care Service or Neonatal Intensive Care Service in a planning area, the aggregate occupancy rate for all similar services in that planning area shall equal or exceed seventy-five percent (75%) for an Obstetric Service and eighty percent (80%) for a Neonatal Intermediate Care Service or Neonatal Intensive Care Service for each of the two (2) most recent years.

(b) Exceptions to need may be considered by the Department as follows:

1. To provide that an applicant for new basic perinatal services shall not be subject to the need standard of section (3)(a)1. or the aggregate occupancy standard of section (3)(a)4. of this Rule if:

   (i) The proposed new service would be located in a county where only one civilian health care facility or health system is currently providing basic perinatal services; and

   (ii) There are not at least three (3) different health care facilities in a contiguous county providing basic perinatal services.

2. To allow expansion of an existing Level I or Level II or Level III service, if the actual utilization of that service has exceeded 80 percent occupancy over the most recent two years; or

3. To remedy an atypical barrier to perinatal services based on cost, quality, financial access, or geographic accessibility. An applicant seeking such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the planning area and/or the communities under review. In approving an applicant through the exception process, the Department shall document the bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(c) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care or Neonatal Intensive Care Service shall document the impact on existing and approved services in the planning area with the goal of minimizing adverse impact on the delivery system and as follows:

1. An existing perinatal physician training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient number and variety of patients to maintain an appropriate number of providers and provider competencies and the training program's accreditation and funding status;

2. An existing nurse midwifery training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain an appropriate number of providers and provider competencies to sustain a sufficient number and variety of patients to maintain the training program's accreditation; and

3. An existing regional perinatal center shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient volume and case mix of patients including both low risk and high risk deliveries to maintain its regional center status.

(d) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that unreimbursed services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the entire facility after Medicare and Medicaid contractual adjustments and bad debt have been deducted;

3. providing a written commitment to participate in the Medicaid program;

4. providing a written commitment to participate in any other public reimbursement programs available for perinatal services for which the hospital is eligible; and

5. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity care.

(e) The desired minimum bed size for a Basic Perinatal Service, Neonatal Intermediate Care Service or Neonatal Intensive Care Service is as follows:

1. At least four beds for a new Basic Perinatal, Neonatal Intermediate Care, or Neonatal Intensive Care Service.

2. The Department may grant an exception to these standards when the Department determines that unusual circumstances exist that justify such action.

(f) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall provide evidence of ability to meet the following continuity of care standards:

1. Document a plan whereby the hospital and its medical staff agree to provide a full array of perinatal services to the community, including but not limited to community education and outreach, prenatal, intrapartum, postpartum, newborn, and postnatal services; and

2. As appropriate, provide a formal transfer agreement with at least one hospital within reasonable proximity that provides services to high-risk mothers and babies.

(g) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall provide evidence of the ability to meet the following quality of care standards:

1. evidence that qualified personnel will be available to ensure a quality service to meet licensure, certification and/or accreditation requirements;

2. written policies and procedures for utilization review consistent with state, federal and other accreditation standards. This review shall include assessment of medical necessity for the service, quality of patient care, and rates of utilization;

3. written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division; and

4. evidence that there are no uncorrected operational standards in any existing Georgia hospitals owned and/or operated by the applicant or the applicant's parent organization. Plans of correction in the applying facility must be included in the application.

(h) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.24
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
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Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.25. Specific Review Considerations for Freestanding Birthing Centers.

(1) A Certificate of Need for a proposed new freestanding birthing center will be issued only if the services to be provided are consistent with the philosophy of family-centered care as defined in the State Health Plan and if there is evidence of safe and quality service at a charge lower than charges for deliveries provided on an inpatient basis.

(2) The applicant must agree to meet the rules and regulations for the development and operation of birthing centers required by the Healthcare Facility Regulation Division.

(3) The applicant must provide evidence that the birthing center will function as part of the established regionalized system of perinatal care. This includes arrangements for referral of those clients who develop complications that make them ineligible for delivery at the birthing center.

(4) A birthing center must have a written agreement for transfer and emergency services with a backup hospital(s) that provides at least Level II perinatal services. Each physician practicing at the center must have admitting privileges at the backup hospital.

(5) It must be demonstrated that agreements for ambulance service are available. In emergency situations, the center must have the capability of transporting the adult and/or newborn patients to the backup hospital within 30 minutes from initiation of transfer to the arrival at the hospital.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.25
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Freestanding Birthing Centers" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.26. Specific Review Considerations for Psychiatric and Substance Abuse Inpatient Programs.

(1) **Applicability.**

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing acute care adult psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded acute care adult psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an acute care adult psychiatric and/or substance abuse inpatient program may offer both acute

care psychiatric and acute care substance abuse inpatient care, acute care substance abuse inpatient care alone, or acute care psychiatric inpatient care alone. A facility approved to offer acute care adult psychiatric and/or substance abuse inpatient services may not offer an acute care pediatric psychiatric and/or substance abuse inpatient program, nor any type of extended care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing acute care pediatric psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded acute care pediatric psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an acute care pediatric psychiatric and/or substance abuse inpatient program may offer both acute care psychiatric and acute care substance abuse inpatient care, acute care substance abuse inpatient care alone, or acute care psychiatric inpatient care alone. A facility approved to offer acute care pediatric psychiatric and/or substance abuse inpatient services may not offer an acute care adult psychiatric and/or substance abuse inpatient program, nor any type of extended care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(c) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing extended care adult psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded extended care adult psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an extended care adult psychiatric and/or substance abuse inpatient program may offer both extended care psychiatric and extended care substance abuse inpatient care, extended care substance abuse inpatient care alone, or extended care psychiatric inpatient care alone. A facility approved to offer extended care adult psychiatric and/or substance abuse inpatient services may not offer an extended care pediatric psychiatric and/or substance abuse inpatient program, nor any type of acute care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(d) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing extended care pediatric psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded extended care pediatric psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as

an extended care pediatric psychiatric and/or substance abuse inpatient program may offer both extended care psychiatric and extended care substance abuse inpatient care, extended care substance abuse inpatient care alone, or extended care psychiatric inpatient care alone. A facility approved to offer extended care pediatric psychiatric and/or substance abuse inpatient services may not offer an extended care adult psychiatric and/or substance abuse inpatient program, nor any type of acute care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(2) **Definitions**.

(a) "Acute care psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means a psychiatric or substance abuse program, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a), that provides acute and/or emergency stabilization and other treatment for acute episodes. An acute care program provides medically oriented evaluation, diagnosis, stabilization, and short-term treatment using individual and/or group therapies as well as other treatment activities. Two acute care programs are defined: adult psychiatric and/or substance abuse and pediatric psychiatric and/or substance abuse.

(b) "Adult", for purposes of these Rules, means a person 18 years of age and over or an emancipated person.

(c) "Expansion" or "Expanded" means exceeding a health care facility's total approved inpatient bed capacity through the addition of beds to an existing CON-authorized or grandfathered psychiatric and/or substance abuse inpatient program. A CON-authorized or grandfathered freestanding psychiatric and/or substance abuse hospital may request a letter of determination to increase its bed capacity by the lesser of ten percent (10%) of existing capacity or ten (10) beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two (2) years and provided that the capital expenditures associated with the increase do not exceed the Capital Expenditure Threshold. If such an increase exceeds the Capital Expenditure Threshold, a Certificate of Need shall be required under these Rules.

(d) "Extended care psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means a psychiatric or substance abuse program, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a), that focuses on self-help and basic living skills to enhance the patient's abilities to perform successfully in society upon discharge by emphasizing psycho-social, vocational and/or prevocational, and educational components in its treatment plan. The program is designed to treat people who do not require acute care and who usually have already had at least one acute care admission. Due to this design, the staffing of extended care programs is different from that of acute care programs by having

proportionately more therapeutic activities, educational, and social work staff and proportionately fewer nurses and physicians. Two extended care programs are defined: adult psychiatric and/or substance abuse and pediatric psychiatric and/or substance abuse.

(e) "Freestanding psychiatric and/or substance abuse hospital", for purposes of these Rules, means a self-contained hospital which provides only psychiatric and/or substance abuse treatment and is licensed as a separate hospital, either as a specialized hospital or specialized hospital/intensive residential treatment facility.

(f) "Inpatient" means services that are provided to patients admitted to a short-stay general hospital, specialized hospital, or specialized hospital/intensive residential treatment facility.

(g) "New" means a psychiatric and/or substance abuse inpatient program that has not offered a similar program in the prior twelve (12) months. Adult programs and pediatric programs and acute care programs and extended care programs shall each be considered independent programs such that a provider seeking to add a program not offered by that provider in the previous twelve (12) months shall be considered to be offering a new program for which a Certificate of Need must be obtained. For purposes of these Rules, an existing program which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(h) "Pediatric", for purposes of these Rules, means a person seventeen (17) years of age and under or persons age twenty-one (21) or under as clinically indicated.

(i) "Planning Region" means one of the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

(j) "Psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means an organized entity with a specific plan and intent to serve a special population via designated staff in designated beds in a licensed hospital. Such a program provides services on a 24-hour, seven days per week basis. The characteristics of a program shall include:

1. a clear, distinct plan which includes admission policies and criteria, treatment protocol, etc.; and

2. appropriately trained personnel for the age and disability group to be served by the program; and

3. all of the beds in a program are designated for patients in that specific program.

(k) "Psychiatric and/or substance abuse service", for purposes of these Rules, means any combination of organized psychiatric and substance abuse programs in a hospital.

(l) "Public sector bed", for purposes of these Rules, means a bed located in state owned and operated psychiatric and substance abuse regional hospitals which are maintained by the Department of Behavioral Health & Developmental Disability.

(m) "Similar existing and approved program", for purposes of these Rules, means an approved or existing organized program as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a) that provides services to the same age group (adults or pediatric), and for the same treatment model (acute or extended).

(3) **Standards.**

(a) An application for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide sufficient documentation of the need for such program(s) in the planning area. In the case of an application for an expanded psychiatric and/or substance abuse inpatient program, the applicant shall justify the need for the expansion by, at a minimum, documenting that the expansion program has achieved an occupancy rate of eighty percent (80%) for an adult program or an occupancy rate of seventy percent (70%) for a pediatric program for the most recent twelve (12) months prior to submitting an application, except that a pediatric program which has obtained an occupancy rate of sixty-five percent (65%) may be permitted to expand if such program demonstrates clinical reasons why seventy percent (70%) occupancy is not attainable.

(b) An application for a new or expanded psychiatric and/or substance abuse inpatient program(s) in an existing hospital shall not be approved unless the applicant provides sufficient documentation that it is not appropriate to convert existing hospital beds to beds designated for the proposed program(s) or to close existing hospital beds.

(c) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall document that the establishment or expansion of its program(s) will not have an adverse impact on similar existing and approved programs in its planning area. State-owned and -operated psychiatric and substance abuse regional hospitals shall not be required to document this standard.

1. Accounting for market share and future population growth, an applicant for a new or expanded adult psychiatric and/or substance abuse inpatient program(s) shall have an adverse impact on similar existing and approved programs if it will:

(i) decrease annual utilization of a similar existing program, whose current utilization is at or above eighty-five percent (85%), to a

projected annual utilization of less than seventy-five percent (75%) within the first twenty-four (24) months following the acceptance of the applicant's first patient; or

(ii) decrease annual utilization of a similar existing program, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twenty-four (24) months following the acceptance of the applicant's first patient.

2. Accounting for market share and future population growth, an applicant for a new or expanded pediatric psychiatric and/or substance abuse inpatient program(s) shall have an adverse impact on similar existing and approved programs if it will:

   (i) decrease annual utilization of a similar existing program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than eighty percent (80%) within the first twenty-four (24) months following the acceptance of the applicant's first patient; or

   (ii) decrease annual utilization of a similar existing program, whose current utilization is below eighty-five percent (85%), by five percent (5%) over the twenty-four (24) months following the acceptance of the applicant's first patient.

(d) A new psychiatric and/or substance abuse inpatient program(s) shall have the following minimum bed sizes based on type of program offered:

1. The minimum bed size of a new acute psychiatric and/or substance abuse program is eight beds.

2. The minimum bed size of a new extended care psychiatric and substance abuse inpatient program is eight beds.

3. The minimum bed size of a new freestanding psychiatric and/or substance abuse hospital primarily providing acute care and licensed as a specialized hospital is 50 beds.

4. The minimum bed size of a new freestanding psychiatric and/or substance abuse hospital primarily providing extended care and licensed as a specialized hospital or a specialized hospital/intensive residential treatment facility is 50 beds.

5. The minimum number of designated beds in the aggregate of any and all acute psychiatric and/or substance abuse programs in a general hospital is ten beds.

6. The minimum number of designated beds in the aggregate of any and all extended care psychiatric and substance abuse inpatient programs in a general hospital is ten beds.

(e) An applicant for a new psychiatric and/or substance abuse inpatient program(s) shall demonstrate the intent to meet the standards of the Joint Commission or another nationally recognized health care accreditation body applicable to the type of program to be offered within twelve (12) months of offering the new program. Extended care programs may demonstrate their intent to meet the standards of the Council on the Accreditation of Rehabilitation Facilities (CARF) or the Council on Accreditation (COA) in lieu of the Joint Commission or another nationally recognized health care accreditation body.

(f) An applicant for an expanded psychiatric and/or substance abuse inpatient program(s) shall be accredited by the Joint Commission for the type of program which the applicant seeks to expand prior to application. The applicant must provide proof of such accreditation. Extended care programs may be accredited by the Council on the Accreditation of Rehabilitation Facilities (CARF) or the Council on Accreditation (COA) in lieu of the Joint Commission or another nationally recognized health care accreditation body.

(g) An applicant for a new freestanding psychiatric hospital or intensive residential treatment facility shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such facilities.

(h) An applicant for an expanded freestanding psychiatric hospital or intensive residential treatment facility shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(i) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide documentation that the applicant has no uncorrected history of conditional level Medicare and Medicaid certification deficiencies in the past three years.

(j) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide sufficient documentation that the proposal is consistent with the following quality standards:

1. The program(s) shall maintain standards for the review and improvement of quality. To document such standards, the program(s) must submit quality improvement policies.

2. The program(s) shall maintain standards to ensure the continuity of patient care. To document such standards, the program(s) must submit policies governing admissions and availability of adequate discharge planning.

(k) An applicant for a new or expanded freestanding psychiatric and/or substance abuse inpatient program(s) shall document the existence of referral arrangements, including transfer agreements, with an acute-care hospital(s) within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(l) An applicant for a new or expanded acute or extended care psychiatric and/or substance abuse program(s) shall document that the program(s) will be financially accessible by:

1. providing sufficient documentation that unreimbursed services for indigent and charity patients in a new or expanded program(s) will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the program after provisions have been made for bad debt, and Medicaid and Medicare contractual adjustments have been deducted. If an applicant, or any facility in Georgia owned or operated by the applicant's parent organization, received a Certificate of Need for a hospital program(s) or service(s) or a total facility and the CON included an expectation that a certain level of unreimbursed indigent and/or charity care would be provided in the program(s), service(s), or hospital(s), the applicant shall provide sufficient documentation of the facility's(ies') provision of such care. An applicant's history, or the history of any facility in Georgia owned or operated by the applicant's parent organization, of not following through with a specific CON expectation of providing indigent and/or charity care at or above the expected level will constitute sufficient justification to deny an application; and

2. agreeing to participate in the Medicare and Medicaid programs, whenever these programs are available to the facility.

(m) Reserved.

(n) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall agree to provide the Department with requested information and statistical data related to the operation of such a program(s) on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.26
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*

History. Original Rule entitled "Specific Review Considerations for Psychiatric and Substance Abuse Inpatient Programs" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Nov. 22, 2006; eff. Dec. 12, 2006.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.27. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.27

Rule 111-2-2-.28. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.28

Rule 111-2-2-.29. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.29

Rule 111-2-2-.30. Specific Review Considerations for Skilled Nursing and Intermediate Care Facilities.

(1) **Applicability**. A Certificate of Need will be required prior to the establishment of a new or expanded skilled nursing facility, intermediate care facility, or an intermingled facility.

(2) **Definitions.**

(a) "Horizon year" means the last year of the three-year projection period for need determinations for a nursing facility.

(b) "Hospital-based nursing facility" means a nursing facility which meets the current definition of "Hospital-Based Nursing Facilities" as defined in the current Policies and Procedures for Nursing Facility Services by the Georgia Department of Community Health, Division of Medical Assistance. A new hospital-based nursing facility can only result from conversion of existing inpatient space on the hospital's campus.

(c) "Intermediate care facility" ("ICF") means an institution which provides, on a regular basis, health related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but who, because of their mental or physical condition, require health related care and services beyond the provision of room and board.

(d) "Intermingled facility" means a nursing facility that provides both skilled intermediate levels of care.

(e) "Medicare distinct part skilled nursing unit" means a unit which meets the current definition of "Distinct Part of an Institution as SNF" as defined in the current Medicare Part A Intermediary Manual by the Centers for Medicare and Medicaid Services ("CMS") of the U.S Department of Health and Human Services.

(f) "Nursing facility" means a facility classified as either a skilled nursing facility, an intermediate care facility or an intermingled facility which admits patients by medical referral and provides for continuous medical supervision via 24-hour-a-day nursing care and related services in addition to food, shelter, and personal care.

(g) "Official State Health Component Plan" means the document related to the above-named services developed by the Department, established by the Georgia State Health Strategies Council, and adopted by the Board of Community Health.

(h) "Planning area" for all nursing facilities, with the exception of state nursing facilities, means the geographic regions in Georgia defined in the "Official State Health Component Plan". "Planning area for a state nursing facility" means the State of Georgia.

(i) "Retirement community-based nursing facility" means a nursing facility which operates as a lesser part of a retirement community which is a planned, age-restricted, congregate living development which offers housing, recreation, security, dietary services, and shared living areas accessible to all residents.

(j) "Skilled nursing facility" ("SNF") means a public or private institution or a distinct part of an institution which is primarily engaged in providing inpatient skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of the injured, disabled or sick persons.

(k) "State nursing facility" is a facility that meets the definition of a Nursing Facility as defined above and is owned and operated by a branch or branches of government of the State of Georgia.

(l) "Urban county" means a county with a projected population for the horizon year of 100,000 or more and population density for that year of 200 or more people per square mile. All other counties are "rural".

(3) **Standards**.

(a) The need for a new or expanded nursing facility in a planning area in the horizon year shall be determined through application of a numerical, supply-oriented need method and an assessment of current planning area utilization designed to measure demand for services.

1. The numerical need for a new or expanded nursing facility in any planning area in the horizon year shall be determined by a population-based formula which is a sum of the following:

   (i) a ratio of 0.43 beds per 1,000 projected horizon year Resident population age 64 and younger;

   (ii) a ratio of 9.77 beds per 1,000 projected horizon year Resident population age 65 through 74;

   (iii) a ratio of 32.5 beds per 1,000 projected horizon year Resident population age 75 through 84; and

   (iv) a ratio of 120.00 beds per 1,000 projected horizon year Resident population age 85 and older.

2. The demand for services in each planning area will be measured by the cumulative facility bed utilization rate during the most recent survey year period. The utilization rate shall be determined by dividing the actual bed days of resident care by the bed days available for resident care.

3. In order to establish need for a new or expanded nursing facility in any planning area, the utilization rate in that planning area shall have equaled or exceeded ninety-five percent (95%) during the most recent survey year.

(b) The required bed size for a new nursing facility in a rural or urban county is as follows: (Rural/urban designation shall be based on the county within which the proposed facility is to be located.)

1. A freestanding nursing facility in a rural county: a minimum of 60 beds;

2. A freestanding nursing facility in an urban county: a minimum of 100 beds;

3. A hospital-based nursing facility in a rural county: a minimum of 10 beds and a maximum of 20 beds;

4. A hospital-based nursing facility in an urban county: a minimum of 20 beds and a maximum of 40 beds;

5. A retirement community-based nursing facility: 1 nursing home bed for each 4 residential units, with a minimum of 20 beds and a maximum of 30 beds.

(c) In competing applications, favorable consideration may be given for the inclusion of services for special needs populations, such as but not limited to, persons with Alzheimer's Disease and related disorders, medically fragile children, or persons

with HIV/AIDS. An applicant must document a need for the service and that it is cost effective.

(d) The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.30(3)(a) under the following circumstances:

1. the establishment of a new Medicare distinct part skilled nursing unit if the proposed unit is to be in a county that does not have an existing Medicare unit; and if the applicant can document that there is limited access in the proposed planning area for skilled nursing services for Medicare patients. Limited access means that existing nursing facilities have not provided the proposed services in response to a demonstrated demand for the services over the three (3) most recent years. The implementation of an approved Certificate of Need will be valid only if the proposed beds will be limited to Medicare recipients. This exception is available to existing nursing facilities and hospitals; or

2. the applicant for a new or expanded nursing facility can show that there is limited access in the proposed geographic service area for special groups such as, but not limited to medically fragile children and HIV/AIDS patients. Limited access means that existing nursing facilities have not provided the proposed services in response to a demonstrated demand for the services over the three (3) most recent years.

(e) An applicant for a new or expanded facility must document provision of continuity of care by meeting each of the following:

1. An applicant shall provide a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care; and

2. An applicant shall document the existence of proposed and/or existing referral agreements with a nearby hospital to provide emergency services and acute-care services to residents of the proposed or existing facility; and

3. An applicant shall provide existing or proposed rehabilitation plans for services to facility residents; and

4. An applicant shall provide existing or proposed discharge planning policies.

(f) An applicant for a new or expanded nursing facility must provide evidence of the intent to meet all appropriate requirements regarding quality of care as follows:

1. An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division;

2. An applicant shall provide evidence that there are no uncorrected operational standards in any existing Georgia nursing homes owned and/or operated by the applicant or by the applicant's parent organization. Plans to correct physical plant deficiencies in the applying facility must be included in the application;

3. An applicant and any facility owned and/or operated by the applicant or its parent organization shall have no previous conviction or Medicaid or Medicare fraud;

4. An applicant shall demonstrate the intent and ability to recruit, hire and retain qualified personnel to meet the current Medicaid certification requirements of the Department's Division of Medical Assistance for the services proposed to be provided and that such personnel are available in the proposed geographic service area;

5. An applicant shall provide a plan for a comprehensive quality improvement program that includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators and measure the facility's performance; accordingly, and

6. In competing applications, favorable consideration will be given to an applicant that provides evidence of the ability to meet accreditation requirements of appropriate accreditation agencies within two years after the facility becomes operational.

(g) An applicant or a new or expanded facility must provide evidence of meeting the following standards pertaining to financial accessibility:

1. An applicant shall provide a written commitment of intent to participate in the Medicaid and Medicare programs if appropriate;

2. An applicant shall demonstrate a case-mix of Medicaid, Medicare and private pay patients; and

3. Document policies and practices of nondiscrimination by past performance of the applicant or its parent organization.

(h) A new or expanded state nursing facility may be exempted from the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.30(3)(a), (b), (c), (d), and (g) when the facility meets all of the following criteria:

1. documentation that the proposed facility will meet the definition of a state nursing facility as defined in Ga. Comp. R. & Regs. r. 111-2-2-.30(1) (k);

2. documentation that the applicant will admit patients from any of Georgia's counties with a primary focus on a pre-designated, multi-county service area or region;

3. the facility intends to become accessible to patients whose care, because of income and other limitations, would normally come under the jurisdiction of the state; and

4. such other considerations as may be considered necessary by the Department at the time of the application.

(i) An applicant for a new or expanded nursing facility shall document an agreement to provide Department requested information and statistical data related to the operation and provision of nursing facility services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.30
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Skilled Nursing and Intermediate Care Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.31. Specific Review Considerations for Personal Care Homes.

(1) **Applicability.** A Certificate of Need for a personal care home will be required prior to the establishment of a new personal care home, of twenty-five beds or more, and the expansion of any personal care home which is or will be twenty-five beds or more.

(2) **Definitions.**

(a) "Health planning area" for all personal care homes, means the geographic regions in Georgia defined in the State Health Plan or Component Plan.

(b) "Horizon Year" means the last year of a three-year projection period for need determinations for a personal care home.

(c) "Official State Health Component Plan" means the document related to personal care homes developed by the Department adopted by the State Health Strategies Council and approved by the Board of Community Health.

(d) "Personal care home" means a residential facility that is certified as a provider of medical assistance for Medicaid purposes pursuant to Article 7 of Chapter 4 of Title 49 having at least twenty-five (25) beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal care homes include those facilities which monitor daily residents' functioning and location, have the capability for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

1. old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

2. boarding facilities that do not provide personal care.

(3) **Standards.**

(a)

1. The numerical need for a new or expanded personal care home in a health planning area shall be determined by a population-based formula which is used to project the number of personal care home beds needed in the horizon year and which is a sum of the following:

   (i) a ratio of 18.00 beds per 1,000 projected horizon year Resident population age 65 through 74;

   (ii) a ratio of 40.00 beds per 1,000 projected horizon year Resident population age 75 through 84; and

   (iii) a ratio of 60.00 beds per 1,000 projected horizon year Resident population age 85 and older.

2. The net numerical unmet need for personal care home beds in each health planning area shall be determined by subtracting the number of existing and approved personal care home beds in the health planning area from the projected number of personal care home beds needed in the horizon year; provided, however, that if the net numerical unmet need exceeds fifty percent (50%) of the current existing and approved beds in the planning area, the net numerical unmet need shall be limited to fifty percent (50%) of the existing and approved beds at the time the calculation is made.

(b) The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.31(3)(a) as follows:

1. to allow expansion of an existing personal care home if actual utilization has exceeded ninety percent (90%) average annual occupancy based on number of licensed beds for the two-year period immediately preceding application;

2. to allow expansion of an existing personal care home if the applicant has substantial occupancy by out-of-state residents. "Substantial occupancy by out-of-state residents" shall be defined as having at least thirty-three percent (33%) of the available licensed beds in the personal care home utilized by individuals who resided outside of the State of Georgia immediately prior to moving into the personal care home; or

3. to remedy an atypical barrier to personal care home services based on cost, quality, financial access, or geographic accessibility.

(c) In competing applications, favorable consideration may be given to any applicant for a new or expanded personal care home which historically has provided and/or provides sufficient documentation of plans to provide a higher percentage of un-reimbursed services to indigent and charity residents than requirement by the indigent and charity standard of Ga. Comp. R. & Regs. r. 111-2-2-.31(3)(j). Favorable consideration also may be given to any applicant for a new or expanded personal care home which historically has provided and/or provides sufficient documentation of plans to provide personal care home residential services at monthly and/or annual rates that are affordable to the greatest number of individuals based on analysis of the national rate for services and the income ranges of individuals at or above age 65 and in the applicant's market area(s).

(d) A new or expanded personal care home shall be approved in a health planning area only if the applicant complies with the following physical standards:

1. the physical plant design and the program design shall support the concept of a non-institutional, home-like setting;

2. the proposed physical plant design is in compliance with the Rules and licensure standards of the Healthcare Facility Regulation Division and the applicant stipulates that the services required by such Rules and licensure standards will be provided and any services prohibited by such Rules and licensure standards will not be provided and will not be implied to be provided either through advertising or other means;

3. there shall be a designated area for staff on duty in each personal care home and on each floor in the case of a multistory facility;

4. the facility has the option of building kitchens or kitchenettes in the living units as long as the facility intends to provide three meals per day to residents. The kitchens or kitchenettes must comply with the Fire Marshal's

and the Healthcare Facility Regulation Division's minimum licensure standards; and

5. the facility provides assurance that it will not lease or contract space within the personal care home to an outside entity to provide services that the personal care home would otherwise not be allowed to provide.

(e) An applicant for a new or expanded personal care home must document provision of continuity of care by providing a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care.

(f) An applicant for a new or expanded personal care home shall provide evidence of intent to comply with all appropriate licensure requirements, resident life safety standards and operational procedures required by the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded personal care home shall provide evidence of the intent and ability to recruit, hire, and retain qualified personnel and that such personnel are available in the proposed geographic service area.

(h) An applicant for a new or expanded personal care home shall provide evidence that no existing Georgia personal care home of any size owned and/or operated by the applicant, a related entity or by the applicant's parent organization has had a permit or license revoked, denied or otherwise sanctioned through formal licensure enforcement action by the Healthcare Facility Regulation Division within the two years immediately preceding application.

(i) An applicant for a new or expanded personal care home shall provide a plan for assuring quality of care which includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators.

(j) An applicant for a new or expanded personal care home shall foster an environment which assures access to services to individuals by providing a written commitment that un-reimbursed services to residents who are indigent or meet the guidelines of a charity policy of the personal care home will be offered at a standard which meets or exceeds one percent (1%) of annual gross revenues for the personal care home after bad debt has been deducted.

(k) An applicant for a new or expanded personal care home shall agree to provide the Department with requested information and statistical data related to the operation and provision of personal care homes and to report that data to the Department in the time frame and format requested.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.31
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Personal Care Homes" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.32. Specific Review Considerations for Home Health Services.

(1) **Applicability.** A Certificate of Need for a home health agency will be required prior to the establishment of a new home health agency or the expansion of the geographic service area of an existing home health agency unless such expansion is a result of a non-reviewable acquisition of another existing home health agency.

(2) **Definitions.**

(a) "Home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which is primarily engaged in providing to individuals who are under a written plan of care of a physician, on a visiting basis in the place of residence used as such individual's home, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the following services: physical therapy, occupational therapy, speech therapy, medical-social services under the direction of a physician, or part-time or intermittent services of a home health aide.

(b) "Horizon year" means the last year of the three-year projection period for need determinations for a new or expanded home health agency.

(c) "Geographic service area" means a grouping of specific counties within a planning area for which the home health agency is authorized to provide services to individuals residing in the specific counties pursuant to an existing or future Certificate of Need. For purposes of establishing a service area for a new home health agency, the geographic service area shall consist of any individual county or combination of contiguous counties which have an unmet need as determined through the numerical need formula or the exception. For purposes of an expansion of an existing agency, the geographic service area shall consist of an individual county or any combination of counties which have an unmet need, and which are within any planning area in which the home health agency already provides service; however, in no case may an existing home health agency apply to provide services outside the health planning areas in which its current geographic service area is located.

(d) "Nursing care" means such services provided by or under the supervision of a licensed registered professional nurse in accordance with a written plan of medical care by a physician. Such services shall be provided in accordance with the scope of nursing practice laws and associated rules.

(e) "Planning area" for all home agencies means the geographic regions in Georgia defined in the State Health Plan or Component Plan.

(3) **Standards.**

(a) The need for a new or expanded home health agency shall be determined through application of a numerical need method and an assessment of the projected number of patients to be served by existing agencies.

1. The numerical need for a new or expanded home health agency in any planning area in the horizon year shall be based on the estimated number of annual home health patients within each health planning area as determined by a population-based formula which is a sum of the following for each county within the health planning area:

   (i) a ratio of 4 patients per 1,000 projected horizon year Resident population age 17 and younger;

   (ii) a ratio of 5 patients per 1,000 projected horizon year Resident population age 18 through 64;

   (iii) a ratio of 45 patients per 1,000 projected horizon year Resident population age 65 through 79; and

   (iv) a ratio of 185 patients per 1,000 projected horizon year Resident population age 80 and older.

2. The net numerical unmet need for home health services shall be determined by subtracting the projected number of patients for the current calendar year from the projected need for services as calculated in (3)(a)1. The projected number of patients for the current calendar year is determined by multiplying the number of patients having received services in each county, as reported in the most recent survey year, by the county population change factor. The county population change factor is the percent change in total population between the most recent survey year and the current calendar year.

(b) 1. The Department shall accept applications for review as enumerated below:

   (i) If the net numerical unmet need in a given planning area is 250 patients or more, the Department shall authorize the submission of applications for an expanded home health agency; or

   (ii) If the net numerical unmet need in a given planning area is 500 patients or more, the Department shall authorize the submission of

applications for a new home health agency as well as an expanded home health agency.

2. An applicant must propose to provide service only within a county or group of counties, each of which reflects a numerical unmet need, and contained within the given planning area for which the Department has authorized the submission of applications.

3. The Department shall only approve applications in which the applicant has applied to serve all of the unmet numerical need in any one county in which need is projected. The need within counties shall not be divided or shared between any two or more applicants.

(c) The Department may authorize an exception to Ga. Comp. R. & Regs. r. 111-2-2-.32(3)(a) if:

1. the applicant for a new or expanded home health agency can show that there is limited access in the proposed geographic service area for special groups such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. For purposes of this exception, an applicant shall be required to document, using population, service, special needs and/or disease incidence rates, a projected need for services in the planning area of at least 200 patients within a defined geographic service area. A successful applicant applying under this section will be restricted to serving the special group or groups identified in the application within the county or counties stipulated in the application; or

2. a particular county is served by no more than two (2) home health agencies and either of the following conditions exists:

   (1) less than one percent (1%) of the county's population has received home health services, or

   (2) one of the two home health agencies has demonstrated a failure to adequately serve Medicaid patients as evidenced by a level of service to such individuals that is less than the statewide average within each of the past two years as reported on the Annual Home Health Services survey. For purposes of this exception, an applicant must already be approved to provide service in a contiguous county or be approved to provide service in a county that is no further than 15 miles from the county authorized through the exception. In all other aspects of the application process, the applicant shall be required to comply with provisions applicable to expanded home health agencies. For purposes of this exception, "served by" shall mean the

agency(ies) are licensed to serve the county by the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

(d) An applicant for a new or expanded home health agency shall provide a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care focusing on coordinated, integrated systems which promote continuity rather than acute, episodic care. Working agreements with other related community services may include the ability to streamline referrals to other appropriate services and to participate in the development of cross-continuum care plans with other providers.

(e) An applicant for a new or expanded home health agency shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

(f) An applicant for a new or expanded home health agency or agency(ies) owned and/or operated by the applicant or its parent organization shall have no history of uncorrected or repeated conditional level violations or uncorrected standard deficiencies as identified by licensure inspections or equivalent deficiencies as noted from Medicare or Medicaid audits.

(g) An applicant for a new or expanded home health agency or agency(ies) owned and/or operated by the applicant or its parent organization shall have no previous conviction of Medicaid or Medicare fraud.

(h) An applicant for a new or expanded home health agency shall provide a written plan which demonstrates the intent and ability to recruit, hire and retain the appropriate numbers of qualified personnel to meet the requirements of the services proposed to be provided and that such personnel are available in the proposed geographic service area.

(i) An applicant for a new home health agency shall provide evidence of the intent to meet the appropriate accreditation requirements of The Joint Commission (TJC), the Community Health Accreditation Program, Inc. (CHAP), and/or other appropriate accrediting agencies.

(j) An applicant for an expanded home health agency shall provide documentation that they are fully accredited by The Joint Commission (TJC), the Community Health Accreditation Program, Inc. (CHAP), and/or other appropriate accrediting agency.

(k) An applicant for a new or expanded home health agency shall provide its existing or proposed plan for a comprehensive quality improvement program.

(l) An applicant for a new or expanded home health agency shall assure access to services to individuals unable to pay and to all individuals regardless of payment source or circumstances by:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, disability, gender, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds one percent (1%) of annual, adjusted gross revenues for the home health agency or, in the case of an applicant providing other health services, the applicant may request that the Department allow the commitment for services to indigent and charity patients to be applied to the entire facility;

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients;

4. providing a written commitment to participate in the Medicare, Medicaid and PeachCare for KidsT programs; and

5. providing a written commitment to participate in any other state health benefits insurance programs for which the home health service is eligible.

(m) An applicant for a new or expanded home health agency shall demonstrate that their proposed charges compare favorably with the charges of existing home health agencies in the same geographic service area.

(n) An applicant for a new or expanded home health agency shall document an agreement to provide Department requested information and statistical data related to the operation and provision of home health services and to report that data to the Department in the time frame and format requested by the Department.

(o) The Department may authorize an existing home health agency to transfer one county or several counties to another existing home health agency without either agency being required to apply for a new or expanded Certificate of Need, provided the following conditions are met:

1. the two agencies agree to the transfer and submit such agreement and a joint request to transfer in writing to the Department at least thirty (30) days prior to the proposed effective date of the transfer;

2. the two agencies document within the written request that the transfer would result in increased and improved services for the residents of the county or counties including Medicare and Medicaid patients;

3. the agency to which the county or counties are being transferred currently offers services in at least one contiguous county or within the health planning area(s) in which county or counties are located; and

4. the two agencies are in compliance with all other requirements of these Rules; such compliance to be evaluated with the written transfer request.

   No such transfer shall become effective without written approval from the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.32
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Home Health Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Repealed: New Rule entitled "Specific Rule Considerations for Home Health Services" adopted. F. Feb. 16, 2010; eff. Mar. 8, 2010.
Amended: New title, "Specific Review Considerations for Home Health Services." F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.33. Specific Review Considerations for Life Plan Community (LPC) Sheltered Nursing Facilities.

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or expanded LPC Sheltered Nursing Facility, if not exempt as provided by O.C.G.A. § 31-6-47(a)(17) and Ga. Comp. R. & Regs. r. 111-2-2-.03(20). These Rules apply to sheltered nursing facilities located in LPC facilities defined herein as Type A and Type B Life Plan Communities. A LPC that has obtained nursing facility beds approved under the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.30 does not qualify for sheltered nursing facility beds, and to convert existing nursing facility beds to sheltered nursing facility beds, such a LPC must apply for a new Certificate of Need. Conversely, a LPC that obtains sheltered nursing facility beds under these Rules may not qualify for beds under Ga. Comp. R. & Regs. r. 111-2-2-.30, and is therefore only required to complete these specific review considerations for the sheltered nursing facility beds.

(2) **Duration.** Notwithstanding Ga. Comp. R. & Regs. r. 111-2-2-.02(6), the initial implementation period of a Certificate of Need granted for a new or expanded LPC Sheltered Nursing Facility pursuant to these Rules shall be twenty-four (24) months from the effective date.

(3) **Definitions.**

(a) "A Life Plan Community" (LPC) is an organization which offers a contract to provide an individual of retirement status, other than an individual related by consanguinity or affinity to the provider furnishing the care, with board and lodging, licensed nursing facility care and medical or other health related services, or both. These services are provided for a minimum period of more than one (1) year and may be for as long as the lifetime of the resident.

(b) "Type A Life Plan Community" (Type A LPC) provides LPC services at the same location for the life of an individual, including mutually terminable contracts, and in consideration of the payment of an entrance fee with or without other periodic charges. A Type A LPC offers nursing facility care for a little or no substantial increase in monthly payments, except normal operating costs and inflation adjustments.

(c) "Type B Life Plan Community" (Type B LPC) provides LPC services at the same location for a period in excess of one year, including mutually terminable contracts, and in consideration of the payment of an entrance fee with other periodic charges. A Type B LPC offers a specified amount of nursing facility care for little or no substantial increase in monthly payments except normal operating costs and inflation adjustments. After the specified amount of nursing care is received, residents pay either a discounted rate or the full per diem rate for nursing care required.

(d) "A Continuing Care Contract" means furnishing pursuant to an agreement shelter, food, and either nursing care or personal services, whether such nursing care or personal services are provided in the facility or in another setting designated by the agreement for continuing care, to an individual not related by consanguinity or affinity to the provider furnishing such care upon payment of an entrance fee. Other personal services provided shall be designated in the continuing care agreement. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party.

(e) "LPC Sheltered Nursing Facility", for purposes of these Rules, is a nursing facility that meets the definition of a nursing facility as defined by Ga. Comp. R. & Regs. r. 111-2-2-.30 of the Rules of the Department. A LPC Sheltered Nursing Facility shall be for the exclusive use of residents of a Type A or Type B LPC.

(f) "Official State Health Component Plan" means the document related to the above-named services developed by the Department, established by the Georgia Health Strategies Council, and signed by the Governor of Georgia.

(g) "Resident" is an individual entitled to receive continuing care in a Type A or Type B Life Plan Community.

(4) **Standards.**

(a) The numerical need for a new LPC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each five independent living units. The applicant for a LPC Sheltered Nursing Facility shall demonstrate to the Department that the potential market for LPC Independent Living Units in the proposed service area is based on a valid feasibility study which takes into account factors such as, but not limited to, the age and annual household income of the target population and the geographic area to be served.

(b) The numerical need for an expanded LPC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each four independent living units provided that the LPC's existing nursing facility has experienced an occupancy rate of at least eighty percent (80%) during the most recent year.

(c) Sheltered nursing facility beds approved under these Rules shall be used exclusively for persons who are residents of the LPC, and who are a party to a continuing care contract with the facility or the parent organization and who have lived in a non-nursing unit of the LPC for a period of at least ninety (90) days. Exceptions shall be allowed when one spouse or sibling is admitted to the nursing unit at the time the other spouse or sibling moves into a non-nursing unit, or when the medical condition requiring nursing care was not known to exist or be imminent when the individual became a party to the continuing care contract.

(d) The applicant shall provide evidence of intent that at no time will the nursing facility be certified for participation in the Medicaid Program.

(e) A LPC which is the applicant for a new or expanded LPC sheltered nursing facility shall provide evidence of the intent and ability to meet all appropriate authorization and disclosure requirements of the Georgia State Department of Insurance and of any appropriate accrediting agency(ies). The LPC shall furnish reports in such form and at such times as may be specified, which accurately and fully disclose it has met specified requirements.

(f) A new or expanded LPC sheltered nursing facility shall provide evidence of the intent and ability to meet all appropriate requirements regarding licensure and accreditation of the nursing facility as follows:

1. Compliance with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division;

2. No uncorrected operational standards in any existing Georgia general or LPC sheltered nursing facilities owned and/or operated by the entity, its affiliates, or its principals. Plans to correct physical plant deficiencies must be provided;

3. No previous conviction of Medicaid and/or Medicare fraud by the entity, its affiliates, or its principals;

4. Provision of a plan for a comprehensive quality improvement program which includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators and measure the facility's performance and patient outcomes accordingly; and

5. Intent to meet accreditation requirements of the appropriate accrediting agency(ies).

(g) A LPC which is the applicant for a new or expanded LPC sheltered nursing facility shall demonstrate the existence of a Health Care Fund whose liability is documented by a relevant Actuarial Study and certified by a qualified actuary; or the existence of a Long Term Care Insurance Policy issued to individual residents; or a Group Long Term Care Insurance Policy issued to the LPC for the coverage of all residents. An Individual or Group Insurance Policy must conform to all the requirements of Chapter 120-20-16 of the Rules and Regulations of the State of Georgia Insurance Department entitled "Long Term Care Insurance Regulation". The period and scope of coverage must be identical to the period and scope of coverage in the continuing care contract.

(h) A LPC in which a new or expanded sheltered nursing facility is to be located shall provide the Department with requested information and statistical data related to the operation and programmatic elements of the LPC and the Sheltered Nursing Facility. Analyses are predicated upon accurate, consistent, and systematically obtained information.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.33
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Continuing Care Retirement Community ("CCRC") Sheltered Nursing Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Nov. 13, 2007; eff. Dec. 3, 2007.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: New title, "Specific Review Considerations for Life Plan Community (LPC) Sheltered Nursing Facilities." F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.34. Specific Review Considerations for Traumatic Brain Injury Facilities.

(1) **Applicability.** The following Rules apply to Traumatic Brain Injury Facilities defined herein as providing transitional living programs and/or lifelong living programs.

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Transitional Living Program, if not exempt as provided by O.C.G.A. § 31-6-47(a)(25) and Ga. Comp. R. & Regs. r. 111-2-2-.03(28). An

application for Certificate of Need for a new or expanded Transitional Living Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Life Long Living Program, if not exempt as provided by O.C.G.A. § 31-6-47(a)(25) and Ga. Comp. R. & Regs. r. 111-2-2-.03(28). An application for Certificate of Need for a new or expanded Life Long Living Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) "Expansion" or "Expanded Service" means increasing the number of beds in an existing Traumatic Brain Injury Facility or program; or an existing Traumatic Brain Injury Facility or program which makes expenditures which exceed the capital expenditure threshold; or an existing Traumatic Brain Injury Facility or program which seeks to add a program which it currently does not offer.

(b) "Life Long Living Program" means such treatment and rehabilitative care as shall be delivered to traumatic brain injury clients who have been discharged from a more intense level of rehabilitation, but who cannot live at home independently, and who require on-going lifetime support. Such clients are medically stable, may have special needs, but need less than 24 hour per day medical support.

(c) "New" means a facility that has not operated as a Traumatic Brain Injury Facility in the previous twelve (12) months. For purposes of these Rules, an existing Traumatic Brain Injury Facility or program which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(d) "Official State Health Component Plan" means the document related to Traumatic Brain Injury Facilities developed by the Department, established by the Georgia State Health Strategies Council and signed by the Governor of Georgia.

(e) "Planning Region" means one of the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

(f) "Transitional Living Program" means such treatment and rehabilitative care as shall be delivered to traumatic brain injury clients who require education and training for independent living with a focus on compensation for skills which cannot be restored. Such care prepares clients for maximum independence, teaches necessary skills for community interaction, works with clients on pre-vocational and vocational training and stresses cognitive, speech, and behavioral therapies structured to the individual needs of clients. Such clients are medically stable, may

have special needs, but need less than twenty-four (24) hour per day medical support.

(g) "Traumatic Brain Injury" means a traumatic insult to the brain and its related parts resulting in organic damage thereto that may cause physical, intellectual, emotional, social, or vocational changes in a person. It shall also be recognized that a person having a traumatic brain injury may have organic damage or physical or social disorders but shall not be considered mentally ill.

(h) "Traumatic Brain Injury Facility" means a building or place which is devoted to the provision of residential treatment and rehabilitative care in a transitional living program or a life long living program for periods continuing for twenty-four (24) hours or longer for persons who have traumatic brain injury. Such a facility is not classified by the Healthcare Facility Regulation Division as a hospital, nursing home, intermediate care facility or personal care home.

(3) **Standards.**

(a) An application for a new or expanded Traumatic Brain Injury Facility or program shall provide sufficient documentation of the need for such a program in the Planning Region. In the case of an application for an expanded program, the applicant shall justify the need for the expansion by, at a minimum, documenting that the expansion program has achieved an occupancy rate of eighty percent (80%) or more for the most recent twelve (12) months prior to submitting application.

(b) An applicant for a new or expanded Traumatic Brain Injury Facility or program shall document that the establishment or expansion of its Facility or program will not have an adverse impact on existing and approved programs of the same type in its Planning Region. An applicant for a new or expanded Traumatic Brain Injury Facility or program shall have an adverse impact on existing and approved facilities or programs of the same type if it will:

1. decrease annual utilization of an existing facility or program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing facility or program, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twelve (12) months following the acceptance of the applicant's first patient.

The applicant shall provide evidence of projected impact by taking into account existing planning region market share of facilities or programs of the same type and future population growth or by providing sufficient evidence that the current population is underserved by the existing

Traumatic Brain Injury facility or program of the same type within the planning region.

(c) The Department may grant an exception to the need methodologies of Ga. Comp. R. & Regs. r. 111-2-2-.34(3)(a) and (3)(b) to remedy an atypical barrier to the services of a Traumatic Brain Injury Facility or program based on cost, quality, financial access, or geographic accessibility.

(d) Minimum bed size for a Traumatic Brain Injury Facility or program is six beds; A Life Long Living Program may not exceed thirty beds, except that an applicant for a new or expanded Life Long Living Program may be approved for total beds to exceed thirty (30) beds only if the applicant provides documentation satisfactory to the Department that the program design, including staffing patterns and the physical plant, are such as to promote services which are of high quality, are cost-effective and are consistent with client needs.

(e) An applicant for a new or expanded Traumatic Brain Injury Facility shall demonstrate the intent to meet the standards of the Commission on Accreditation of Rehabilitation Facilities (CARF) which apply to post acute brain injury programs and residential services within twenty-four (24) months of accepting its first patient. An applicant for an expanded Traumatic Brain Injury Facility or program shall be CARF-certified as of the date of its application and shall furnish proof of the certification as a part of the Certificate of Need application process.

(f) An applicant for a new or expanded Traumatic Brain Injury Facility shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such facilities. An applicant for an expanded Traumatic Brain Injury Facility or program shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded Traumatic Brain Injury Facility shall have written policies and procedures for utilization review. Such review shall consider the rehabilitation necessity for the service, quality of client care, rates of utilization and other considerations generally accepted as appropriate for review.

(h) An applicant for a new or expanded Traumatic Brain Injury Facility shall document the existence of referral arrangements, including transfer agreements, with an acute care hospital within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(i) An applicant for a new or expanded Traumatic Brain Injury Facility shall document that the Facility will be financially accessible by:

1. providing sufficient documentation that un-reimbursed services for indigent and charity patients in a new or expanded Facility shall be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the Facility after provisions have been made for bad debt and Medicaid/Medicare contractual adjustments have been deducted. If an applicant, or any facility owned or operated by the applicant's parent organization, received a Certificate of Need for a Traumatic Brain Injury Facility and the Certificate of Need included an expectation that a certain level of un-reimbursed indigent and/or charity care would be provided in the Facility(ies), the applicant shall provide sufficient documentation of the Facility's provision of such care. An applicant's history, or the history of any facility owned or operated by the applicant's parent organization, of not following through with a Certificate of Need expectation of providing indigent and/or charity care at or above the level agreed to will constitute sufficient justification to deny an application; and

2. agreeing to participate in the Medicare and Medicaid programs, whenever these programs are available to the Facility.

(j) Reserved.

(k) An applicant for a new or expanded Traumatic Brain Injury Facility shall document an agreement to provide the Department requested information and statistical data related to the operation of such a Facility and to report that information and statistical data to the Department on a yearly basis, and as needed, in a format requested by the Department and in a timely manner.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.34
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Traumatic Brain Injury Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Nov. 22, 2006; eff. Dec. 12, 2006.
Amended: F. Nov. 13, 2007; eff. Dec. 3, 2007.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.35. Specific Review Considerations for Comprehensive Inpatient Physical Rehabilitation Services.

(1) **Applicability.**

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Comprehensive Inpatient Physical Rehabilitation Adult Program. An application for Certificate of Need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Adult Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Comprehensive Inpatient Physical Rehabilitation Pediatric Program. An application for Certificate of Need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Pediatric Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) "Adults" means persons eighteen (18) years of age and over. However, a Certificate of Need authorized or grandfathered Comprehensive Inpatient Physical Rehabilitation Adult Program will not be in violation of the Certificate of Need laws and regulations if it provides service to a patient older than fifteen years if the provider has determined that such service is medically necessary, provided that the treatment days and patient census associated with patients sixteen and seventeen years of age do not exceed ten percent (10%) of annual treatment days and annual census, respectively. Rehabilitation programs specifically focused towards treatment of spinal cord injuries and disorders and which existed prior to the effective date of this version of Ga. Comp. R. & Regs. r. 111-2-2-.35 shall not be subject to the adult age limitations; such programs may treat any patient aged twelve (12) and over.

(b) "Comprehensive Inpatient Physical Rehabilitation Programs" means rehabilitation services, which have been classified by Medicare as an inpatient rehabilitation facility pursuant to 42 C.F.R. § 412.23(b)(2), provided to a patient who requires hospitalization, which provides coordinated and integrated services that include evaluation and treatment, and emphasizes education and training of those served. The program is applicable to those individuals who require an intensity of services which includes, as a minimum, physician coverage twenty-four (24) hours per day, seven (7) days per week, with daily (at least five (5) days per week) medical supervision, complete medical support services including consultation, 24-hour-per-day nursing, and daily (at least five (5) days per week) multidisciplinary rehabilitation programming for a minimum of three hours per day. For regulatory purposes, the definition includes a program which asserts its intent to be Medicare-classified as an inpatient rehabilitation facility no later than twenty-four (24) months after accepting its first patient. If a program, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within the timeframe outlined above, the CON issued to that entity shall be revoked.

(c) "Expansion" and "Expanded" mean the addition of beds to an existing CON-authorized or grandfathered Comprehensive Inpatient Physical Rehabilitation Program. However, a CON-authorized or grandfathered provider of Comprehensive Inpatient Physical Rehabilitation in a freestanding rehabilitation hospital may increase the bed capacity of an existing program by the lesser of ten percent (10%) of existing capacity or ten (10) beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two years and provided that the capital expenditures associated with the increase do not exceed the capital expenditure threshold. If such an increase exceeds the capital expenditure threshold, the increase will be considered an expansion for which a Certificate of Need shall be required under these Rules.

(d) "Freestanding Rehabilitation Hospital" means a specialized hospital organized and operated as a self-contained health care facility that provides one or more rehabilitation programs and which has been classified as an inpatient rehabilitation facility by the Medicare program pursuant to 42 C.F.R. § 412.23(b)(2). For regulatory purposes, the definition includes a hospital which asserts its intent to be Medicare-classified as an inpatient rehabilitation facility no later than twenty-four (24) months after accepting its first patient. If an entity, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within the timeframe outlined above, the CON issued to that entity shall be revoked. An entity, which has had its CON revoked pursuant to this Rule, shall not have the authority to operate as a general acute care hospital.

(e) "New" means a Program that has not been classified by the Medicare program as a rehabilitation hospital or program in the previous twelve (12) months. Adult programs described in Ga. Comp. R. & Regs. r. 111-2-2-.35(1)(a) and pediatric programs described in Ga. Comp. R. & Regs. r. 111-2-2-.35(1)(b) shall be considered independent programs such that a provider seeking to add a program not offered by that provider in the previous twelve (12) months shall be considered to be offering a new program for which a Certificate of Need must be obtained. For purposes of these Rules, an existing program which proposes to be relocated to a location more than three (3) miles from its present location shall be considered "new".

(f) "Official State Health Component Plan" means the document related to Physical Rehabilitation Programs and Services developed by the Department, established by the Georgia Health Strategies Council and signed by the Governor of Georgia.

(g) "Pediatric" means persons seventeen (17) years of age and under. However, a CON-authorized or grandfathered Comprehensive Inpatient Rehabilitation Pediatric Program will not be in violation of the CON laws and regulations if it provides service to a patient younger than twenty-two (22) years if the provider has determined that such service is medically necessary, provided that the

treatment days and patient census associated with patients eighteen, nineteen, twenty, and twenty-one years of age do not exceed ten percent (10%) of annual treatment days and annual census, respectively. Rehabilitation programs specifically focused towards treatment of spinal cord injuries and disorders and which existed prior to the effective date of this version of Ga. Comp. R. & Regs. r. 111-2-2-.35 shall not be subject to the pediatric age limitations; such programs may treat any patient aged twelve (12) and over.

(h) "Planning Region" means one of the four sub-state regions for Physical Rehabilitation Programs and Services as follows:

1. Rehabilitation Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Elbert, Madison, Jackson, Barrow, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Carroll, Douglas, DeKalb, Rockdale, Walton, Oconee, Clarke, Oglethorpe, Greene, Morgan, Newton, Butts, Henry, Clayton, Fayette, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, and Upson

2. Rehabilitation Region 2, including the following counties: Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Hancock, Glascock, Putnam, Jasper, Monroe, Jones, Baldwin, Washington, Jefferson, Richmond, Burke, Screven, Jenkins, Emmanuel, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, and Crawford

3. Rehabilitation Region 3, including the following counties: Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Dooly, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Crisp, Ben Hill, Irwin, Turner, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Cook, Tift, Berrien, Lanier, Echols, Lowndes, Brooks, Thomas, Grady, Decatur, and Seminole

4. Rehabilitation Region 4, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, McIntosh, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch

(3) **Service-Specific Review Standards.**

(a) The need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program ("CIPR") shall be determined and applied as follows:

1. The need for new or expanded Comprehensive Inpatient Physical Rehabilitation Adult Program in a planning region shall be determined using the following demand-based need projection:

   (i) Determine the comprehensive inpatient physical rehabilitation utilization rate per 1,000 for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharges from licensed providers of inpatient rehabilitation in the planning region for patients aged eighteen (18) and over by current year projected resident population (aged 18 and over) for the planning region and multiplying by 1,000. The source of current year discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire. The source for current and horizon year resident population shall be resident population projections from the Governor's Office of Planning and Budget. For the first Horizon Year projection using this Rule, and for the first horizon year projection only, the utilization rate per 1,000 for each planning region shall be reduced by sixteen percent (16%) to account for anticipated utilization reduction after full implementation of the Center for Medicare and Medicaid Services' ("CMS") seventy-five percent (75%) rule.

   (ii) Calculate the projected horizon year discharges for each planning region by multiplying the planning region utilization rate obtained in Step (i) by the horizon year resident population projection (aged 18 and over) for that planning region.

   (iii) Determine the comprehensive inpatient physical rehabilitation average length of stay for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharge days of care from licensed providers of inpatient rehabilitation in the planning region for patients aged eighteen (18) and over by the current year inpatient rehabilitation discharges determined in Step (i).

   (iv) Multiply the projected discharges obtained in Step (ii) by the current year's average length of stay (aged 18 and over) determined in Step (iii) to determine the horizon year projected patient days for each planning region.

   (v) Divide the product obtained in Step (iv) by the number of calendar days in the horizon year to obtain the average projected daily census in each planning region.

(vi) Divide the result obtained in Step (v) by .85 to determine the number of projected beds utilizing an eighty-five percent (85%) capacity standard for each planning region.

(vii) Determine the current inventory of comprehensive inpatient physical rehabilitation beds for adults in the planning region from Departmental data. For all CIPR providers, which have been licensed as a Rehabilitation Hospital by the Healthcare Facility Regulation Division, the current inventory of CIPR beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed Long Term Care Hospitals; the beds of such facilities shall be included in the applicable Long Term Care Hospital inventory.

(viii) If the projected bed need in Step (vi) is greater than the current inventory of adult CIPR beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

2. The need for new or expanded Comprehensive Inpatient Physical Rehabilitation Pediatric Program in a planning region shall be determined using the following demand-based need projection:

(i) Determine the comprehensive inpatient physical rehabilitation utilization rate per 1,000 for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharges from licensed providers of inpatient rehabilitation in the planning region for patients aged seventeen (17) and under by current year resident population (aged 17 and under) for the planning region. The source of current year discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire.

(ii) Calculate the projected horizon year discharges for each planning region by multiplying the planning region utilization rate obtained in Step (i) by the horizon year resident population projection (aged 17 and under) for that planning region.

(iii) Determine the comprehensive inpatient physical rehabilitation average length of stay for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharge days of care from licensed providers of inpatient rehabilitation in the planning region for patients aged seventeen (17) and under by the current year inpatient rehabilitation discharges determined in Step (i).

(iv) Multiply the projected discharges obtained in Step (ii) by the current year's average length of stay (aged 17 and under) determined in Step (iii) to determine the horizon year projected patient days for each planning region.

(v) Divide the product obtained in Step (iv) by the number of calendar days in the horizon year to obtain the average projected daily census in each planning region.

(vi) Divide the result obtained in Step (v) by .85 to determine the number of projected beds utilizing an eighty-five percent (85%) capacity standard for each planning region.

(vii) Determine the current inventory of comprehensive inpatient physical rehabilitation beds for pediatric patients in the planning region from Departmental data. For all CIPR providers, which have been licensed as a Rehabilitation Hospital by the Healthcare Facility Regulation Division, the current inventory of CIPR beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed Long Term Care Hospitals; the beds of such facilities shall be included in the applicable Long Term Care Hospital inventory.

(viii) If the projected bed need in Step (vi) is greater than the current inventory of pediatric CIPR beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

(b) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall document that the establishment or expansion of its program will not have an adverse impact on existing and approved programs of

the same type in its planning region. An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall have an adverse impact on existing and approved programs of the same type if it will:

1. decrease annual decrease annual utilization of an existing program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing program, whose current utilization is below eighty-five percent (85%), by ten percent over the twelve (12) months following the acceptance of the applicant's first patient.

(c) The Department may grant the following exceptions:

1. The Department may grant an exception to the need methodology of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(b) for an applicant proposing a program to be located in a county with a population of less than 75,000 and to be located a minimum of fifty (50) miles away from any existing program in the state.

2. The Department may grant an exception to the need methodologies of either Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. or 111-2-2-.35(3)(a) 2. and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-22-.35(3)(b) to remedy an atypical barrier to Comprehensive Inpatient Physical Rehabilitation Programs based on cost, quality, financial access or geographic accessibility or if the applicant's annual census demonstrates thirty percent (30%) out of state utilization for the previous two years.

3. The Department may grant an exception to the need methodologies of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 1. or Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a) 2. in a planning area which has no existing provider provided that the applicant demonstrates a need for the service based on patient origin data.

(d) A new Comprehensive Inpatient Physical Rehabilitation Program shall have the following minimum bed sizes based on type of program offered:

1. A new Comprehensive Inpatient Physical Rehabilitation Adult Program shall have a minimum bed size of twenty (20) beds in a freestanding rehabilitation hospital already offering another Comprehensive Inpatient Physical Rehabilitation Program, twenty (20) beds or in an acute-care hospital, and forty (40) beds for a new freestanding rehabilitation hospital

not already offering another Comprehensive Inpatient Physical Rehabilitation Program.

2. A new Comprehensive Inpatient Physical Rehabilitation Pediatric Program shall have a minimum of 10 beds in a freestanding rehabilitation hospital already offering another Comprehensive Inpatient Physical Rehabilitation Program, 10 beds in an acute-care hospital, and forty (40) beds for a new freestanding rehabilitation hospital not already offering another Comprehensive Inpatient Physical Rehabilitation Program.

(e) An applicant for a new Comprehensive Inpatient Physical Rehabilitation Program shall demonstrate the intent to meet the standards of the Commission on Accreditation of Rehabilitation Facilities ("CARF") applicable to the type of Program to be offered within eighteen (18) months of offering the new service.

(f) An applicant for an expanded Comprehensive Inpatient Physical Rehabilitation Program shall be accredited by the CARF for the type of Program which the applicant seeks to expand prior to application. The applicant must provide proof of such accreditation.

(g) An applicant for a new freestanding rehabilitation hospital shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such hospitals.

(h) An applicant for an expanded freestanding rehabilitation hospital shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(i) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall have written policies and procedures for utilization review. Such review shall consider, but is not limited to, factors such as medical necessity, appropriateness and efficiency of services, quality of patient care, and rates of utilization.

(j) An applicant for a new or expanded freestanding rehabilitation hospital shall document the existence of referral arrangements, including transfer agreements with an acute-care hospital(s) within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(k) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall foster an environment that assures access to services

to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that un-reimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted; and

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of un-reimbursed indigent and charity care.

(l) Reserved.

(m) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall agree to provide the State Health Department with requested information and statistical data related to the operation of such a Program on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.35
Authority: O.C.G.A. §§ 31-2*et seq*., 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Comprehensive Inpatient Physical Rehabilitation Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Nov. 22, 2006; eff. Dec. 12, 2006.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.36. Specific Review Considerations for Long Term Care Hospitals.

(1) **Applicability.** A Certificate of Need ("CON") shall be required prior to the establishment of a new or the expansion of an existing Long Term Care Hospital. An application for Certificate of Need for a new or expanded Long Term Care Hospital shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) "Expansion" or "Expanded" means the addition of beds to an existing CON-authorized or grandfathered Long Term Care Hospital. A CON-authorized or grandfathered Long Term Care Hospital may increase the bed capacity of an existing hospital by the lesser of ten percent (10%) of existing capacity or 10 beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two years and provided that the capital expenditures associated with the increase do not exceed the Capital Expenditure Threshold. If such an increase exceeds the Capital Expenditure Threshold, the increase will be considered an expansion for which a Certificate of Need shall be required under these Rules.

(b) "Free-standing LTCH" or "Free-standing LTACH" means a Long Term Care Hospital organized and operated as a self-contained health care facility.

(c) "Hospital-within-a-Hospital LTCH" or "Hospital-within-a-Hospital LTACH" means a Long Term Care Hospital co-located within the same building or the same campus as another CON-Authorized hospital.

(d) "Long Term Care Hospital" or "LTCH" or "Long Term Acute Care Hospital" or "LTACH" means a hospital that is classified as a long term hospital by the Medicare program pursuant to 42 CFR 412.23(e). These hospitals typically provide extended medical and rehabilitative care for patients who are clinically complex and may suffer from multiple acute or chronic conditions. Services typically include comprehensive rehabilitation, respiratory therapy, head trauma treatment, and pain management. For regulatory purposes, the definition includes a hospital which asserts its intent to be Medicare-classified as a long term hospital within twenty-four (24) months of accepting its first patient. If an entity, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within this timeframe, the CON issued to that entity shall be revoked. An entity, which has had its CON revoked pursuant to this Rule, shall not have the authority to operate as a general acute care hospital. However, an acute care hospital, which has been awarded a CON to convert acute care beds for use as a long term care hospital, may again use such beds for acute care if such beds have not been Medicare-classified as a long term care hospital within twenty-four (24) months of accepting its first patient. Furthermore, a hospital that has been approved through the Certificate Of Need process to use all of its short-stay beds for a Freestanding LTCH shall have such beds removed from the official inventory of available short-stay beds when the LTCH is certified by Medicare; provided, however, that the hospital's beds will revert to the official inventory of available short-stay beds at any point that the facility ceases to be certified by Medicare as an LTCH.

(e) "New" means a hospital that has not been classified by the Medicare program as a long term hospital in the previous twelve (12) months. For purposes of these

Rules, an existing hospital which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(f) "Occupancy Rate" means the ratio of beds occupied by inpatients as reported on the most recent Annual Hospital Questionnaire divided by the total licensed beds.

(g) "Official State Health Component Plan" means the document related to Long Term Care Hospitals developed by the Department, established by the Georgia Health Strategies Council and signed by the Governor of Georgia.

(h) "Planning Region" means one of the four sub-state regions for Long Term Care Hospitals, as follows:

1. LTCH Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Elbert, Madison, Jackson, Barrow, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Carroll, Douglas, DeKalb, Rockdale, Walton, Oconee, Clarke, Oglethorpe, Greene, Morgan, Newton, Butts, Henry, Clayton, Fayette, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, and Upson

2. LTCH Region 2, including the following counties: Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Hancock, Glascock, Putnam, Jasper, Monroe, Jones, Baldwin, Washington, Jefferson, Richmond, Burke, Screven, Jenkins, Emmanuel, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, and Crawford

3. LTCH Region 3, including the following counties: Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Dooly, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Crisp, Ben Hill, Irwin, Turner, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Cook, Tift, Berrien, Lanier, Echols, Lowndes, Brooks, Thomas, Grady, Decatur, and Seminole

4. LTCH Region 4, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, McIntosh, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch

(3) **Service-Specific Review Standards.**

(a) The need for new or expanded Long Term Care Hospital in a LTCH planning region shall be determined using the following need projection:

1. Determine the total discharges from general acute care hospitals less LTCH discharges, and less perinatal and neonatal discharges, and less psychiatric and substance abuse discharges, and less comprehensive inpatient physical rehabilitation discharges for the planning region in which the Long Term Care Hospital is or will be located. The source of discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire.

2. Calculate the discharge rate for each planning region by dividing the number of current acute care discharges obtained in Step 1 in each planning region by the corresponding year's resident population projection from the Governor's Office of Planning and Budget in each planning region.

3. Calculate the projected discharges for each planning region by multiplying the discharge rate obtained in Step 2 by the horizon year resident population projection for that planning region and then reduce that figure by six percent (6%) to account for overlap with rehabilitation facilities.

4. Calculate gross beds needed in the horizon year as follows:

   (i) Multiply the projected discharges obtained in Step 3 by a utilization factor of 1.3% to determine the projected number of acute care discharge who may benefit from services at a LTCH.

   (ii) Multiply the product obtained in Step 4(i) by the average LTCH length of stay for the most recent previous three-year period. Beginning with the first need calculation and continuing until the third complete year of survey data collected pursuant to this Rule, the Department shall use 28.1 as a proxy for the average LTCH length of stay for the previous three years.

   (iii) Divide the product obtained in Step 4(ii) by 365 to determine the projected daily LTCH census.

   (iv) Divide the result obtained in Step 4(iii) by .85 to determine the number of projected LTCH beds utilizing an eighty-five percent (85%) capacity standard.

5. Determine the current inventory of LTCH beds in the planning region from Departmental data. For all long term care hospital providers, which have been licensed as a Long Term Care Hospital by the Healthcare Facility Regulation Division, the current inventory of LTCH beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward

only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed rehabilitation hospitals even if such hospitals have a reported average length of stay of greater than twenty-five (25) days for Medicare patients; the beds of such facilities shall continue to be included in the applicable Comprehensive Inpatient Physical Rehabilitation inventory.

6. If the projected LTCH bed need in Step 4(iv) is greater than the current inventory of LTCH beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

(b) An applicant for a new or expanded Long Term Care Hospital shall document that the establishment or expansion of its hospital will not have an adverse impact on an existing and approved long term care hospital in its planning region. An applicant for a new or expanded Long Term Care Hospital shall have an adverse impact on existing and approved hospitals of the same type if it will:

1. decrease annual utilization of an existing hospital, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing hospital, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twelve (12) months following the acceptance of the applicant's first patient.

The applicant shall provide evidence of projected impact by taking into account existing planning region market share of hospitals of the same type and future population growth or by providing sufficient evidence that the current population is underserved by the existing Long Term Care Hospitals within the planning region.

(c) The Department may grant an exception to the need methodology of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(a) and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(b) for an applicant proposing a program to be located in a county with a population of less than 75,000 and to be located a minimum of fifty (50) miles away from any existing program in the state; or to remedy an atypical barrier to the services of a Long Term Care Hospital based on cost, quality, financial access or geographic accessibility. The Department may grant an exception to the need methodologies of either Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(a) and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-22-

.36(3)(b) if the applicant's annual census demonstrates thirty percent (30%) out of state utilization for the previous two years.

(d) A new or expanded Long Term Care Hospital shall have the following minimum bed sizes:

1. A new freestanding LTCH shall have a minimum bed size of forty (40) beds.

2. A new Hospital-within-a-Hospital LTCH shall have a minimum bed size of twenty (20) beds.

3. The minimum number of beds for the expansion of an existing Long Term Care Hospital, including satellite locations, shall be ten (10) beds or ten percent (10%) of the total current licensed bed total of current Long Term Care Hospital, whichever is less.

(e) An applicant for a new Long Term Care Hospital shall demonstrate the intent to meet the standards of the Joint Commission or another nationally recognized health care accreditation body within twenty-four (24) months of accepting its first patient. An applicant for an expanded Long Term Care Hospital shall be Joint Commission-certified or certified by another nationally recognized health care accreditation body as of the date of its application and shall furnish proof of the certification as a part of the Certificate of Need application process.

(f) An applicant for a new Long Term Care Hospital shall demonstrate the intent to meet the Licensure Rules of the Healthcare Facility Regulation Division for such hospitals. An applicant for an expanded Long Term Care Hospital shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded Long Term Care Hospital shall have written policies and procedures for utilization review. Such review shall consider, but is not limited to, factors such as medical necessity, appropriateness and efficiency of services, quality of patient care, and rates of utilization.

(h) An applicant for a new or expanded Long Term Care Hospital shall document the existence of referral arrangements, including transfer agreements, with an acute-care hospital(s) within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(i) An applicant for a new or expanded Long Term Care Hospital shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that un-reimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted;

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of un-reimbursed indigent and charity care;

4. providing documentation of current or proposed charges and policies, if any, regarding the amount or percentage of charges that charity patients, self pay patients, and the uninsured will be expected to pay; and

5. agreeing to participate in the Medicare and Medicaid programs if such programs reimburse for such services.

(j) Reserved.

(k) An applicant for a new or expanded Long Term Care Hospital shall agree to provide the Department with requested information and statistical data related to the operation of such a Program on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.36
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
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Rule 111-2-2-.37. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.37

Rule 111-2-2-.38. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.38

Rule 111-2-2-.39. Reserved.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.39

Rule 111-2-2-.40. Specific Review Considerations for Ambulatory Surgery Services.

(1) **Applicability**. For Certificate of Need purposes, an Ambulatory Surgery Service is considered a new institutional health service if it is to be offered in an ambulatory surgery facility ("ASF") or in a diagnostic, treatment, or rehabilitation center ("DTRC").

(a) If the ambulatory surgery service is or will be provided as "part of a hospital", the hospital's provision of such service is not subject to Certificate of Need review under this Rule. For purposes of this Rule, the following are always considered to be "part of a hospital":

a) if the service is located within a hospital; or

b) if the service is located in a building on the hospital's primary campus and that building, or relevant portion thereof, is included within the hospital's permit issued by the State's licensing agency, subject to determination by the Department. The Department also will make a determination of reviewability on a case-by-case basis in other situations involving hospitals.

(b) The entity that develops any ambulatory surgery service shall be the applicant.

(c) A single specialty ambulatory surgery service will be issued a single specialty CON. A new CON will be required to become a multi-specialty service.

(d) These Rules do not apply to adult open-heart surgery, adult cardiac catheterization, pediatric cardiac catheterization, pediatric open-heart surgery, and obstetrical services because these services are covered under other CON Rules. If an ambulatory surgery service, which is part of a hospital, expands the number of ambulatory surgery operating rooms and the capital expenditure exceeds the CON threshold, the project will be reviewed under Ga. Comp. R. & Regs. r. 111-2-2-.40. If an ambulatory surgery service, which is part of a hospital, involves a capital expenditure, which exceeds the CON threshold and does not increase the number of ambulatory surgery operating rooms, the project will be reviewed under the General Review Considerations (Ga. Comp. R. & Regs. r. 111-2-2-.09).

(2) **Definitions.**

(a) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services ("CMS"),

the Department's Division of Medical Assistance ("DMA"), the State Health Benefit Plans, or by any successor entities, as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed twenty-four (24) hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(b) "Ambulatory surgery facility" means a public or private facility, not part of a hospital, which provides surgical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization. In addition to operating rooms, an ambulatory surgery facility includes all components of pre and post-operative ambulatory surgery care.

(c) "Ambulatory surgery operating room" means an operating room located either in a hospital, in an ambulatory surgery facility, or in a DTRC facility that is equipped to perform surgery and is constructed to meet the specifications and standards of the Healthcare Facility Regulation Division.

(d) "Ambulatory surgery service" means the provision of ambulatory surgery including pre and post-operative care to patients not requiring hospitalization. An ambulatory surgery service may be provided within any of the following types of healthcare facilities: hospitals, ambulatory surgery facilities, or DTRCs.

(e) "Ambulatory surgery services patient" means a person who makes a single visit to an operating room during which one or more surgical procedures are performed.

(f) "Authorized ambulatory surgery service" means a Department sanctioned ambulatory surgery service, which is either existing or approved prior to the date on which the Department renders a decision on a proposed project. An existing ambulatory surgery service is an authorized service, which has become operational, and an approved ambulatory surgery service is an authorized service, which has not yet become operational, including any approvals under appeal.

(g) "Diagnostic, treatment, or rehabilitation center ("DTRC") facility" means, for purposes of this Rule, any professional or business undertaking, whether for profit or not-for-profit, which offers or proposes to offer an ambulatory surgery service in a setting that is not part of a hospital.

(h) "Most recent year" means the most current twelve-month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. If the Department has received an annual or ad hoc survey within six (6) months of the date of completion of the application (or first application when applications are joined), the Department may consider the report period covered in such a survey as the most recent year.

(i) "Multi-specialty ambulatory surgery service" means an ambulatory surgery service offering surgery in more than one of, but not limited to, the following specialties; dentistry/oral surgery, gastroenterology, general surgery, obstetrics/gynecology, ophthalmology, orthopedics, otolaryngology, pain management/anesthesiology, plastic surgery, podiatry, pulmonary medicine, or urology.

(j) "Not requiring hospitalization" means patients who do not require an inpatient admission to an acute care general hospital prior to receiving ambulatory surgery services, who normally would not require a stay that is overnight or exceeds twenty-four (24) hours, and who are not expected to require an inpatient admission after receiving such services.

(k) "Official inventory" means the inventory of all facilities authorized to perform ambulatory surgery services maintained by the Department based on responses to the most recent Annual Hospital Questionnaire ("AHQ") Surgical Services Addendum and Freestanding Ambulatory Surgery Center Survey and/or the most recent appropriate surveys and questionnaires.

(l) "Official state component plan" means the document related to ambulatory surgery services adopted by the State Health Strategies Council, approved by the Board of Community Health, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the state.

(m) "Operating room environment" means an environment, which meets the minimum physical plant and operation standards specified by Chapter 111-8-4 of the Rules of the Healthcare Facility Regulation Division or such substantially equivalent standards as determined by the Department. Such acceptable standards shall be maintained on the Department's website.

(n) "Planning Area" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Ambulatory Surgery Services.

(o) "Single specialty ambulatory surgery service" means an ambulatory surgery service providing surgery in only one of the specialty areas as defined in Ga. Comp. R. & Regs. r. 111-2-2-.40(2)(i).

(3) **Standards.**

(a) The need for an ambulatory surgery service shall be determined through application of a numerical need method and an assessment of the aggregate utilization rate of existing services.

1. The numerical need for an ambulatory surgery service shall be determined by a demographic formula which includes the number of ambulatory surgery services cases in a planning area. The following need calculation applies to each planning area:

(i) determine the projected ambulatory surgery services patients for the horizon year by multiplying the planning area ambulatory surgery patients' rate by the total Resident population for the planning area for the horizon year;

(ii) determine the number of operating rooms needed by dividing the number of projected ambulatory surgery services patients (step i) by the capacity per operating room. Capacity per operating room per year is 1,000 patients. (This is based on 250 operating room days per year (50 weeks x 5 days/weeks) x 5 patients per room per day x 80% utilization.);

(iii) determine the existing and approved inventory of ambulatory surgery operating rooms by adding:

(I) The pro-rata portion of hospital shared inpatient/ambulatory surgery operating rooms devoted to ambulatory surgery services. This portion is determined as follows: (# ambulatory surgery patients x 90 min.) {(ambulatory surgery patients x 90 min)+(inpatient patients x 145 min.)} x # shared rooms

(II) # of hospital dedicated ambulatory surgery operating rooms; and

(III) # of freestanding ambulatory surgery operating rooms.

(iv) determine the projected net surplus or deficit for ambulatory surgery services by subtracting the total ambulatory surgery operating rooms needed (step iii) from the inventory of existing and approved ambulatory surgery services operating rooms in the planning area.

2. Prior to approval of a new or expanded ambulatory surgery service in any planning area, the aggregate utilization rate of all existing and approved ambulatory surgery service in that planning area shall equal or exceed eighty percent (80%) during the most recent year; and

3. A proposed multi-specialty ambulatory surgery service shall have a minimum of three operating rooms and a single specialty ambulatory surgery service shall have a minimum of two operating rooms.

(b) The Department may allow an exception to the need standard referenced in (3)(a), in order to remedy an atypical barrier to ambulatory surgery services based on cost, quality, financial access, or geographic accessibility. An applicant seeking

such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the planning area and/or the communities under review. In approving an applicant through the exception process, the Department shall document the bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(c) Each applicant shall have a hospital affiliation agreement and/or the medical director must have admitting privileges and other acceptable documented arrangements to insure the necessary backup for medical complications. The applicant must document the capability to transfer a patient immediately to a hospital with adequate emergency room services.

(d) An applicant shall submit written policies and procedures regarding discharge planning. These policies should include, where appropriate, designation of responsible personnel, participation by the patient, family, guardian or significant other, documentation of any follow-up services provided and evaluation of their effectiveness.

(e) An applicant shall provide evidence of a credentialing process that provides that surgical procedures will be performed only by licensed physicians who have been granted privileges to perform these procedures by the organization's governing body.

(f) An applicant shall assure that an anesthesiologist, a physician qualified to administer anesthesia, an oral surgeon, or a nurse anesthetist trained and currently certified in emergency resuscitation procedures is present on the premises at all times a surgical patient is present.

(g) An applicant shall submit evidence that qualified personnel will be available to insure a quality service to meet licensure, certification and/or accreditation requirements.

(h) An applicant shall submit a policy and plan for reviewing patient care, including a stated set of criteria for identifying those patients to be reviewed and a mechanism for evaluating the patient review process.

(i) An applicant shall submit written policies and procedures for utilization review consistent with state federal and accreditation standards. This review shall include review of the medical necessity for the service, quality of patient care, and rates of utilization.

(j) An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division.

(k) An applicant for a new ambulatory surgery service shall provide a statement for the intent to meet, within twelve (12) months of obtaining state licensure, the appropriate accreditation requirements of the Joint Commission or another nationally recognized health care accreditation body, the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory surgery Facilities, Inc. (ASF) and/or other appropriate accrediting agency.

(l) An applicant for an expanded ambulatory surgery service shall provide documentation that they fully meet the appropriate accreditation requirements of the Joint Commission or another nationally recognized health care accreditation body, the Accreditation Association for Ambulatory Health Care ("AAAHC"), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. ("ASF") and/or other appropriate accrediting agency.

(m) An applicant shall provide documentation that charges are reasonable compared to other similar surgery services serving the same planning area.

(n) An applicant shall foster an environment that assures access to services to individual's unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that unreimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted; and

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant or the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity care.

(o) An applicant for an ambulatory surgery service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of ambulatory surgery and to report that data to the Department in the time frame and format requested by the Department. This information shall include, but not be limited to, any changes in number of ambulatory surgery operating rooms that may occur as a result of service expansion.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.40
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Ambulatory Surgery Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Amended: F. Dec. 14, 2007; eff. Jan. 3, 2008.
Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.41. Specific Review Considerations for Positron Emission Tomography Units.

(1) **Applicability.**

(a) A Certificate of Need shall be required for a new or expanded positron emission tomography ("PET") unit.

(b) On or after January 1, 2008, the Department shall only consider and approve applications for dual modality PET units; stand-alone PET units shall not be approved.

(c) On or after January 1, 2008, an applicant for a mobile unit site shall be the hospital or DTRC which has entered into an agreement to receive mobile services. The actual mobile service provider shall not be the applicant. The hospital or DTRC that is serviced by the mobile provider shall be responsible for the provision of annual surveys and the provision of information to the Department.

(d) On or after January 1, 2008, a mobile provider shall be required to obtain a CON only if the fair market value or purchase price of the unit and any and all functionally related equipment exceeds the equipment threshold. If the fair market value or purchase price exceeds the equipment threshold, the mobile provider shall apply for a Certificate Of Need under the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1).

(e) A Certificate of Need obtained by a hospital or DTRC to offer mobile PET services shall be valid for the provision of mobile PET services only. A hospital or DTRC approved to offer mobile PET services must obtain a separate CON prior to offering fixed PET services.

(2) **Definitions.**

(a) "Health Planning Area" or "planning area" means the thirteen (13) geographic regions in Georgia as defined in the official State Health Component Plan for use in planning for PET Scan services.

(b) "Horizon Year" means the last year of a five-year projection period for need determinations.

(c) "Expansion" or "expanded service" means the addition of a fixed or mobile unit at a hospital or DTRC. The addition of a component or components, such as computer tomography (CT) imaging, to an existing fixed or mobile unit or the upgrade of an existing fixed or mobile unit shall not be considered an expansion and shall not be subject to the need standards; provided, however, that if any such addition or upgrade is subject to review due to the equipment threshold at that time, the applicant shall demonstrate compliance with or document a plan and agreement to comply with Ga. Comp. R. & Regs. r. 111-2-2-.41(3)(d), (e), (f) and (g).

(d) "Fixed Unit" means a unit that is stationary within one approved facility.

(e) "Mobile Unit" means a unit that is operated by one or shared by two or more health care facilities and which has a data acquisition system and a computer. In order to meet the definition of mobile unit, the applicant must provide proof of the following:

1. The unit must not be on site at any Facility more than three (3) consecutive operating days per week or sixteen (16) total days per month.

2. The facilities involved with the mobile unit are fully informed and participating in the service as evidenced by written agreements or correspondence provided in the application.

3. For applications approved prior to January 1, 2008, a mobile provider is limited to providing service only to those facilities approved in the mobile provider's application for CON. On or after January 1, 2008, a mobile provider may serve any hospital or DTRC that receives a Certificate of Need for mobile PET services, provided that no hospital or DTRC may be serviced by more than one mobile provider at a time.

4. The applicant shall project scans per facility on a pro-rated basis for the first year of operation, and such projections shall be used in any need determinations during that first year of operation. Thereafter, in annual surveys, the applicant, if successful, must document scans by each service facility for use in need determinations.

(f) "Optimal Utilization" refers to scans per year and shall be defined as 2,750 PET scans per year. A PET Scan or Study means the gathering of data during a single patient visit from which one or more images may be constructed.

(g) "PET Scan Service" or "Service" means a facility that owns one or more units and provides diagnostic imaging through positron emission tomography exclusively or as a dedicated PET/CT or dual modality unit.

(h) "Positron Emission Tomography" or "PET" means a noninvasive diagnostic technology, which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals.

(i) "Unit" means a single piece of equipment that performs PET scans.

(3) **Standards.**

(a) The need for a new or expanded service shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing and approved units.

1. The numerical need for a new unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by fifty percent (50%) to determine the projected number of patients diagnosed with cancer who might benefit from a scan.

(iii) Add the number of cancer cases that might benefit from a scan for each county within a Health Planning Area to determine the estimated need for services within a Health Planning Area for persons diagnosed with cancer.

(iv) Multiply the number of cancer cases for each Health Planning Area from subsection (iii) by 1.4 to accommodate for non-oncology patients and for follow-up scans for oncology patients in the projected need for services. On or after January 1, 2010, in lieu of multiplying by 1.4 each year, the Department shall use actual data from the previous 2 survey years to determine the multiplication factor by adding 1 to the ratio of cardiology, neurology and follow up oncology scans to the number of initial oncology scans.

(v) Calculate the number of needed units by dividing the number of individuals who might receive scanning services as determined from subsection (iv) by 2,750, which represents the optimal utilization of a unit.

(vi) Determine the net numerical unmet need for PET scan unit(s) by subtracting the total number of PET/CT or dual modality units currently existing or approved for use from the number of needed units. Mobile units shall be subtracted based on the number of days providing service to sites within a planning area in the most recent survey year divided by 365. Stand-alone PET units shall not be included in the inventory and shall not be subtracted to determine the net numerical unmet need.

(vii) If the net numerical unmet need in any Health Planning Area is at or above seventy-five percent (75%) of a unit (approximately 2,062 individuals needing scans), the needed units shall be rounded up by one unit. If the balance net numerical need in any Health Planning Area is at or above 3.2875% of a unit (approximately (90) individuals needing scans), a mobile unit may be approved to serve the planning area. The maximum number of days a mobile unit may be approved to provide services in the planning area shall be determined using the following formula:

APPROVED DAYS PER YEAR

< NET NUMERICAL UNMET NEED

365

2. Prior to the approval of a new or expanded unit in a planning area, the aggregate utilization rate for all units in that planning area that existed during the most recent survey year and that provided data to the Department for the most recent survey year shall equal or exceed eighty percent (80%) of optimal utilization for the most recent survey year.

(b) Exceptions to the need standards and requirements in (3)(a) may be granted by the Department:

1. to an applicant seeking to remedy an atypical barrier to services based on cost, quality, financial access, or geographic accessibility when the applicant has documented such a barrier;

2. to an applicant seeking the addition of a fixed unit who has been served solely by a mobile PET when the applicant demonstrates that 850 studies have been performed on the mobile unit at the applicant's facility in the most recent survey year; and

3. to an applicant hospital that treats as inpatients persons who have been diagnosed with cancer and are undergoing treatment for the disease and who will offer the PET service to its patients through a contract with a mobile PET provider.

(c) In considering applications joined for review, the Department may give favorable consideration to an applicant that has historically provided a higher annual percentage of un-reimbursed services to indigent and charity patients.

(d) An applicant for a new or expanded service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant that stipulates that any such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds five percent (5%) of annual, adjusted gross revenues of the PET scan service; or

3. providing a written commitment to participate in Medicaid, Peach Care and Medicare programs, to the extent such programs reimburse for PET scan services, and to accept any Medicaid-, Peach Care- and/or Medicare-eligible patient for services;

4. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(e) An applicant for a new or expanded service shall provide evidence of the ability to meet the following quality of care standards:

1. Document certification or a plan for securing certification for operation of a unit from the Georgia Department of Natural Resources.

2. Document that the unit proposed for purchase is approved for use by the U.S. Food and Drug Administration and for reimbursement by the Center for Medicare and Medicaid Services.

3. Document that the service will function as a component of a comprehensive diagnostic service and that appropriate referral to treatment and follow-up will be provided. The applicant must have accessible the following modalities and capabilities on site or through agreements, as evidenced by documentation provided at the time of application: computed tomography, magnetic resonance imaging, nuclear medicine, and conventional radiography.

4. Document that the PET service shall be under the direction of a physician who is board certified in nuclear medicine or diagnostic radiology; and is licensed as an authorized user of radioactive materials in accordance with the Rules of the Georgia Department of Natural Resources.

5. Document that the PET services has arrangements with board-certified interpreting physician(s) that are licensed in the State of Georgia.

6. Document the training and experience in PET scan services of the physician, nuclear medicine technologist, and radiology technologist. Such personnel shall be certified by appropriate national accreditation bodies.

7. Document fully the safe and timely access to radiopharmaceuticals.

(f) An applicant for a new or expanded service shall provide evidence of the ability to meet the following continuity of care standards:

1. Document that the applicant provides or has signed emergency transfer agreements and arrangements with one or more acute care hospital(s) located within the applicant's health planning area or in the case where the nearest acute care hospital is located in an adjacent health planning area, the nearest acute care hospital.

2. Document a referral system that includes a feedback mechanism for communicating scan results and any other pertinent patient information to the referring physician.

3. Document that the applicant will maintain current listings of appropriate clinical indications for PET procedures and will provide such listings to referring physicians and patients.

4. Document how medical emergencies will be managed in conformity with accepted medical practice.

(g) An applicant for a new or expanded service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.41
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Positron Emission Tomography Units" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Repealed: New Rule of same title adopted. F. May 13, 2008; eff. June 2, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.42. Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units.

(1) **Applicability.**

(a) A Certificate Of Need will be required for the establishment of any new or expanded MegaVoltage Radiation Therapy Service.

(b) MegaVoltage Radiation Therapy, including Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) may be conducted on non-special units or on special purpose units.

(c) A Certificate of Need will be required for the addition of a non-special MRT unit. An application for the addition of a non-special MRT unit shall address the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.42(3) in addition to the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a non-special unit may not provide service on a special purpose unit without obtaining a special purpose MRT Certificate of Need.

(d) A Certificate of Need will be required for the addition of a special purpose MRT unit. An application for the addition of a special purpose MRT unit shall address the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.42(4) in addition to the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a special purpose unit may not provide service on a non-special unit without obtaining a non-special MRT Certificate of Need.

(e) An application for the establishment of a new or expanded MegaVoltage Radiation Therapy Service with the addition of both non-special and special purpose MRT units shall address the standards of Ga. Comp. R. & Regs. r. 111-2-2-.42(3), 111-2-2-.42(4) and the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1).

(2) **Definitions.**

(a) "Brachytherapy" means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, Palladium-103 and Iridium-192.

(b) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(c) "Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(d) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(e) "Health Planning Area" or "Planning Area" means the geographic regions in Georgia for use in planning for MRT services.

1. The Health Planning Areas or Planning Areas for non-special MRT services are the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

2. The Health Planning Areas or Planning Areas for special purpose MRT services are five sub-state regions comprised as follows:

(i) Special Purpose MRT Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Douglas, DeKalb, Rockdale, Newton, Henry, Clayton, and Fayette;

(ii) Special Purpose MRT Region 2, including the following counties: Elbert, Madison, Jackson, Barrow, Oconee, Clarke, Oglethorpe, Greene, Morgan, Walton, Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Glascock, Jefferson, Richmond, Burke, Screven, Jenkins, and Emmanuel;

(iii) Special Purpose MRT Region 3, including the following counties: Carroll, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, Upson, Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Brooks, Thomas, Grady, Decatur, and Seminole;

(iv) Special Purpose MRT Region 4, including the following counties: Hancock, Putnam, Jasper, Butts, Monroe, Jones, Baldwin, Washington, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, Crawford, Dooly, Crisp, Ben Hill, Irwin, Turner, Cook, Tift, Berrien, Lanier, Echols, and Lowndes; and

(v) Special Purpose MRT Region 5, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, McIntosh, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch.

(f) "Heavy particle accelerator" means a machine such as a cyclotron, which produces beams of high-energy particles such as protons, neutrons, pions, or heavy ions with rest masses greater than that of an electron (mc2 = 0.511 MeV).

(g) "Horizon Year" means the last year of a five-year projection period for need determinations for MRT services.

(h) "Intensity modulated radiation therapy" or "IMRT" means a treatment delivery utilizing a radiotherapy treatment plan optimized using an inverse or forward planning technique to modulate the particle or energy fluence to create a highly conformal dose distribution. This beam modulated treatment delivery can be accomplished either by the use of the computer controlled multi-leaf collimator or high resolution milled or cast compensators.

(i) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(j) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by an MRT unit.

(k) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(l) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MeV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(m) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit.

(n) "Operating room based intraoperative MRT unit" or "OR-based IORT unit" means an MRT unit that is designed to emit only electrons, is located in an operating room in the surgical department of a licensed hospital and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(o) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(p) "Simulation" is the process of defining relevant normal and abnormal anatomy, acquiring the images and data necessary to develop the patient's approved radiation treatment plan. Simulation always occurs prior to treatment and may be repeated multiple times during the course of treatment depending on the type of cancer, the radiation therapy technique utilized and the patient's clinical response to treatment. Simulation is used to direct the treatment beams to the specific volume.

(q) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units:

(i) heavy particle accelerator;

(ii) gamma knife;

(iii) dedicated linear accelerator stereotactic radiosurgery unit (SRS LINAC), including CyberKnife; or

(iv) an OR-based IORT unit.

(r) "Stereotactic body radiation therapy (SBRT)" is a term used to describe extracranial stereotactic radiosurgery (SRS) or radiotherapy (SRT). SBRT is a radiotherapy treatment method to deliver a high dose of radiation to the target, utilizing either a single dose or a small number of fractions with a high degree of precision within the body.

(s) "Stereotactic treatment visit" or "SRS treatment visit" means a visit involving SRS or SBRT treatment techniques.

(t) "Stereotactic Radiosurgery (SRS)" is performed in a limited number of treatment visits (up to a maximum of five), using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic image-guidance system to treat lesions in the body (extracranial) or brain (intracranial). Technologies that are used to perform SRS include linear accelerators, particle beam accelerators and multi source Cobalt-60 units.

(u) "SRS LINAC" is a dedicated linear accelerator stereotactic radiosurgery unit that consists of three key components:

(i) an advanced linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation),

(ii) a device which can point the linear accelerator from a wide variety of angles, and

(iii) image-guidance patient positioning system using kilovoltage x-rays for either in-room diagnostic x-rays or tomographic images. The devices obtain pictures of the patient (planar x-ray or computed tomography) before or during treatment and use this information to target the radiation beam emitted by the linear accelerator, SRS LINAC includes units such as CyberKnives.

(v) "Treatment site" means the anatomical location of the MRT treatment.

(w) "Treatment visit" means one patient encounter during which MRT is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(x) "Unit" means a single machine used for MRT services.

(y) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) **Standards for Non-Special MRT.**

(a) The need for the addition of a non-special MRT unit shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing services not including units added through the exception in section (3)(b)(2) of this Rule.

1. The numerical need for the addition of a non-special MRT unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

   (i) Calculate the projected incidence of cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

   (ii) Multiply the projected incidence of cancer by fifty percent (50%) to determine the number of projected cancer cases in each county that could be treated with a non-special MRT unit;

   (iii) Add the number of treatable cases for each county within a Health Planning Area to determine the projected number of patients needing treatment with a non-special MRT unit within the Health Planning Area in the horizon year;

   (iv) Multiply the number obtained in step (iii) above by the most recent two year average of treatment visits per patient for the respective planning area of each county to project the number of projected patient visits in the horizon year;

   (v) Determine the percentage of total visits in each planning area attributable to (1) Simple treatment visits, (2) Intermediate treatment visits, (3) Complex treatment visits, (4) IMRT, and (5) SRS treatment visits performed on non-special equipment as based on a running average of the most recent two annual surveys for facilities located in each respective planning area. Prior to the 2008 survey year, the percentage of total visits in each planning area shall be based on the most recent annual survey for facilities located in each respective planning area;

   (vi) Determine the number of projected equivalent visits in the horizon year for each planning area as follows:

      A. Project the number of equivalent simple visits by multiplying the percentage obtained in step (v) for simple visits by the

projected patient visits in the horizon year obtained in step (iv);

B. Project the number of equivalent intermediate visits by multiplying the percentage obtained in step (v) for intermediate visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for intermediate visits, 1.1;

C. Project the number of equivalent complex visits by multiplying the percentage obtained in step (v) for complex visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for complex visits, 1.3;

D. Project the number of equivalent IMRT visits by multiplying the percentage obtained in step (v) for IMRT visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for IMRT visits, 1.8;

E. Project the number of equivalent SRS visits by multiplying the percentage obtained in step (v) for SRS visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for SRS visits, 7.0; and

F. Sum the products obtained in step (vi)A. through step (vi)E.;

(vii) Calculate the number of needed non-special MRT units by dividing the number of projected equivalent visits obtained in step (iv)F. by 9,000, which represents the weighted equivalent capacity of a non-special MRT unit within a given year; and

(viii) Determine the net numerical unmet need for non-special MRT units by subtracting the total number of non-special MRT units currently existing or approved for use, not including units approved pursuant to the exception in section (3)(b)2. of this Rule, from the number of needed non-special MRT units obtained in step (vii).

2. Prior to approval of an additional non-special MRT unit in a planning area, the aggregate utilization rate for all existing non-special MRT units, not

including units approved pursuant to the exception in section (3)(b)2. of this Rule, in that planning area shall equal or exceed eighty percent (80%) of capacity based on 9,000 weighted equivalent visits. For those existing non-special MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate.

(b) Exceptions to the need standard referenced in (3)(a) may be granted for applicants proposing any of the following:

1. To assure geographic access to non-special MRT services in rural areas when the proposed service is:

   (i) to be located in a rural county;

   (ii) to be located a minimum of 45 miles away from any existing or approved non-special MRT service; and

   (iii) projected to serve a minimum of 150 patients per year. For purposes of this requirement, service projections must be submitted by the applicant using, at a minimum, state cancer registry data and documented cancer treatments within the service area.

2. To allow expansion of an existing service if the actual utilization of each radiation therapy unit within that service has exceeded ninety percent (90%) of optimal utilization over the most recent two years. Any such units approved pursuant to this exception shall not be included in the calculation of need and aggregate utilization for the applicable service delivery region but will be included in the Department non-special MRT unit inventory.

3. To allow the addition of a non-special MRT unit at the same defined location if the applicant has a substantial out-of-state patient base. 'Substantial out of state patient base' shall be defined as using at least thirty-three percent (33%) of capacity or 2,970 weighted equivalent visits at the applicant's own percentage of treatment visits weighted by treatment type using the statewide weighted equivalent factor for each non-special MRT unit over the most recent two years to treat patients who reside outside of the State of Georgia.

4. To remedy an atypical barrier to non-special MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded non-special MRT service shall document the impact on existing and approved services which already provide non-special MRT to the residents of the planning area with the goal of minimizing adverse impact on

existing and approved services of the same type in its planning area. An applicant for a new or expanded non-special MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service, whose current utilization is at or above eighty percent (80%), to a projected utilization of less than seventy percent (70%) within the first twenty-four (24) months of the initial operation of the service or additional non-special MRT unit; or

2. decrease annual utilization of an existing service, whose current utilization is below eighty percent (80%), by ten percent (10%) or more within the first twenty-four (24) months of the initial operation of the service or additional non-special MRT unit.

   An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing non-special MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing non-special MRT services, if any, within the planning area. An applicant proposing an additional non-special MRT unit pursuant to the exceptions to need standards referenced in (3)(b)2. shall not be required to document impact on existing and approved services as required by this paragraph.

(d) An applicant for a new or expanded non-special MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the non-special MRT service;

3. providing a written commitment to participate in the Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded non-special MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the non-special MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a Brachytherapy package;

3. Non-Special MRT capability including electron beam capability;

4. Capability to fabricate treatment aids; and

5. Access to brachytherapy;

(f) The applicant must provide a written commitment that physicians providing professional radiation oncology services at the MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff, or are eligible for and have an active pending application for privileges, of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

   (i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry;

and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:

1. One (1) FTE board-certified or board-qualified physician trained in radiation oncology, which shall be available by continuous means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

2. One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with a special competence in radiation oncology physics; and who shall be available by means of direct

communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

3. One (1) medical dosimetrist, who shall be a member of the radiation oncology team who has the knowledge of the overall characteristics and clinical relevance of radiation oncology treatment machines and equipment, is cognizant of procedures commonly used in brachytherapy and has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologists; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

4. Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); and who shall be on-site at all times of operation of the facility; and

5. One (1) program director, who shall be a board-certified physician trained in radiation oncology who may also be the physician required under (h)1.; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

(i) An applicant for a new or expanded non-special MRT service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

(4) **Standards for Special Purpose MRT.**

(a) The need for the addition of a special purpose MRT unit shall be determined through analysis of the capacity and utilization of the existing units of the same type in the planning area and an applicant's reasonable and documented projection of a minimum volume as follows:

Special MRT Equipment	**Capacity**	**Minimum Aggregate Utilization**	**Minimum Projected Volume**
Gamma Knife	500	80%	300 by 3rd Year of Operation
Heavy Particle Accelerator	4,000 per Gantry	80%	2,400 per Gantry by 3ed Year of Operation

Dedicated SRS LINAC (including CyberKnife)	850	80%	510 by 3rd Year of Operation
OR-based IORT	350	80%	150 by 3rd Year of Operation

Where capacity is measured in annual procedures; where minimum aggregate utilization is the aggregate utilization rate for all existing special purpose MRT units of the same type (Gamma Knife utilization for Gamma Knife, etc.) in the planning area, except that for those existing special purpose MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate for special purpose equipment of the same type; and where the minimum projected volume is measured in procedures per year.

(b) Exceptions to the need standards referenced in (3)(a) may be granted for applicants proposing to remedy an atypical barrier to special purpose MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded special purpose MRT service shall document the impact on existing and approved services of the same type (Gamma Knife for Gamma Knife application, etc.) which already provide special purpose MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded special purpose MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service of the same type, whose current utilization is at or above seventy percent (70%), to a projected utilization of less than sixty percent (60%) within the first twenty-four (24) months of the initial operation of the service or additional special purpose MRT unit; or

2. decrease annual utilization of an existing service of the same type, whose current utilization is below seventy percent (70%), by ten percent 10% or more within the first twenty-four (24) months of the initial operation of the service or additional special purpose MRT unit.

   An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing special purpose MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing special purpose MRT services, if any, within the planning area.

(d) An applicant for a new or expanded special purpose MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the special purpose MRT service;

3. providing a written commitment to participate in the Medicaid and PeachCare for KidsT programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded special purpose MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the special purpose MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient; and

3. Capability to fabricate treatment aids as applicable.

(f) The applicant must provide written commitment that physicians providing professional radiation oncology services at the special purpose MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

   (i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

   (ii) meets at least on a quarterly basis; and

   (iii) is responsible for the following:

      A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

      B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

      C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available;

1. For applicants seeking the addition of a Gamma Knife:

   (i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating a Gamma Knife and who shall be available on-site; and

   (ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating a Gamma Knife; and who shall be available on-site;

2. For applicants seeking the addition of a Heavy Particle Accelerator, Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists ("ARRT") or the American Registry of Clinical Radiography Technologists ("ARCRT"); who shall have received special training in operating a Heavy Particle Accelerator and who shall be on-site at all times of operation of the facility;

3. For applicants seeking the addition of a dedicated SRS LINAC:

   (i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating an SRS LINAC and who shall be available on-site; and

   (ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an SRS LINAC; and who shall be available on-site;

   (iii) One (1) radiation therapy technologist, who shall be registered or eligible by the American Registry of Radiological Technologists or the American Registry of Clinical Radiography Technologists; who shall have received special training in operating an SRS LINAC; and who shall be on-site at all times of operation of the facility; and

4. For applicants seeking the addition of an OR-Based IORT unit:

   (i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site; and

   (ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site.

(i) An applicant for a new or expanded special purpose MRT service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.42
Authority: O.C.G.A. §§ 31-2*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Radiation Therapy Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.
Repealed: New Rule entitled "Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units" adopted. F. May 13, 2008; eff. June 2, 2008.
Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Rule 111-2-2-.43. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.43
Authority: O.C.G.A. Secs. 31-5A*et seq.*, 31-6 *et seq.*
History. Original Rule entitled "Specific Review Considerations for Stereotactic Radiosurgical Services" adopted. F. Nov. 17, 2005; eff. Dec. 7, 2005.
Repealed: F. May 13, 2008; eff. June 2, 2008.

Subject 111-2-3. PATIENT'S RIGHT TO INDEPENDENT REVIEW.

Rule 111-2-3-.01. Applicability.

These Rules shall apply to the applicants for certification as independent review organizations, and all attendant procedures thereto; any and all independent review organizations certified by the State Health Planning Agency, or its successor Agency, the Department of Community Health, pursuant to the authority granted by O.C.G.A. § 33-20A-30, which article shall be known

and cited as the "Patient's Right to Independent Review Act", and the procedures for the request for independent review; and the procedures for independent review of services previously rendered as well as concurrent or prospective services by a managed care entity to an eligible enrollee as those terms are defined herein. Any independent review organization that has been certified by an independent national accrediting organization that has developed standards for the purpose of bestowing certification or accreditation upon entities of this type, and that can provide documentation to the Department of such certification or accreditation, shall be deemed certified by the Department and shall not have to apply for certification as an independent review organization in Georgia in order to be added to the Department's list of certified independent review organizations.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.01
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Applicability" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.02. Definitions.

(1) "Act" means O.C.G.A. § 33-20A-30*et seq.*, which shall be known and cited as the "Patient's Right to Independent Review Act."

(2) "Adverse Outcome" means a decision issued by a managed care entity to an eligible enrollee after the grievance procedure provided for in O.C.G.A. § 33-20A-5, which was a denial of the claim in whole or in part of the eligible enrollee or a refusal to pay for a treatment sought.

(3) "Affiliate" means a person who directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the person specified.

(4) "Applicant" means a party that seeks approval from the Department to be certified as an independent review organization, or to have a previous certification renewed.

(5) "Commissioner" means the Commissioner of the Georgia Department of Insurance.

(6) "Dental Plan" means an insurance policy or health benefit plan, including a policy written by a company subject to the provisions of O.C.G.A. § 33-20A-1*et seq.* that provides coverage for expenses for dental services.

(7) "Dentist" means a licensed doctor of dentistry holding either a D.D.S. or a D.M.D. degree.

(8) "Department" means the Department of Community Health created pursuant to O.C.G.A. § 31-5A-4.

(9) "Eligible Enrollee" means a person who:

(a) Is an enrollee or an eligible dependent of an enrollee of a managed care plan or was an enrollee or an eligible dependent of an enrollee of such plan at the time of the request for treatment and,

(b) Seeks a treatment which reasonably appears to be a covered service or benefit under the enrollee's evidence of coverage; provided, however, that this subparagraph shall not apply if the notice from a managed care plan of the outcome of the grievance procedure was that a treatment is experimental.

(10) "Emergency Services" or "Emergency Care" means those health care services that are provided for a condition of recent onset and sufficient severity, including but not limited to severe pain, that would lead a prudent layperson, possessing an average knowledge of medicine and health, to believe that his or her condition, sickness, or injury is of such a nature that failure to obtain immediate medical care could result in:

(a) Placing the patient's health in serious jeopardy;

(b) Serious impairment to bodily functions; or

(c) Serious dysfunction of any bodily organ or part.

(11) "Expert reviewer" means a person assigned by the independent review organization to review a request, and whose qualifications are consistent with the criteria as set forth in the Act and/or this Rule.

(12) "Grievance Procedure" means the internal grievance procedure of a managed care entity established for that entity pursuant to O.C.G.A. § 33-20A-5.

(13) "Health Benefit Plan" means a plan of benefits that defines the coverage provisions for health care offered or provided by any organization, public or private, other than health insurance.

(14) "Health Care Provider" or "provider" means any physician, dentist, podiatrist, pharmacist, optometrist, psychologist, clinical social worker, advance practice nurse, registered optician, licensed professional counselor, physical therapist, marriage and family therapist, chiropractor, occupational therapist, speech language pathologist, audiologist, dietician, or physician's assistant.

(15) "Health Insurance Policy" means an insurance policy, including a policy subject to the provisions of O.C.G.A. § 33-20A*et seq.*, that provides coverage for medical or surgical expenses incurred as a result of accident or sickness.

(16) "Independent Review" means a system of administrative appeal an eligible enrollee is entitled to receive when any of the conditions set forth in Rule 111-2-3-.04 have been met.

(17) "Independent Review Organization" means any organization certified as such by the State Health Planning Agency or its successor Agency, the Department of Community Health, pursuant to O.C.G.A. § 33-20A-39.

(18) "Independent Review Plan" means the screening criteria and review procedures of an independent review organization.

(19) "Managed Care Entity" includes an insurance company, hospital or medical service plan, hospital, health care provider network, physician hospital organization, health care provider, health maintenance organization, health care corporation, employer or employee organization, or managed care contractor that offers a managed care plan.

(20) "Managed Care Plan" means a major medical, hospitalization, or dental plan that provides for the financing and delivery of health care services to persons enrolled in such plan through:

(a) Arrangements with selected providers to furnish health care services;

(b) Explicit standards for the selection of participating providers and,

(c) Cost savings for persons enrolled in the plan to use the participating providers and procedures provided for by the plan; provided, however, that the term "managed care plan" does not apply to Chapter 9 of Title 34, relating to workers' compensation.

(21) "Medical and Scientific Evidence" means:

(a) Peer reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

(b) Peer reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS data base or Health Services Technology Assessment Research (HSTAR);

(c) Medical journals recognized by the United States Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act;

(d) The following standard reference compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluation, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopoeia-Drug Information; or

(e) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

(22) "Medical Necessity", "Medically Necessary Care", or "Medically Necessary and Appropriate" means care based upon generally accepted medical practices in light of conditions at the time of treatment which is:

(a) Appropriate and consistent with the diagnosis and the omission of which could adversely affect or fail to improve the eligible enrollee's condition;

(b) Compatible with the standards of acceptable medical practice in the United States;

(c) Provided in a safe and appropriate setting given the nature of the diagnosis and the severity of the symptoms;

(d) Not provided solely for the convenience of the eligible enrollee or the convenience of the health care provider or hospital; and

(e) Not primarily custodial care, unless custodial care is a covered service or benefit under the eligible enrollee's evidence of coverage.

(23) "Nurse" means a registered nurse.

(24) "Open Records Act" means the provisions codified in O.C.G.A. § 50-18-70*et seq.*, including those provisions to be effective on July 1, 1999.

(25) "Out of Network" or "Point of Service" refers to health care items or services provided to an eligible enrollee by providers who do not belong to the provider network in the managed care plan.

(26) "Patient" means a person who seeks or receives health care services under a managed care plan.

(27) "Person" means an individual, corporation, partnership, association, joint stock company, trust, unincorporated organization, any similar entity, or any combination of the foregoing acting in concert.

(28) "Physician" means a licensed doctor of medicine or a doctor of osteopathy.

(29) Reserved.

(30) "Provider of Record" means the physician or other health care provider that has primary responsibility for the care, treatment, and services requested on behalf of the patient and includes any health care facility when treatment is rendered on an inpatient or outpatient basis.

(31) "Receipt" means the date of the taking of actual physical possession of an item sent, or the date evidencing such possession by the normal and customary confirmation available for facsimile transmissions, other computer assisted electronic transmissions, courier delivery services, private delivery services, and the U.S. Mail service.

(32) "Screening Criteria" means the written policies, medical protocols, or guidelines used by the independent review organization as part of the independent review process.

(33) "Treatment" means a medical service, diagnosis, procedure, therapy, drug, or device.

(34) "Working Day" means a weekday, excluding any officially designated State holiday.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.02
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Definitions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.03. Standards.

(1) Certification of Independent Review Organizations.

(a) Filing Information. An application for certification of an independent review organization and certification fee must be filed with the Department of Community Health, Division of Health Planning, at the following address: 2 Peachtree Street, N.W., Atlanta, Georgia, 30303-3142. The certification fee must be in the form of a certified bank check, certified cashiers check, or certified money order, and made payable to the State of Georgia. The application must consist of an original and three copies. There shall be a fee for the application to become an independent review organization, and to renew the certification as an independent review organization, and the provisions governing such fees shall be as follows:

The Department shall establish, administer, and enforce the certification and renewal fees under this section, and the fee for initial application to receive certification as an independent review organization shall be $500; and the fee for annual certification renewal as an independent review organization shall be $250.00.

(b) How to Obtain Forms. The application must be submitted on a form which can be obtained from the Department of Community Health, Division of Health Planning at 2 Peachtree Street, N.W., Atlanta, Georgia, 30303-3142.

(c) Certification Application Content. The applicant must provide information required by the Department, which includes, but is not limited to the following:

(i) a summary of the independent review plan which meets the requirements of this Rule as outlined below and must include:

(A) the screening criteria and review procedures to be used to determine medical necessity, medically necessary care, or medically necessary and appropriate care;

(B) a certification signed by an authorized representative that such screening criteria and review procedures to be applied in review determinations are established with input from appropriate health care providers, including physicians;

(C) procedures ensuring that the information regarding the reviewing physicians and providers is updated in accordance with this Rule as outlined below relating to Revisions During Review Process and relating to Renewal of Certificate of Registration to ensure the independence of each health care provider or physician making review determinations; and

(D) specific procedures which will be used to determine if a proposed treatment is experimental.

(ii) copies of policies and procedures which ensure that all applicable state and federal laws to protect the confidentiality of medical records and personal information are followed. These procedures must comply with this Rule as outlined below relating to Confidentiality; and the applicant shall also submit a certification signed by an authorized representative that the independent review organization will protect the confidentiality of medical records and personnel information and will comply with all applicable state and federal laws pertaining thereto.

(iii) a certification signed by an authorized representative that the independent review organization will comply with the provisions of the Act and these Rules;

(iv) a description of personnel and the accrediting policies and procedures of the applicant, and a completed profile for each expert reviewer and provider, in compliance with this Rule as outlined below relating to Personnel and Credentialing;

(v) a description of hours of operation, which must conform to Eastern Standard Time or Eastern Daylight Time, whichever is applicable, and how the independent review organization may be contacted during weekends

and holidays, as set forth in this Rule as outlined below relating to Independent Review Organization's Telephone Access;

(vi) the organizational information, documents and all amendments, including:

(A) the bylaws, Rules and regulations, or operating agreement regulating the conduct of the internal affairs of the applicant with a notarized certification bearing the original signature of an officer or authorized representative of the applicant that they are true, accurate, and complete copies of the originals;

(B) for an applicant that is publicly held, the name of each stockholder or owner of more than five percent of any stock or options;

(C) a chart listing the internal organizational structure of the applicant's management and administrative staff;

(D) a chart showing contractual arrangements of the independent review system; and

(E) evidence of the applicant's authorization to conduct business in the state of Georgia.

(vii) the name of any holder of bonds or notes of the applicant that exceed $ 100,000;

(viii) the name and type of business of each corporation or other organization that the applicant controls or is affiliated with and the nature and extent of the affiliation or control and a chart or list clearly identifying the relationships between the applicant and any affiliates;

(ix) biographical information about officers, directors, and staff, including:

(A) the independent review organization must submit the name and biographical information for each director, officer, and executive of the applicant, any entity listed in this section of these Rules, and each expert reviewer conducting independent review, and a description of any relationship, including but not limited to, any past, present or known future professional, personal, familial, financial, fiduciary, or contractual relationship which the named individual has with:

(aa) a health benefit plan;

(bb) a health maintenance organization;

(cc) an insurer;

(dd) a nonprofit health corporation;

(ee) a payor;

(ff) a health care provider; or

(gg) a group representing any of the entities described by paragraphs (aa) through (gg) of this subsection;

(B) any relationship between the independent review organization and any affiliate or other organization in which a shareholder has 10 percent (10%) or more interest must be clearly identified;

(C) a list of any currently outstanding loans or contracts to provide services between the applicant and any of its affiliates or any officers of its affiliates;

(x) information related to out-of-state licensure, permit, certification or other similar business, and service of legal process. All applicants must furnish a copy of the certificate of registration, licensing, or other similar document from the domiciliary state's licensing authority. As a condition of being certified to conduct the business of independent review in this state, an independent review organization that maintains its principal offices or any portion of its books, records, or accounts outside this state must appoint and maintain a person in this state as attorney for service of process on whom all judicial and administrative process, notices, or demands may be served, and must notify the Department of any change of appointment or appointee's address immediately.

(xi) written disclosure of types of compensation arrangements made to physicians and providers in exchange for the provision of independent review, including any financial incentives for physicians and providers.

(xii) the percentage of the applicant's revenues that are anticipated to be derived from independent reviews conducted.

(xiii) the names of any predecessor affiliates and/or companies, including trade names.

(2) Independent Review Organization Conflict of Interest Criteria. Neither the independent review organization nor any expert reviewer of the independent review organization may

have any material professional, familial, or financial conflict of interest with any of the following:

(a) A managed care plan or entity being reviewed;

(b) Any officer, director, or management employee of a managed care plan which is being reviewed;

(c) The physician, the physician's medical group, health care provider, or the independent practice association proposing a treatment under review;

(d) The institution at which a proposed treatment would be provided;

(e) The eligible enrollee or the eligible enrollee's representative; or

(f) The development or manufacture of the treatment proposed for the eligible enrollee whose treatment is under review.

(3) As used in subsection (iv) above, the term "conflict of interest" shall not be interpreted to include a contract under which an academic medical center or other similar medical research center provides health care services to eligible enrollees of a managed care plan, except as subject to the requirement of line item (D) of subsection (iv) above; nor affiliations which are limited to staff privileges at a health care facility; or an expert reviewer's participation as a contracting plan provider where the expert is affiliated with an academic medical center or other similar medical research center that is acting as an independent review organization under the Act. An agreement to provide independent review for an eligible enrollee or managed care entity is not a conflict of interest under subsection (iv) of these Rules.

(4) The independent review organization shall have and submit as a part of its application a written quality assurance mechanism in place that ensures the timeliness and quality of the reviews, the qualifications and independence of the expert reviewers, and the confidentiality of medical records and review materials.

(5) The Department shall provide upon the request of any interested person a copy of all information filed with it pursuant to these Rules. Screening criteria and other review procedures of the independent review organization shall not be considered proprietary and privileged information, and shall be subject to disclosure. The Department shall provide at least quarterly a current list of certified independent review organizations to all managed care entities and to any interested persons.

(6) The expert reviewers assigned by the independent review organizations must be physicians or other appropriate providers who meet the following minimum requirements:

(a) Are experts in the treatment of the medical condition at issue and are knowledgeable about the recommended treatment through actual clinical experience;

(b) Hold a non-restricted license issued by a State of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of review; and

(c) Have no history of disciplinary action or sanctions, including, but not limited to, loss of staff privileges or participation restriction, taken or pending by any hospital, government, or regulatory body.

(7) Department Review of Certification Application. The application process is as follows:

(a) Upon receipt of an original and three copies of the application, along with the correct application fee, the Department will have ten (10) working days to determine if the application contains all necessary information needed to deem the application complete. When the Department has determined that the application contains all necessary information for a decision on certification to be made, the Department shall deem the application to be complete.

(b) The Department will notify the applicant, no later than ten (10) working days after the application has been received, if there are any items or additional information necessary for the review for certification that need to be submitted to the Department. If the Department requests additional items or information, the applicant shall have no more than thirty (30) calendar days to provide the additional items or information. If the applicant does not provide the information requested within thirty (30) calendar days from the date of the Department's request, the application shall be deemed withdrawn, and the applicant will be required to submit an entirely new application.

(c) The Department shall notify the applicant of any omissions or deficiencies in the application no later than thirty (30) calendar days after the date on which the application has been deemed complete. The applicant shall have five (5) working days after the receipt of notification from the Department of any omissions or deficiencies to provide the Department with any additional, supplemental, or clarifying information.

(d) The Department shall issue a written decision to the applicant that either approves or denies the application for certification no later than sixty (60) calendar days after the date the Department deems the application complete for review. If the applicant is denied certification, the written notification to the applicant must state, with specificity, the reasons for denial. Either the Department or the applicant may request a thirty (30) calendar day extension of the sixty (60) day review period. In this case, the Department may accept additional, supplemental, or clarifying information up to the 65th day of the review period. In no

circumstances shall the certification review period be longer than ninety (90) calendar days from the date the application has been deemed complete for review.

(e) The Department shall maintain a master file that shall contain the application, and any and all written correspondence between the applicant and the Department during the certification review period, as well as any written comments on the application from other parties sent to the Department during the review period.

(f) If any of the information contained in the application should change during the review period, the applicant must provide the Department with the new information no later than thirty-five (35) days after the application has been deemed complete, or no later than the date for submission of additional or clarifying information requested by the Department as referenced above, or no later than the sixty-fifth (65th) day of the review period if the period is extended to ninety (90) days.

(8) On-Site Examinations. The Department may conduct an on-site examination of an applicant as a requirement of certification as an independent review organization. Documents must be available for inspection at the time of such examination at the administrative offices of the independent review organization as set forth in this Rule as outlined below relating to On-Site Review by the Department.

(9) Withdrawal of an Application.

(a) Upon written notice to the Department, an applicant may request withdrawal of an application from consideration.

(b) Upon the Department's receipt of a request to withdraw an application pursuant to this section, the application shall be withdrawn from consideration. Subsequent applications by the same applicant must be new submissions in their entirety.

(10) Renewal of Certificate of Registration.

(a) The Department shall designate annually each organization that meets the standards as an independent review organization.

(b) An independent review organization must apply for renewal of its certificate of registration every year, not later than ninety (90) days prior to the anniversary date of the issuance of the registration. A renewal form must be used for this purpose. The renewal form can be obtained from the address listed for the Department elsewhere in this Rule. The completed renewal form, the current screening criteria, renewal fee, and certification of no material changes not already filed with the Department must be submitted to the Department.

(c) An independent review organization may continue to operate under its certificate of registration after a completed renewal application form and the current

screening criteria has been timely received by the Department until the renewal is finally denied or issued by the Department.

(d) If a completed renewal form and the current screening criteria is not received no later than ninety (90) days prior to the anniversary date of the year in which the certificate of registration must be renewed, the certificate of registration will automatically be canceled and the independent review organization must complete and submit a new application for certificate of registration.

(e) A previously certified independent review organization shall report any material changes in the information contained in its original certification application within 30 days of any change, and all such new information must be reflected in any submissions by the independent review organization in its request for certification renewal. A material change shall be those changes listed in the Act at O.C.G.A. § 33-20A-39(a)(3).

(11) Appeal of Denial of Application or Renewal. If an application or renewal is initially denied under this subchapter, the applicant may appeal such denial pursuant to the provisions of the Georgia Administrative Procedure Act, codified at O.C.G.A. § 50-13*et seq.*

(12) Independent Review Plan. The independent review plan shall be adhered to by the designated expert reviewer and conducted in accordance with the screening criteria and procedures developed with input from appropriate health care providers, including physicians. The independent review plan shall include the following components:

(a) a description of the elements of review which the independent review organization provides, including but not limited to:

(i) prospective review;

(A) second opinion;

(B) hospital admission;

(C) procedures;

(D) courses of outpatient treatment;

(E) choice of provider;

(ii) concurrent review;

(A) second opinion;

(B) discharge planning;

(C) readmission review;

(D) continued stay authorization;

(iii) retrospective review; and

(iv) procedures for addressing experimental treatment.

(b) written procedures, in accordance with the Act for:

(i) notification of the independent review organization's decisions provided to the eligible enrollee or the eligible enrollee's representative, the managed care entity, and the Department.

(ii) review, including:

(A) any form used during the review process;

(B) time frames that shall be met during the review; and

(iii) contacting and receiving information from health care providers in accordance with this Rule relating to Independent Review Organization's Contact With and Receipt of Information from Health Care Providers.

(13) Screening Criteria. Each independent review organization shall utilize written medically acceptable screening criteria and review procedures which are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers. All determinations of medical necessity shall be made by the designated expert reviewer of the independent review organization. Such written screening criteria and review procedures shall be available for review and inspection and copying as necessary by the Department in order for the Department to carry out the duties provided for under the Act.

(14) The personnel of an independent review organization must conform to the following criteria:

(a) Personnel employed by or under contract with the independent review organization to perform independent review shall be appropriately trained and qualified and, if applicable, currently licensed, registered, or certified. Personnel who obtain information directly from a physician, dentist, or other health care provider, either orally or in writing, and who are not physicians or dentists, shall be nurses, physician assistants, or health care providers qualified to provide the service requested by the provider. This provision shall not be interpreted to require such qualifications for clerical or administrative personnel who do not perform independent review.

(b) The independent review organization is required to provide to the Department the number, type, and minimum qualifications of the personnel either employed or under contract to perform the independent review. Independent review organizations shall be required to adopt written procedures used to determine whether physicians or other health care providers utilized by the independent review organization are licensed, qualified, and appropriately trained, and must maintain records on such. In addition, the independent review organization must maintain complete profiles of any designated expert reviewer. Such profiles must include all information required by these Rules as outlined below relating to Information Required, and must be kept current.

(c) Independent review conducted by an independent review organization shall be under the direction of an expert reviewer in accordance with these Rules as outlined.

(d) Dental plans shall be independently reviewed by an expert reviewer who is a dentist currently licensed by a state licensing agency in the United States, and who meets all the other requirements for an expert reviewer.

(e) The independent review organization is required to provide to the department a copy of the applicant's selection policies and procedures, including:

(i) a description of the categories and qualifications of persons employed or under contract to perform independent review;

(ii) copies of policies and procedures for orientation and training of persons who perform independent review, including any expert reviewers, and evidence that the applicant meets any applicable provisions of this chapter relating to the qualifications of independent review organizations or the performance of independent reviews, including section (xvii) of these Rules.

(15) Independent Review Organization Contact With and Receipt of Information from Health Care Providers and Patients.

(a) A health care provider may designate one or more individuals as the initial contact or contacts for independent review organizations seeking routine information or data. In no event shall the designation of such an individual or individuals preclude an independent review organization or the expert reviewer from contacting a health care provider or others in his or her employ where a review might otherwise be unreasonably delayed or where the designated individual is unable to provide the necessary information or data requested by the independent review organization.

(b) An independent review organization may not engage in unnecessary or unreasonably repetitive contacts with the health care provider or patient and shall

base the frequency of contacts or reviews on the severity or complexity of the patient's condition or on necessary treatment and discharge planning activity.

(c) The managed care entity or the eligible enrollee or the eligible enrollee's representative shall be responsible for delivering to the independent review organization any written information required to conduct the independent review as provided for in a timely manner as specified in the Act and these Rules.

(d) When conducting independent review, the independent review organization shall collect any information necessary to review the adverse outcome not already provided by the managed care entity or the eligible enrollee or the eligible enrollee's representative. This information may include, but is not limited to, identifying information about the eligible enrollee, the benefit plan, the treating health care provider, and/or facilities rendering care. It may also include clinical information regarding the diagnoses of the eligible enrollee and the medical history of the eligible enrollee relevant to the diagnoses; the eligible enrollee's prognosis; and/or the treatment plan prescribed by the treating health care provider along with the provider's justification for the treatment plan. Second opinion information may also be required when applicable. The burden of proof shall rest with the managed care entity in all questions before the independent review organization.

(e) The independent review organization should share all clinical and demographic information on individual eligible enrollees among its various divisions to avoid duplication of requests for information from eligible enrollees or providers.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.03
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Standards" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.04. Request for Independent Review.

An eligible enrollee shall be entitled to appeal to an independent review organization when:

(1) The eligible enrollee has received notice of an adverse outcome pursuant to a grievance procedure or the managed care entity has not complied with the requirements of Code Section 33-20A-5 with regard to such procedures; or

(2) A managed care entity determines that a proposed treatment is excluded as experimental under the managed care plan, and all of the following criteria are met:

(a) The eligible enrollee has a terminal condition that, according to the treating physician, has a substantial probability of causing death within two years from the date of the request for independent review or the eligible enrollee's ability to

regain or maintain maximum function, as determined by the treating physician, would be impaired by withholding the experimental treatment;

(b) After exhaustion of standard treatment as provided by the evidence of coverage or a finding that such treatment would be of substantially lesser or of no benefit, the eligible enrollee's treating physician certifies that the eligible enrollee has a condition for which standard treatment would not be medically indicated for the eligible enrollee or for which there is no standard treatment available under the evidence of coverage of the eligible enrollee more beneficial than the treatment proposed;

(c) The eligible enrollee's treating physician has recommended and certified in writing treatment which is likely to be more beneficial to the eligible enrollee than any available standard treatment;

(d) The eligible enrollee has requested a treatment as to which the eligible enrollee's treating physician, who is a licensed, board certified or board eligible physician qualified to practice in the area of medicine appropriate to treat the eligible enrollee's condition, has certified in writing that scientifically valid studies using accepted protocols, such as control group or double-blind testing, published in peer reviewed literature, demonstrate that the proposed treatment is likely to be more beneficial for the eligible enrollee than available standard treatment; and

(e) A specific treatment recommended would otherwise be included within the eligible enrollee's certificate of coverage, except for the determination by the managed care entity that such treatment is experimental for a particular condition.

(3) The Department shall determine that an eligible enrollee is entitled to independent review because of the managed care entity's failure to comply with the requirements of Code Section 33-20A-5 if the managed care entity has failed to grant appropriate relief without delay after a determination favorable to the eligible enrollee; has failed to provide notice meeting the requirements of the Code Section to the eligible enrollee of the outcome of the grievance procedure within 60 days from the date of the grievance request, or 30 days where the grievance involves a case where the requested care or service has not been rendered, or in the case of an eligible enrollee who meets the requirements of Rule 111-2-3-.06(8) [Code Section 33-20A-37(c)], the managed care entity has failed to notify the eligible enrollee of the outcome of the grievance procedure within 72 hours from the date of the grievance request; or has otherwise failed to comply with the Code Section in question.

(4) The following additional criteria, in accordance with the Act, shall be required for independent review:

(a) Except where required pursuant to Code Section 51-1-49, a proposed treatment must require the expenditure of a minimum of $500.00 to qualify for independent review, provided that the minimum $500.00 expenditure shall include the full cost

during the course of treatment of the items and services furnished by all providers and shall include the cost to the managed care entity and/or any provider at risk for the cost and any cost sharing by the eligible enrollee.

(b) The parent or guardian of a minor who is an eligible enrollee may act on behalf of the minor in requesting independent review. The legal guardian or representative of an incapacitated eligible enrollee shall be authorized to act on behalf of the eligible enrollee in requesting independent review. Except as provided in Code Section 51-1-49, independent review may not be requested by persons other than the eligible enrollee or a person acting on behalf of the eligible enrollee as provided in these Rules in accordance with the Act.

(c) A managed care entity shall be required to pay the full cost of applying for and obtaining the independent review, including the flat fee rate plus any ancillary costs as outlined in these Rules.

(d) The eligible enrollee and the managed care entity shall cooperate with the independent review organization to provide the information and documentation, including executing necessary releases for medical records, which are necessary for the independent review organization to make a determination of the claim.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.04
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Request for Independent Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.05. Procedure for Request for Independent Review.

(1) In the event that the outcome of the grievance procedure under Code Section 33-20A-5 is adverse to the eligible enrollee, the managed care entity shall include with the written notice of the outcome of the grievance procedure a statement specifying that any request for independent review must be made to the Department on forms made available by the Department in accordance with this Rule, and such forms must be included with the notification. Such statement shall be in simple, clear language in boldface type, which is larger and bolder than any other typeface that is in the notice and in at least 14-point typeface.

(2) An eligible enrollee must submit the written request for independent review to the Department. This request need not be in any required format, but may be a simple written request for an independent review of an adverse outcome of a grievance procedure of a managed care entity. The request must include the name and address of the eligible enrollee, and/or the name and address of the eligible enrollee's guardian in the case of a minor, the eligible enrollee's legal guardian in the case of an eligible enrollee's incapacity, and/or the eligible enrollee's representative. The written request must also include a copy of the notification to the eligible enrollee, or the eligible enrollee's applicable

representative, of the adverse outcome determination of the grievance procedure of the managed care entity involved.

(3) Upon receipt of a written request by an eligible enrollee or the eligible enrollee's applicable representative made in accordance with these Rules as outlined above, the Department shall, no later than three (3) working days after receipt, notify the eligible enrollee, or the eligible enrollee's applicable representative, of receipt of the request and assign the request to an independent review organization on a rotating basis according to the date the request was received in accordance with these Rules as outlined below.

(4) Upon assignment of a request for independent review to an independent review organization, the Department shall provide written notification of the name and address of the assigned organization to both the requesting eligible enrollee, or the eligible enrollee's applicable representative, and the managed care entity.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.05
Authority: O.C.G.A. Sec. 31-6*et seq*.
History. Original Rule entitled "Procedure for Request for Independent Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.06. The Conduct of the Review by the Independent Review Organization.

(1) Within three working days of receipt of notice from the Department of assignment of the request for independent review, the managed care entity shall submit to that organization the following:

   (a) Any information submitted to the managed care entity by the eligible enrollee or his/her provider in support of the eligible enrollee's grievance procedure filing;

   (b) A copy of the contract provisions or evidence of coverage of the managed care plan, including the entire contract or policy; and

   (c) Any other relevant documents or information used by the managed care entity in determining the outcome of the eligible enrollee's grievance.

(2) Upon request, the managed care entity shall provide a copy of all documents required by these Rules, except for any proprietary or privileged information, to the eligible enrollee, or the eligible enrollee's applicable representative. The eligible enrollee, or the eligible enrollee's applicable representative, may provide the independent review organization with any additional information the eligible enrollee may deem relevant. Proprietary or privileged information shall not include screening criteria or any procedure, studies, documents, communications, or any other information used by the managed care entity in making a determination in the eligible enrollee's case.

(3) The independent review organization shall request any additional information required for the review from the managed care entity and the eligible enrollee, or the eligible enrollee's applicable representative, within five working days of receipt of the documentation required under these Rules as outlined above. Any additional information requested by the independent review organization shall be submitted within five working days of receipt of the request, or an explanation of why the additional information is not being submitted shall be provided. In no case shall a managed care entity or an eligible enrollee, or an eligible enrollee's applicable representative, receive any more than an extension of ten working days to submit the required additional information. It shall not be grounds for a managed care entity to refuse to supply or to delay submission to the independent review organization any medical record based on an assertion by the managed care entity, or a provider or facility with which the managed care entity has a contract, that said records are then incomplete or un-reviewed.

(4) Additional information obtained from the eligible enrollee, or the eligible enrollee's applicable representative, shall be transmitted to the managed care entity, which may determine that such additional information justifies a reconsideration of the outcome of the grievance procedure. A decision by the managed care entity to cover fully the treatment in question upon reconsideration using such additional information shall terminate independent review. The managed care entity shall notify the eligible enrollee, or the eligible enrollee's representative, the Department, and the independent review organization when such a decision is made. Upon such notification, the independent review organization shall not terminate its review until it has determined that the managed care entity's decision constitutes full coverage of the treatment in question. If the independent review organization determines that the managed care entity's decision does not constitute full coverage of the treatment in question, the eligible enrollee shall not be required to make a new request for independent review, and the managed care entity shall be bound by the entire independent review process both before and after any decision it made to offer coverage.

(5) The expert reviewer of the independent review organization shall make a determination within 15 working days after expiration of all additional information time limits set forth in these Rules, but such time limits may be extended or shortened by mutual agreement between the eligible enrollee, or the eligible enrollee's applicable representative, and the managed care entity subject to the provisions outlined above. The determination by the expert reviewer of the independent review organization shall be in writing and shall state the basis of the reviewer's decision. The determination shall contain the specific findings of fact, regulation, and policy, the basis and reasons thereof, and copies of the documents, studies, and all other information utilized and relied upon by the expert reviewer and the independent review organization in reaching its determination. A copy of the decision shall be delivered to the managed care entity, the eligible enrollee, the eligible enrollee's applicable representative, and the Department by Certified Mail, Return Receipt Requested.

(6) The independent review organization's decision shall be based upon a review of the information and documentation submitted to it.

(7) Information required or authorized to be provided pursuant to these Rules may be provided by facsimile transmission, and/or electronic mail if feasible for both sender and receiver. For purpose of any time deadline for the receipt of information in accordance with these Rules and the Act, the date of receipt by mail shall be the postmark date on the item(s) being sent, however this provision with regard to mailing does not supersede any applicable time deadline heretofore specified in the Act or these Rules.

(8) In the event that, in the judgment of the treating health care provider, the health condition of the eligible enrollee is such that following the procedure provisions outlined herein would jeopardize the life or health of the eligible enrollee or the eligible enrollee's ability to regain maximum function, as determined by the treating health care provider, an expedited review shall be available. The expedited review process shall encompass all applicable provisions outlined in these Rules, provided, however, that a decision by the expert reviewer shall be rendered within 72 hours (three calendar days) after the expert reviewer's receipt of all available requested documentation.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.06
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "The Conduct of the Review by the Independent Review Organization" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.07. Independent Review Organization Decision.

(1) The expert reviewer of the independent review organization shall make a determination as to whether a treatment is experimental based upon the following criteria:

(a) Whether such treatment has been approved by the federal Food and Drug Administration; or

(b) Whether medical and scientific evidence demonstrates that the expected benefits of the proposed treatment would be greater than the benefits of any available standard treatment and that the adverse risks of the proposed treatment will not be substantially increased over those of standard treatments.

(c) For either determination, the expert reviewer shall apply prudent professional practices and shall assure that at least two documents of medical and scientific evidence support the decision. The expert reviewer shall take into account evidence and opinions of practitioners in the field who are experts in the treatment proposed to be offered.

(2) In making a decision as to whether a treatment is medically necessary or appropriate, the expert reviewer shall use the definition of medical necessity, medically necessary care, and medically necessary and appropriate, as defined in these Rules and the Act. Criteria must be objective, clinically valid, compatible with established principles of health care,

and flexible enough to allow deviations from the norms when justified on a case-by-case basis.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.07
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Independent Review Organization Decision" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.08. Independent Review Organization Telephone Access.

(1) An independent review organization shall have appropriate personnel reasonably available by telephone, in accordance with Eastern Standard or Eastern Daylight time, whichever is applicable, at least forty (40) hours per week during normal business hours, to discuss eligible enrollee's care and to allow response to telephone questions. The independent review organization must also allow reasonable telephone access on evenings and weekends.

(2) An independent review organization must have a telephone system capable of accepting or recording or providing instructions to incoming calls during other than normal business hours and shall respond to such calls not later than two working days of the later of the date on which the call was received or the date the details necessary to respond have been received from the caller. The independent review organization shall request the specific information needed from the caller not later than two working days after initial receipt of the call in question. In the event of an emergency, the independent review organization shall respond within the time appropriate to circumstances relating to the delivery of the services and the condition of the eligible enrollee.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.08
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Independent Review Organization Telephone Access" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.09. Independent Review Organization Confidentiality Provisions.

(1) An independent review organization, and all agents, contractors, and employees thereof, shall preserve the confidentiality of individual medical records and personal information to the extent required by law and by the doctor-patient relationship.

(2) An independent review organization may not disclose or publish individual medical records or other confidential information about an eligible enrollee without the prior written consent of the eligible enrollee or as otherwise required by law. An independent review organization may provide confidential information to a third party under contract

or affiliated with the independent review organization for the sole purpose of performing or assisting with independent review. Information provided to third parties shall remain confidential.

(3) The independent review organization may not publish data which identifies a particular physician or health care provider, or particular health benefit plan or managed care entity, including any quality review studies or performance tracking data, without prior written notice to the involved provider, plan, or entity. This prohibition does not apply to internal systems or reports used by the independent review organization.

(4) All patient, physician, health care provider, and health benefit plan data shall be maintained by the independent review organization in a confidential manner which prevents unauthorized disclosure to third parties. Nothing in this chapter shall be construed to allow an independent review organization to take actions that violate a state or federal statute or regulation concerning confidentiality of eligible enrollee records.

(5) To assure confidentiality, an independent review organization must, when contacting a physician's or provider's office, or hospital, provide its certification number and the caller's name and professional qualifications to the provider or the provider's named independent review representative.

(6) The independent review organization's procedures shall specify that specific information exchanged for the purpose of conducting review will be considered confidential, be used by the independent review organization solely for the purposes of independent review, and be shared by the independent review organization with only those third parties who have authority to receive such information. The independent review organization's plan shall specify the procedures that are in place to assure confidentiality and that the independent review organization agrees to abide by any federal and state laws governing the issue of confidentiality. Summary data that does not provide sufficient information to allow identification of individual eligible enrollees, providers, or health benefit plans need not be considered confidential.

(7) Medical records and eligible enrollee-specific information shall be maintained by the independent review organization in a secure area with access limited to essential personnel only.

(8) Destruction of documents in the custody of the independent review organization that contain confidential eligible enrollee information or physician or health care provider financial data shall be by a method which ensures complete destruction of the information, when the organization determines that the information is no longer needed.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.09
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Independent Review Organization Confidentiality Provisions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.10. Complaints and Inquiries Regarding Conduct of Independent Review Organizations.

(1) Complaints to the Department. Within a reasonable time period, upon receipt of a written complaint alleging a violation of these Rules or the Act by an independent review organization from an eligible enrollee's health care provider, a person acting on behalf of the eligible enrollee, the eligible enrollee, or a managed care entity, the Department shall investigate the complaint and furnish a written response to the complainant and the independent review organization named.

(2) Authority of the Department to make inquiries. In addition to the authority of the Department to respond to complaints described in subsection (a) of this section, the Department is authorized to address inquiries to any independent review organization in relation to the organization's business condition or any matter connected with its transactions which the Department may deem necessary for the public good or for a proper discharge of its duties. It shall be the duty of the independent review organization to promptly answer such inquiries in writing, and in all cases within thirty days of the request for response.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.10
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Complaints and Inquiries Regarding Conduct of Independent Review Organizations" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.11. On-Site Inspections by the Department.

(1) The Department is authorized to make examinations concerning the quality, availability, accessibility, and performance of independent review services as often as is deemed necessary.

(2) A representative of the Department is authorized to visit the administrative offices or any branch office of each independent review organization annually, or as frequently as necessary, during normal business hours, to review the books and operations of the independent review organization.

(3) The independent review organization must make available during such on-site visits the following documents:

  (a) the minutes of the applicant's organizational meetings, indicating the time of each meeting and the date;

  (b) a list of and information regarding physicians and other providers to be used by the independent review organization as follows:

    (i) for physicians, indicate:

(A) medical specialty;

(B) board certification, if any;

(C) state license number;

(D) business address; and

(E) any professional association or other medical group with whom physicians are affiliated;

(ii) for other providers, indicate:

(A) address; and

(B) license or certification, if applicable;

(c) any other records concerning the operation of the independent review organization.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.11
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "On-Site Inspections by the Department" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.12. Violations by Independent Review Organizations.

(1) If the Department believes that any person conducting independent review is in violation of the Act, or these Rules, the Department shall notify the independent review organization of the alleged violation and may compel the production of any and all documents or other information as necessary to determine whether or not such violation has taken place.

(2) The Department may initiate appropriate proceedings in accordance with the Act and these Rules. Notification to the independent review organization shall be in accordance with the Georgia Administrative Procedure Act, O.C.G.A. § 50-13*et seq.*

(3) Proceedings under this article are a contested case for the purpose of O.C.G.A. § 50-13-13. The Department of Community Health shall be the party bringing any action pursuant to these Rules.

(4) If the independent Hearing Officer appointed, pursuant to the Georgia Administrative Procedure Act, determines that the independent review organization has violated or is violating any provision of the Act or these Rules, the Hearing Officer may:

(a) impose sanctions with regard to the assignment of review requests to the independent review organization;

(b) require the independent review organization to cease and desist from the action(s) found to be in violation of the Act or these Rules; and/or

(c) revoke or suspend the certification of an independent review organization.

(5) The commission of fraudulent or deceptive acts or omissions in obtaining, attempting to obtain, or use of certification or designation.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.12
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Violations by Independent Review Organizations" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.13. Fees for Independent Review.

(1) Any reviews which involve either a Medical Doctor or a Doctor of Osteopathy will be tier-one reviews with a flat fee of $ 1,500.

(2) All other type of reviews shall be tier-two reviews with a flat fee of $ 1,000.

(3) The fees referenced above shall be the flat rate for the applicable type of review, and the independent review organizations may also bill the managed care entities for their costs incurred in the review. Such costs are intended to include such items as photocopying, facsimile, postage, package delivery, and courier costs.

(4) Independent review organizations shall bill the managed care entity directly for the fees and costs of independent review.

(5) Managed Care Entities shall pay independent review organizations directly within 30 days of receipt of an invoice.

(6) Failure to Pay Invoice. Failure by a managed care entity to pay invoices from independent review organization within 30 days of receipt shall constitute a violation subject to the penalty referenced under the Act, and codified at O.C.G.A. § 33-20A-35.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.13
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Fees for Independent Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Rule 111-2-3-.14. Assignment of Requests for Independent Review.

(1) The Department shall assign each request for independent review to an independent review organization.

(2) Independent review organizations shall be added to the list from which assignments for independent review are made in order of the date of certification by the Department.

(3) Assignment shall be made chronologically from the list of independent review organizations with ultimate assignment being to the first in line with no apparent conflicts of interest.

(4) Non-selection for presence of conflicts of interest does not move the independent review organization to the bottom of the list. Such independent review organization retains its chronological position until selected for independent review.

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.14
Authority: O.C.G.A. Sec. 31-6*et seq.*
History. Original Rule entitled "Assignment of Requests for Independent Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Subject 111-2-4. RURAL HOSPITAL ASSISTANCE ACT.

Rule 111-2-4-.01. Implementation.

The Department of Community Health, Office of Rural Health Services, is authorized to issue one or more request(s) for proposals, at the discretion of the Department, to implement the Rural Hospital Assistance Act in accordance with O.C.G.A. § 31-7-94*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-2-4-.01
Authority: O.C.G.A. Secs. 31-5*et seq.*,31-7-94.
History. Original Rule entitled "Implementation" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Chapter 111-3. MEDICAL ASSISTANCE.

Subject 111-3-6. INDIGENT CARE TRUST FUND.

Rule 111-3-6-.01. Definitions.

(1) "Disproportionate share hospital" means a hospital licensed in Georgia which meets the criteria established by the Department for designation as a hospital which serves a disproportionate number of low-income patients with special needs.

(2) "Medically indigent" means a person with an income no greater than 200 percent of the federal poverty level guidelines as published by the United States Department of Health and Human Services.

(3) "Trust Fund" means the Indigent Care Trust Fund created by O.C.G.A. Title 31, Chapter 8, Article 6.

(4) "Private Hospital" means any hospital licensed in Georgia which is not a public hospital.

(5) "Public Hospital" means any hospital licensed in Georgia that is owned by the State of Georgia, a city, county, or an authority organized pursuant to the "Hospital Authorities Law," O.C.G.A. § 31-7-70*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-3-6-.01
Authority: O.C.G.A. Secs. 31-8-155, 49-4-142.
History. Original Rule entitled "Definitions" adopted. F. May 31, 2006; eff. June 20, 2006.
Amended: F. Mar. 3, 2008; eff. Mar. 23, 2008.

Rule 111-3-6-.02. Contributions and Deposited and Transferred Revenues.

(1) Contributions to the Trust Fund may be made by any person authorized to contribute to the Trust Fund pursuant to O.C.G.A. § 31-8-153. Contributions to the Trust Fund shall be irrevocable and shall not include any limitation upon use of such contributions except as permitted in this article or by the Department. Contributions shall only be used for the purposes contained in O.C.G.A. § 31-8-154.

(2) Contributions to the Trust Fund may be made within the time periods established by the Department during each calendar year. Such contributions may be deposited to the Trust Fund by means of electronic funds transfer, when pre-authorized by the Department.

(3) Hospital authorities, counties, municipalities, or other state or local public or governmental entities are authorized to deposit or transfer moneys to the Trust Fund. Transfer of these funds shall be a valid public purpose for which those funds may be expended. Such transfers shall be irrevocable and shall not include any limitation upon use of such transfer except as permitted in this article or by the Department. Transfers shall only be used for the purposes authorized by O.C.G.A. § 31-8-154.

(4) Entities authorized to deposit or transfer moneys to the Trust Fund shall execute a contract, agreement or other instrument for the purpose of facilitating such deposit or transfer. Such contracts, agreements or other instruments shall be effective for a period of no more than twelve (12) months. Violation of the terms of a contract, agreement or other instrument executed pursuant to this Rule, or the failure of an entity to execute a contract, agreement, or other instrument, may result in the withholding or recoupment of Trust Fund payment adjustments to the subject disproportionate share hospital unless remedial

action satisfactory to the Department is taken by such hospital within thirty (30) days of notice of deficiency by the Department.

(5) Contributions and revenues deposited and transferred to the Trust Fund may be made for expansions of Medicaid eligibility and services, for programs to support rural and other health care providers, primarily hospitals, who serve the medically indigent, for primary health care programs for medically indigent citizens and children of this state, or for any combination of purposes specified in this paragraph.

(6) Contributions and revenues deposited and transferred by or on behalf of a disproportionate share hospital later determined to be inappropriately so designated or which fails to meet the conditions of these Rules and the contracts, agreements, or other instruments executed pursuant to Rules 111-3-6-.02(4) and 111-3-6-.03(4)(e)14., shall be returned to the contributor, depositor, or transferor with interest earned after collection of payments made to such hospital pursuant to the provisions of these rules.

(7) Contributions, revenues, or moneys deposited and transferred by or on behalf of a disproportionate share hospital which closes during the fiscal year in which the funds are received shall be returned with interest earned pro rata to such hospital, provided that the hospital has not received a disproportionate share hospital payment for that fiscal year. Such hospital shall not be eligible for further payments during that fiscal year.

(8) All contributions, revenues, or moneys transferred or deposited to the Trust Fund and any interest earned thereon which have not been appropriated by the end of the fiscal year or which have been appropriated but have been determined to be:

(a) Void because of having been appropriated in violation of O.C.G.A. § 31-8-156;

(b) Ineligible for anticipated federal matching funds;

(c) Not contractually obligated at the end of the fiscal year for which they were appropriated;

(d) Subject to return pursuant to any rule of the Department; or

(e) Void because of violation by the Department of the terms of a contract, agreement, or other instrument executed pursuant to subsection (c) of O.C.G.A. § 31-8-155; shall be returned to the Trust Fund and refunded pro rata to the entities responsible for the deposit, transfer or contribution. The refund shall be made by the director of the Fiscal Division of the Department of Administrative Services no less than thirty (30) days following the end of the fiscal year or such a determination by the Department, as applicable.

Cite as Ga. Comp. R. & Regs. R. 111-3-6-.02
Authority: O.C.G.A. Secs. 31-8-155, 49-4-142.
History. Original Rule entitled "Contributions and Deposited and Transferred Revenues" adopted. F. May 31, 2006;

eff. June 20, 2006.

Rule 111-3-6-.03. Use of Funds.

(1) Funds appropriated by the General Assembly to the Department pursuant to O.C.G.A. § 31-8-156 shall be used for the purposes stated in Rule 111-3-6-.02(5) and shall be used to match federal funds which are available for such purposes.

(2) The Department shall provide for public notice of the manner of disbursement of the Trust Fund appropriation as provided in Rule 350-1-.02(3) and 350-2-.08. Such funds may be transferred to disproportionate share hospitals by electronic funds transfer.

(3) The Department shall issue a manual of policies and procedures and other instructions for disproportionate share hospital programs (the "Manual"), and shall adopt the Manual as an appendix to Part II of the Department's Policies and Procedures for Hospital Services. The Manual shall contain policies, procedures, instructions, public notification plan requirements, forms and other items for hospitals' use in operating their programs consistent with these Rules. The Manual shall contain a procedure for accepting and resolving complaints concerning a hospital's compliance with these Rules. The Department may approve a plan for the operation of a disproportionate share hospital to coordinate its program with an existing program of care for the medically indigent sponsored by a local government, provided that the program is operated in a manner consistent with these Rules and further provided that the program is operated in a manner consistent with these Rules and further provided that no patients are rendered ineligible for services without charge or at a reduced charge who would have been eligible if the variance had not been granted.

(4) As a condition of receipt of such funds, providers of medical assistance must:

(a) continue participation in the Medicare program;

(b) comply with the Rules and the Department's Policies and Procedures, including specifically Part II of the Department's Policies and Procedures for Hospital Services and the Manual;

(c) comply with the Department's requests for reports on the use of funds;

(d) use the funds to provide health care services to Medicaid recipients and medically indigent citizens of the state;

(e) use the funds during the fiscal year in which the payment is disbursed; and

(f) if the provider is a disproportionate share hospital, meet the following additional conditions:

1. continue participation in the Medicare program;

2. make available its services to Medicaid and Medicare recipients without discrimination;

3. continue to provide obstetrical care services if such services are presently provided;

4. comply with the patient transfer requirements provided in the Emergency Medical Treatment and Active Labor Act of 1986, as amended;

5. ensure that patients are not transferred or denied services based solely or in significant part on economic reasons;

6. make arrangements with sufficient numbers of physicians on each service to assure that Medicaid patients have full access to the facility's services without being required to pay physicians for Medicaid covered services;

7. make arrangements with physicians to ensure Medicaid and medically indigent patients are not required to have a physician with staff privileges as a condition of admission or treatment when such admission or treatment is determined to be medically necessary and within the scope of service capability of the hospital;

8. document which physicians with staff privileges accept and will treat Medicaid patients in their offices, and assist Medicaid patients with referrals to such physicians. The hospital shall encourage full provider participation in the Medicaid program;

9. ensure that preadmission deposits are not required on demand as a condition of treatment of Medicaid eligible persons or medically indigent persons;

10. for treatment of medically indigent patients, ensure that ability to pay does not act to deny or substantially delay receipt of medically necessary services. The hospital shall provide assistance to medically indigent patients by operating a program under which such patients may receive care without charge or at a reduced charge, except that no hospital shall be required to provide services without charge or at a reduced charge once the hospital's medical indigency services expenditures equals the amount described in Rule 111-3-6-.03(4)(e)12. (iii). Consistent with the Rules and the Manual, the hospital shall:

    (i) provide services for no charge to persons with incomes below 125 percent of the federal poverty level; and

(ii) provide services for no charge or adopt a sliding fee scale for persons with incomes between 125 percent and, at a minimum, 200 percent of the federal poverty level;

11. as more specifically set forth in the Manual, effectively advise the public of the hospital's participation in the program, the availability of services provided, the terms of eligibility for free and reduced charge services, the application process for free and reduced charge services, and the person or office to whom complaints or questions about the hospital's participation in or operation of the program may be directed; The hospital shall comply with such other provisions as may be reasonably established by the Department in the Manual. Upon request by the Department, the hospital shall demonstrate its compliance with the public notification requirements of this section and with the Manual.

12. submit to the Department a report on the use of Trust Fund payment adjustments each calendar year. Such reports shall:

    (i) be in a format established by the Department;

    (ii) be available to the public for examination; and

    (iii) include a report of the number of medically indigent persons served without charge in both inpatient and primary care settings and the dollars expended for such services. Hospitals shall report dollars expended using a cost-to-charges ratio of 65 percent. Over a twelve month period, each hospital will be expected to report a medical indigency services expenditure of an amount equal to no less than 100 percent of the hospital's total Trust Fund payment adjustments minus the amount transferred or deposited to the Trust Fund by or on behalf of the hospital. Failure to provide such reports in the format prescribed and within the time periods established by the Department, or to demonstrate timely accessibility to Trust Fund supported services, may result in a withholding or recoupment of Trust Fund payment adjustments.

13. sign a letter of Agreement which incorporates the provisions of these Rules, the Department's Policies and Procedures and the Manual.

14. comply with the requirements of the Certificate of Need program under the Division of Health Planning of the Department, as set forth more specifically in O.C.G.A. §§ 31-6-40*et seq.*, and the rules promulgated thereunder, and the annual reporting requirements under O.C.G.A. § 31-6-70.

(5) The Department shall annually report to the General Assembly on the use of monies appropriated to the Department from the Trust Fund. Such report shall be submitted to the Lieutenant Governor, Speaker, legislative counsel and legislative budget officer no later than January 31 of each calendar year. Such reports shall be made available to the public pursuant to Rule 111-3-6-.04.

(6) In the event that a disproportionate share hospital fails to comply with the Rules, the Department's Policies and Procedures or the Manual, the Department may, in addition to any other legal remedies available, assess liquidated damages against the disproportionate share hospital under its Letter of Agreement in an amount(s) established by the Department for each calendar day in which the hospital is non-compliant. These liquidated damages are not, and shall not be construed to be penalties, and shall be in addition to every other remedy now or hereinafter enforceable at law, in equity, by statute, or under contract.

(7) In the event that a disproportionate share hospital knowingly and willfully makes or causes to be made any false statement or misrepresentation of material fact with respect to the hospital's use of funds from the Trust Fund or in response to any request for information from the Department related to the Trust Fund, including without limitation the submission of any report required pursuant to these Rules, the Department may, in addition to any other legal remedies available, assess liquidated damages against the disproportionate share hospital under its Letter of Agreement in an amount not to exceed the disproportionate share payment for the year in which the false statement or misrepresentation occurred. These liquidated damages are not, and shall not be construed to be penalties, and shall be in addition to every other remedy now or hereinafter enforceable at law, in equity, by statute, or under contract.

(8) Disproportionate share hospital payment adjustments to private hospitals shall be funded by state general funds appropriated for this purpose, which shall be used to match federal funds available for this purpose.

(9) Disproportionate share hospital payment adjustments to public hospitals shall be funded by intergovernmental transfers or by certified public expenditures, or a combination thereof, which shall be used to match federal funds available for this purpose.

Cite as Ga. Comp. R. & Regs. R. 111-3-6-.03
Authority: O.C.G.A. Secs. 31-8-155, 49-4-142.
History. Original Rule entitled "Use of Funds" adopted. F. May 31, 2006; eff. June 20, 2006.
Amended: F. Mar. 3, 2008; eff. Mar. 23, 2008.

Rule 111-3-6-.04. Open Records.

All Department records related to the Indigent Care Trust Fund shall be open for public inspection in accordance with the Open Records Act, O.C.G.A. § 50-18-70*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-3-6-.04
Authority: O.C.G.A. Sec. 31-6.
History. Original Rule entitled "Open Records" adopted. F. May 31, 2006; eff. June 20, 2006.

Rule 111-3-6-.05. Applicability of Medical Assistance Generally.

Except where inconsistent with O.C.G.A., Title 31, Chapter 4 8, Articles 6, 6A, and 6B (Indigent Care Trust Fund), the provisions of O.C.G.A., Title 49, Chapter 4, Article 7 (Georgia Medical Assistance Act of 1977) shall apply to the Department in carrying out the purposes of the Trust Fund.

Cite as Ga. Comp. R. & Regs. R. 111-3-6-.05
Authority: O.C.G.A. Sec. 31-6.
History. Original Rule entitled "Applicability of Medical Assistance Generally" adopted. F. May 31, 2006; eff. June 20, 2006.

Subject 111-3-8. ESTATE RECOVERY.

Rule 111-3-8-.01. Legal Authority.

In accordance with Title XIX of the Social Security Act, 42 U.S.C. § 1396p, the State of Georgia has defined a process to recover the cost of medical assistance payments from the estates of deceased Members. The Official Code of Georgia gives the state the authority to recover these monies. O.C.G.A. § 49-4-147.1. In addition, the recovery methodology must adhere to statutory provisions of the Georgia Revised Probate Code of 1998, O.C.G.A. Title 53.

Cite as Ga. Comp. R. & Regs. R. 111-3-8-.01
Authority: O.C.G.A. § 49-4-147.1.
History. Original Rule entitled "Legal Authority" adopted. F. July 16, 2004; eff. August 5, 2004.
Amended: F. Aug. 17, 2004; eff. Sept. 6, 2004.
Amended: F. Oct. 19, 2006; eff. Nov. 8, 2006.
Amended: F. Mar. 27, 2020; eff. Apr. 16, 2020.

Rule 111-3-8-.02. Definitions.

(1) "Authorized representative" means a guardian or a person designated by the Member to act on his or her behalf during the Member's life.

(2) "Creditor" means an entity (person or institution) to whom an obligation is owed because a Member received something of value in exchange.

(3) "Debt" means a sum of money owed from one person to another, including the right of the creditor to receive and enforce payment.

(4) "Department" means the Georgia Department of Community Health, Division of Medical Assistance.

(5) "Discharge from the medical institution and return home" means a qualifying discharge, which involves the Member's dismissal from the nursing institution and/or facility for at least thirty (30) days wherein the Member's personal effects and bed are released at the same time of his or her discharge.

(6) "Equity interest in the home" means value of the property in which the Member holds legal interest beyond the amount owed on it in mortgages and liens.

(7) "Estate" means all real and personal property under the probate code, including real and personal property passing by reason of joint tenancy, right of survivorship, life estate, survivorship, trust, annuity, Individual Retirement Accounts, homestead or any other arrangement. Estate also includes excess funds from a burial trust or contract, promissory notes, cash, and personal property. Estates with a gross value of $25,000 or less are exempt from estate recovery.

(8) "Hearing" means a formal proceeding before an Administrative Law Judge or Probate Judge in which an aggrieved party affected by an action or an intended action of the Department shall be allowed to present testimony, documentary evidence, and argument as to why such action should or should not be taken.

(9) "Heirs" means heirs-at-law who are entitled under the statutes of intestate succession to property of a decedent and beneficiaries who are entitled to inherit the estate if there is a lawful will.

(10) "Lawfully residing" means permissive use by the owner/power of attorney at the law.

(11) "Lien" means a claim, encumbrance or charge against the Medicaid Member's real or personal property on account of medical assistance paid to the Member correctly under the State Plan. A Lien may be placed on the real property of a Member who is an inpatient of a nursing facility, intermediate care facility for individuals with intellectual disabilities, or other institution or a Lien may be placed on both real and personal property of a Member after the Member's death.

(12) "Long-term care" means a service provided in a long-term care facility or in the home, pursuant to federally approved home and community based services, as an alternative to institutionalization.

(13) "Medical assistance" means payment by the State's program under Title XIX of the Social Security Act or Medicaid program administered by the Department.

(14) "Member" means a person who has been certified as Medicaid eligible, pursuant to the terms of the State Plan, to have medical assistance paid on his or her behalf.

(15) "Member's home" means a true, fixed and permanent domicile and principal establishment to which the Member has the intention of returning to whenever absent.

(16) "Permanently institutionalized" means residing in a nursing facility or intermediate care facility for individuals with intellectual disabilities and developmentally disabled for six (6) consecutive months or more.

(17) "Personal representative" means an executor, administrator, guardian, conservator, committee, trustee, fiduciary, or other person having a status which by operation of law or written instrument confers upon such person a duty of distributing property to Heirs.

(18) "On a continuous basis" means that the qualifying relative lived with the Member in the Member's home at his or her principal place of residence during an uninterrupted timeframe. An absence of residence greater than six months is presumed to disrupt the continuity of residence.

(19) "Residing in the home for at least one or two years" means one is domiciled in the principal place of residence.

(20) "State Plan" means all documentation submitted by the Commissioner, on behalf of the Department, to and for approval by the Secretary of Health and Human Services pursuant to Title XIX of the federal Social Security Act of 1935, as amended.

Cite as Ga. Comp. R. & Regs. R. 111-3-8-.02
Authority: O.C.G.A. § 49-4-147.1.
History. Original Rule entitled "Definitions" adopted. F. July 16, 2004; eff. August 5, 2004.
Amended: F. Aug. 17, 2004; eff. Sept. 6, 2004.
Amended: F. Oct. 19, 2006; eff. Nov. 8, 2006.
Amended: F. Mar. 27, 2020; eff. Apr. 16, 2020.

Rule 111-3-8-.03. Notification to Member or Their Heirs.

(1) If a debt is due pursuant to this section from the estate of a Member, the administrator of the nursing facility, intermediate care facility for individuals with intellectual disabilities, or medical institution in which the Member resided at the time of their death, the Medicaid case manager for community based services and/or the personal representative, if applicable, shall report the death to the Department within thirty (30) days of the death of the Member.

(2) If the personal representative of an estate makes a distribution either in whole or in part of the property of an estate to the Heirs, next of kin, distributes, legatees, or devisees without having executed the obligations pursuant to this section, the personal representative may be held personally liable for the amount of medical assistance paid on behalf of the Member, for the full value of the property belonging to the estate which may have been in the custody or control of the personal representative.

(3) When the Department receives notification of an affected Medicaid Member's death, a written notice will be provided to any known personal representative and any known Heirs which:

(a) Explains the terms and conditions of estate recovery and refers to the applicable statute and regulations;

(b) Advises of the Department's intent to recover the value of Medicaid benefits correctly paid on the Member's behalf from the Member's estate and states the amount;

(c) Explains that the Department's recovery action may include filing a lien on real property when recovery is delayed;

(d) Explains that the Heirs may file an undue hardship waiver and the procedures and time frames for filing the waiver;

(e) Advises the Heirs of their right to a hearing and the method by which they may obtain a hearing; and

(f) Includes a statement advising the amount of the claim may increase if there are additional Medicaid claims that have not yet been processed.

Cite as Ga. Comp. R. & Regs. R. 111-3-8-.03
Authority: O.C.G.A § 49-4-147.1.
History. Original Rule entitled "Notification to Member or Their Heirs" adopted. F. July 16, 2004; eff. August 5, 2004.
Amended: F. Aug. 17, 2004; eff. Sept. 6, 2004.
Amended: F. Oct. 19, 2006; eff. Nov. 8, 2006.
Amended: F. Mar. 27, 2020; eff. Apr. 16, 2020.

Rule 111-3-8-.04. Recovery for Payments Made on Behalf of Medicaid-Eligible Persons.

(1) These regulations shall be construed and applied to further the intent of the Legislature to supplement Medicaid funds that are used to provide medical services to eligible persons. Estate recovery shall be accomplished by the Department or its agent filing a statement of claim against the estate or with the closest identifiable surviving family members of a deceased Medicaid Member or any person who has an interest in property of the deceased member. Recovery shall be made pursuant to federal authority in § 13612 of the Omnibus Budget Reconciliation Act of 1993 which amends § 1917(b)(1) of the Social Security Act, 42 U.S.C. 1396p(b)(1).

(2) Adjustment or recovery for all medical assistance and/or services pursuant to the State Plan will be from Medicaid Members:

(a) Who, at the time of death, were any age and an inpatient in a nursing facility, intermediate care facility for individuals with intellectual disability, or other medical institution if the Member is required, as a condition of receiving services in the facility under the State Plan, to spend for costs of medical care all but a minimal amount of the person's income required for personal needs; or

(b) Who, at the time of death, were fifty-five (55) years of age or older when the Member received medical assistance, but only for medical services consisting of nursing facility services, personal care services, home and community based services, and hospital and prescription drug services provided to Members in nursing facilities or receiving home and community based services.

(3) The Department shall provide written notice of the Estate Recovery program to Members at the time of application for medical assistance and the Members must sign a written acknowledgement of receipt of such notice. Notice will be given to Members thereafter at the annual redetermination. Members currently receiving medical assistance prior to the Estate Recovery program's effective date set forth in Paragraph (17) of this Rule will be notified at his or her annual redetermination. A notification by the Medicaid Eligibility Systems that the notice was sent and acknowledged by the Member and the Member's personal representative by U.S. mail or electronic means of communication for those who have elected to receive electronic communications to the last known address of the Member or the Member's personal representative shall be deemed to satisfy this notice requirement.

(4) The acceptance of public medical assistance, as defined by Title XIX of the Social Security Act, including mandatory and optional supplemental payments under the Social Security Act, shall create a debt to the agency in the amount recoverable under the State Plan. The Department shall be given priority status, upon filing a statement of claim in the estate proceeding if an estate proceeding has been filed. In addition, priority status attaches to the Department's interest regardless whether an estate proceeding has been initiated.

(5) The Department may amend the claim as a matter of right until the Member's estate has been closed.

(6) The Department's provider processing reports shall be admissible as prima facie evidence in substantiating the agency's claim.

(7) Any trust provision that denies recovery for medical assistance is void on and after the time of its making.

(8) Adjustment or recovery of debt will be made only after the death of the Member's surviving spouse, if any, and only at a time when the Member has no surviving child who is under the age of twenty-one (21), or a child who is blind or permanently and totally disabled pursuant to the eligibility requirements of Title XIX of the Social Security Act.

(9) With respect to a lien placed on the home of a permanently institutionalized Member, the Department will not seek adjustment or recovery of Medical assistance correctly paid on behalf of the Member until the following persons are not residing in the Member's home:

(a) A sibling of the Member with an equity interest in the home who was residing in the Member's home for at least one (1) year on a continuous basis immediately before the date that the Member was institutionalized; and

(b) A child of the Member who was residing in the Member's home for at least two (2) years on a continuous basis before the date that the Member was institutionalized and who has established to the satisfaction of the Department that he or she provided care that permitted the Member to reside at home rather than to become institutionalized.

(10) The sibling or child of the Member must demonstrate that he or she has been lawfully residing in the Member's home on a continuous basis for the periods described in Paragraphs (9)(a) and (b) respectively, since the date of the Member's admission to the medical institution, and must provide the Department with clear and convincing evidence to prove residency which may include, but not be limited to, receipts, mortgage statements, bills, mail forwarded to Member's address, or voter's registration. The sibling or child of the Member must demonstrate that he or she did not reside in any other residence except the Member's home during the periods of time set forth in Paragraphs (9)(a) and (b) respectively. The sibling or child shall maintain the burden of proof in all proceedings.

(11) No debt under this section shall be enforced against any property that is determined to be exempt from the claims of creditors under the constitution or laws of this state.

(12) The Department may delay or waive recovery from an estate if doing so would cause undue hardship for the qualified Heirs, as defined in Rule 111-3-8-.08. The personal representative of an estate and any Heir may request that the agency waive recovery.

(13) The state's right to full reimbursement of the costs of medical assistance shall not be diminished by the recovery of any judgment, settlement, or award of an amount less than the value of the original or settled claim. To enforce its rights, the state may intervene or join in any action or proceeding brought by a claimant against a third party. To aid in the recovery of the cost of medical assistance, the state shall have a first lien in the full amount of the costs of medical assistance against the proceeds from all damages awarded in a suit or settlement.

(14) Transfers of real or personal property, on or after the look-back dates defined in 42 U.S.C. § 1396p, by a Member of such aid, or by their spouse, without adequate consideration are voidable and may be set aside by an action in court.

(15) Counsel fees, costs, or other expenses shall not reduce any third party recovery obtained by the state incurred by the Member or the Member's attorney.

(16) If, after the reported death of the Member, the Department is prohibited from Estate Recovery because of exemption conditions, the Department may postpone recovery until all exemption conditions are no longer present. An estate does not have to be open in order for the Department to execute its claim after all exemption conditions are no longer present. Termination of recovery will occur when all real and personal property included as part of the Member's estate is no longer accessible due to all estate property having been depleted through payment of costs of medical care for the Member and the Member's spouse.

(17) The effective date of the Medicaid Estate Recovery Program is May 3, 2006. Adjustment or recovery shall apply to those costs associated with medical assistance and/or services a Member received on or after the effective date.

(18) To prevent substantial and unreasonable hardship, the Commissioner shall waive any claim against the first $25,000.00 of any estate subject to an Estate Recovery claim for the deceased Medicaid Member with a date of death on or after July 1, 2018.

Cite as Ga. Comp. R. & Regs. R. 111-3-8-.04
Authority: O.C.G.A. § 49-4-147.1, 42 U.S.C. 1396p.
History. Original Rule entitled "Recovery for Payments Made on Behalf of Medicaid-Eligible Persons" adopted. F. July 16, 2004; eff. August 5, 2004.
Amended: F. Aug. 17, 2004; eff. Sept. 6, 2004.
Amended: F. Oct. 19, 2006; eff. Nov. 8, 2006.
Amended: F. Mar. 27, 2020; eff. Apr. 16, 2020.

Rule 111-3-8-.05. Recovery of Assistance; Probate.

(1) After receipt of notice of the death of an affected Member, the Department will file a claim against the estate for the full value of the Medicaid benefits paid on behalf of the Member.

(2) No action to recover a debt due by the deceased Member shall be commenced against the personal representative until the expiration of six (6) months from the date of qualification of the first personal representative to serve.

(3) Notwithstanding any other law, a claim filed for recovery of Medicaid assistance has priority in order of payment from the estate over all other claims, except the following:

(a) Years support for the family;

(b) Funeral expenses in an amount not to exceed ten thousand dollars ($10,000). However, this amount is zero (0) if the deceased Member has prepaid funeral expenses that were excluded as a resource for Medicaid eligibility;

(c) Necessary expenses of administration;

(d) Reasonable expenses of the deceased Member's last illness; and

(e) Unpaid taxes or other debts due the state or the United States. The category of Medicaid Estate Recovery is a debt due the state.

(4) The affidavit of a person designated by the Commissioner to administer this action is prima facie evidence of the amount of the claim.

(5) Notwithstanding any statute of limitations or other claim presentation deadline provided by law, a state claim against an estate is not barred for lack of timely presentation if it is presented in the probate proceeding within the time specified in the published notice to creditors.

(6) The personal representative must notify the Department in writing at 2 Peachtree St. N.W. 5th Floor Atlanta, Georgia 30303 of the Member's death at least thirty (30) days before disbursing assets of the Member and shall not disburse assets prior to obtaining a release from the Department. The personal representative is personally liable for any incorrectly paid assets if the Department is not informed of the Member's death and assets are distributed to Heirs and/or creditors without having first obtained a release from the Department. The Department shall issue a release within ten (10) business days from the satisfaction of the claim with the Department.

Cite as Ga. Comp. R. & Regs. R. 111-3-8-.05
Authority: O.C.G.A. §§ 49-4-147.1, 53-7-42.
History. Original Rule entitled "Recovery of Assistance; Probate" adopted. F. July 16, 2004; eff. August 5, 2004.
Amended: F. Oct. 19, 2006; eff. Nov. 8, 2006.
Amended: F. Mar. 27, 2020; eff. Apr. 16, 2020.

Rule 111-3-8-.06. Recovery of Assistance; No Estate.

(1) The administrator of the program may present an affidavit to a financial institution requesting that the financial institution release account proceeds to recover the cost of services correctly provided to a Member. The affidavit shall include the following information:

(a) The name of the deceased Member;

(b) The name of any person who gave notice that the Member was a Medicaid Member and that person's relationship to the deceased Member;

(c) The name of the financial institution;

(d) The account number;

(e) A description of the claim for estate recovery; and

(f) The amount of funds to be recovered.

(2) A financial institution shall release account proceeds to the administrator of the program if all of the following conditions apply;

(a) The deceased Member held an account at the financial institution that was in his or her name only;

(b) No estate has been, and it is reasonable to assume that no estate will be, opened for the deceased Member;

(c) The deceased Member has no outstanding debts known to the administrator of the program; and

(d) The financial institution has received no objections or has determined that no valid objections to release proceeds have been received.

(3) If proceeds have been released pursuant to this section and the Department receives notice of a valid claim to the proceeds that has a higher priority under O.C.G.A. 53-7-40 than the claim of this section, the Department may refund the proceeds to the financial institution or pay them to the person or government entity with the claim.

Cite as Ga. Comp. R. & Regs. R. 111-3-8-.06
Authority: O.C.G.A. §§ 49-4-147.1, 53-7-40.
History. Original Rule entitled "Recovery of Assistance; No Estate" adopted. F. July 16, 2004; eff. August 5, 2004.
Amended: F. Oct. 19, 2006; eff. Nov. 8, 2006.
Amended: F. Mar. 27, 2020; eff. Apr. 16, 2020.

Rule 111-3-8-.07. Imposition of Liens.

(1) The basis for authority to impose liens is based on the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). The TEFRA lien law provides that the agency can place a Lien on the available real estate of a Member who enters a nursing home and is "permanently institutionalized."

(2) The state may place a Lien on the Member's home when there is not a reasonable expectation that the Member will return home and when none of the following persons are living in the home:

(a) The Member's spouse;

(b) A child under twenty-one (21) years of age;

(c) A disabled child of any age; or

(d) A sibling with an equity interest in the home who has lived in the home for at least one (1) year before the Member entered the nursing home, and is lawfully residing in such home. The sibling must provide the State with clear and convincing evidence which demonstrates residency on a continuous basis and the sibling's equity interest. Additionally, the sibling must demonstrate that he or she did not reside in any other residence except the Member's home during the period of time specified in this subparagraph (2)(d). The sibling has the burden of proof in all proceedings.

(3) Liens may be imposed to protect recovery of benefits correctly paid to Medicaid Members when permitted by federal and state law. However, the use of lien authority requires prior notification to the Member or any known Heirs.

(4) The Department shall notify the Member and the authorized representative, if applicable, of its determination that the Member is permanently institutionalized and not reasonably expected to return home and its intent to file a Lien on Member's real property. Notice must include an explanation of liens and their effect on a Member's ownership of real property. A Lien may not be filed less than thirty-one (31) days from the date of the notice to the Member and after any hearing process has been completed, if a hearing is requested.

(5) A Member or his or her authorized representative may, within thirty (30) days after receipt of notice request an administrative hearing under this Rule 111-3-8-.07. A Member is deemed to have received notice within five (5) days from the date of the notice. Administrative hearings and appeals for Medicaid Members are governed by the procedures and time limits set forth in 42 C.F.R. § 431.200*et seq*. Only one (1) appeal shall be afforded on behalf of a Member, for each notice received. The administrative law judge shall make the determination if a Member can or cannot reasonably be expected to be discharged from the medical institution and returned home or if a specific exception set forth in 111-3-8-.07(2) applies.

(6) The Department or its agent shall file a notice of Lien with the recorder of the county in which the real property subject to the Lien is located. The notice shall be filed prior to the Member's death and shall include the following:

(a) Name and place of residence, including the street and county in which the property is located, of the real property subject to the Lien; or

(b) Legal description of the real property subject to the Lien.

(7) The Department shall file one (1) copy of the notice of Lien with the local DFCS office in the county in which the real property is located. The county in which the real property is located shall retain a copy of the notice with the county office's records. The Department or its agent shall provide one (1) copy of the notice of Lien to the Member and the Member's authorized representative, if applicable, whose real property is affected.

(8) The Lien continues from the date of filing until the Lien is satisfied, released or expires. From the date on which the notice of Lien is recorded in the office of the county recorder, the notice of lien:

(a) Constitutes due notice against the Member or Member's estate for any amount then recoverable under this article; and

(b) Gives a specific Lien in favor of the Department on the Medicaid Member's interest in the real property.

(9) The Department has the authority to release any lien placed upon the property of a Member deemed permanently institutionalized should that Member be subject to a discharge from a medical institution and return home. The Department shall release a lien obtained under this rule within thirty (30) days after the Department receives notice that the Member is no longer institutionalized and is living in his or her home. If the real property subject to the lien is sold, the office shall release its lien at the closing and the lien shall attach to the net proceeds of the sale.

Cite as Ga. Comp. R. & Regs. R. 111-3-8-.07
Authority: O.C.G.A. § 49-4-147.1, Ga. Comp. Rules & Regs., R. 290-1-1-.01.
History. Original Rule entitled "Imposition of Liens" adopted. F. July 16, 2004; eff. August 5, 2004.
Amended: F. Sept. 15, 2005; eff. Oct. 5, 2005.
Amended: F. Oct. 19, 2006; eff. Nov. 8, 2006.
Amended: F. Mar. 27, 2020; eff. Apr. 16, 2020.

Rule 111-3-8-.08. Hardship Waiver.

(1) Hardship waivers will be submitted to the program administrator for review. The denial of a hardship waiver may be appealed as provided under the Administrative Procedures Act, O.C.G.A. § 50-13-1 et. seq. The waiver is limited to the period in which the undue hardship exists.

(2) There is no hardship waiver provided at the time of lien placement against the real property of a deceased Medicaid Member. The equity interest of the heir will be considered to determine the percentage of the deceased member's interest in the property.

(3) Lien placement is utilized to delay recovery until such time as an exemption to recovery does not exist, or in the case of an undue hardship, until such time as the undue hardship no longer exists. The state's lien would be for the Medicaid benefits paid on behalf of the Member or the percentage of interest of the deceased Member at the time of sale, whichever is less.

(4) Recovery will be waived in whole or in part pursuant to Rule 111-3-8-.08(1) of any estate or lien recovery when the requesting party is able to show, through clear and convincing

evidence, that the state's pursuit of recovery subjects them to undue hardship. In determining whether an undue hardship exists, the following criteria will be used:

(a) The asset to be recovered is an income producing farm and sole income source of one or more of the Heirs and the annual gross income is limited to $25,000 or less and is not merely rental income; or

(b) The recovery of assets would cause the applicant to become eligible for needs based governmental public assistance based on need and/or medical assistance programs.

(5) Notwithstanding the provisions of Paragraph (4) of this Rule, an undue hardship exists when an estate has a gross value of $25,000 or less. Therefore, estates with a gross value of $25,000 or less are exempt from estate recovery. In this instance, undue hardship does not need to be asserted.

(6) Undue hardship does not exist when:

(a) The adjustment or recovery of the Member's cost of assistance would merely cause the Member's family members inconvenience or restrict the family's lifestyle; or

(b) The Member and/or the Heirs divest assets to qualify under the undue hardship provision.

(7) To the extent that there is any conflict between the preceding criteria and the standards that may be specified by the secretary of the U.S. Department of Health and Human Services, the federal standards shall prevail.

(8) The personal representative and/or Heirs shall apply for an undue hardship exemption by:

(a) Making a written request to the Department within thirty (30) days of receipt of the notice; and

(b) Verifying to the Department's satisfaction the criteria specified in this section for an undue hardship waiver.

(9) The Department shall issue a decision on an undue hardship exemption request within thirty (30) days of receipt of the request and supporting documentation.

(10) If the state denies the personal representative's request for an undue hardship waiver, the personal representative may request an appeal. The denial of a waiver must state the requirements of an application for an adjudicative proceeding to contest the Department's decision to deny the waiver and where assistance may be obtained to make such application.

(11) If an appeal is requested, a hearing shall be conducted by the probate judge if the estate is in probate court. An administrative law judge shall conduct the administrative hearing if the case is not in probate court.

(12) If the Department deems an undue hardship does exist, the state may waive recovery or defer recovery until the death of eligible exempt dependents, on the sole discretion of the Department.

(13) The provisions of this section are severable. If any provision of this section is held invalid, the remaining provisions remain in effect.

Cite as Ga. Comp. R. & Regs. R. 111-3-8-.08
Authority: O.C.G.A. § 49-4-147.1.
History. Original Rule entitled "Hardship Waiver" adopted. F. July 16, 2004; eff. August 5, 2004.
Amended: F. Aug. 17, 2004; eff. Sept. 6, 2004.
Amended: F. Oct. 19, 2006; eff. Nov. 8, 2006.
Amended: F. Mar. 27, 2020; eff. Apr. 16, 2020.

Subject 111-3-9. HOSPITAL PROVIDER PAYMENT PROGRAM.

Rule 111-3-9-.01. Definitions.

As used in Chapter 111-3-9:

(1) "Board" means the Board of Community Health, the body created under O.C.G.A. § 31-2-3, appointed by the Governor, that establishes the general policy to be followed by the Department of Community Health.

(2) "Department" means the Department of Community Health established under O.C.G.A. § 31-2-1.

(3) "Hospital" means an institution licensed pursuant to Chapter 7 of Title 31, which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. Such term includes public, private, rehabilitative, geriatric, osteopathic, and other specialty hospitals but shall not include psychiatric hospitals, which shall of O.C.G.A. § 37-3-1, critical access hospitals as defined in paragraph (3) of O.C.G.A. § 33-21A-2, or any state owned or state operated hospitals.

(4) "Net Patient Revenue" means the total gross patient revenue of a Hospital less contractual adjustments; charity care; bad debt; Hill-Burton commitments; indigent care as defined by and calculated in the Department's annual Hospital Financial Survey; and gross patient revenues and contractual adjustments realized pursuant to section 1902(a)(10)(A)(i)(VIII) of the Social Security Act.

(5) "Provider Payment" means a payment assessed by the Department pursuant to this Chapter for the privilege of operating a Hospital.

(6) "Segregated Account" means an account for the dedication and deposit of Provider Payments which is established within the Trust Fund.

(7) "State Plan Amendment" means all documentation submitted by the Commissioner, on behalf of the Department, to and for approval by the Secretary of Health and Human Services pursuant to Title XIX of the federal Social Security Act of 1935, as amended.

(8) "Trauma Center" means a Hospital designated by the Department of Public Health as a Level I, II, III or IV Trauma Center.

(9) "Trust Fund" means the Indigent Care Trust Fund created by Article 6 of Chapter 8 of Title 31.

(10) "Waiver" means a waiver of the requirements for permissible health care related taxes, as provided for in 42 C.F.R. § 433.68.

Cite as Ga. Comp. R. & Regs. R. 111-3-9-.01
Authority: Act I of the 2013 Session of the Georgia General Assembly.
History. Original Rule entitled "Definitions" adopted. F. May 13, 2013; eff. June 2, 2013.

Rule 111-3-9-.02. Payments to the Segregated Account.

(1) There is established within the Trust Fund a Segregated Account for revenues raised through the imposition of the Provider Payment. Any Provider Payment assessed pursuant to this Chapter shall be deposited into the Segregated Account. No other funds shall be deposited into the Segregated Account. All funds shall be invested in the same manner as authorized for investing other moneys in the state treasury.

(2) Each Hospital shall be assessed a Provider Payment in the amount of 1.45 percent of the Net Patient Revenue of the Hospital; provided, however, that Trauma Centers shall be assessed a Provider Payment in the amount of 1.40 percent of the Net Patient Revenue of the Trauma Center.

(3) The Provider Payment shall be paid quarterly by each Hospital to the Department. The assessment shall be based on the Department's annual Hospital Financial Survey. Payment of the Provider Payment shall be due on the last day of the last month of each calendar quarter; the first payment shall be due on September 30, 2013 or 30 calendar days after the receipt of State Plan Amendment approval, whichever is later.

(4) The Department shall prepare and distribute a form on which each Hospital shall submit information to comply with this Chapter.

(5) Each Hospital shall keep and preserve for a period of seven (7) years such books and records as may be necessary to determine the amount for which it is liable under this Chapter. The Department shall have the authority to inspect and copy the records of a Hospital for purposes of auditing the calculation of the Provider Payment. All information obtained by the Department pursuant to this Chapter shall be confidential and shall not constitute a public record.

(6) The Department shall impose a penalty of up to six percent (6%) for any Hospital that fails to pay a Provider Payment within the time required by the Department for each month or fraction thereof that the Provider Payment is overdue. If a required Provider Payment has not been received by the Department by the last day of the last month of the calendar quarter, the Department shall withhold an amount equal to the Provider Payment and penalty owed from any medical assistance payment due such Hospital under the Medicaid program. Any Provider Payment assessed pursuant to this Chapter shall constitute a debt due the state and may be collected by civil action and the filing of tax liens in addition to such methods provided for in this Chapter. Any penalty that accrues pursuant to this Rule shall be credited to the Segregated Account.

(7) In the event the Department determines that a Hospital has underpaid the Provider Payment, the Department shall notify the Hospital of the balance of the Provider Payment that is due. Such payment shall be due within thirty (30) days of the Department's notice.

(8) The Provider Payment imposed under this Chapter shall be recognized by the Department as a form of expenditure for indigent or charity care under any agreement by a Hospital to provide a specified amount of clinical health services to indigent patients pursuant to subsection (c) of O.C.G.A. § 31-6-40.1 and may be considered a community benefit for purposes of any required or voluntary community benefit report filed or prepared by a Hospital; provided, however, that the Provider Payment shall not be considered charity or indigent care for purposes of calculating Net Patient Revenue pursuant to this Chapter.

Cite as Ga. Comp. R. & Regs. R. 111-3-9-.02
Authority: Act I of the 2013 Session of the Georgia General Assembly.
History. Original Rule entitled "Payments to the Segregated Account" adopted. F. May 13, 2013; eff. June 2, 2013.

Rule 111-3-9-.03. Use of Provider Payments.

(1) The Department shall collect the Provider Payments imposed pursuant to this Chapter. All revenues raised pursuant to this Chapter shall be deposited into the Segregated Account. Such funds shall be dedicated and used for the sole purpose of obtaining federal financial participation for medical assistance payments to Hospitals and other providers on behalf of Medicaid recipients pursuant to Article 7 of Chapter 4 of Title 49.

(2) Revenues appropriated to the Department by the General Assembly pursuant to Article 6C of Chapter 8 of Title 31 shall be used to match federal funds that are available for the purpose for which such funds have been appropriated.

(3) In recognition of the Provider Payments made by Hospitals pursuant to this Chapter, the Department shall add 11.88 percent to hospital inpatient base rates, capital add-on rates, graduate medical education add-on rates, outlier per case payments and outpatient payment rates.

(4) The Department may conduct an annual review of the percentage defined in paragraph 3 and may make prospective adjustments to such percentage to ensure the amount of the add-on payments to Hospitals are substantially equivalent in the aggregate to the total amount of Provider Payments made by Hospitals pursuant to this Chapter.

Cite as Ga. Comp. R. & Regs. R. 111-3-9-.03
Authority: Act I of the 2013 Session of the Georgia General Assembly.
History. Original Rule entitled "Use of Provider Payments" adopted. F. May 13, 2013; eff. June 2, 2013.

Rule 111-3-9-.04. Effective Date.

Upon the adoption by the Board, Chapter 111-3-9 shall become effective on July 1, 2013.

Cite as Ga. Comp. R. & Regs. R. 111-3-9-.04
Authority: Act I of the 2013 Session of the Georgia General Assembly.
History. Original Rule entitled "Effective Date" adopted. F. May 13, 2013; eff. June 2, 2013.

Subject 111-3-10. HOSPITAL MEDICAID FINANCING PROGRAM.

Rule 111-3-10-.01. Definitions.

As used in this Chapter 111-3-10:

(1) "Advisory Committee" means the Georgia Hospital Medicaid Financial Program Advisory Committee created by Executive Order executed by the Governor on March 5, 2013.

(2) "Board" means the Board of Community Health, the body created under O.C.G.A. § 31-2-3, appointed by the Governor, that establishes the general policy to be followed by the Department of Community Health.

(3) "Department" means the Department of Community Health established under O.C.G.A. § 31-2-1.

(4) "Hospital" means an institution license pursuant to Chapter 7 of Title 31, which is Primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. Such term includes public, private, rehabilitative, geriatric, osteopathic, and other specialty hospitals but shall not include psychiatric hospitals, which shall have the same meaning as facilities as defined in paragraph (7) of O.C.G.A. § 37-3-1, critical assess hospitals as defined in paragraph (3) of O.C.G.A. § 33-21A-2, or any state owned or state operated hospitals.

(5) "Long Term Acute Care Hospital" means a hospital defined in section 1886(d)(1)(B)(iv) of the Social Security Act that is enrolled in the Medicaid program as of the effective date of Article 6C of Chapter 8 of Title 31.

(6) "Non-Governmental Hospital" means a subclass of Hospitals, authorized to be defined by the Board pursuant to paragraph (a) of O.C.G.A. § 31-8-179.2, that shall not include public, Long Term Acute Care, children's, rehabilitative, geriatric, osteopathic, and other specialty hospitals, psychiatric hospitals which shall have the same meaning as facilities as defined in paragraph (7) of O.C.G.A. § 37-3-1, critical assess hospitals as defined in paragraph (3) of O.C.G.A. § 33-21A-2, or any state owned or state operated hospitals.

(7) "Provider Payment" means a payment assessed by the Department pursuant to this chapter for the privilege of operating a Non-Governmental Hospital.

(8) "Segregated Account" means an account for the dedication and deposit of Provider Payments which is established within the Trust Fund.

(9) "State Plan Amendment" means all documentation submitted by the Commissioner, on behalf of the Department, to and for approval by the Secretary of Health and Human Services pursuant to Title XIX of the federal Social Security Act of 1935, as amended.

(10) "Trust Fund" means the Indigent Care Trust Fund created by Article 6 of Chapter 8 of Title 31.

(11) "Waiver" means a waiver of the requirements for permissible health care related taxes, as provided for in 42 C.F.R § 433.68.

Cite as Ga. Comp. R. & Regs. R. 111-3-10-.01
Authority: Act I of the 2013 Session of the Georgia General Assembly.
History. Original Rule entitled "Definitions" adopted. F. May 13, 2013; eff. June 2, 2013.

Rule 111-3-10-.02. Payments to the Segregated Account.

(1) There is established within the Trust Fund a Segregated Account for revenues raised through the imposition of the Provider Payment. Any Provider Payment assessed

pursuant to this Chapter shall be deposited into the Segregated Account. No other funds shall be deposited into the Segregated Account. All funds shall be invested in the same manner as authorized for investing other moneys in the state treasury.

(2) Each Non-Governmental Hospital shall be assessed a Provider Payment not to exceed the amount necessary to obtain federal financial participation for medical assistance payments allowable under 42 C.F.R. § 447.272 and 42 C.F.R. § 447.321. The amount of each Non-Governmental Hospital's Provider Payment shall be determined by the Department using available hospital financial data and other information as applicable, including, but not limited to, hospital cost reports and the annual Hospital Financial Survey. The Department shall seek any Waivers and State Plan Amendments necessary to fully implement this Chapter.

(3) The Provider Payment shall be paid quarterly by each Non-Governmental Hospital to the Department. Payment of the Provider Payment shall be due on the last day of the last month of each calendar quarter; the first payment shall be due on September 30, 2013 or 30 calendar days after the receipt of State Plan Amendment approval, whichever is later.

(4) The Department shall prepare and distribute a form on which each Non-Governmental Hospital shall submit information to comply with this Chapter.

(5) Each Non-Governmental Hospital shall keep and preserve for a period of seven (7) years such books and records as may be necessary to determine the amount for which it is liable under this Chapter. The Department shall have the authority to inspect and copy the records of a Non-Governmental Hospital for purposes of auditing the calculation of the Provider Payment. All information obtained by the Department pursuant to this Chapter shall be confidential and shall not constitute a public record.

(6) The Department shall impose a penalty of up to six percent (6%) for any Non-Governmental Hospital that fails to pay a Provider Payment within the time required by the Department for each month or fraction thereof that the Provider Payment is overdue. If a required Provider Payment has not been received by the Department by the last day of the last month of the calendar quarter, the Department shall withhold an amount equal to the Provider Payment and penalty owed from any medical assistance payment due such Non-Governmental Hospital under the Medicaid program. Any Provider Payment assessed pursuant to this Chapter shall constitute a debt due the state and may be collected by civil action and the filing of tax liens in addition to such methods provided for in this Chapter. Any penalty that accrues pursuant to this Rule shall be credited to the Segregated Account.

(7) In the event the Department determines that a Non-Governmental Hospital has underpaid the Provider Payment, the Department shall notify the Non-Governmental Hospital of the balance of the Provider Payment that is due. Such payment shall be due within thirty (30) days of the Department's notice.

Cite as Ga. Comp. R. & Regs. R. 111-3-10-.02
Authority: Act I of the 2013 Session of the Georgia General Assembly.

History. Original Rule entitled "Payments to the Segregated Account" adopted. F. May 13, 2013; eff. June 2, 2013.

Rule 111-3-10-.03. Use of Provider Payments.

(1) The Department shall collect the Provider Payments imposed pursuant to this Chapter. All revenues raised pursuant to this Chapter shall be deposited into the Segregated Account. Such funds shall be dedicated and used for the sole purpose of obtaining federal financial participation for medical assistance payments to Non-Governmental Hospitals and Long Term Acute Care Hospitals on behalf of Medicaid recipients pursuant to Article 7 of Chapter 4 of Title 49. Such payments to Non-Governmental Hospitals and Long Term Acute Care Hospitals may include, among other things:

(a) general Medicaid rate increases;

(b) targeted payments for higher acuity Medicaid beneficiaries; and/or

(c) targeted payments for specific services such as organ transplant, certified breast or cancer centers, psychiatric, telemedicine or other services.

(2) Revenues appropriated to the Department by the General Assembly pursuant to Article 6C of Chapter 8 of Title 31, shall be used to match federal funds that are available for the purpose for which such funds have been appropriated.

(3) The Department shall remit any payments required under this Rule within ten (10) days of the Department's quarterly receipt of the Provider Payments pursuant to this Chapter.

Cite as Ga. Comp. R. & Regs. R. 111-3-10-.03
Authority: Act I of the 2013 Session of the Georgia General Assembly.
History. Original Rule entitled "Use of Provider Payments" adopted. F. May 13, 2013; eff. June 2, 2013.

Rule 111-3-10-.04. Advisory Committee.

(1) The Advisory Committee shall develop and recommend to the Department new and amended rules, state plan amendments and waivers for the implementation of any provider payments established pursuant to Act 1 of the 2013 Georgia General Assembly.

(2) The Committee shall develop and recommend to the Department the methodology to calculate the annual UPL applicable to hospital payments under federal Medicaid law.

Cite as Ga. Comp. R. & Regs. R. 111-3-10-.04
Authority: Act I of the 2013 Session of the Georgia General Assembly.
History. Original Rule entitled "Advisory Committee" adopted. F. May 13, 2013; eff. June 2, 2013.

Rule 111-3-10-.05. Effective Date.

Upon the adoption by the Board, Chapter 111-3-10 shall become effective on July 1, 2013;

provided however, the Advisory Committee which was created by Executive Order of the Governor became effective on March 5, 2013.

Cite as Ga. Comp. R. & Regs. R. 111-3-10-.05
Authority: Act I of the 2013 Session of the Georgia General Assembly.
History. Original Rule entitled "Effective Date" adopted. F. May 13, 2013; eff. June 2, 2013.

Subject 111-3-11. HOSPITAL DIRECTED PAYMENT PROGRAM.

Rule 111-3-11-.01. Definitions.

As used in this Chapter 111-3-11:

(1) "Board" means the Board of Community Health, the body created under O.C.G.A. § 31-2-3, appointed by the Governor, that establishes the general policy to be followed by the Department of Community Health.

(2) "Care Management Organization" means a managed care organization defined in 42 CFR § 438.2 and O.C.G.A. § 33-21A-2(1).

(3) "Department" means the Department of Community Health established under O.C.G.A. § 31-2-3.

(4) "Directed Payment" means any payment made to hospitals by Care Management Organizations pursuant to their Medicaid managed care contracts with the Department as authorized under 42 CFR § 438.6(c).

(5) "Hospital" means an institution license pursuant to Chapter 7 of Title 31, which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. Such term includes public, private, rehabilitative, geriatric, osteopathic, and other specialty hospitals but shall not include psychiatric hospitals, which shall have the same meaning as facilities as defined in paragraph (7) of O.C.G.A. § 37-3-1, critical access hospitals as defined in paragraph (3) of O.C.G.A. § 33-21A-2, or any state owned or state operated hospitals.

(6) "Non-Governmental Hospital" means a subclass of Hospitals, authorized to be defined by the Board pursuant to paragraph (a) of O.C.G.A. § 31-8-179.2, that shall not include public, long term acute care, children's, rehabilitative, geriatric, osteopathic, and other specialty hospitals, psychiatric hospitals which shall have the same meaning as facilities

as defined in paragraph (7) of O.C.G.A. § 31-8-179.2, critical access hospitals as defined in paragraph (3) of O.C.G.A. § 33-21A-2, or any state-owned or state-operated hospitals.

(7) "Provider Payment" means a payment assessed by the Department pursuant to this chapter for the privilege of operating a Non-Governmental Hospital.

(8) "Segregated Account" means an account for the dedication and deposit of Provider Payments which is established within the Trust Fund.

(9) "Trust Fund" means the Indigent Care Trust Fund created by Article 6 of Chapter 8 of Title 31.

(10) "Waiver" means a waiver of the requirements for permissible health care related taxes, as provided for in 42 C.F.R § 433.68.

Cite as Ga. Comp. R. & Regs. R. 111-3-11-.01
Authority: O.C.G.A. § 31-8-179.3.
History. Original Rule entitled "Definitions" adopted. F. July 20, 2022; eff. Aug. 9, 2022.

Rule 111-3-11-.02. Payments to the Segregated Account.

(1) There is established within the Trust Fund a Segregated Account for revenues raised through the imposition of the Provider Payment. Any Provider Payment assessed pursuant to this Chapter shall be deposited into the Segregated Account. No other funds shall be deposited into the Segregated Account. All funds shall be invested in the same manner as authorized for investing other moneys in the state treasury.

(2) Each Non-Governmental Hospital shall be assessed a Provider Payment not to exceed the amount necessary to obtain federal financial participation for Directed Payments allowable under 42 CFR § 438.6(c). The amount of each Non-Governmental Hospital's Provider Payment shall be determined by the Department using available hospital financial data and other information as applicable, including, but not limited to, hospital cost reports and the annual Hospital Financial Survey. The Department shall seek any Waivers and federal approvals necessary to fully implement this Chapter.

(3) The Provider Payment shall be paid at least annually by each Non-Governmental Hospital to the Department within 14 calendar days of the Department's notice to the Non-Governmental Hospital that payment is due. The Department shall send such Provider Payment notices to each Non-Governmental Hospital within 30 calendar days or as soon as reasonably practical after the receipt of federal approval of Directed Payment(s) for the applicable rating period.

(4) The Department or its designee shall prepare and distribute a form on which each Non-Governmental Hospital shall submit information to comply with this Chapter.

(5) Each Non-Governmental Hospital shall keep and preserve for a period of seven (7) years such books and records as may be necessary to determine the amount for which it is liable under this Chapter. The Department shall have the authority to inspect and copy the records of a Non-Governmental Hospital for purposes of auditing the calculation of the Provider Payment. All information obtained by the Department pursuant to this Chapter shall be confidential and shall not constitute a public record.

(6) The Department may impose a penalty of up to six percent (6%) for any Non-Governmental Hospital that fails to pay a Provider Payment within the time required by the Department for each month or fraction thereof that the Provider Payment is overdue. If a required Provider Payment has not been received by the Department 14 days after the payment due date as specified in 111-3-11-.02(3), the Department may withhold an amount equal to the Provider Payment and penalty owed from any medical assistance payment due such Non-Governmental Hospital under the Medicaid program. Any Provider Payment assessed pursuant to this Chapter shall constitute a debt due the state and may be collected by civil action and the filing of tax liens in addition to such methods provided for in this Chapter. Any penalty that accrues pursuant to this Rule shall be credited to the Segregated Account.

(7) If the Department determines that a Non-Governmental Hospital has underpaid the Provider Payment, the Department shall notify the Non-Governmental Hospital of the balance of the Provider Payment that is due. Such payment shall be due within thirty (30) days of the Department's notice.

Cite as Ga. Comp. R. & Regs. R. 111-3-11-.02
Authority: O.C.G.A. § 31-8-179.3.
History. Original Rule entitled "Payments to the Segregated Account" adopted. F. July 20, 2022; eff. Aug. 9, 2022.

Rule 111-3-11-.03. Use of Provider Payments.

(1) The Department shall collect the Provider Payments imposed pursuant to this Chapter. All revenues raised pursuant to this Chapter shall be deposited into the Segregated Account. Such funds shall be dedicated and used for the sole purpose of obtaining federal financial participation for Directed Payments to Non-Governmental Hospitals from Care Management Organizations on behalf of Medicaid recipients pursuant to Article 7 of Chapter 4 of Title 49. Directed Payments shall be exclusively used to provide Medicaid payments to Non-Governmental Hospitals based on each Non-Governmental Hospital's individual claims to Care Management Organizations.

(2) Revenues appropriated to the Department by the General Assembly pursuant to Article 6C of Chapter 8 of Title 31, shall be used to match federal funds that are available for the purpose for which such funds have been appropriated.

(3) The Department shall require the Care Management Organizations to remit any payments required under this Rule within ten (10) days of the Department's receipt of the Provider Payments pursuant to this Chapter.

Cite as Ga. Comp. R. & Regs. R. 111-3-11-.03
Authority: O.C.G.A. § 31-8-179.3.
History. Original Rule entitled "Use of Provider Payments" adopted. F. July 20, 2022; eff. Aug. 9, 2022.

Rule 111-3-11-.04. Use of Directed Payments.

(1) The Department may, in its sole discretion, create one or more directed payment programs in accordance with this Chapter.

(2) Non-Governmental Hospitals shall comply with Department requests to submit reports to the Department when necessary to comply with the requirements of 42 CFR 438.6(c)(2)(ii).

Cite as Ga. Comp. R. & Regs. R. 111-3-11-.04
Authority: O.C.G.A. § 31-8-179.3.
History. Original Rule entitled "Use of Directed Payments" adopted. F. July 20, 2022; eff. Aug. 9, 2022.

Subject 111-3-12. RULES AND REGULATIONS FOR HOSPITAL CARE FOR THE INDIGENT.

Rule 111-3-12-.01. Authority.

(1) Act No. 397, Georgia Laws 1957, contains legislative authority for the creation of a "Hospital Care for the Indigent" program. The purpose of the program is "to assist counties in the purchase of hospital care for persons who are ill or injured, and who can be helped by treatment in a hospital, and who are financially unable to meet the full cost of hospital care from their own resources or from the resources of those upon whom they are legally dependent."

(2) This program is a State-County jointly financed and administered approach to providing hospital care for the medically indigent. However, participation in the program is voluntary with each county. The program will support the preservation of the professional freedom of physicians and the local control of hospitals. Furthermore, local program administration will be encouraged.

(3) Generally speaking, payment for hospital care is the responsibility of the individual and the local community. It is the intent of this program to supplement local action. Accordingly, the program should not be construed as replacing Federal, State, or local

programs for the indigent. It is a basic program objective to provide financial means for the payment of hospital care for indigent patients who are hospitalized outside of their respective county or residency.

(4) The "Hospital Care for the Indigent" Program has been developed in close liaison with the Medical Association of Georgia, the Georgia Association of County Commissioners, the Georgia Association of Hospital Governing Boards, and the Georgia Hospital Association. Each of these organizations have representation on the Hospital Care Advisory Council.

(5) The Legislature delegated the administration of the program to the Department of Community Health. The purpose of this program is to assist counties in the purchase of hospital care for persons who are ill or injured and who can be helped by treatment in a hospital but are financially unable to meet the full cost of hospital care from their own resources or from the resources of those upon whom they are legally dependent.

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.01
Authority: Ga. L. 1933, p. 7., O.C.G.A. § 31-8-1 (2009).
History. Original Rule entitled "Authority" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-3-12-.02. Method for County Participation in the Program.

(1) Procedure for County Participation:

(a) For a county to initiate participation in the Program, the governing authority of such county, by formal resolution or by contract agreement, must satisfy the provisions of 111-3-12-.02(2).

(b) For continued participation in the Program, the county must comply with the Rules and Regulations governing the administration of the Program, and the governing authority of the county annually must adopt a renewal resolution or renew its contract agreement. The annual resolution or contract must satisfy the provisions of 111-3-12-.02(2) and the required document must be filed with the Georgia Department of Community Health on or before the first day of April to assure participation for the entire ensuing fiscal year.

(c) The Georgia Department of Community Health shall make the determination, on a uniform state-wide basis, or whether a formal resolution, a contract agreement, or both shall be submitted by the county for participation in the Program.

(2) Requirements Regarding the Resolution or the Contract:

(a) The resolution or contract must declare the desire of the County to participate in the Program.

(b) The resolution or contract must certify that the County has approved a local budget providing funds necessary for participation in the Program. The amount of this local budget shall be specified in the resolution or contract. (See 111-3-12-.02(3) for comments on "Determining the Local Budget.")

(c) The resolution or the contract must indicate that the County has designated the County Board of Health as the local administrative agency or that the County has so designated an agency acceptable to both the governing authority of the county and the Georgia Department of Community Health.

(d) The resolution or contract must state that the County agrees to pay, within the limitations of the Program budget, for authorized or emergency out-of-county hospital care rendered to county residents who are properly certified as indigent or medically indigent.

(e) The resolution or contract should indicate that both the local medical society and the local hospital authority, if such exist, favor participation by the county in the Program.

(f) The resolution or contract must declare that the County will comply with the Rules and Regulations of the Program as promulgated by the Department of Community Health.

(3) Determining the Local Budget:

(a) The amount of local funds budgeted for the Program shall be determined by the governing authority of the county; however, such local budget should match available State funds except where a lesser amount is reasonably related to Program needs.

(b) The availability of State funds does not reduce local responsibility regarding hospital care, and it should not be used to justify termination of existing agreements with hospitals regarding the financing of operating deficits.

(c) The amount of State funds budgeted under the Program to each county shall be determined by the Georgia Department of Community Health on the basis of available State funds, the matching formula, and the available county funds.

(4) Effective Date of Participation. A County may request participation the Program at any time; however, after the first year of the Program, the actual commencement of Program participation, as evidenced by an allotment of State funds, shall be only on July 1 or January 1.

(5) A County may request the Georgia Department of Community Health to approve a revised resolution or contract prior to the expiration of a previously filed document for a

given year. Decisions regarding such requests will be based on the circumstances and facts as submitted in each instance.

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.02
Authority: Ga. L. 1933, p. 7; O.C.G.A. § 31-8-1*et seq*.
History. Original Rule entitled "Method for County Participation in the Program" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-3-12-.03. Method of Allotment and Matching of State Funds.

(1) Calculating the Allotment of State Funds:

(a) Within the one dollar ($1.00) per capita legal limitation, State funds shall be allotted to each participating county according to two factors: population and median income.

1. The population shall be the latest official decennial population count of the U.S. Census Bureau, adjusted to exclude military personnel and wards of State institutions.

2. The median income, which is an index of relative economic ability, shall be obtained from the most recent "Characteristics of Population" for Georgia as prepared by the U. S. Census Bureau in connection with its official decennial population count.

(b) In calculating the county allotment, the following statistical procedure shall be used:

1. One thousand (1,000) divided by each county's median income to obtain the reciprocal weighting value.

2. Each county's population multiplied by the county's reciprocal weighting value to obtain county's weighted population.

3. The appropriation (or State funds available) divided by the sum of weighted population of all counties to obtain per capita allotment.

4. Per capita allotment multiplied by each county's weighted population to obtain each county's allotment.

(c) The above procedure shall be used in the initial allocation of State funds during a year, in the reallocation of any unexpended or unallotted funds, and in the allocation of any additional funds which may become available during a year.

(2) Matching Formula:

(a) All State funds allocated to a County, through an agreed joint participating budget, must be matched by local funds according to the matching formula.

(b) The matching formula for each county shall be determined by the following table:

1950 Population of County	State Share	Local Share
5,000 and under	75%	25%
5,001 - 10,000	65%	35%
10,001 - 20,000	55%	45%
20,001 - 50,000	50%	50%
50,001 - 100,000	40%	60%
Over 100,000	30%	70%

(3) Method of Payment:

(a) Each Participating County must establish a "Hospital Care for the Indigent" Fund which shall consist of the local share of the approved joint budget.

(b) The Georgia Department of Community Health shall establish a State "Hospital Care for the Indigent" Fund which shall consist of all State funds available to the Program.

(c) The method of payment shall be to hospitals on an individual patient basis according to a dual payment procedure. Under this method, the County shall pay the hospital for the local share of authorized hospitalization and the Georgia Department of Community Health shall pay the hospital for the State share of authorized hospitalization.

(d) Disbursement to a hospital from the Georgia Department of Community Health will be made only on proper local certification and after the County has paid the local share of the request for payment as submitted by the Participating Hospital.

(e) The official per diem rate shall be used by each Participating County when authorizing hospital care under the Program and the local share of such rate shall be the basis for county payment under the Program.

(f) The County is primarily responsible for obligations authorized by its certifications and the Georgia Department Community Health will assist only to the extent of State funds allocated to that county.

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.03
Authority: Ga. L. 1933, p. 7; O.C.G.A. § 31-8-1*et seq*.
History. Original Rule entitled "Method of Allotment and Matching of State Funds" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-3-12-.04. Method of Local Administration.

(1) Supervision of Local Program:

(a) The governing authority of the county shall have the following Program role:

1. to determine whether the Program should be activated in the county and to establish the local budget needed;

2. to review and to adopt the County Program Plan;

3. to make an annual review of Program performance and to determine whether the Program is to be continued in its county.

(b) The County Board of Health shall have the following Program role:

1. to bear responsibility for the proper administration of the Program in its county;

2. to develop or supervise the development of a County Program Plan;

3. to adopt local policies necessary to Program administration;

4. to delegate administrative Program functions as it deems desirable.

(c) The County Board of Health, except as indicated in paragraph (a) above shall represent the county in official negotiations with the Division of Hospital Services, Georgia Department of Community Health.

(2) County Program Plan:

(a) Annually, the County Board of Health shall prepare a County Program Plan which contains the following elements:

1. a selection of hospitals to be used by the County in accordance with 111-3-12-.04(3);

2. resolutions from the medical staff and the governing board of each selected hospital stating acceptance of participation in the local Program;

3. a policy or standard for determining indigency and medical indigency in accordance with 111-3-12-.05;

4. a policy or method for determining the need for hospitalization in accordance with 111-3-12-.06;

5. a policy or method relating to out-of-county hospital care in accordance with 111-3-12-.06(3);

6. a method or procedure for the payment of funds in accordance with 111-3-12-.03(3);

7. a statement defining the area of responsibility for any agency to which the county has delegated administrative Program responsibility in accordance with 111-3-12-.04(4).

(b) The County Program Plan shall be prepared so as to provide a logically interrelated set of policies for the local Program.

(c) The County Program Plan shall be submitted for review and approval to the governing authority of the county and to the Georgia Department of Community Health.

(3) Selection of Participating Hospitals:

(a) The County Program Plan shall contain the selection of a reasonable number of Participating Hospitals so that geographic Program Coverage will conform, in General, with the pattern of medical care for the area.

(b) In the selection of Participating Hospitals to be used by the local Program, consideration should be given to the probable needs of individual patients, the necessity for referrals between hospitals, the geographic convenience of patients, and the desires of local practicing physicians.

(c) To the fullest degree consistent with sound local Program management, the local selection of Participating Hospitals should be limited to general hospitals providing medical and surgical services.

(d) The Eugene Talmadge Memorial Hospital shall not be selected for inclusion in any County Program Plan; however, emergency or highly specialized hospital care may be authorized at this hospital.

(e) In an emergency wherein the medical condition of the patient prevents utilization of a selected participating hospital, hospitalization may be authorized in any Participating Hospital without reference to the County Program Plan.

(f) The county may amend its selection of Participating Hospitals by written notice to the Georgia Department of Community Health.

(4) Local Program Administration:

(a) The County Board of Health shall have authority to administer the local Program, including the following areas:

1. to make the necessary investigation for the final determination of indigency and medical indigency;

2. to make the final determination of the need for hospitalization;

3. to authorize and to approve payments for hospital care;

4. to maintain Program records and to prepare reports of its activities;

5. to properly account for funds made available to the local Program;

6. to maintain liaison with public and private agencies interested in the Program.

(b) The County Board of Health may delegate definable aspects of local Program administration to a governmental official, an agency, or an organization which perform a public and necessary governmental function. Any delegation must be on an annual basis and does not relieve the County Board of Health of its total Program responsibility.

(c) The County Board of Health, at its option, may elect to establish a Screening Committee to advise in local program administration.

1. The Act specifies that a Screening Committee, created by a County, should be delegated the function of making determinations and certifications relative to the indigency of persons applying for assistance under this Program.

2. Such a Screening Committee should consist of three responsible and public-minded local citizens. At least one member of a Screening Committee must be designated by the local medical society.

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.04
Authority: Ga. L. 1933, p. 7; O.C.G.A. § 31-8-1*et seq*.
History. Original Rule entitled "Method of Local Administration" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-3-12-.05. Criteria for Determining Indigency.

(1) General Statement on Determining Financial Eligibility:

(a) The Department of Community Health desires that each county have as much freedom as possible in determining the eligibility of its residents under the provisions of this Program.

(b) Recognizing the differences in the socio-economic level of the several counties, there shall be no rigid state-wide formula devised for determining indigency and medical indigency.

(2) A Local Policy or Standard Required:

(a) The County Board of Health shall develop a policy or standard which shall be used in determining indigency and medical indigency under the Program for the residents of that county.

(b) The local policy or standard shall be established in such a manner as to satisfy the following provisions:

1. It must contain reasonable assurance of a uniform basis of review for all requests for financial assistance under the Program for residents of that county.

2. It must contain specified standards of eligibility relative to family income, family assets, hospitalization insurance, and number of dependents.

3. It must contain a procedure which requires and specifies an inventory of economic resources on persons for whom assistance is requested.

4. It must recognize the need for a higher priority in those instances where an indigent or medically indigent resident is hospitalized outside of the county.

(3) Investigation of Individual Applicants:

(a) There shall be an investigation or review of the economic condition of each applicant to determine eligibility.

(b) Each applicant shall be required to certify that he is unable to pay for the full cost of hospital care as deemed necessary by a physician.

(c) Each applicant, from family resources or hospitalization insurance, shall be required to pay as large a share as possible of the cost of his hospitalization.

(4) Payment from Other Sources:

(a) For days of hospitalization authorized under the Program, there may be a supplemental county payment above the amount based on the official per diem rate, provided such action is based upon a contract agreement between the hospital and the governing authority of the county. There shall be no State participation in a supplemental county payment.

(b) When payment is made or expected to be made to the hospital on behalf of the patient from hospitalization insurance or family resources, the amounts so

collected by or due to the hospital shall be deducted from that sum which would otherwise be payable to the hospital under the Program, except as stated in 111-3-12-.05(4)(c).

(c) When the patient's stay in the hospital is greater than the days of hospitalization authorized under the Program, payment to the hospital from hospitalization insurance or family resources may be applied, according to the hospital's normal business practice, to those days of hospital care not authorized under the Program.

(d) After payment has been made for days of hospital care not authorized under the Program, any balance of hospitalization insurance or family resources shall be applied to days of authorized hospital care in accordance with 111-3-12-.05(4)(b).

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.05
Authority: Ga. L. 1933, p. 7.; O.C.G.A. § 31-8-1*et seq*.
History. Original Rule entitled "Criteria for Determining Indigency" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-3-12-.06. Criteria for Hospitalization.

(1) Certification of Hospital Care:

(a) This Program shall provide essential hospitalization for the acutely ill or injured who are eligible otherwise under Program requirements and who are certified by the county of residency.

(b) Each Participating County has the option of including or excluding normal obstetrics as eligible under the Program.

(c) A standard application form shall be required for all patients who receive services under the Program.

(d) All applications for hospitalization under the Program must be initiated by a physician.

(e) Hospitalization under the Program for any one patient shall not exceed thirty days in any twelve-month period.

(f) The applicant's attending physician, in recommending hospitalization shall certify the following:

1. That the applicant is acutely ill or injured;

2. That in his professional judgment intensive care normally provided by a hospital is required;

3. That there is likelihood of substantial benefit from hospitalization;

4. That he has reason to believe that the applicant is indigent;

5. That he has reason to believe the applicant is NOT eligible for care under any other program.

(g) The applicant's attending physician in recommending hospitalization shall indicate, to the best of his judgment, the number of days of hospitalization required and the hospital providing the type of care needed by the applicant.

(h) The County Board of Health, or its authorized agent, shall make the final decision on the following matters:

1. Selection of the Hospital to be used by the applicant.

2. The number of hospitalization days which will be authorized.

(i) The County Board of Health, or its authorized agent, shall promptly notify the Georgia Department of Community Health regarding all hospital care authorized under the Program.

(2) Relationship with Other Medical Care Programs:

(a) The Program shall not be construed as replacing existing Federal, State or local hospital and medical care programs for the indigent but may supplement such programs.

(b) The Program may supplement other Federal or State programs in the following manner:

1. On proper local certification, a person who is acutely ill or injured may receive hospital care under the Program even though the person is currently eligible for or receiving care under another program for a different type of disability or illness.

2. After exhausting eligibility under another program and on proper local certification, a person who is acutely ill or injured may receive hospital care under the Program for an acute illness or injury normally cared for under the program of prior sponsorship.

3. On proper local certification, persons with diagnosed tuberculosis, who because of the critical degree of their condition cannot be safely transported to Battey State Hospital may be temporarily hospitalized under provisions of the Program.

(c) When a person receives hospitalization under both this Program and another program, the authorization under this Program shall be prepared in such a manner as to avoid an overlapping payment for hospital care received.

(3) Out-of-County Hospital Care:

(a) There shall be free movement of patients and funds between counties so that the location of hospital care may become a medical determination and that payment for such hospital care may become void of artificial barriers.

(b) Out-of-county hospital care may be a medical referral in which the patient goes from the county of residence to an out-of-county hospital after it is determined that care is needed. In this instance, the county of residency shall determine both the need for hospitalization and whether the person is eligible as indigent or as medically indigent.

(c) Out-of-county hospital care may be an emergency wherein neither the patient nor his physician would have advanced plans regarding hospitalization. In this instance, the medical staff of the hospital shall determine the need for hospitalization relating to the emergency condition, and the county of residency shall determine whether the person is eligible as indigent or medically indigent.

(d) In emergency cases, the hospital and the attending physician shall complete the appropriate parts of the application form, and such application shall be received by the patient's county of residency within five days after admission of the patient. In such instances, the hospital shall indicate its approved per diem rate when transmitting the application.

(e) In the event there is an absence of negotiations between the parties concerned regarding the financial aspect of out-of-county hospital care, the Georgia Department of Community Health may earmark and reserve that sum of State funds which it deems advisable for the purpose of payment for out-of-county hospital care.

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.06
Authority: Ga. L. 1933, p. 7; O.C.G.A. § 31-8-1*et seq*.
History. Original Rule entitled "Criteria for Hospitalization" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-3-12-.07. Method for Approval of Participating Hospitals.

(1) Procedure for Becoming a Participating Hospital:

(a) Prerequisite to any hospital becoming a Participating Hospital under the Program, the governing authority of the hospital must elect to participate in the Program.

(b) In expressing the desire of the hospital to participate in the Program, a responsible officer of the hospital shall complete a standard application form and shall submit such application to the Georgia Department of Community Health.

(c) A hospital once approved will continue as a Participating Hospital until it voluntarily withdraws or its approval is revoked.

(2) Requirements for Becoming a Participating Hospital:

(a) To be eligible to participate in the Program, a hospital must have a physician as chief of staff and must have been issued a current licensure permit, either annual or provisional, under authority of the Georgia Hospital Regulations Act No. 623, Georgia Laws, 1946.

(b) Any hospital electing to participate in the Program must select one of the two following methods of payment for hospital care that it renders:

1. A calculated per diem related to the non-profit basic cost;

2. A fixed sum not to exceed ten dollars ($10.00) per patient-day of care.

(c) Any hospital selecting method (b) 1. above must submit appropriate accounting data necessary to substantiate a "non-profit basic cost".

(3) Lists of Participating Hospitals. The Georgia Department of Community Health shall maintain a roster of hospitals participating in the Program and shall furnish a list of such hospitals to each County Board of Health annually or more frequently if justified by the volume of changes.

(4) Discontinuance as a Participating Hospital:

(a) A participating Hospital has the right to withdraw from the Program at any time, after proper notice of this intent to the Georgia Department of Community Health, provided that the rights of patients are not jeopardized.

(b) Should a Participating Hospital, at some future date, fail to comply with the Act and the Regulations thereunder, the Georgia Department of Community Health shall remove the hospital from the roster of participating hospitals and shall advise the hospital concerned and the County Board of Health in each participating county that the hospital is no longer a Participating Hospital under the Program.

(5) Calculating the Per Diem Rate:

(a) The non-profit basic cost shall be determined from an analysis of the hospital's financial records and reports, and all submitted cost statements must bear the certification of a qualified auditor who is not an employee of the hospital.

(b) The Georgia Department of Community Health shall establish for each Participating Hospital an official per diem rate, which shall be an established percentage of the non-profit basic cost.

(c) The method of calculation of the official per diem rate for this Program shall be in harmony with the policies of other medical care programs under the sponsorship of the State of Georgia.

(d) By electing the calculated per diem method, the hospital grants to the Georgia Department of Community Health the right to audit its financial records and the right to inform counties of its per diem rate.

(e) For any Participating Hospital, the official per diem rate shall not exceed the average patient-day income for the hospital.

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.07
Authority: Ga. L. 1933, p. 7; O.C.G.A. § 31-8-1*et seq*.
History. Original Rule entitled "Method for Approval of Participating Hospitals" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-3-12-.08. General Provisions.

(1) Definition of Terms. The following words, terms, or phrases when used in these Rules and Regulations, shall have the meaning ascribed to them in this section, except when the context clearly indicates a different meaning:

(a) "Program" means the Hospital Care for the Indigent Program, established by Act No. 397, Georgia Laws, 1957;

(b) "Physician" means a doctor of medicine duly licensed to practice medicine in Georgia in accordance with Section 84-901, et seq., Georgia Code Annotated.

(c) "Indigent Person" or "indigent" means any person who is ill or injured and who from his own resources or from resources of those upon whom he is legally dependent is financially unable to meet the full cost of hospital care as prescribed or ordered by a physician.

(d) "financially unable" means an economic status in which a person, who because of his level of income, property, or intrafamily assistance, is not able to pay for the cost of needed hospital care without depriving himself or his dependents of necessary food, shelter, clothing, and the other minimum necessities of life within specified limits of an economic inventory.

(e) "full cost" means the total cost of an entire period of hospitalization wherein the ill or injured person is or becomes indigent in reference to a portion of the hospital cost.

(f) "hospital care needed" means the hospital care as prescribed or ordered by a physician.

(g) "resident" means any person who is in the county for other than temporary or transitory purposes and who has lived continuously in Georgia for a period of not less than six months. The six months residency requirement may be waived when a physician certifies that the illness or injury constitutes an emergency which requires immediate hospital care.

(h) "Applicant" means a resident indigent ill or injured person who makes applications for service under this Program, according to prescribed rules and regulations.

(i) "ill or injured" means indisposed for a medical reason which requires, in the professional judgment of a physician, intensive care normally provided by a hospital, and there is a likelihood of material benefit from hospitalization.

(j) "Participating County" means a county, the governing authority of which by appropriate action has agreed to participate in the Program, has adopted the rules and regulations set forth for the administration of the Program, and is current with its prorated share of funds necessary for the hospital care of county residents.

(k) "County" means the governing or taxing authority of a county.

(l) "Participating Hospital," "Participating Hospitals," or "participating hospital" means hospitals that have agreed to cooperate with the Program and have been certified as eligible according to the eligibility criteria set forth in the Rules and Regulations.

(m) "County Board of Health" means a County Board of Health created under and by virtue of an Act of the General Assembly of Georgia (Acts of 1914, page 124-125 as amended) codified as Section 88-201 et. seq., Georgia Code Annotated; or the agency designated under the provision of 111-3-12-.02(c) of these Rules and Regulations.

(2) Appeal Procedure:

(a) An applicant, a physician, or a Participating Hospital may appeal to the County Board of Health wherein the applicant resides, if the application is not acted upon within a reasonable length of time or if the application is denied, in whole or in part, by seemingly arbitrary action.

(b) The governing authority of the county, the Count Board of Health, a Participating Hospital, or the local medical society have the right to appeal by a written request and to be granted a fair hearing by the Georgia Department of Public Health on administrative matters pertaining to local policies, procedures, or methods.

(c) The governing authority of a Participating County, or the County Board of Health have the right to ap peal by a written request and to be granted a fair hearing by the State Board of Health relative to administrative procedures and decisions of the Georgia Department of Community Health.

(3) Revision of Rules and Regulations. Within the framework and intent of the Act, these Rules and Regulations may be revised or modified from time to time by the Department of Community Health after consultation with the Hospital Care Advisory Council.

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.08
Authority: Ga. L. 1933, p. 7; O.C.G.A. § 31-8-1 et seq.
History. Original Rule entitled "General Provisions" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-3-12-.09. Appendix.

Act No.397

Georgia Laws 1957

AN ACT

To provide additional powers and duties to be vested in the State Board of Health in order to promote and preserve the life and health of the people of the State through a program for the hospital care of the indigent; to provide assistance to the several counties of the State in purchasing hospital care for citizens thereof who are in need of and are financially unable to provide such care for themselves; to appropriate funds to be used to match and supplement local, federal or other funds made available for this purpose; to provide for the administration of the Act by the State Board of Health; to authorize the appointment of a Hospital Care Council by the Governor to advise and assist in the development of rules, regulations and standards necessary and proper to the implementation and administration of this Act; to repeal conflicting laws, and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1. In order to promote and preserve the public health there is hereby established a "Hospital Care for the Indigent" program to be administered by the State Board of Health. The purpose of this program is to assist counties in the purchase of hospital care for persons who are ill or injured, and who can be helped by

treatment in a hospital, and who are financially unable to meet the full cost of hospital care from their own resources or from the resources of those upon whom they are legally dependent. The purchase of such hospital care shall be limited to the non-profit basic cost of hospital care needed for the treatment of the ill or injured, as deemed necessary and ordered by the physician in charge of the case in accordance with the provisions of this Act and the rules, regulations and standards adopted and promulgated by the Board hereunder.

SECTION 2. The following words, terms and phrases, when used in this Act shall have the following meaning ascribed to them in this section, except when the context clearly indicates a different meaning:

a. Board-The State Board of Health;

b. Program-The "Hospital Care for the Indigent" program;

c. Participating Hospital-A publicly or privately owned hospital holding a valid permit issued pursuant to Section 99-1707, Georgia Code Annotated, and having a physician as chief of staff and provided further that the governing authority of the hospital elects to participate in the program in accordance with the provisions of this Act;

d. Physician-A doctor of medicine duly licensed to practice medicine in Georgia in accordance with Sections 84-901, et seq., Georgia Code Annotated;

e. Indigent Person-Any person who is ill or injured and who from his own resources or from the resources of those upon whom he is legally dependent is financially unable to meet the full cost of hospital care as prescribed or ordered by a physician;

f. Resident-Any person who is in the State of Georgia for other than temporary or transitory purposes and who has lived continuously in this State for a period of not less than six (6) months;

g. Participating County-A county, the governing authority of which, by appropriate action, has agreed to participate in the program and is current with its prorata share of funds necessary for the hospital care for its ill or injured indigent as herein defined and in accordance with the provisions of this Act.

SECTION 3. Until such time as a specific appropriation may be made to the State Board of Health for the purpose of carrying out the provisions of this Act, the Budget Bureau is hereby authorized to make an allotment to the Board in such amounts as the bureau may deem necessary and proper for such purpose in accordance with the provisions of section 40-408 of the Georgia Code of 1933.

SECTION 4. State funds appropriated to the board for the purpose of carrying out the provisions of this Act shall be expended by the board or its duly authorized agent so as to provide for the administration of this Act as it deems necessary and proper and to assist counties in providing hospital care for indigent residents. The board shall establish a graduated matching formula for the disbursement of State funds to assist counties as provided herein; provided the State share of any participating county budget shall not exceed one dollar ($1.00) per capita based on the latest official decennial population count of the United States Census Bureau. The board may establish an amount of State funds of the total State and county participating budget to provide hospital care for indigent resident patients who may be hospitalized outside of the county of residency; provided, however, that any unexpected State funds budgeted to provide hospital care for the indigent resident patient who may be hospitalized outside the county of residency may be reallocated by the board according to the matching formula.

SECTION 5. After the effective date of this Act the governing authority of the participating county shall on or before the first day of April of each year submit to the Board a Hospital Care for the Indigent budget containing an estimate and supporting data setting forth the amount of moneys needed to provide hospital care for the indigent residents for said county.

SECTION 6. Upon certification, approved by the board, any participating county may receive credit for direct expenditures made during the period covered by the budget by the county to a hospital or hospitals when such expenditures can be shown to have been made for the care of indigent residents as herein defined.

SECTION 7. The board, after consultation with the Hospital Care Council, shall adopt and promulgate such rules and regulations as it deems necessary to carry out the provisions of this Act.

SECTION 8. A person to qualify for assistance under this program must be an indigent resident of this State and hospital care is not available to the person under any other program. The six (6) months residency requirement may be waived; provided a physician certifies that the illness or injury constitutes an emergency which requires immediate hospital care.

SECTION 9. To qualify a county for assistance under this program the governing authority of said county shall have certified that:

a. The county elects to participate in the program;

b. A local budget providing the funds required by the graduated matching formula has been approved;

c. A local administrative agency or officer has been appointed;

d. A screening committee or agency has been appointed to make determinations and certifications relative indigency of persons applying for assistance as provided for in this Act.

SECTION 10. The board is authorized and empowered to enter into agreements with other State Departments, boards and agencies of the United States Government, local governmental agencies, and voluntary organizations to obtain funds for hospital care that may be available for needy persons and the board is authorized to receive and administer any funds available by such agreements in conformity with the provisions of this Act; provided, that the authority granted in this Act shall not prevent the State Department of Public Welfare from complying with the provisions of a Social Security Act Governing Medical Care (U.S.C.A. 14-701, et seq.).

SECTION 11. The board is authorized and empowered to accept and expand any and all gifts and donations that may be made available to said board for purposes of this Act.

SECTION 12. There shall be established a Hospital Care Council, the members of which shall be appointed by the Governor. The council shall advise with the board relative to policies, procedures and standards to be embodied in rules and regulations adopted and promulgated by the board. The membership of the council shall consist of two (2) county commissioners appointed from nominations made by the Association of County Commissioners of Georgia; two (2) hospital trustees appointed from nominations made by the Association of Hospital Governing Boards; two (2) physicians appointed from nominations made by the Medical Association of Georgia; two (2) hospital administrators appointed from nominations made by the Georgia Hospital Association; and three (3) citizens, not members of any of the foregoing groups, appointed by the Governor and representing the State at large, the Director of the State Department of Public Health, ex officio; and the Director of the State Department of Public Welfare, ex officio. Appointments made by the Governor as provided for above shall be from lists of nominees furnished by the Associations herein named and such lists shall contain two nominees for each appointment to be made. If any of the above named Associations ceases to function then the Governor shall make appointments for the association. When the appointments are first made one member from each of the associations shall be appointed for a term of two (2) years and one (1) member from each association shall be appointed for a term of four (4) years, and of the three members representing the State at large, one (1) shall be appointed for a term of two (2) years, one (1) for a term of three (3) years, and one (1) for a term of four (4) years. After the expiration of the first appointments all appointments shall be made for a period of four (4) years. The term of any ex officio member shall expire with his term of office and his successor in office shall succeed him as a member of the council. An ex

officio member may designate a deputy to serve in his place as a member of the council. Such deputy member shall be subject to the same duties and responsibilities as would be imposed upon the ex officio member. Vacancies in the membership of said council shall be filled in the same manner as the original appointments. The council shall select one of its members to serve as chairman and one of its membership to serve as vice chairman. The council shall meet at the call of the chairman or upon written request of any seven (7) members and seven (7) members shall constitute a quorum for the transaction of business. The council is authorized to adopt such by-laws, rules and regulations as it may deem necessary for the proper conduct of its proceedings in the carrying out of its duties. The Director of the State Department of Public Health shall furnish the necessary clerical assistance from among employees of the Department of Public Health as may be required by the council.

SECTION 13. The ex officio members of the Hospital Care Council shall be paid actual and necessary travel and other expenses incurred in carrying out the functions and duties of the Council and all other members shall receive twenty dollars ($20.00) per day for each day they are engaged in their duties as members of the council, in lieu of their personal expense incurred thereby, and shall receive mileage, at the rate provided by law, to and from the place of meeting by the nearest practical route for their respective homes. All such expenses, shall be paid from the funds appropriated to the Department of Public Health. Members of the council shall receive no emoluments or compensation for their services as such members.

SECTION 14. This Act shall not be construed as replacing Federal, State or local programs for the indigent but may supplement such programs for hospital care of the indigent.

SECTION 15. Any person knowingly obtaining or attempting to obtain, or who aids or abets any other person to obtain or attempt to obtain by means of a willfully false statement or representation or impersonation, or other fraudulent device, any benefits provided by this Act, to which he is not lawfully entitled shall be deemed guilty of a misdemeanor and upon conviction thereof shall be punished as provided by law.

SECTION 16. In the event any section, subsection, sentence, clause or phrase of this Act shall be declared or adjudged invalid or unconstitutional, such adjudication shall in no manner affect the other sections, subsections, sentences, clauses or phrases of this Act, which shall be and remain in full force and effect, as if the section, subsection, sentence, clause or phrase so declared or adjudged invalid or unconstitutional was not originally a part thereof. The legislature hereby declares that it would have passed the remaining parts of this Act if it had known that such part or parts thereof would be declared or adjudged invalid or unconstitutional.

SECTION 17. This Act shall become effective when State funds become available for carrying out the provisions of this Act.

SECTION 18. All laws and parts of laws in conflict herewith are hereby repealed.

Cite as Ga. Comp. R. & Regs. R. 111-3-12-.09
Authority: Ga. L. 1933, p. 7.
History. Original Rule entitled "Appendix" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Subject 111-3-14. AMBULANCE PROVIDER MATCHING PAYMENT PROGRAM.

Rule 111-3-14-.01. Definitions.

As used in this Chapter 111-3-14:

(1) "Board" means the Board of Community Health, the body created under O.C.G.A. § 31-2-3, appointed by the Governor, that establishes the general policy to be followed by the Department of Community Health.

(2) "Department" means the Department of Community Health established under O.C.G.A. § 31-2-1.

(3) "Ambulance Service" for the purpose of this rule means a private entity performing services as defined in O.C.G.A. § 31-11-2(4)(A), specifically, for providing emergency care and transportation on the public streets and highways of this state for a wounded, injured, sick, invalid, or incapacitated human being to or from a place where medical or hospital care is furnished, and where such private entity is licensed by the Department of Public Health and is a 911 responding ambulance provider, either designated as a 911 provider or providing services under a service delivery contract for a designated 911 provider.

(4) "Net Patient Revenue" means the total gross patient revenue of an Ambulance Service less contractual adjustments, charity care, bad debt, or any other write-offs.

(5) "Provider Matching Payment" means payment assessed by the Department pursuant to this Chapter on providers which operate a Private Ambulance Service.

(6) "Private Ambulance Service" means an Ambulance Service, as defined in this Chapter, other than:

(a) An Ambulance Service owned and operated by the Federal government

(b) An Ambulance Service owned and operated by a unit of State government

(c) An Ambulance Service owned and operated by a unit of Local (non-state) government

(7) "Segregated Account" means an account for the dedication and deposit of Provider Matching Payments which is established within the Trust Fund.

(8) "State Plan Amendment" means all documentation submitted by the Commissioner, on behalf of the Department, to and for approval by the Secretary of Health and Human Services pursuant to the Title XIX of the Federal Social Security Act of 1935, as amended.

(9) "Trust Fund" means the Indigent Care Trust Fund created by article 6 of Chapter 8 of Title 31.

(10) "Waiver" means a waiver of the requirements for permissible health care related taxes, as provided for in 42 C.F.R. § 433.68.

Cite as Ga. Comp. R. & Regs. R. 111-3-14-.01
Authority: O.C.G.A. § 31-11-31.2.
History. Original Rule entitled "Definitions" adopted. F. Aug. 15, 2022; eff. Sep. 4, 2022.

Rule 111-3-14-.02. Payments to the Segregated Account.

(1) There is established within the Trust Fund a Segregated Account for revenues raised through the imposition of the Provider Matching Payment. Any Provider Matching Payment assessed pursuant to this Chapter shall be deposited into the Segregated Account. No other funds shall be deposited into the Segregated Account. All funds shall be invested in the same manner as authorized for investing other moneys in the state treasury.

(2) Each Private Ambulance Service shall be assessed a Provider Matching Payment in an amount that shall not exceed the amount necessary for this program to obtain federal financial participation allowable under Title XIX of the Social Security Act.

(3) The Provider Matching Payment shall be paid quarterly by each Private Ambulance Service to the Department. Payment of the Provider Matching Payment shall be due on the last day of the last month of each calendar quarter; the first payment shall be due on September 30, 2022, or 30 calendar days after Board approval of this rule, whichever is later.

(4) The Department shall prepare and distribute a form on which each Ambulance Service shall submit information to comply with this Chapter.

(5) Each Ambulance Service shall keep and preserve for a period of seven (7) years such books and records as may be necessary to determine the amount for which it is liable under this Chapter. The Department shall have the authority to inspect and copy the records of an Ambulance Service for purposes of auditing the calculation of the Provider Matching Payment. All information obtained by the Department pursuant to this Chapter shall be confidential and shall not constitute a public record.

(6) The Department may impose a penalty of up to six percent (6%) for any Ambulance Service that fails to pay a Provider Matching Payment within the time required by the Department for each month or fraction thereof that the Provider Matching Payment is overdue. If a required Provider Matching Payment has not been received by the Department by the last day of the last month of the calendar quarter, the Department may withhold an amount equal to the Provider Matching Payment and penalty owed from any medical assistance payment due such Ambulance Service under the Medical program. Any Provider Payment assessed pursuant to this Chapter shall constitute a debt due the state and may be collected by civil action and the filing of tax liens in addition to such methods provided for in this Chapter. Any penalty that accrues pursuant to this Rule shall be credited to the Segregated Account.

(7) If the Department determines that an Ambulance Service has underpaid the Provider Payment, the Department shall notify the Ambulance Service of the balance of the Provider Payment that is due. Such payment shall be due within thirty (30) days of the Department's notice.

Cite as Ga. Comp. R. & Regs. R. 111-3-14-.02
Authority: O.C.G.A. § 31-11-31.2.
History. Original Rule entitled "Payments to the Segregated Account" adopted. F. Aug. 15, 2022; eff. Sep. 4, 2022.

Rule 111-3-14-.03. Use of Provider Payments.

(1) The Department shall collect the Provider Matching Payments imposed pursuant to this Chapter. All revenues collected pursuant to this Chapter shall be deposited into the Segregated Account. Such funds shall be dedicated and used for the sole purpose of obtaining federal financial participation for medical assistance payments to Private Ambulance Service providers on behalf of Medicaid recipients pursuant to Article 7 of Chapter 4 of Title 49.

(2) Revenues appropriated to the Department by the General Assembly pursuant to Article 6C of Chapter 8 of Title 31, shall be used to match federal funds that are available for the purpose for which such funds have been appropriated.

Cite as Ga. Comp. R. & Regs. R. 111-3-14-.03
Authority: O.C.G.A. § 31-11-31.2.
History. Original Rule entitled "Use of Provider Payments" adopted. F. Aug. 15, 2022; eff. Sep. 4, 2022.

Rule 111-3-14-.04. Effective Date.

Upon the adoption by the Board, Chapter 111-3-14 shall become effective on July 1, 2022.

Cite as Ga. Comp. R. & Regs. R. 111-3-14-.04
Authority: O.C.G.A. § 31-11-31.2.
History. Original Rule entitled "Effective Date" adopted. F. Aug. 15, 2022; eff. Sep. 4, 2022.

Chapter 111-4. STATE HEALTH BENEFIT PLAN.

Subject 111-4-1. STATE HEALTH BENEFIT PLAN.

Rule 111-4-1-.01. Definitions.

(1) **"Active"** means that the Employee is receiving compensation or is on Approved Leave of Absence Without Pay through a department, school system, Local Employer, agency, authority, board, commission, county department of family and children services, county department of health, community service board, or Contract Employer and for whom the Employee's cost of Coverage is stated as a payroll Deduction or Reduction.

(2) **"Acts"** or **"The Acts"** or **"The Health Insurance Acts"** mean the legislative Acts that establish the Health Insurance Plans for State Employees, Teachers, and Public School Employees and are designated in the Official Code of Georgia Annotated as Article 1 of Chapter 18 of Title 45 and Articles 880 and 910 of Chapter 2 of Title 20.

(3) **"Administrator"** means the Department of Community Health or the Commissioner of the Department of Community Health.

(4) **"Administrative Services"** means the services that are provided by contract for a self-insured Health Benefit Plan.

(5) **"Approved Leave of Absence Without Pay"** means a period of time approved by the appropriate organizational official during which the Employee is absent from work and is not in pay status.

(6) **"Annual Required Contribution"** means an actuarially determined amount to pay for future OPEB liability over a period of years.

(7) **"Beneficiary"** means an Employee, Surviving Spouse, divorced or legally separated Spouse, or eligible Dependent child who loses Coverage under these regulations.

(8) **"Benefits"** mean the schedule of Benefits of health care services eligible for approval of payments under the Options approved by the Board.

(9) **"Board of Community Health"** or **"Board"** means the governing body authorized to exercise jurisdiction over the SHBP pursuant to O.C.G.A. § 31-2-3.

(10) **"Cafeteria Plan"** means a plan which meets the requirements of the regulations of the Internal Revenue Service under Internal Revenue Code (IRC) 125.

(11) **"Certificated Capacity"** means the Employee holds valid certification; is not assigned to a position that requires certification as a qualification; the Employee's compensation is determined, at least in part, based upon the certificate; and the Employee is a member of the Teachers Retirement System or other Public School Teacher retirement system.

(12) **"Certificated Position"** means the Employee holds valid certification; is assigned to a position that requires certification as a qualification; the Employee's compensation is determined, at least in part, based upon the certificate; and the Employee is a member of the Teachers Retirement System or other Public School Teachers retirement system.

(13) **"Claim"** means any bill, invoice, or other written statement from a specific provider for health care services or supplies submitted in accordance with the requirements of the SHBP for a specific eligible Member.

(14) **"Commissioner"** means the Commissioner of the Department of Community Health as created by O.C.G.A. § 31-2-6.

(15) **"Contract Employee"** means a person employed by one of the entities that contracts with the Board of Community Health to provide health benefit Coverage under the SHBP, and who is not considered to be an independent contractor.

(16) **"Contract Employer"** means one of the organizational entities that has elected to contract with the Board of Community Health for inclusion of their Employees in the SHBP.

(17) **"Contribution"** means the amount or percentage of salaries to be paid by an Employing Entity or State Department of Education for Employees and Retirees for health benefit Coverage.

(18) **"Coverage"** means the type, Tier, and Option of contract offered to an Enrolled Member pursuant to the Health Insurance Acts. "Coverage" does not include TRICARE Supplemental Coverage.

(19) **"Covered Dependent"** means any individual eligible under these regulations and for whom the Premium has been paid by the Employee, Retiree, or Extended Beneficiary.

(20) **"Creditable Coverage"** means health insurance that may serve to reduce a Pre-existing Condition limitation period. Creditable Coverage shall include health plan offerings under the following type plans: group health plans; individual health policies; Health Maintenance Organizations (HMOs); Medicaid; Medicare; or other governmental health programs. Disease specific policies (i.e., cancer insurance), disability insurance, and

insurance that provides incidental health insurance (i.e., auto insurance) is not Creditable Coverage.

(21) **"Deduction"** or **"Reduction"** means the Premium amount to be remitted to the Administrator as the Employee's or Retiree's share of the cost of the elected Coverage.

(22) **"Dependent"** means any eligible Spouse, Dependent child, or Totally Disabled Child.

(23) **"Employee"** means any eligible, Active State Employee, Teacher, or Public School Employee.

(24) **"Employing Entity"** means any department, school system, Local Employer, Contract Employer, agency, authority, board, commission, county department of family and children services, county department of health, community service board or retirement system that employs or issues an annuity check to an Employee, Contract Employee or Retiree as defined in these regulations.

(25) **"Enrolled Member"** means the contract holder who may be the Employee, Retiree, Contract Employee, or Extended Beneficiary who is currently enrolled in Coverage and who has paid the necessary Deduction or Premium for such Coverage.

(26) **"Extended Beneficiary"** means the individual who was covered as an Active or Retired Employee, Employee on Approved Leave of Absence Without Pay or person who was covered as a Spouse or eligible Dependent of an Active or Retired Employee or Employee on Approved Leave of Absence Without Pay on the day SHBP Coverage was lost as a result of a Qualifying Event under the requirements of federal law and regulation known as the Consolidated Omnibus Budget Reconciliation Act (COBRA), as amended.

(27) **"Fund"** or **"Health Benefit Fund"** or **"Health Insurance Fund"** means the State Employees Health Insurance Fund, the Teachers Health Insurance Fund, and the Public School Employees Health Insurance Fund.

(28) **"Georgia Retiree Health Benefit Fund"** or **"GRHBF"** means the fund which provides for costs of retiree post employment health insurance benefits. The fund shall be a trust fund of public funds; the Board in its official capacity shall be the fund's trustee; and the Commissioner in his or her official capacity shall be its administrator.

(29) **"Group"** means all eligible Employees authorized under a specific chapter, article or part of the Official Code of Georgia Annotated for Coverage under the SHBP.

(30) **"Health Maintenance Organization"** or **"HMO"** means an organization authorized and certified to provide services under Chapter 21 of Title 33 of the Official Code of Georgia Annotated.

(31) **"Local Employer"** means a county or independent board of education, regional or county libraries of Georgia, the governing authority of the Georgia Military College, or Regional Educational Service Areas.

(32) **"Managed Care Plan"** means plans that provide health Coverage through a specified network of providers with benefit differentials in cost sharing between in-network and out-of-network providers.

(33) **"Medicare Advantage"** means an Option that is offered to Retirees and is approved through the Centers for Medicare and Medicaid Services (CMS) as a Medicare Advantage plan under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and federal regulations thereunder.

(34) **"Member"** means a benefit eligible or ineligible Employee, former Employee, Retiree, or Extended Beneficiary.

(35) **"Option"** means a type of benefit schedule or premium rating category that is offered to an eligible Member through the SHBP.

(36) **"Other Post Employment Benefits"** or **"OPEB"** means retiree post-employment health insurance benefits.

(37) **"Partial Disability"** means the Employee is unable to perform the normal, full-time duties of the individual's occupation or employment due to disability, but is certified by his/her physician to return to work on a part-time basis following a period of disability for a fixed period of time in that individual's occupation or in a modified work capacity.

(38) **"Payor, Primary"** means the entity which is required by contract or law to reimburse or pay for covered health services without regard to any other benefit entitlement or contractual provision.

(39) **"Payor, Secondary"** means the entity which does not have the primary liability for providing benefit reimbursement for covered health services.

(40) **"Plan"** or **"Health Insurance Plan"** means the insurance Options formed by the combination of Health Insurance Plans for State Employees, Teachers, and Public School Employees.

(41) **"Plan Year"** means the twelve-month period beginning on January 1, and ending on the following December 31. The Commissioner shall have the flexibility to modify the SHBP Plan Year.

(42) **"Pre-existing Condition"** is a term defined by the Health Insurance Portability and Accountability Act of 1996 and regulations thereunder. In general, it means a sickness, injury, or other condition (except for pregnancy) for which medical advice, diagnosis, care or treatment was recommended or received within the six (6) months immediately before Coverage began under the Plan.

(43) **"Premium"** means the Enrolled Member's cost as set by the Board of Community Health for the elected Coverage

(44) **"Public School Employee"** means a person who is employed by the local school system, meets the eligibility requirements under these regulations and is receiving a salary for services.

(45) **"Qualifying Event"** means an event as defined by federal law or regulation that authorizes:

(a) eligibility for Extended Coverageor

(b) change in coverage election under a health benefit plan. Qualifying Events include changes in employment or family status as outlined in Sections 111-4-1-.06, 111-4-1-.07, and 111-4-1-.08 of these regulations.

(46) **"Rate"** means an amount set by the Board for the Enrolled Member Premium or an amount or percentage of salary set by the Board as the Employer's Contribution.

(47) **"Regular Insurance"** means Options that are not Medicare Advantage Options.

(48) **"Retired Employee"** or **"Retiree"** or **"Annuitant"** means a former State Employee, former Teacher, or former Public School Employee who met the eligibility criteria when Active or was included by specific legislation and who receives a monthly benefit from the Employees' Retirement System, Georgia Legislative Retirement System, Teachers Retirement System, Public School Employees Retirement System, Superior Court Judges Retirement System, District Attorneys' Retirement System, or local school system retirement system and an eligible and former Employee of a county department of family and children services or county department of health who receives a monthly benefit from the Fulton County Retirement System. In the case of a county health department Employee, the Employee must have been covered as an Active Enrolled Member and continued Coverage upon receiving an annuity from the Fulton County Retirement System. Retiree shall also include Enrolled Members who remit payment directly to the SHBP and who are eligible for Coverage as a Surviving Spouse of the eligible Employee or Retiree, and Extended Beneficiary who is eligible by virtue of State law, or an Annuitant whose monthly benefit from a retirement system is insufficient to pay the Premium for the Coverage in which enrolled.

(49) **"Retiring Employee"** means a Enrolled Member who is eligible to receive an immediate retirement benefit payment from the Employees' Retirement System, Georgia Legislative Retirement System, Teachers Retirement System, Public School Employees Retirement System, Superior Court Judges Retirement System, District Attorneys' Retirement System or local school system retirement system or an Enrolled Member of a county department of family and children services or county department of health who is eligible to receive an immediate retirement benefit payment from the Fulton County Retirement System.

(50) **"Spouse"** means an individual who is not legally separated, who is of the opposite sex to the Enrolled Member and who is legally married or who submits satisfactory evidence to the Administrator of common law marriage to the Employee or Retired Employee entered into prior to January 1, 1997 and is not legally separated.

(51) **"State Employee"** means a person employed by the State or a community service board and who meets the eligibility definitions of these regulations and who is receiving a salary or wage for services rendered.

(52) **"State Health Benefit Plan"** or **"SHBP"** means the health benefit plan administered by the Department of Community Health covering State Employees, Public School Teachers, Public School Employees, Retirees and their eligible Dependents, and other entities under The Acts for health insurance.

(53) **"Summary Plan Description"** is a booklet that describes the health benefits and other provisions of the State Health Benefit Plan (SHBP) specific to the Coverage elected by the Enrolled Member.

(54) **"Surviving Spouse"** means the living Spouse of a deceased Enrolled Member.

(55) **"Teacher"** or **"Public School Teacher"** means a person employed by a local school system in a Certificated Position and who meets the eligibility definitions of these regulations and who is receiving a salary or wage for services rendered.

(56) **"Tier"** means the number and relationship to the Enrolled Member of the persons enrolled under the Member's Coverage.

(57) **"Total Disability"** means that the Enrolled Member is not able to perform any and every duty of the individual's occupation or employment or that the Dependent is not able to perform the normal activities of a person of like age or sex.

(58) **"TPA"** or **"Third-party Administrator"** means an approved contractor for adjudicating paying Claims, and performing other administrative processes.

(59) "**TRICARE Supplemental Coverage**" means insurance made available to Members who are eligible for SHBP Coverage and entitled to health care benefits under the TRICARE program, and for which premiums are collected by the Administrator and transferred to the company that sells the TRICARE Supplemental Coverage. TRICARE Supplemental Coverage provides health care benefits that are supplementary to health care benefits under TRICARE. The purchase of TRICARE Supplemental Coverage by eligible Members is facilitated by the Administrator and Employing Entities in accordance with the John Warner National Defense Authorization Act for Fiscal Year 2007 and implementing regulations. TRICARE Supplemental Coverage is a voluntary, unsubsidized benefit and is not endorsed or subsidized by the Administrator or any Employing Entity. The Administrator and Employing Entities provide minimal administrative duties with regard to TRICARE Supplemental Coverage, which duties are limited to providing information about the TRICARE Supplemental Coverage to

Members and facilitating the collection of premiums for such coverage and transmittal of the premiums to the company that sells the TRICARE Supplemental Coverage. Neither the Board, nor the Administrator nor any Employing Entity provides any incentive to Members to enroll in TRICARE Supplemental Coverage. Neither the Board, nor the Administrator, nor any Employing Entity receives any compensation or consideration for offering TRICARE Supplemental Coverage. TRICARE Supplemental Coverage is not considered SHBP Coverage.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.01
Authority: O.C.G.A. Secs. 20-2-881, 20-2-892, 20-2-911, 45-18-2, Health Insurance Portability and Accountability Act of 1996 (HIPAA), Consolidated Omnibus Budget Reconciliation Act (COBRA). Patient Protection and Affordable Care Act (PPACA); John Warner National Defense Authorization Act for Fiscal Year 2007.
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Rule 111-4-1-.02. Organizations.

(1) **Functions, Duties and Responsibilities of the Board of Community Health.** The Board shall provide policy direction for the operation of the State Health Benefit Plan. Other responsibilities as defined by law are:

(a) **Establish and Design Plan**. The Board is authorized to establish a Health Insurance Plan for group medical insurance against the financial costs of hospitalizations and medical care. The Plan may also include, but is not required to include, prescription drugs, prosthetic appliances, hospital inpatient and outpatient Benefits, dental Benefits, vision care Benefits, and other types of medical Benefits. The Plan shall be designed to:

1. Provide reasonable hospital, surgical, and medical benefits with cost sharing of expenses for each such type to be incurred by the Enrolled Members, Dependents and the Plan, and

2. Include reasonable controls, which may include deductible and reinsurance provisions applicable to some or all of the benefits, to reduce unnecessary utilization of the various hospital, surgical and medical services to be provided and to provide reasonable assurance of financial stability in future years of the Plan.

(b) **Promulgate Regulations.** The Board is authorized to adopt and promulgate rules and regulations for the effective administration of the SHBP; to adopt and promulgate regulations for defining the contract(s) for Retiring Employees and

their Spouses and Dependent children; to adopt and promulgate regulations for prescribing the conditions under which an Employee or Retiring Employee may elect to participate in or withdraw from the SHBP; to adopt and promulgate regulations defining the conditions for covering the eligible Member's Spouse and Dependent children and for discontinuance and resumption by eligible Members of Coverage for the Spouse, Surviving Spouse, and Dependents; to adopt and promulgate regulations to establish and define terms and conditions for former and terminated eligible Member participation; adopt and promulgate rules and regulations which define the conditions under which eligible Members who originally rejected Coverage may acquire Coverage at a later date; and adopt and promulgate rules and regulations for withdrawing from the SHBP upon eligibility for the aged program of the Social Security Administration. Additionally, the Plan shall be required to establish the same eligibility requirements, unless either State or federal law, or regulations promulgated by the State of Georgia's Insurance Commissioner requires a modification.

(c) **Establish Member Premium Rates.** The Board shall establish Member Premium Rates for each Coverage Option. The Board shall consider the actuarial estimate of the SHBP costs and the funds appropriated to the various departments, boards, agencies, and school systems in establishing the Employee Deduction amount. Other Member Premium amounts shall be established in accordance with these regulations. All Enrolled Member Premium Rates shall be established by resolution and shall remain in effect until changed by resolution.

1. **Tobacco Surcharge.** An Enrolled Member may be charged a tobacco surcharge in an amount approved by the Board if either the Enrolled Member or any of his or her Covered Dependents have used tobacco products in the previous twelve (12) months. The surcharge amount will be added to the Enrolled Member's base monthly Premium. Any Enrolled Member who fails to answer any designated question(s) relating to the surcharge during Open Enrollment will automatically be charged a surcharge for the remainder of the Plan Year, unless the tobacco user successfully completes a tobacco cessation program, or other similar program, specifically designated by the SHBP.

2. **Spousal Surcharge.** An Enrolled Member may be charged a spousal surcharge in an amount approved by the Board if the Enrolled Member elects to cover his or her Spouse and the Spouse is eligible for health benefits through his or her employer but opts not to take those benefits. Notwithstanding the foregoing, if the Spouse is already eligible for Coverage with the SHBP through his or her employment, and the Spouse answered the surcharge question(s) on-line, the SHBP will not add the surcharge to the Premium amount. Any Enrolled Member who fails to answer any designated question(s) relating to the surcharge during Open

Enrollment will automatically be charged the surcharge for the remainder of the Plan Year.

(d) **Establish Employer Rates.** The Board shall establish by Resolution, subject to the Governor's approval, Employer Contribution Rates. These rates may be a dollar amount for each Member, a dollar amount for each Enrolled Member, a percentage of Member salary or any other method permitted by law. If the rates are expressed as a percentage of Member salary, the requirements of (4) and (5) below apply. The Commissioner is authorized to establish necessary procedures to facilitate the receipt of Employer Contributions on a timely and accurate basis.

1. The Employer Contribution Rate for Teachers who retired prior to January 1, 1979 may be a dollar amount as identified in the Appropriations Act.

2. The State Department of Education Employer Contribution Rate for the Public School Employee Health Insurance Fund may be a dollar amount as identified in the Appropriations Act.

3. The local school system Employer Contribution Rate for the Public School Employee Health Insurance Fund may be a dollar amount per Enrolled Member and shall be remitted to the Administrator on a monthly basis. The Employer's Contribution amount shall be due to the Administrator on the first of the month coincident with the Employees' monthly Premium amounts.

4. The Employer Contribution Rate for the Teachers Health Insurance Fund may be a percentage of the salary approved by the State Board of Education under the Quality Basic Education Act for persons holding "Certificated Positions" or in a "Certificated Capacity". If it is expressed as a percentage of salary, the monthly Employer Contribution shall be a percentage of state based salaries. County or district libraries shall pay as the Employer Contribution the Board approved percentage of total salaries, exclusive of per diem and casual labor, which is defined as part-time Employees who work less than seventeen and a half (17 ½) hours per week. The Employer's contribution amount shall be due to the Administrator on the date coincident with the Employees' monthly Premium amounts.

5. The Employer Contribution Rate for the State Employees Health Insurance Fund may be a percentage of the total salaries of all Members. Total salaries include temporary salaries, overtime pay, terminal leave pay, and all types of supplemental pay. If it is expressed as a percentage of salary, the monthly Employer Contribution shall be based on salaries for the previous month and shall be due on the date coincident with the Employees' monthly Premium amounts.

6. The Employer Contribution Rate required for coverage of local school board members shall be based on the actual claims experience of all county officers, employees, and local school board members enrolled in the SHBP.

7. The Contributions required from Contract Employers shall be calculated in a manner designed to ensure that Contract Employers pay the full cost of coverage for Enrolled Members, plus an administration fee.

(e) **Approve Contracts.** The Board is authorized to approve contracts for insurance, reinsurance, health services, and administrative services for the operation of the Plan. The Board is authorized to approve contracts as authorized by law with governments, authorities, or other organizations for inclusion in the Plan.

1. **Insurance**. The Board may execute a contract or contracts to provide the Benefits under the Plan. Such contract or contracts may be executed with one or more corporations licensed to transact accident and health insurance business in Georgia. The Board shall invite proposals from qualified insurers who, in the opinion of the Board, would desire to accept any part of the health benefit Coverage. Any contracts that the Board executes with insurers shall require compliance with O.C.G.A. § 10-1-393(b)(30.1) relating to certain unfair practices in consumer transactions. The Board may reinsure portions of a contract for the Plan. At the end of any contract year, the Board may discontinue any contract or contracts it has executed with any corporation or corporations and substitute a contract or contracts with any other corporation or corporations licensed to transact accident and health insurance business in Georgia.

2. **Self Insurance.** The Board in its discretion may establish a self-insured Plan in whole or in part. The contract for Administrative Services in connection with a self-insured health benefit plan may be executed with an insurer authorized to transact accident and sickness insurance in Georgia; with a hospital service nonprofit corporation, nonprofit medical service corporation, or health care corporation; with a professional claim Administrator authorized or licensed to transact business in Georgia; or with an independent adjusting firm with Employees who are licensed as independent adjusters pursuant to Article 2 of Chapter 23 of Title 33.

3. **Local Governments.** The Board is authorized to contract with the various counties of Georgia, the County Officers Association of Georgia, the Georgia Cooperative Services for the Blind, public and private nonprofit sheltered employment centers which contract with or employ persons within the Division of Rehabilitation Services and the Division of Mental Health and Mental Retardation of the Department of Human Resources; and to contract with the Georgia Development Authority, the Georgia Agrirama Development Authority, the Peace Officer's Annuity and Benefit Fund, the

Georgia Firefighters' Pension Fund, the Sheriffs' Retirement Fund of Georgia, the Georgia Housing and Financing Authority, the Georgia-Federal State Inspection Service for the inclusion of eligible Members, retiring Enrolled Members and Dependents in the SHBP. The Board is authorized to include the Georgia-Federal State Inspection Service Employees who retired under the Employees' Retirement System of Georgia on or before July 1, 2000. The term of these contracts shall be established by the Department in accordance with these regulations and Board resolutions. The Board is authorized to contract with local boards of education for inclusion of current board members and their Dependents in the SHBP. The terms of such contracts are established by these regulations once an election for inclusion has been submitted to the Department by the local board of education. Each Contract Employer shall deduct from the Enrolled Members salary the Member's cost of Coverage. In the case of the Georgia Development Authority, the Peace Officers' Annuity and Benefit Fund, the Georgia Firefighters' Pension Fund, the Sheriffs' Retirement Fund of Georgia, the Georgia Housing Authority, and the Georgia Agrirama Development Authority, the Retiree's cost of Coverage shall be deducted from the Retired Enrolled Member's annuity payment. In addition, each Contract Employer shall make the Employer Contribution required for inclusion in the Plan and remit such payments in accordance with procedures as the Administrator may require.

4. **Consumer Driven Health Plans (CDHPs).** The Board may contract with any CDHP qualified and licensed to conduct business in Georgia pursuant to Chapter 21 of Title 33 of the Official Code of Georgia Annotated.

5. **Other Organizations.** The Board is authorized to contract with other organizations, including any public or nonprofit critical access hospital, and any federally qualified health center as defined in 42 U.S.C.A. 1395x(aa)(4), that meets such requirements as the Administrator may establish for the inclusion of eligible Members and Dependents in the SHBP. Each Contract Employer shall deduct from the Enrolled Member's salary the Member's share of the cost of Coverage. Each Contract Employer shall remit the total Premium amount as established by the Administrator for inclusion of its Members in the Plan and in accordance with such procedures as the Administrator may require. The Board may require that specified Groups provide a bond to ensure payment performance before allowing SHBP Coverage.

6. **Health Maintenance Organizations (HMOs)**. The Board may contract with any HMO qualified and licensed to conduct business in Georgia pursuant to Chapter 21 of Title 33, relating to Health Maintenance Organizations.

7. **Local School Systems.** When a school system has elected not to participate in the SHBP for Public School Employees, the Employees may petition the local school system to contract with the Board for an Employee-Pay-Group. The local system may contract with the Board after agreeing to:

   (i) Collect the Enrolled Member Premium amounts for the Rates established by the Board; and

   (ii) Enroll and maintain enrollment at 75% of the eligible Public School Employees as defined in these regulations.

(2) **Functions, Duties and Responsibilities of the Commissioner.** The Commissioner is the chief administrative officer of the Department of Community Health. The Commissioner and Administrator as used in these regulations are synonymous. The Commissioner shall employ such personnel as may be needed to administer the SHBP, to appoint and prescribe the duties of positions, all positions of which shall be included in the classified service except as otherwise provided in the law, and may delegate administrative functions and duties at the Commissioner's discretion.

(a) **Administer Regulations and Policies.** The Commissioner shall administer the SHBP consistent with applicable law, Board regulation and policy.

(b) **Custodian of Funds.** The Commissioner shall be the custodian of the health benefit Funds and shall be responsible under a properly approved bond for all monies coming into said Funds and paid out of said Funds.

1. All amounts contributed to the Funds by the Member and the Employers and all other income from any source shall be credited to and constitute a part of such trust Funds. Any amounts remaining in such Fund(s) after all expenses have been paid shall be retained in such Fund(s) as a special reserve for adverse fluctuation.

2. The Commissioner shall establish accounting procedures for maintaining trust Funds for the Premium income, interest earned on the income and expenses and benefits paid. Any amounts remaining in each trust Fund after all expenses have been paid shall be retained wholly for the benefit of the members who are eligible and who continue to participate in each health insurance trust.

3. The Commissioner shall submit to the Director of the Office of Treasury and Fiscal Services any amounts available for investment, an estimate of the date such Funds shall no longer be available for investment, and when Funds are to be withdrawn. The director of the Office of Treasury and Fiscal Services shall deposit the Funds in a trust account for credit only to the Plan and shall invest the Funds subject only to the terms, conditions, limitations

and restrictions imposed by the laws of Georgia upon domestic life insurance companies.

4. The Commissioner may administratively discharge a debt or obligation not greater than $400.00 due the Health Insurance Fund or Funds.

5. **Accurate and Timely Payment of Employer or Employee Contributions.**

   (i) **Payroll System and Other Supporting Documentation Required.** Employing Entities that pay Employer Contributions calculated based on salaries or state based salaries must submit the documentation set forth below, in the format required by the Administrator.

      (I) Annually and upon request of the Administrator, the Employing Entity must submit documentation showing that the Employing Entity's payroll software is set up to correctly reflect the salary or state-based salary used to determine the required Employer Contribution for each month. This requirement may be satisfied by the State Accounting Office on behalf of all Employing Entities that use payroll software managed by the State Accounting Office.

      (II) At the time of each payment of Contributions, the Employing Entity must submit the summary page from the payroll software that displays the total salary or state-based salary used to determine the required Employer Contribution for that month, documentation showing that Employee Contributions were properly calculated and remitted, and documentation showing that Employer and Employee Contributions required for employees on unpaid leave of absence were properly calculated and remitted.

   (ii) **Local Employers.** When a required payment from a local Board of Education, RESA, library or charter school is not received by the deadline, the Administrator shall notify the appropriate superintendent or official and the State Board of Education of the delinquency. The State Board of Education is required by law to withhold all allotments to the local Board of Education, RESA, library or charter school until the full required payment is received.

   (iii) **Entities Included in the SHBP Pursuant to Contract.** Upon providing written notice, the Commissioner may terminate Coverage for any Group that either contracts for SHBP Coverage or is designated by applicable state law as eligible for such Coverage

for failure to remit either Employee or Employer Contributions. Upon remittance of the required contributions from any Group that either contracts for SHBP Coverage or is designated by applicable state law as eligible for such Coverage, the SHBP may reinstate Coverage that has been terminated previously for failure to remit Premiums.

(c) **Regulations**. The Commissioner shall recommend to the Board amendments to the regulations, submit the approved regulations to appropriate filing entities, cause all regulations to be published and provide a copy to the Employing Entities.

(d) **Elicit and Evaluate Proposals from Health Care Contractors and/or Administrators.** As required for the appropriate administration of the Plan, the Commissioner shall cause to be prepared requests for proposals for selection of health care contractors, vendors, or administrators. Upon receipt of the proposals, the Commissioner shall secure an evaluation of the proposals and submit recommendations for the selection of health care contractors, vendors, or administrators to the Board for approval.

(e) **Calculate Employer Contribution Rates**. The Commissioner shall cause to be calculated Employer Contribution Rates expressed in the manner specified in Section 111-4-1-.02(d)(1) - (5) of these regulations. These Employer Contribution Rates shall be calculated and presented to the board by such time as is required for the Commissioner to meet the notification deadline set forth in (h) below.

(f) **Premium Payments to a Contractor.** The Commissioner shall cause to be calculated the Premium amounts due to any underwriter of insurance or re-insurance and remit payments from the appropriate trust Funds for Member Coverage.

(g) **Develop and Publish Enrollment Materials, Legal Notices, and Plan Documents.**The Commissioner shall cause to be developed enrollment materials, legal notices, and plan documents for Coverage Options. Plan documents shall include, for each Option, a Summary Plan Description (SPD) or Certificate of Coverage which incorporates the approved schedule of Benefits, eligibility requirements, Termination of Coverage provisions, Extended Coverage provisions, to whom benefits will be payable, to whom claims should be submitted, and other administrative requirements. The Commissioner or designee shall publish enrollment materials, legal notices and plan documents on the portion of the Department Website dedicated to the State Health Benefit Plan, and shall provide electronic versions of the enrollment materials, legal notices and plan documents to each local and state Employer for distribution to eligible Members and Enrolled Members. The Commissioner or designee shall cause to

distribute the enrollment materials, legal notices and plan documents to Retired Enrolled Members and Extended Beneficiaries at their last known address.

(h) **Provide Notice of Employer Contribution.** The Commissioner shall provide notice and certification of the required Employer Contribution Rate to each of the Employing Entities and the Department of Education no less than thirty (30) days prior to the commencement of the plan year. The Commissioner shall notify the Employing Entities before the Rate is effective of any Rate change which may be required at times other than the beginning of a fiscal year.

(i) **Provide Notice of Eligibility.** The Commissioner shall develop procedures for notifying Extended Beneficiaries of the Extended Coverage provisions of Section 111-4-1-.08 of these regulations upon notification by the Employing Entity of the Enrolled Member's employment termination, death, or reduced hours or upon notification by the Member of divorce, legal separation, or child no longer meeting the definition of Dependent.

(j) **Provide Certification of Creditable Coverage**. The Administrator shall establish procedures for providing a Certificate of Creditable Coverage to each Enrolled Member in compliance with federal law. In general, this Certificate of Creditable Coverage must be provided at the time Coverage cancels or upon request of the Member or Covered Dependent and for a period of twenty-four (24) months after coverage cancellation. The Member may use the certification to limit a subsequent plan's imposition of a Pre-existing Condition limitation or exclusion period.

(k) **Correction for Administrative Error.** An administrative error is defined as any clerical error in submitting pertinent records or a delay in making any changes by the Employing Entity or Administrator that affects the Coverage for a Member or Dependent who has followed all established procedures and met the time deadlines regarding enrollment or maintenance of Coverage. If the error has placed the Member or Dependent at a substantial financial risk or risk of loss of Coverage, the facts shall be reviewed and corrective action taken. If the Administrator concludes that the Member or Dependent was substantially harmed, the Member or Dependent shall be restored to the former position or shall be granted the request in whole or in part. Any determination of an administrative error shall be left to the discretion of the Administrator and is not subject to challenge.

(l) **Perform Minimal Administrative Duties and Maintain Documentation Associated with Tricare Supplemental Insurance.**Any TRICARE Supplemental Insurance made available to Members shall be made available in accordance with the John Warner National Defense Authorization Act for Fiscal Year 2007 (the "DAA") and implementing regulations. The Administrator shall not endorse or subsidize TRICARE Supplemental Insurance and shall ensure that it provides only administrative support associated with enabling Members to elect TRICARE

Supplemental Insurance and pay for such Insurance through salary deductions or annuity payments. The Administrator shall maintain the certification required by the DAA on behalf of all Employing Entities and provide such certification to the Department of Defense upon request. The Administrator shall take such other actions are necessary to ensure compliance with the DAA.

(3) **Duties and Responsibilities of Employing Entity.** Each Employing Entity is responsible for complying with these regulations. Statements made by the staff of the Employing Entities or any third party representing the Employing Entity, that are in conflict with these regulations, the Schedule of Benefits, Decision Guide, or the Summary Plan Description (SPD) shall not be binding on the Administrator. Failure of the Employing Entities to fulfill the duties and responsibilities listed in these regulations does not negate the time requirements specified throughout these regulations.

(a) **Enroll Eligible Employees.** Each Employing Entity shall determine which of its employees meet the SHBP eligibility requirements, which are set forth in the regulations. Each Employing Entity is solely responsible for compliance with State and federal employment laws with respect to its own employees. Each Employing Entity is solely responsible for complying with State and federal obligations to verify eligibility for receipt of health benefits that meet the definition of "public benefits" under applicable immigration laws. Each Employing Entity is solely responsible for obtaining all documentation required under applicable immigration laws, and taking all actions necessary to verify the employee's eligibility to receive "public benefits." Each Employing Entity shall provide enrollment materials, legal notices and plan documents to eligible Members and Enrolled Members, and shall instruct and assist all persons who become eligible to become Enrolled Members under these regulations how to complete the SHBP enrollment or declination process. The Employing Entity shall require each eligible new Member to complete, within thirty-one (31) calendar days of reporting to work, a form for enrolling or declining SHBP Coverage. The Employing Entity shall be responsible for collecting any Premiums due for the selected Coverage. Any penalties or claim expenses resulting from the Employing Entity's enrollment of an ineligible Member, or from the Employing Entity's failure to timely obtain the completed enrollment or declination form, or from the Employing Entity's failure to provide Plan Documents, legal notices or enrollment information to an eligible Member, shall be assessed against the Employing Entity. By facilitating the enrollment of a Member in the SHBP or communicating that a Member is eligible for the SHBP, the Employing Entity is affirming that it has taken all actions required by law for the provision of "public benefits" to that individual. Any penalties arising from the Employing Entity's failure to take such actions shall be assessed against the Employing Entity. Neither the Board nor the Administrator nor the Commissioner shall be liable for the failure of an Employing Entity to comply with employment laws or properly verify SHBP eligibility in accordance with State and federal immigration laws.

(b) **Deduct Enrolled Member Premium Amounts**. The Employing Entity shall withhold the Enrolled Member Premium amount as approved by the Board, or the Premium amount authorized by the applicable Georgia Code sections from earned compensation as the Enrolled Member's share of the cost of Coverage under the Plan. Any retirement system under which retired or retiring Enrolled Members may continue Coverage under the SHBP as an Annuitant shall withhold the Premium amount as approved by the Board from the annuity as the Enrolled Member's share of the cost of Coverage under the Plan.

(c) **Remit Enrolled Members' Premiums and Required Employer Contributions.** Employing Entities shall remit the following within five business days of the SHBP billing invoice's coverage month effective date:

1. Enrolled Members' premiums paid through salary deductions or annuity deductions;

2. Premiums collected from employees who have continued their coverage during an Approved Leave of Absence without Pay; and

3. Required Employer Contributions, which include contributions separately calculated for employees on an Approved Leave of Absence without Pay.

   For any contribution that is based on actual SHBP enrollment, each Employing Entity is responsible for reconciling any discrepancies between the billed amount and actual enrollment. All corrections to the employee coverage or deductions should be made prior to the coverage month's effective date. The Employing Entity shall follow the manner prescribed by the Administrator for both corrections and reconciliation. The amounts billed on the invoice will be considered final if reconciliations are not completed within 30 day of the billing invoice.

(d) **Administer Leave Without Pay Provisions.** Each Employing Entity shall administer Approved Leave of Absence Without Pay, Military Leave, and Family and Medical Leave Act Programs in compliance with the federal laws and shall provide information regarding the conditions for continuing Coverage under the SHBP to eligible Enrolled Members. Each Employing Entity shall also provide continuation of Coverage enrollment information to Members. Each Employing Entity shall insure Members on Approved Leave of Absence Without Pay are properly notified of the annual Open Enrollment period and afforded the opportunity to enroll or change Coverage. Each Employing Entity shall maintain procedures to ensure that Member Premiums are collected during these leave periods. If a Member fails to timely pay a Premium during the leave period, that failure causes a loss of eligibility for coverage unless federal law requires otherwise.

(e) **Provide Member Loss of Eligibility Information to the Administrator.** Each Employing Entity shall report to the Administrator the last date employed/eligible and the reason for the loss of employment/eligibility no later than thirty (30) days following the event leading to loss of eligibility to participate in the Plan. The reasons for loss of eligibility shall be limited to: failure of a Member to pay a required Premium during an approved leave of absence (unless federal law requires continuing coverage), resignation, transfer, retirement, termination of employment for gross misconduct, separation from employment for reasons other than gross misconduct, including, but not limited to loss of eligibility to work under applicable immigration laws, reduction in employment hours below the number of hours required for eligibility, lay-off, failure of an Enrolled Member to timely submit a required Premium during an approved leave of absence without pay, discontinuation, and death. Each Employing Entity is solely responsible for penalties or other liabilities arising from its failure to timely notify the Administrator of loss of eligibility for Coverage. Any claim expenses borne by the SHBP, and any penalties assessed upon the Administrator as a result of the Employing Entity's failure to timely notify the Administrator of a Member's loss of eligibility shall be billed to the respective Employing Entity. The Employing Entity shall reimburse the Administrator in full for claim liability and expenditures incurred by the Plan as a result of the Employing Entity's failure to comply with notification requirements.

(f) **Protect the Privacy of Enrollment Information.** The SHBP only shares enrollment information with designated employees of the Employing Entity who help with Plan enrollment. Each Employing Entity shall ensure that the SHBP is promptly notified whenever such an employee is no longer permitted to review and share enrollment information about Members with the SHBP. The Employing Entity shall ensure that designated employees are properly trained to protect the privacy and security of the enrollment information. The Employing Entity shall never use enrollment information for any purpose other than helping with enrollment in the Plan.

(g) **Refrain from Endorsing TRICARE Supplemental Coverage or Providing Incentives for Members to Elect TRICARE Supplemental Coverage.** If TRICARE Supplemental Insurance is made available, Employing Entities shall refrain from endorsing TRICARE Supplemental Insurance or providing any incentives to those who elect TRICARE Supplemental Insurance. Any TRICARE Supplemental Insurance is to be offered only in accordance with the requirements of the John Warner National Defense Authorization Act for Fiscal Year 2007 (the "DAA") and implementing regulations. Employing Entities shall not pay any portion of TRICARE Supplemental Coverage. Nor shall they provide any incentive to individuals who elect TRICARE Supplemental Coverage. Enrolled Members must elect TRICARE Supplemental Coverage by salary deduction or annuity deduction in the same manner they elect SHBP Coverage Options. Any penalties arising from impermissible incentives by the Employing Entity shall be

assessed against the Employing Entity. Employing Entities shall provide certifications described in regulations to the Administrator or to the Department of Defense upon request.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.02
Authority: O.C.G.A. Secs. 20-2-55, 20-2-881, 20-2-883 to 20-2-885, 20-2-891 to 20-2-896, 20-2-911 to 20-2-916, 20-2-918 to 20-2-922, 20-2-924, 31-5A, 45-18-1*et seq.*, Health Insurance Portability and Accountability Act (HIPAA), Consolidated Omnibus Budget Reconciliation Act (COBRA), Family Medical Leave Act (FMLA). John Warner National Defense Authorization Act for Fiscal Year 2007; Illegal Immigration Reform and Enforcement Act of 2011; Georgia Security and Immigration Compliance Act; Personal Responsibility and Work Opportunity Reconciliation Act of 1996.
History. Original Rule entitled "Organization" adopted. F. Apr. 18, 2005; eff. May 8, 2005.
Amended: F. Sept. 26, 2006; eff. Oct. 16, 2006.
Repealed: New Rule entitled "Organizations" adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.
Amended: F. May 25, 2007; eff. June 14, 2007.
Amended: F. Aug. 20, 2008; eff. Sept. 9, 2008.
Repealed: New Rule of same title adopted. F. Apr. 14, 2010; eff. May 4, 2010.
Amended: F. Jan. 26, 2011; eff. Feb. 16, 2011.
Amended: F. Jan. 17, 2012; eff. Feb. 6, 2012.

Rule 111-4-1-.03. General Provisions.

(1) **Applicability.** All Members who become eligible for Coverage under the SHBP shall be enrolled or permitted to change Coverage election only in accordance with these regulations. All Employing Entities covered by the Acts shall administer the SHBP in accordance with these regulations. All Annuitants or Extended Beneficiaries shall be enrolled or permitted to change Coverage election only in accordance with these regulations.

(2) **Extension of SHBP to Eligible Groups.** The Board shall review and approve provisions for extending Coverage to eligible Groups as required by law. The special provisions may include allowing Members or Beneficiaries to reenroll in the SHBP.

(3) **Conformity with Federal Requirements.** When federal law is enacted requiring public employers to comply with certain requirements for continued receipt of public health or other grant funds, the Commissioner shall submit proposed regulations to the Board for approval.

(4) **Records.** The Plan records shall be maintained in accordance with applicable State and federal law and regulations, including, but not limited to, Chapter 33 of Title 31 of the Georgia Code and the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Records which are not private, confidential or otherwise excluded from disclosure shall be available for public inspection and copying, in accordance with the Georgia Open Records Act. Any medical records and other individually identifying health information presented to the Administrator or to any

of the Third Party Administrators in the Claim adjudication process or medical review process shall be confidential and shall be accessible only in accordance with applicable State and federal law and regulations.

(5) **Member Responsibility.** The Member has responsibility for notifying the Employer and the Plan of discrepancies in the Member's Coverage records. Notwithstanding the foregoing, the requirements of this provision do not negate the Employer's responsibility. The Employing Entity must still fulfill notification and all other requirements set forth under these regulations.

(a) The Enrolled Member is responsible for assuring that the proper Premium payments are deducted or reduced from the Enrolled Member's salary or retirement benefit for the Coverage that the Enrolled Member selected. Premiums of Enrolled Members that are paid through direct pay are to be paid in accordance with their Coverage selection.

(b) The Enrolled Member is responsible for submitting such documentation as the Plan requires to verify the eligibility of Dependents to be added to Coverage within the timeframe allotted by the Plan. Any Dependents not verified within the Plan's allotted time shall not be eligible for Coverage until the next annual Open Enrollment period or subsequent Qualifying Event as described in these regulations.

(c) The Enrolled Member is responsible for updating Spouse and Dependent information and requesting appropriate changes in Coverage as the circumstances may warrant. The Enrolled Member shall reimburse the Plan in full for Claim liability and expenditures incurred by the Plan on behalf of a Dependent who does not meet the definition of an eligible Dependent under these regulations. Any refunds of Premiums (for reasons other than administrative error) will be limited to twelve (12) calendar months from the date that the Administrator receives evidence from the Enrolled Member that the Plan had no liability for additional covered persons.

(d) When the Enrolled Member desires to reduce the period under the insurance Options of limited Coverage for Pre-existing conditions which may apply to himself/herself or any Covered Dependent, the Enrolled Member shall provide the Administrator certification of prior Creditable Coverage from the appropriate health plan administrator.

(6) **Gender and Number.** Except when otherwise indicated by the context, any masculine terminology herein shall also include the feminine and the definition of any terms herein of the singular may also include the plural.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.03
Authority: O.C.G.A. Secs. 20-2-881, 20-2-894, 20-2-897, 20-2-911, 20-2-922, 20-2-925, 45-18-1*et seq.*, 50-18-72, 50-18-94, Health Insurance Portability and Accountability Act (HIPAA).
History. Original Rule entitled "General Provisions" adopted. F. Apr. 18, 2005; eff. May 8, 2005.

Amended: ER. 111-4-1-0.1-.03 adopted. F. June 13, 2005; eff. June 16, 2005, as specified by the Agency.
Amended: Permanent Rule adopted. F. Sept. 15, 2005; eff. Oct. 5, 2005.
Repealed: New Rule of same title adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.

Rule 111-4-1-.04. Eligibility for Coverage.

(1) Active Employees. Employees who are actively at work or on approved leave of absence and have not terminated their employment may participate in the SHBP if classified as the following:

(a) **Full-Time.**

1. State Employees who work a minimum of thirty (30) hours per weeks are considered full-time.

2. A regular full-time Employee who receives a salary or wage payment from a state department, board, agency, commission, the general assembly, a community service board, or a local government or other organization to which the Department of Community Health provides SHBP coverage through a contract authorized by the Board of Community Health; except contingent workers of the Labor Department, specially classified Employees of the Jekyll Island State Park Authority, Employees working as an independent contractor or on a temporary, seasonal, or intermittent basis and Employees whose duties are expected to require less than nine (9) months of service.

3. A regular full-time Employee who receives a salary or wage payment from a state authority that participates in the Employees' Retirement System;

4. Part-time Employees of the General Assembly who had coverage prior to January 1981, and Administrative and clerical personnel of the General Assembly;

5. A full-time district attorney, assistant district attorney who was appointed pursuant to O.C.G.A. § 15-18-14, or district attorneys' investigators appointed pursuant to O.C.G.A. § 15-18-14.1 of the superior courts of this state;

6. A full-time Employee who receives a salary or wage payment from a county board of health or a county board of family and children services that receives financial assistance from the Department of Human Resources; except for sheltered workshop Employees;

7. Full-time secretaries and law clerks who are employed by district attorneys and judges and are employed under O.C.G.A. §§ 15-6-25 through 15-6-28 and O.C.G.A. §§ 15-18-17 through 15-18-19.

(b) Teachers who are employed not less than half time, which must be at least seventeen and a half (17½) hours per week, in the public school systems of Georgia are eligible to participate under these regulations. An eligible teacher shall not include any independent contractor, emergency or temporary person and is further defined as:

1. A person employed in a professionally Certificated Capacity or Position in the public school systems of Georgia;

2. A person employed by a regional or county library of Georgia;

3. A person employed in a professionally Certificated Capacity or Position in the public vocational and technical schools operated by a local school system;

4. A person employed in a professionally Certificated Capacity or Position in the Regional Educational Service Areas of Georgia;

5. A person employed in a professionally Certificated Capacity or Position in the high school program of the Georgia Military College.

(c) Public School Employees who are employed by a local school system that have elected to participate in the Plan, and are not considered independent contractors, are eligible to enroll under the conditions of these regulations.

1. An Employee who is eligible to participate in the Public School Employees Retirement System as defined by Paragraph (20) of O.C.G.A. § 47-4-2 may enroll, provided the Employee works the greater of at least 60 percent of the time required to carry out the duties of such position or a minimum of fifteen (15) hours per week and is not employed on an emergency or temporary basis.

2. An Employee who holds a non-certificated public school position and who is eligible to participate in the Teachers Retirement System (or other independent local school retirement system), provided the Employee is not employed on an emergency or temporary basis and the Employee works at least 60 percent of the time required to carry out the duties of such position or a minimum of twenty (20) hours per week, whichever is greater may enroll.

(d) **Local Boards of Education** that elect to provide group medical insurance for members of the local board of education, their spouses, and dependents in accordance with O.C.G.A. § 45-18-5 are eligible to enroll under the conditions of these regulations. Collection and remittance of Enrolled Member premium and employer contribution amounts shall be in accordance with O.C.G.A. § 20-2-55 and these regulations.

(2) **Retired Employees.** Any Employee who was eligible to participate under 111-4-1-.04(1)(a), 111-4-1-.04(1)(b), or 111-4-1-.04(1)(c) and who was enrolled in the Plan at the time of retirement shall be eligible to continue coverage if:

(a) The Retired Employee is eligible to immediately receive an annuity from the Employees' Retirement System, Georgia Legislative Retirement System, Judicial Retirement System, Superior Court Judges or District Attorneys' Retirement System, Teachers Retirement System, Public School Employees Retirement System, any local school system teachers retirement system, or other retirement system with which the Board is authorized to contract; or

(b) The Retired Employee as an Employee of a county department of family and children services or a county department of health is eligible to receive an annuity from the Fulton County Retirement System.

(3) **Eligibility for Coverage as an Enrolled Member and a Dependent.** In the situation where both husband and wife are eligible to be covered under the SHBP as an Enrolled Member, each may enroll as a Member and enroll the eligible dependents. The benefits provided under the SHBP will be coordinated in accordance with the Coordination of Benefits or the Medicare Coordination of Benefits provisions of the Summary Plan Description. In no case shall the sum of the total benefits provided by the SHBP exceed the reasonable charges for covered services.

(4) **Eligibility for Coverage as an Enrolled Member Limited.** In the situation where the Enrolled Member is entitled to Coverage under the SHBP as an Active Employee under a health insurance act and Retired Employee under a different health insurance act, or any combination of provisions, the Member may choose among the Active Employee provisions under which the Member will be covered, but may not choose Coverage as a Retiree or Beneficiary of a Retiree as long as the Member is eligible for Coverage under one of the Active Employee provisions. In no circumstance shall the individual be an Enrolled Member under more than one provision of these regulations.

(5) **Eligibility for Coverage as an Active Employee with Two (2) Employing Entities.** Dual eligibility and overlapping Coverage shall be handled as follows:

(a) **Dual Eligibility.** In the situation where the Enrolled Member is eligible for Coverage under the SHBP as an Active Employee of two (2) separate Employing Entities, the Employee may, during the annual Open Enrollment period, elect which Employing Entity shall deduct the Employee Premium in the upcoming Plan Year. Each Employing Entity is responsible for remitting Employer Contribution amounts in accordance with 111-4-1-.02(3)(d) of these regulations.

(b) **Overlapping Coverage.** In the situation where the Enrolled Member experiences a period of overlapping Coverage as a result of transferring employment between two (2) separate Employing Entities, the Coverage effective date with the second Employer shall determine the Coverage termination date with the first Employer.

The Employing Entities shall be responsible under this provision for deducting or refunding Employee Premiums as appropriate.

(6) **Employees on Leave Without Pay.** Active Employees who are Enrolled Members of the SHBP may continue the Coverage in which enrolled during a period of "Approved Leave of Absence Without Pay", subject to the conditions in these regulations. Enrolled Employees who are on suspension or Approved Leave of Absence Without Pay who did not continue Coverage shall not be eligible to enroll or re-enroll for Coverage while on Approved Leave of Absence Without Pay under any provision of these regulations except during the annual Open Enrollment period. Except for military leave Coverage shall not be extended for an Employee who is self employed or gainfully employed by another party during a period of Approved Leave of Absence Without Pay. A request to continue Coverage while on Approved Leave Without Pay must be received by the Employing Entity within thirty-one (31) calendar days of the termination of paid Coverage through payroll Deductions. Employees who qualify for continued Coverage under multiple leave types may continue Coverage under a combination of leave types; however, the total period of Coverage on Approved Leave of Absence Without Pay shall not exceed twelve (12) calendar months, unless otherwise noted in these provisions. Premium payments must be in an amount sufficient to provide continuous Coverage between termination of paid Coverage through payroll Deductions and the beginning of Approved Leave of Absence Without Pay Coverage. When an Employee on Approved Leave of Absence Without Pay enrolls during the annual Open Enrollment, Period the twelve (12) calendar month Coverage period shall be reduced by the number of prior months of Approved Leave of Absence Without Pay during which the Employee did not elect to participate in the SHBP. Employees on Leave Without Pay must timely submit required Premiums to the Employing Entity, and the Employing Entity must timely pay required Employer Contributions associated with such Employees. An Employee's failure to timely submit a required Premium to the Employing Entity causes a loss of eligibility for Coverage, and the Employing Entity must timely notify the Administrator of loss of eligibility in accordance with these regulations.

(a) **Disability Leave.** A disability leave is the period of time an Approved Leave of Absence Without Pay has been granted to the Employee due to personal illness, accident or disability. Coverage may be continued under this paragraph for the period of disability, but not longer than twelve (12) consecutive calendar months. Certification of the disability period by a licensed physician shall be required to continue coverage under this provision.

(b) **Reduced Working Hours Due to Partial Disability.** A Partial Disability leave is the period of time during which an Employer approves an Employee's return to work on a part-time basis from a period of disability leave or paid leave if the part-time work is part of a process to gradually return the Employee to full-time work. Coverage may be continued under this provision for the period of disability approved by a licensed physician, but not longer than twelve (12) consecutive calendar months, inclusive of any time from a period of disability leave without

pay. Certification of the Partial Disability period shall be required to continue coverage under this provision.

(c) **Leave of Absence for the Employer's Convenience.** Employer's convenience leave is a period of time during which an Approved Leave of Absence Without Pay has been granted by the appropriate organizational official due to a regular programmatic plan for Employee absence and pursuant to appropriate regulation. The Employee may continue the Coverage such leave of absence, but not longer than twelve (12) consecutive calendar months.

(d) **Educational Leave.** Educational leave is the period of time during which an Approved Leave of Absence Without Pay has been granted by the appropriate organizational official for educational or training purposes. The Employee may continue the Coverage under such leave for the period of absence, but not longer than twelve (12) consecutive calendar months.

(e) **Family Medical Leave.** Family medical leave is the period of time during which an Approved Leave of Absence Without Pay has been granted to the Employee by the appropriate organizational official for personal illness, the care of the Employee's child after birth or placement for adoption or the care of an Employee's seriously ill Spouse, child, or parent. An Employee's personal illness, if properly certified and approved may be granted under the disability leave provisions. Coverage while on Approved Leave of Absence Without Pay for family medical leave may be continued for the period of approved leave, but not longer than twelve (12) weeks in any twelve (12) consecutive month period.

(f) **Military Leave.** Military leave is the period of time during which an Approved Leave of Absence Without Pay has been granted by the appropriate organization official when an Employee is ordered to military duty or the period, as provided by law, during which an Employee is attending military training. Military leave also applies to an Employee who qualifies for an exigency leave or service member care leave, as defined under Federal law. The Employee may continue the Coverage under such leave for the period of absence.

(g) **Suspension or Other Leave of Absence.** Suspension or other leave of absence is the period of time during which suspension is in effect or an Approved Leave of Absence Without Pay has been granted by the appropriate organization official for the Employee's convenience. The Employee may continue the Coverage for the period of suspension or approved leave, but not to exceed twelve (12) calendar consecutive months, provided the Employee is not self employed or gainfully employed by another party during such leave of absence.

(h) **Extensions of Leave of Absence.** If the Employee is unable to return to work at the expiration of the approved leave and the maximum period has not been exhausted, a request to extend the leave of absence may be filed. The Administrator must receive the Employee's request for extension no later than

thirty-one (31) calendar days following expiration of Coverage under the leave of absence. The Employing Entity must certify approval of the extension. The attending physician must complete a new disability certification for an extension of a disability leave.

(i) **Sequential Periods of Leave.** Health benefits may be continued during sequential types of leave, provided that continuation of health benefits during continuous, sequential periods of time shall not exceed the time limitation of the most recently approved type of leave.

(j) **Premiums.** Premiums for continued Coverage during a period of Approved Leave of Absence Without Pay shall be paid monthly to the Employing Entity. When establishing the monthly Premium amount to be paid by the Employee, the Board may add a processing fee. The Premium Rate, excluding the processing fee, shall be based on the type of approved leave. The Premium Rate for disability, family leave or military leave of absence shall be the same as the Employee Deduction; the Premium Rate for all other types of leave shall be the total cost of coverage as set forth in Board resolution. Failure to pay the full Premium to the Employing Entity within the allotted time shall result in loss of eligibility for Coverage.

(7) **Spouse.** An Active Employee shall be entitled to enroll the Employee's Spouse upon employment, during Open Enrollment, or under conditions specified in Section 111-4-1-.06 of these regulations. A Retiree shall be entitled to continue Coverage for the Spouse upon retirement or may enroll the Spouse in accordance with Section 111-4-1-.06(5) or 111-4-1-.06(6). The Administrator shall require the Social Security Number for the Spouse as well as appropriate documentation from an Enrolled Member in order to verify a Spouse's eligibility for Coverage.

(8) **Dependent Child.** An Active Employee shall be entitled to enroll eligible Dependent children upon employment, during Open Enrollment, or under conditions specified in Section 111-4-1-.06 of these regulations. A Retiree shall be entitled to continue Coverage for eligible Dependent children upon retirement or may enroll eligible Dependent children in accordance with Section 111-4-1-.06(5). The Administrator shall require the Social Security Number for every child, starting at age two, as well as appropriate documentation from an Enrolled Member in order to verify a Dependent child's eligibility for Coverage. An eligible Dependent child must meet one of the following definitions;

(a) A natural child, for which the natural guardian has not relinquished all guardianship rights through a judicial decree. Eligibility begins at birth and ends at the end of the month in which the child reaches age twenty-six (26);

(b) An adopted child. Eligibility begins on the date of legal placement for adoption and ends at the end of the month in which the child reaches age twenty-six (26);

(c) A stepchild. Eligibility begins on the date of marriage to the natural parent and ends at the end of the month in which the child reaches age twenty-six (26), or at

the end of the month in which he or she loses status as the stepchild of the Enrolled Member, whichever date is earlier; or

(d) Guardianship. A child for whom the Enrolled Member is the legal guardian. Eligibility begins on the date the legal guardianship is established and ends at the end of the month in which the child reaches age twenty-six (26), or at the end of the month in which the legal guardianship terminates, whichever is earlier. Certification documentation requirements are at the discretion of the Administrator. However, a judicial decree from a court of competent jurisdiction is required unless the Administrator concludes that documentation is satisfactory to establish legal guardianship and financial dependence and that other legal papers present undue hardship on the Member or living natural parent(s).

(9) **Totally Disabled Child.** An Enrolled Member shall be entitled to apply for Coverage of a natural child, legally adopted child or stepchild age twenty-six (26) or older if the child was physically or mentally disabled before age twenty-six (26), continues to be physically or mentally disabled, lives with the Enrolled Member or is institutionalized and depends primarily on the Enrolled Member for support and maintenance.

(a) **Application Period.** The Enrolled Member may apply for Coverage during Open Enrollment, as a New Hire, or as the result of a Qualifying Event. At all other times, an Enrolled Member whose Totally Disabled Child was a covered dependent on the Member's Family Plan prior to turning age twenty-six (26) must apply for continuation of Coverage and include all supporting documentation no later than thirty-one (31) calendar days following the end of the month in which the child reaches age twenty-six (26). If the Enrolled Member fails to complete the request within the allotted time, eligibility for Coverage until the next Open Enrollment is limited to the conditions outlined for Extended Beneficiaries.

(b) **Documentation and Approval.** The Administrator shall require documentation as necessary to provide certification that the child was physically or mentally incapable of sustaining, self-supporting employment because of the physical or mental disability before age twenty-six (26), continues to be physically or mentally incapable of sustaining, self-supporting employment because of the physical or mental disability, and lives at the Enrolled Member's home or is institutionalized. The documentation may include but is not limited to certification from a qualified medical practitioner that outlines the physical and psychological history, diagnosis, and provides an estimate of length of time for disability, and an estimate of the child's earning capacity. If the documentation is satisfactory to substantiate the physical or mental disability as required in these regulations, the Administrator may approve Coverage for the period of incapacitation. The Administrator may require periodic recertification of the disabling condition and circumstances, provided the recertification is not more frequent than each twelve (12) calendar months or at the end of the projected disability period if that date is less than twelve (12) calendar months.

(10) **Surviving Beneficiary.** An Enrolled Member's Surviving Spouse and eligible Dependent children, who were included in the Coverage by the Enrolled Member immediately before death, may continue Coverage provided an application for continuing Coverage is received by the Administrator within ninety (90) calendar days following Coverage termination as a result of the death of the Enrolled Member in the situations set forth below. In the application, the Surviving Spouse shall be required to list all eligible Covered Dependents who will continue Coverage and shall not be allowed to add any future spouse or children not listed. Surviving Covered Spouses and Dependent children are entitled by federal law to continue Coverage under the Extended Beneficiary provisions set forth in Section 111-4-1-.08. By electing to continue coverage under any of these Surviving Beneficiary provisions, the Surviving beneficiary waives rights to continuation coverage under the Extended Beneficiary provisions of Section 111-4-1-.08.

(a) The Surviving Spouse of an Active Employee may continue Coverage for him or herself and surviving eligible Covered Dependent children if the Spouse is eligible to immediately receive a monthly benefit payment from a state supported retirement system in an amount sufficient to pay the Premium established by the Board. The Spouse must elect to continue Coverage as a Surviving Spouse under this provision or as an Employee as a result of the Spouse's own employment, and cannot elect double or dual Coverage under separate provisions of the SHBP. Eligibility of Dependent children shall terminate in accordance with provisions for Dependent children of these regulations. An election to take a lump sum distribution rather than the monthly Annuity negates eligibility to continue Coverage as a Surviving Spouse

(b) The Surviving Spouse of an Annuitant may continue Coverage for him or herself and surviving eligible Covered Dependent children if the Spouse is eligible to immediately receive a monthly benefit payment from a state supported retirement system in amount sufficient to pay the Premium established by the Board. The Surviving Spouse must elect to continue Coverage as a Surviving Spouse under this provision or as an Employee as a result of the Spouse's own employment, and cannot elect double or dual Coverage under separate provisions of the SHBP Eligibility of Dependent children shall terminate in accordance with provisions for Dependent children. An election to take a lump sum distribution rather than the monthly Annuity negates eligibility to continue Coverage as a Surviving Spouse.

(c) Upon the death of an Active Employee, an eligible Covered Dependent child who is the principal Beneficiary under one of the state supported retirement systems may continue Coverage, provided the Dependent child is not covered as a Dependent child under another contract under the SHBP, and provided the monthly benefit payment from a state supported retirement system is in an amount sufficient to pay the Premium established by the Board. Eligibility to continue Coverage shall terminate in accordance with provisions for Dependent

children. An election to take a lump sum distribution rather than the monthly Annuity negates eligibility to continue Coverage under this provision.

(d) Upon the death of a Retired Employee, an eligible Covered Dependent child who is the principal beneficiary under one of the state supported retirement systems may continue Coverage, provided the Dependent child is not covered as a Dependent child under another contract under the SHBP, and provided the monthly benefit payment from a state supported retirement system is in an amount sufficient to pay the Premium established by the Board. Eligibility to continue coverage shall terminate in accordance with provisions for Dependent children. An election to take a lump sum distribution rather than the monthly Annuity negates eligibility to continue Coverage under this provision.

(e) The Surviving Spouse of a Retired Employee who is included in Coverage at the time of death of the enrolled Retiree and who will not receive a monthly annuity payment from one of the state supported retirement systems shall be eligible to continue Coverage for him or herself and any of the Retiree's Dependent children who were Covered at the time of the Retiree's death, if the following conditions are met:

1. The Surviving Spouse must make written application no later than ninety (90) calendar days following Coverage termination as a result of the death of the Retired Employee; and

2. The parties must have been married at least one full year prior to the death of the Retired Employee; and

3. The Surviving Spouse agrees to pay the monthly premium payment established by the Board in accordance with the established requirements; and

4. Coverage under this provision shall terminate for the Surviving Spouse and any enrolled Dependent children in the event the Surviving Spouse remarries.

(f) The eligible Covered Spouse and Dependent children of a Covered Active State Employee who is killed or receives injury that results in death while acting in the scope of his or her employment may continue Coverage provided the deceased Enrolled Member's Coverage was continuous during the period between injury and death. The eligible Covered Dependents may elect Coverage as a surviving Dependent or as an Employee as a result of the person's own employment, but cannot elect double or dual Coverage under separate provisions of the SHBP. Surviving Covered Dependents must agree to pay the monthly Premium payment established by the Board for Active State Employees. The Surviving Spouse may elect to continue Coverage for eligible Covered Dependent children. Eligibility of

Dependent children shall terminate in accordance with provisions for Dependent children.

(11) **Dependent Eligibility Unverified.** The Administrator shall define the supporting documentation requirements for verifying Dependent eligibility. Coverage for Dependents whose eligibility is unverified will pend awaiting receipt and review of the documentation. When the Administrator has verified eligibility of the Dependent, the Coverage will be activated in accordance with the provisions of this Section. If the Administrator cannot verify Dependent eligibility within the allotted time, the Dependent will be ineligible for Coverage. The next opportunity to enroll the Dependent and verify the Dependent's eligibility will be the annual Open Enrollment period or subsequent Qualifying Event. Changes to a different coverage tier will not be allowed based on unverified dependent eligibility.

(12) **Retired Employees Having Intermittent Periods of Active Employment.** Retired Employees who are eligible to continue Coverage under these regulations may elect to return to or continue Active employment with any of the Employing Entities. In such case, the retirement benefit may be suspended or continued; however, the federal Social Security Act requires the health benefit Coverage must be purchased as an Active Employee whenever the eligibility requirements of Section 111-4-1-.04 of these regulations are met. At the point the Employee discontinues Active employment, continuous health benefit Coverage shall be reinstated with the state supported retirement system which previously collected the Premium. In no case, however is an individual who retired prior to the initial legislated funding for that Group of Employees to be entitled to enroll as a Retiree, unless the final Active service period qualifies the Employee for a retirement benefit by one of the state supported retirement systems.

(13) **Judicial Reinstatement of State Employees.** State Employees who are reinstated to employment by the State Personnel Board or the judiciary shall have Coverage reinstated for themselves and any eligible Dependents. If employment reinstatement occurs within twelve (12) calendar months of discharge and back-pay for continuous employment is awarded, all retroactive Premiums must be collected and remitted to the Plan before and Claims incurred during the period may be filed for reimbursement. If back-pay to provide for continuous employment is not awarded, Coverage may be reinstated with the Employee's return to work. If reinstatement occurs following a period longer than twelve (12) calendar months after the discharge, Coverage for the Employee and previously Covered Dependents will be reinstated when the Employee returns to work or in accordance with the judicial review. In any case where the reinstatement overlaps an Open Enrollment period, the Employee will be given fifteen (15) calendar days after reinstatement to modify Coverage in compliance with Open Enrollment guidelines. Pre-existing condition limitations will be waived for the reinstated Employee and all previously enrolled Dependents. Employing Entities shall be responsible for collecting and remitting any Premiums due for the selected Coverage.

(14) **Contract Employees.** Employees who are on approved leave of absence and/or have not terminated their employment may participate in the Plan if their Employer has contracted with the Board to provide inclusion in the SHBP. The Employee will be eligible to participate in accordance with the provisions of the contract.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.04
Authority: O.C.G.A. Secs. 20-2-55, 20-2-880, 20-2-881, 20-2-885 to 20-2-887, 20-2-895, 20-2-910 to 20-2-912, 20-2-915, 20-2-916, 20-2-923, 31-3-2.1, 45-18-1*et seq.*, 45-20-2, 47-2-313, 47-6-41, Family and Medical Leave Act of 1993 (FMLA), Social Security Act, Uniformed Services Employment & Reemployment Act, Americans With Disabilities Act (ADA). Patient Protection and Affordable Care Act (PPACA).
History. Original Rule entitled "Eligibility for Coverage" adopted. F. Apr. 18, 2005; eff. May 8, 2005.
Repealed: New Rule of same title adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.
Amended: F. May 25, 2007; eff. June 14, 2007.
Amended: F. Aug. 20, 2008; eff. Sept. 9, 2008.
Amended: F. Jan. 26, 2011; eff. Feb. 16, 2011.
Amended: F. Jan. 17, 2012; eff. Feb. 6, 2012.

Rule 111-4-1-.05. Effective Date of Coverage.

(1) **Upon Employment.** The Employee's Coverage under the SHBP shall become effective on the first of the month following employment for the full preceding calendar month if the Employee has not terminated employment on or before that date. Coverage for a transferring Employee shall be effective the first of the month following the end of Coverage under a previous Employing Entity. Coverage for eligible Dependents will become effective on the date the Employee's Coverage is effective.

(2) **Upon Change in Coverage.** If the Member changes Coverage to include eligible Dependents based upon acquisition of Dependent(s), Coverage for the Dependents shall become effective on the later of the first of the month following the request for Coverage, or subject to guidelines for acquisition of Dependent(s).

(3) **Upon Open Enrollment Change or Enrollment.** The effective date for enrollments or changes in Coverage election to add eligible dependents shall be January 1st unless the Member no longer meets the definition of an Active Employee on or before that date. The termination date for Open Enrollment discontinuation of Coverage shall be December 31st. Subject to the provisions of Section 111-4-1-.06 of these regulations, Coverage elections shall be binding upon the Member for the duration of the Plan Year.

(4) **Upon Return from Leave Without Pay.** The effective date for re-enrollments following an Approved Leave of Absence Without Pay shall be the first of the month following the return to work. The effective date for re-enrollments following a military leave without pay shall be the first of the month following the return to work or the date employment is reinstated. In all instances, the appropriate Premiums must be deducted and remitted by the Employing Entity.

(5) **Upon Acquisition of a Dependent.** The effective date of Coverage for acquired Dependents is subject to the requirements as outlined for the Member and shall be the later of the first of the month following the request for Coverage or:

(a) **Legally Married Spouse.** The effective date of Coverage shall be no earlier than the first of the month of marriage to the Member. The Plan is not responsible for payment of the Spouse's medical services incurred prior to the actual date of the marriage.

(b) **Natural Children.** The effective date of Coverage shall be the date of birth.

(c) **Stepchildren.** The effective date of Coverage shall be no earlier than the date of marriage of the Member and the natural parent of the children.

(d) **Adopted Children.** The effective date of Coverage shall be no earlier than the date of legal placement for adoption.

(e) **Other Children.** The effective date of Coverage shall be no earlier than the date that sole legal guardianship is established.

(6) **Premium.** The Administrator shall terminate Coverage of Enrolled Members and Covered Dependents for which the Plan has not received full payment of the required Premium prior to the first day of the Coverage month. Terminated Coverage will be reactivated upon receipt of full payment of the required monthly Premium.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.05
Authority: O.C.G.A. Secs. 20-2-881, 20-2-911, 45-18-2, Health Insurance Portability and Accountability Act (HIPAA), Internal Revenue Code Section 125, Uniformed Services Employment and Reemployment Act 5. Patient Protection and Affordable Care Act (PPACA)
History. Original Rule entitled "Effective Date of Coverage" adopted. F. Apr. 18, 2005; eff. May 8, 2005.
Repealed: New Rule of same title adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.
Amended: F. May 25, 2007; eff. June 14, 2007.
Amended: F. Jan. 26, 2011; eff. Feb. 16, 2011.

Rule 111-4-1-.06. Changes in Coverage and Option.

(1) **Open Enrollment Period and Retiree Option Change Period.** The Open Enrollment period and Retiree Option change period shall be a minimum period of fifteen (15) days and shall begin no earlier than October 1 and shall end no later than November 15 of each year. The Commissioner shall announce the dates of the periods each year. Eligible Employees, enrolled Retirees and Extended Beneficiaries shall be given an opportunity to make the changes in Coverage election as reflected in the following paragraphs.

(a) **Active Employees.** Eligible Active Employees, eligible Employees on Approved Leave of Absence Without Pay and Extended Beneficiaries shall be given an opportunity to enroll or change Coverage during the Open Enrollment period.

(b) **Retirees.** During the Retiree Option Change Period, enrolled Retirees shall be given an opportunity to change Coverage Option to any Option for which the Retiree is eligible.

(2) **Returning Employee from an Approved Leave of Absence.** An eligible Employee who did not continue Coverage during an Approved Leave of Absence Without Pay which included the Open Enrollment period shall be offered the opportunity to enroll, discontinue, or change Coverage within fifteen (15) calendar days of the date the Employee returns to work.

(3) **Qualifying Event During a Period of Ineligibility.** When an Employee loses eligibility for Coverage and subsequently resumes eligibility for Coverage within the same Plan Year, and a Qualifying Event under these regulations occurs during the period of ineligibility, the Employee shall have the opportunity to request a change in Coverage election for the remainder of the Plan Year that is consistent with that Qualifying Event. The request to change Coverage election must be received by the Administrator within thirty-one (31) calendar days following the date the Employee resumes eligibility through an Employing Entity. The effective date of the requested action shall be consistent with the new employment provisions of these regulations. The Administrator shall request supporting documentation to demonstrate the Qualifying Event has occurred. Failure to fully document the occurrence of the Qualifying Event within the allotted time shall result in reversal of the new Coverage election and restoration of the Employee's former Coverage election.

(4) **Retired Employee's Discontinuation of Coverage.** An Enrolled Retired Employee may discontinue Coverage for him or herself at any time. A discontinuation may be made by advance notice to the Administrator or by failing to timely pay required Premiums. Once a Retired Employee discontinues Coverage for him or herself, the discontinuation is permanent except as described below.

(a) **TRICARE Supplemental Coverage.** If a Retired Employee discontinues SHBP Coverage and elects TRICARE Supplemental Coverage, which is offered by the Administrator, the Retired Employee may re-enroll in SHBP Coverage during the next Retiree Option Change Period as long as he or she has maintained continuous coverage under either SHBP Coverage or TRICARE Supplemental Coverage.

(b) **Termination of Medicare Advantage Coverage by CMS.** If a Retired Employee's Medicare Advantage coverage is terminated by CMS due to enrollment in another plan or failure to pay Medicare Part B premiums, the Retired Employee will be automatically enrolled in another SHBP Option in accordance with the procedures of the Administrator, and will be charged the required Premiums.

(c) **Employment as an Active Employee.** If a Retired Employee who has discontinued Coverage becomes employed as an Active Employee, he or she may re-enroll in the SHBP as an Active Employee.

An Enrolled Retired Employee may discontinue Coverage for a Dependent at any time. A discontinuation of Coverage for a Dependent will be permanent except as described below.

(d) **PeachCare for Kids Coverage.** If a Retired Employee discontinues SHBP Coverage for a Dependent child and enrolls that Dependent child in PeachCare for Kids, the Retired Employee may re-enroll the Dependent child in SHBP Coverage during the next Retiree Option Change Period as long as the Dependent child has maintained continuous coverage under either SHBP Coverage or PeachCare for Kids.

(e) **Qualifying Event.** If an Enrolled Retired Employee discontinues Coverage for a Dependent and experiences a qualifying event described in Internal Revenue Service Regulation 1.125.4, subsection (6) below will apply and the Retired Employee may be able to re-enroll the Dependent.

(5) **Reinstatement of Employee Across Plan Years.** If an Employee was reinstated to employment for a period of time inclusive of the applicable Open Enrollment period, the Employee shall be offered the opportunity to enroll or change Coverage within fifteen (15) calendar days of the return to work.

(6) **Qualifying Event Coverage Changes.**

(a) A Member shall be eligible to make a change in coverage or tier on account of the qualifying events set forth, and in the manner described, in Internal Revenue Service Regulation 1.125-4, so long as the Member and the Employing Entity (if applicable) satisfy requirements established by the Administrator. This subsection does not apply to a Retired Employee who has discontinued SHBP coverage for him or herself. In general, requests to enroll, change, or discontinue coverage must be received by the Administrator no later than thirty-one (31) calendar days following the qualifying event. Requests to enroll newly eligible Dependent children must be received by the Administrator no later than ninety (90) calendar days following the qualifying event. Requests to make election changes as a result of death must be received by the Administrator no later than ninety (90) calendar days following the qualifying event. Where necessary to comply with federal law, election changes may be accepted within the deadline established by the law. The effective date of the Coverage election shall be the first of the month following receipt of the request, unless otherwise noted in Internal Revenue Service Regulation 1.125-4. The Administrator shall request supporting documentation to demonstrate the Qualifying Event has occurred. Failure to fully document the occurrence of the Qualifying Event within the allotted time shall result in reversal of the Coverage election and restoration of the Member's prior Coverage election.

(b) **Additional Changes Permitted for Retirees.** An enrolled Retiree may change to any Option to which the Retiree is eligible upon occurrence of one or more of the following events, provided the request is received by the Administrator within thirty-one (31) calendar days following the Qualifying Event: at the time of retirement; at the time that the annuity amount to be received from a state supported participating retirement system becomes insufficient to satisfy the Option premium; at the time that the Retired Member becomes eligible for Medicare coverage; or, subject to approval by the Centers for Medicare and Medicaid Services, at the time the enrolled Retiree requests in writing to move from his or her current Option to a Medicare Advantage plan offered by the same Third Party Administrator.

(c) Married enrolled Retirees may change Tier in order to become individual Enrolled Members at any time when no individuals other than the Spouse are enrolled in the Coverage. The change in Coverage will be effective within two (2) calendar months following the requested change.

(7) **Documentation.** The Administrator may require documentation that a Qualifying Event permitting enrollment, change or discontinuation of Coverage has in fact occurred outside the annual enrollment period. When required, documentation appropriate to the event will be specifically described and must be received by the Administrator within the allotted time. Failure to document appropriately or within the allotted time shall result in the reversal of the requested Coverage action and restoration of the Member's prior Coverage.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.06
Authority: O.C.G.A. Secs. 20-2-295, 20-2-881, 20-2-894, 20-2-897, 20-2-911, 20-2-922, 45-18-1*et seq.*, 50-18-72, 50-18-94, Internal Revenue Code Section 125 - Family and Medical Leave Act of 1993 (FMLA), Consolidated Omnibus Budget Reconciliation Act (COBRA), IRS Code Section 125, Health Insurance Portability and Accountability Act (HIPAA), Child Support Performance and Incentive Act, U.S.E.R.R.A.
History. Original Rule entitled "Changes in Coverage and Option" adopted. F. Apr. 19, 2005; eff. May 8, 2005.
Amended: ER. 111-4-1-0.1-.06 adopted. F. June 13, 2005; eff. June 16, 2005, as specified by the Agency.
Amended: Permanent Rule adopted. F. Sept. 15, 2005; eff. Oct. 5, 2005.
Repealed: New Rule of same title adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.
Amended: F. May 25, 2007; eff. June 14, 2007.
Amended: F. May 1, 2009; eff. May 21, 2009.
Amended: F. Oct. 16, 2009; eff. Nov. 5, 2009.
Amended: F. Jan. 17, 2012; eff. Feb. 6, 2012.

Rule 111-4-1-.07. Extended Coverage Under State Law.

(1) **Employee.** Employees are permitted to continue the current Coverage under conditions outlined by State law. Application for Extended Coverage must be made to the Administrator within thirty-one (31) calendar days following Coverage termination as an Active Employee or Extended Beneficiary. Coverage election under Section 111-4-1-.08, Extended Coverage Under Federal law, delays eligibility to enroll under State law

provisions until the expiration of the Extended Beneficiary Coverage privileges, except as specifically stated in these provisions.

(a) **State Employee.**

1. Any State Employee who resigns from employment or who is not re-elected on and after July 1, 1978 and who has completed eight (8) or more years of service as an Employee, exclusive of Approved Leaves of Absence Without Pay for which health benefit Coverage may have been continued, under Section 111-4-1-.04(1)(a) shall have the privilege of continuing Coverage.

2. Any State Employee who has been eligible for Coverage under this Plan for a period of ten (10) years, is discharged and is appealing the discharge to the State Personnel Board shall be entitled to continue Coverage for a period required for the State Personnel Board to render a decision but no longer than six (6) calendar months. The Premium for such Coverage will be the same amount as paid by the Active Employee through payroll Deduction/Reduction. The Employing Entity must notify the Member and the Administrator of the Member's eligibility to continue Coverage. Failure to pay the full Premium within the allotted time shall result in suspension of benefit payments and/or termination of Coverage and forfeit all eligibility for continued Coverage.

(b) **General Assembly Member.** Any member of the General Assembly who ceases to hold office after July 1, 1981, and who was eligible to retire at the time of leaving office, except for the attainment of retirement age, pursuant to a public retirement system to which the General Assembly appropriates Funds, and who does not withdraw Employee contributions from public retirement systems shall be eligible to continue Coverage for the Enrolled Member and eligible Dependents, subject to the conditions of these regulations. The Premium shall be the same amount as an Active Employee. Coverage shall cease if the Member fails to pay the required Premium billed by the Administrator within thirty (30) calendar days following receipt of a Premium notice or the Member withdraws Employee contributions from the respective retirement system. Failure to pay the full Premium within the allotted time shall result in suspension of benefit payments and/or termination of coverage and forfeit all eligibility for continued Coverage.

(c) **Teacher.** Any Teacher as defined in Section 111-4-1-.04(1)(b) and any Surviving Spouse of a Teacher who died prior to January 1, 1979 who has eight (8) or more years of creditable service in a teachers retirement system in Georgia and who is not presently eligible to receive retirement benefits shall have the privilege of continuing Coverage.

(d) **Public School Employee.** Any Public School Employee as defined in Section 111-4-1-.04(1)(c) and who has eight (8) or more years of creditable service in a

retirement system in Georgia and who is not eligible to receive retirement benefits because of age shall have the privilege of continuing Coverage. Prior to December 1, 1986, a Public School Employee whose employment terminated after January 1, 1985, and prior to July 1, 1986, under these conditions shall have the privilege of re-enrolling for Coverage by making application to the Administrator; provided that Coverage shall not become effective earlier than the first of the month in which the application for Coverage was received by the Administrator.

1. **Correctional Officers Injured in Service.** The SHBP shall provide a Coverage exception from the eight-year or more employment requirement for continued Coverage under the SHBP for a correctional officer injured by inmate violence while on duty if the correctional officer demonstrates that he or she was injured within a time period of five (5) years or less from becoming eligible for Medicare. The correctional officer must remit the Premium amount established for Active Employees. Eligibility for Coverage shall extend to an eligible correctional officer's Spouse or Dependents.

(e) **Required Premiums.** Except as noted in subparagraphs (a)(2) and (b), premiums for continuing Coverage under this provision shall be billed to the Enrolled Member monthly in an amount equal to the total cost for Coverage, which is the Employee's share and the Employer's cost for benefits and administration, plus processing and administrative fees where applicable. Failure to pay the full Premium within the allotted time shall result in suspension of benefit payments and/or termination of Coverage and forfeit all eligibility for continued c overage.

(f) **Notice.** The Administrator shall include a notice of payment requirements and penalties on application forms for continued Coverages.

(2) **Pending Retiree.** An Enrolled Member who has made application for disability or service retirement and who may be eligible for retirement shall have the privilege of continuing any health benefit Coverage during the period between termination of Coverage as an Active Employee and the effective date of Coverage as a Retiree, subject to conditions as outlined in these regulations. The Member may request Coverage as a Pending Retiree within thirty-one (31) calendar days following Coverage termination as an Active Employee. The Administrator shall have the option to enroll and bill the Member directly for Pending Retiree Coverage should a break in Coverage occur.

(a) **Coverage as a pending Retiree** must be based on a reasonable expectation that the Enrolled Member is eligible for retirement except for completion of the administrative processing to begin the annuity payments. The Administrator may define reasonable expectation; however, continuation of coverage under this provision shall not exceed six (6) calendar months, unless a decision on the retirement application has not been rendered by the respective retirement system's

administrative processes. Any months of coverage as a Pending Retiree shall be inclusive of Extended Coverage provisions under Federal law.

(b) **Denial of Annuity Payments.** At the point that a Board of trustees or retirement Administrator denies the immediate onset of annuity payments, the separated Employee shall no longer be eligible to continue Coverage under this provision. Any Coverage under this provision is inclusive of the maximum length of time allowed under the Extended Coverage provisions that are allowed under Federal law.

(c) **Reinstatement of Retiree Coverage.** Upon receipt of information that the respective retirement system has reversed an earlier denial to award retirement benefits to an Employee, Coverage may be reinstated as a Retiree. Coverage reinstatement is allowed if the Retiree requests reinstatement within thirty-one (31) calendar days following the reversal of the retirement system's decision. Reinstatement shall be effective as soon as administrative processes for Deduction are completed, but no later than sixty (60) calendar days following notification to the Administrator. The Retiree and Dependents who were enrolled in the Plan will be reinstated without regard to the Pre-existing Condition limitations. The Administrator may review the circumstances and, if undue hardship will be imposed upon the Retiree, may allow retroactive coverage for up to six (6) calendar months from the date of notification that the Retiree is eligible for reinstatement.

(d) **Required Premiums.** Premiums for continuing coverage under this provision shall be the same as the Employee Deduction Rate plus a processing fee and shall be paid monthly. Failure to pay the full Premium within the allotted time shall result in suspension of benefit payments and/or termination of Coverage and forfeit all eligibility for continued Coverage.

(3) **Retiree Retirement Benefit.** If the retirement benefit to be received by a Retiree of any one of the respective retirement systems is not sufficient to pay the Premium amount by annuity Deduction, the Retiree shall be permitted to continue Coverage by paying a monthly Premium as set by the Board directly to the Plan. The Premium Rate shall be the same as the Retiree Deduction Rate plus a processing fee. Failure to pay the full Premium within the allotted time shall result in suspension of benefit payments and/or termination of Coverage and forfeit all eligibility for continued Coverage.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.07
Authority: O.C.G.A. Secs. 20-2-888, 20-2-915, 20-2-915.1, 45-18-1*et seq.*
History. Original Rule entitled "Extended Coverage Under State Law" adopted. F. Apr. 18, 2005; eff. May 8, 2005.
Amended: F. Sept. 26, 2006; eff. Oct. 16, 2006.
Repealed: New Rule of same title adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.

Rule 111-4-1-.08. Extended Coverage Under Federal Law (COBRA).

(1) **Extended Beneficiary.** Persons who lose coverage under the Plan and who meet requirements as specified in these regulations or as specified by federal law are eligible to continue Coverage in the enrolled Option, without evidence of insurability. An Extended Beneficiary shall have the same opportunities for enrolling eligible Dependents and changing Coverage election as Active Employees. The SHBP will be administered in compliance with federal law or regulation under the Consolidated Omnibus Budget Reconciliation Act (COBRA).

(a) **Terminated Employee.** An enrolled Employee who terminates employment or is separated from his employment for any reason other than for gross misconduct, or whose Approved Leave Without Pay Coverage period expires shall be eligible to continue Coverage under the Plan for a period not longer than eighteen (18) calendar months following the termination of Coverage as an Employee.

(b) **Reduction of Required Hours.** An enrolled Employee who continues SHBP eligibility under the definition of Employee, except for working the required number of hours, shall be eligible to continue Coverage under the Plan for a period not longer than eighteen (18) calendar months following the end of the month in which the reduction of hours occurred. If the reduced hours take effect on a day other than the first work day of the month, the eighteen (18) calendar month period would begin on the first of the month following termination of Coverage through payroll Deductions.

(c) **Laid-off Employee.** An Enrolled Employee who is determined to be a laid-off Employee shall be eligible to continue Coverage under the Plan for a period not longer than eighteen (18) months. The extended period begins on the first of the month following termination of Coverage through payroll Deductions.

(d) **Spouse of Deceased Employee.** The spouse of a deceased enrolled Employee who is not eligible as a Surviving Spouse, an Employee, or an Annuitant shall be eligible to continue Coverage for the Spouse and any Covered, eligible dependents under the Plan for a period not longer than thirty-six (36) calendar months. The extended period of Coverage begins on the first of the month following termination of Coverage through the deceased Employee's payroll Deductions, or if the Employee is on an Approved Leave Without Pay, the later of the end of the month or the end of one month following the month in which the Employee died when Premium was paid in advance.

(e) **Surviving Dependent Child.** An eligible Dependent child of a deceased enrolled Employee who is not eligible as a Dependent of another Employee, a Surviving Beneficiary under Section 111-4-1-.04(10), and Employee, or an Annuitant shall be eligible to continue individual Coverage under the Plan for a period not longer than thirty-six (36) calendar months following the end of the month in which death occurred. Any months for which Coverage was granted under Section 111-4-1-.04 will be included in the maximum allowance under this provision. The Extended

Coverage period begins on the first of the month following termination of the deceased Employee's Coverage through payroll Deductions.

(f) **Dependent Child.** An eligible Dependent child of an enrolled Employee who is not eligible as an Employee or an Annuitant shall be eligible to continue Coverage under the Plan for a period not longer than thirty-six (36) calendar months following the end of the month in which the child is no longer an eligible Dependent under the Plan.

(g) **Legally Separated or Divorced Spouse.** A legally separated or divorced Spouse of an enrolled Employee who is not eligible as a Surviving Spouse, an Employee, or an Annuitant shall be eligible to continue Coverage for a period not longer than thirty-six (36) calendar months for the Spouse and any Covered dependents, who are no longer Covered Dependents of the Employee, under the SHBP. The Extended Coverage period begins on the first of the month following the month in which the legal separation documents were approved by a court of competent jurisdiction or the divorce was final.

(h) **Disability under Social Security.** An additional eleven (11) calendar months of Coverage may be provided to an Extended Beneficiary who meets the definition of disability under Title II or XVI of the Social Security Act prior to or within sixty (60) calendar days of the Qualifying Event. The eleven (11) additional months of Coverage applies to all Beneficiaries eligible under the contract. Eligibility for the additional eleven (11) months is based on the Beneficiary notifying the Administrator of the determination of disability no later than sixty (60) calendar days following the date of the determination. Such notices must be given within the initial eighteen (18) month continuation period. Additionally, the Extended Beneficiary must notify the Administrator within thirty (30) calendar days of the date of any final determination that the Beneficiary is no longer disabled. The Administrator is authorized to charge one hundred fifty percent (150%) of the applicable Premium as outlined in this section.

(i) **Multiple qualifying events.** If additional Qualifying Events occur which provide for a thirty-six (36) calendar month maximum period during the period when an Extended Beneficiary is covered, the maximum period of Coverage may be extended to a maximum of thirty-six (36) calendar months for Spouse or Dependent Child.

(j) **Beginning of the maximum period.** The maximum period of Extended Coverage as a result of one or more Qualifying Events shall begin on the day following termination of Coverage as a result of the first Qualifying Event.

(k) **Limitation for Individuals Added to Coverage of ExtendedBeneficiary.** Individuals enrolled under an Extended Beneficiary's Coverage shall not be eligible to become an Extended Beneficiary as a result of the enrollment.

(l) **Payment for Extended Beneficiary Coverages.** The applicable Premium for any Coverage election shall include the total Employer and Employee cost plus two percent (2%) of the total Premium cost as established by the Board for Active Employees with eligibility under this section, except that the Extended Beneficiary shall pay this Premium on a monthly basis. An additional forty eight percent (48%) of the total Premium for the Coverage election under the Plan shall be required for the eleven (11) months extension as a result of disability under the Social Security Act. One (1) advance monthly premium plus any retroactive premiums for unpaid periods of Coverage will, however, be requested as a part of the application. Failure to pay the full Premium within the allotted time shall result in suspension of benefit payments and/or termination of Coverage and forfeit all eligibility for continued Coverage.

(m) **Notice Requirements.** At the time of implementation of the Extended Beneficiary provisions, the Administrator shall distribute to the Employing Entities, having Active Employees, a notice of reasons for the extended eligibility. The Employing Entities shall distribute this notice to each eligible Employee. The Administrator shall incorporate the Extended Beneficiary eligibility provisions in the Employee Summary Plan Description.

1. The Employing Entity must notify the Administrator of the Employee's termination, death, layoff, or reduce hours within thirty (30) calendar days following the event.

2. The enrolled Employee or eligible Beneficiary must notify the Administrator of a Qualifying Event in case of divorce, legal separation, or the Dependent child's loss of eligibility within sixty (60) calendar days of the later of the Qualifying Event or termination of Coverage as a result of the Qualifying Event. Failure to notify the Administrator within the sixty (60) calendar days will forfeit eligibility to enroll as an Extended Beneficiary.

3. The Administrator shall notify the Extended Beneficiary at the known address. The Administrator shall provide notice of the continuation rights within fourteen (14) calendar days following notification from the Employing Entity of the enrolled Employee's death, termination of employment, or reduction of hours. Notice to the Employee's Spouse other than upon the Employee's termination or reduction of hours shall be deemed to be notification to all other Beneficiaries under the contract.

4. The Administrator shall notify the Extended Beneficiary of the continuation rights at the address specified by the Employee or Extended Beneficiary within fourteen (14) calendar days following notification from the Employee of a divorce, legal separation, or the Dependent child's Coverage ineligibility as a Dependent.

5. The Administrator shall notify each newly covered Spouse of the Plans Extended Beneficiary continuation rights within fourteen (14) calendar days of the Spouse's effective date.

6. If the Administrator fails to notify the Extended Beneficiary of the continuation rights within the required time limits as a result of failure of the Employing Entity to notify the Administrator, any penalty required of the Administrator shall be billed to the Employing Entity who failed to notify the Administrator.

(n) **Extended Beneficiary's Election Period.** The Extended Beneficiary may elect to continue Coverage during the later of sixty (60) calendar days following the Administrator's notification to the Extended Beneficiary or the sixty (60) calendar days following Coverage termination. Coverage will be continued from the Coverage termination date through the months for which payment is received, provided payment is received no later than forty-five (45) calendar days following the Beneficiary's election to continue Coverage.

(o) **Extended Beneficiary's Independent Election.** Each Beneficiary eligible for Extended Coverage shall be afforded the opportunity to make an independent election to continue Coverage in the enrolled Option, provided the Beneficiary is not enrolled under the SHBP as an Employee, Spouse, Dependent, or Annuitant. If a Beneficiary, either the Employee or Spouse of a enrolled Employee makes an election to provide Coverage for the other Extended Beneficiary, the election shall be binding on that other Beneficiary. An election on behalf of a minor child can be made by the child's parent or legal guardian. An election on behalf of an eligible Beneficiary who is incapacitated can be made by the legal representative of the Beneficiary. Except for any child who is born to or placed with an Extended Beneficiary, Dependents enrolled in the Plan during a period of Extended Coverage under federal law do not themselves become Extended Beneficiaries and may not make separate Coverage elections or participate in Open Enrollment.

(p) **Required Documentation.** The Administrator may require a monthly certification on the Premium billing by the Extended Beneficiary that the conditions as outlined in Section 111-4-1-.09(11) have not occurred.

(q) **Recovery of Paid Benefits.** The Administrator shall have the right to recover all benefit payments made on behalf of any Extended Beneficiary as a result of and after the occurrence of any of the conditions outlined in Section 111-4-1-.09(11).

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.08
Authority: U.S. Internal Revenue Code and Consolidated Omnibus Budget Reconciliation Act (COBRA).
History. Original Rule entitled "Extended Coverage Under Federal Law (COBRA)" adopted. F. Apr. 18, 2005; eff. May 8, 2005.

Repealed: New Rule of same title adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.

Rule 111-4-1-.09. Termination of Coverage.

(1) **Termination from Employment.** Termination from employment includes resignation, abandonment of job, release from job, forfeiture of job, and all other types of termination. Health benefit Coverage shall terminate at the end of the month following the month of the last date of employment that was transmitted to the Administrator unless continued under the provision of Extended Coverage. This date will normally be the end of the month following the month in which separation or termination of employment occurred.

(2) **Employment Layoff.** Employment layoff means that the Employer has formalized a reduction in staff plan and the Employee will no longer be employed by one of the Employing Entities. Health Benefit Coverage shall terminate at the end of the month following the month of the last date of employment that was transmitted to the Administrator, unless continued under the provisions of Extended Coverage. The Coverage termination date will normally be the end of the month following the month in which the layoff occurred.

(3) **Reduction of Hours.** A reduction in hours worked may result in loss of eligibility to continue health benefit Coverage.

(a) If for any reason the number of worked hours is reduced for a covered State Employee to less than thirty (30) hours per week, Coverage shall terminate at the end of the month following the month in which the reduced hours took effect; unless continued under the provisions of Extended Coverage.

(b) If for any reason the number of worked hours is reduced for a covered Teacher to less than half-time or a minimum of seventeen and one-half (17 ½) hours per week, Coverage shall terminate at the end of the month following the month in which the reduced hours took effect; unless continued under the provisions of Extended Coverage.

(c) If for any reason the number of worked hours is reduced for a covered Public School Employee to less than sixty (60) percent of that required to perform the position duties, Coverage shall terminate at the end of the month following the month in which the reduced hours took effect; unless continued under the provisions of Extended Coverage. However, the sixty (60) percent cannot be less than twenty (20) hours if the Member is a participant in the Teachers Retirement System and less than fifteen (15) hours if the member is a participant in the Public School Employees Retirement System.

(4) **Failure to Return from an Approved Leave of Absence Without Pay.** If an Employee on an Approved Leave of Absence Without Pay fails to return to Active employment, Coverage will terminate at the earlier of the end of the month for which the Leave

Without Pay was approved or the end of the month for which a valid Premium payment has been received. Failure to return to Active employment from an Approved Leave of Absence Without Pay will be considered termination of employment for the purposes of Extended Coverage eligibility.

(5) **Legal Separation or Divorce.** Coverage for a legally separated or divorced Spouse will terminate at the end of the month in which the separation papers were approved by a court of competent jurisdiction or in which the divorce decree is approved by the court of competent jurisdiction unless continued as an Extended Beneficiary.

(6) **Dependent Child.** Coverage for an eligible Dependent child shall terminate at the end of the month in which the child reaches age twenty-six (26) unless a Qualified Medical Child Support Order (QMCSO) or other court order bears an earlier expiration date or Coverage is continued under the provisions for a Totally Disabled Child or an Extended Beneficiary.

(7) **Failure to Remit Premium.** Failure to remit the billed Premium amount in full within thirty (30) calendar days following the end of the month for which Coverage has been paid will result in suspension of benefit payments and will constitute forfeiture of eligibility to continue Coverage while on Approved Leave of Absence Without Pay or Extended Coverages of any kind. Coverage will not be reinstated for payments received thirty (30) calendar days following termination of Coverage for insufficient payment, unless an administrative error has been made. Failure to remit Premium will constitute a declination of eligibility to continue coverage as an Extended Beneficiary without further notice by the Administrator.

(8) **Expiration of Approval Leave of Absence Without Pay.** Coverage will terminate at the end of the month following expiration of the Approved Leave of Absence Without Pay period unless the leave is extended by the appropriate organizational official and such extension is approved by the Administrator or the Employee returns to work, or the Employee extends coverage under the provisions of Extended Coverage. Coverage may be terminated earlier than the expiration of such leave when the Failure to Remit Premium provisions of these regulations apply.

(9) **Expiration of Coverage as a Pending Retiree.** Health benefit Coverage will terminate at the end of the month following determination that the Retiree is not immediately eligible to receive an annuity under a state supported participating retirement system operated for Employees, unless the Retiree is eligible to continue Coverage under the Extended Coverage provisions of these regulations. Pending Retirees appealing a denial of retirement benefits may continue up to the maximum period outlined in Section 111-4-1-.07.

(10) **Expiration of Extended Beneficiary Coverage Privileges.** Health benefit Coverage for Extended Beneficiaries will terminate at the end of the month in which the earliest of the following conditions occur:

(a) The full Premium amount is not paid within the time allowed under these regulations;

(b) The maximum Coverage period permitted under these regulations is exhausted;

(c) The Extended Beneficiary becomes enrolled in Medicare benefits;

(d) The Extended Beneficiary becomes covered under another group health care plan by reason of employment or marriage, and pre-existing condition exclusions are not applied under the new coverage;

(e) Cancellation of contract with an organization with whom the Board of Community Health is authorized to contract;

(f) The State Health Benefit Plan is terminated.

(11) **Deceased Enrolled Member.** Coverage shall terminate no later than the end of the month of death of a Member enrolled in employee only Coverage. Coverage shall terminate no later than the end of the month following the month of death of a Member when the Coverage includes Dependents. The Employing Entity, retirement system or deceased's estate shall remit the appropriate Premium. A surviving Beneficiary may continue coverage as outlined in 111-4-1-.04, the Extended Coverage provisions of these regulations.

(12) **Discontinuation of Coverage Outside Open Enrollment.** Coverage shall terminate no earlier than the end of the month following receipt of the request to discontinue Coverage outside the annual Open Enrollment period. Requests to discontinue Coverage must be approved by the Administrator. The Administrator may require documentation of other Coverage.

(13) **Suspension of Benefits Due to Nonpayment.** If an Employing Entity fails to remit Premiums or documentation or fails to reconcile bills in the manner required by the Plan, the Plan may suspend benefit payments for Enrolled Members of the Employing Entity.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.09
Authority: O.C.G.A. Secs. 20-2-881, 20-2-911, 45-18-1*et seq.*, IRS Code Section 125. Patient Protection and Affordable Care Act (PPACA).
History. Original Rule entitled "Termination of Coverage" adopted. F. Apr. 18, 2005; eff. May 8, 2005.
Repealed: New Rule of same title adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.
Amended: F. Jan. 26, 2011; eff. Feb. 16, 2011.

Rule 111-4-1-.10. Plan Benefits.

(1) **Creation of Benefit Schedule.** The Board is authorized to establish benefit schedules for Options to be included in a health benefit plan for eligible persons as defined in Georgia law. Benefit schedules shall comply with applicable state and federal law. Benefit schedules shall further the plan design goals set forth by O.C.G.A. Sections 45-18-3; 20-2-883; 20-2-913: "to (1) Provide a reasonable relationship between the hospital, surgical and medical benefits to be included and the expected distribution of expenses of each such type to be incurred by the covered employees and dependents; and (2) Include reasonable controls, which may include deductible and reinsurance provisions applicable to some or all of the benefits, to reduce unnecessary utilization of the various hospital, surgical, and medical services to be provided and to provide reasonable assurance of stability in the future years of the plan." Benefit schedules for Options may include a different schedule for Medicare enrolled Retirees and non-Medicare enrolled Retirees. Benefit schedules of Options shall be considered in the calculation of Employer and Employee Contribution Rates. The Regular Insurance Option benefit schedules shall be established upon approval of the Employer and Employee Contribution Rates for such Options. The Medicare Advantage Option benefit schedules shall be established upon approval of the Employer and Employee Contribution Rates for such Options. The dates of approval of Employer and Employee Contribution Rates shall be recorded in official minutes of Board meetings. Medicare Advantage Options must be developed and administered in the manner approved by the Centers for Medicare and Medicaid Services. Accordingly, the following subsections apply only to Regular Insurance Options.

(a) The Administrator shall authorize the use of established procedures by the TPA to terminate benefit payments if continuation of treatment in the mode being billed is not medically necessary. The TPA's procedures must ensure that the Member shall have the right to ask for a record review by medical consultants.

(b) The Administrator shall interpret the general schedules into specific benefit language for inclusion in the Summary Plan Description and for use by the TPA in adjudicating claim payments.

(c) The Administrator shall incorporate specific benefit language to be used by the TPA for review of utilization patterns and to implement claim cost containment features, including but not limited to, medical review of excessive utilization and audits of hospital or other claims.

(d) The Administrator shall be authorized to require pre-authorization by the TPA of any new medical service before approval for benefit payment. Generally, the service will not be considered for coverage unless medical consultants/advisors substantiate through literature research that clinical trials demonstrate the medical effectiveness of the service. Other guidelines, such as those of the Federal Drug Administration of the Centers for Medicare & Medicaid Services may also be used, at the discretion of the Administrator, in the determination of coverage.

(e) The Administrator shall authorize the use of established procedures by the TPA for obtaining additional medical information from members and from providers of

medical services and supplies, in order to determine the amount and appropriateness of benefit payments.

(f) The Administrator shall establish procedures for permitting the Member to appeal an adverse determination of eligibility for Coverage or of a benefit, service, or Claim. These procedures shall be outlined in the Summary Plan Description to advise the Member of the process to initiate an appeal. However, the Administrator has delegated the final authority to the TPA for approval in accordance with the schedule of Benefits and the interpretation thereof. The Administrator shall have final authority for approval of al eligibility appeals.

(g) The Administrator may contract for or employ professionals from any medical discipline to advise the Administrator on continuing medical necessity, quality of medical care, or the level of fees charged by the providers of medical care.

(h) The Administrator is authorized to develop appropriate medical policy in conformity with the schedule of benefits and these regulations so that new procedures will be included for coverage when the new procedures are adopted as accepted medical practice and that medical procedures which are excessively used without significantly improving the treatment of an illness or injury are reviewed.

(2) **Exclusions.** Plan benefits shall exclude expenses incurred by or on account of an individual prior to the effective date of coverage; expenses for services received for injury or sickness due to war or any act of war, whether declared or undeclared, which war or act of war shall have occurred after the effective date of this plan; expenses for which the individual is not required to make payment; expenses to the extent of benefits provided under any employer group plan other than this plan of benefits in which the state participates in the cost thereof. In addition, for all Regular Insurance Options, the Administrator shall publish in the Summary Plan Description interpretative language showing the exclusions for the following types of charges:

(a) Charges for treatment for Pre-existing Conditions in excess of one thousand dollars ($1,000), to the extent this exclusion is permitted by federal law;

(b) Charges for treatment or supplies which are determined to be not medically necessary;

(c) Charges for treatment before the effective date of coverage or after coverage termination, except for Extended Coverage benefits;

(d) Charges other than Wellness/Preventive benefits, that are not specifically related to the care and treatment of a sickness or an injury;

(e) Charges for treatment specifically for dental or vision care;

(f) Charges for treatment for experimental or investigative services or supplies;

(g) Charges that are considered educational or treatment to restore learning capacity;

(h) Charges in connection with custodial care, extended care facilities or a nursing home;

(i) Charges in connection with rehabilitation, rehabilitation therapy, or restorative therapy when the condition is no longer expected to improve significantly in a reasonable and generally predictable period of time;

(j) Charges in connection with therapy for learning disabilities;

(k) Charges for prosthesis or equipment which are determined to be not medically necessary.

(3) **Actions.** In creating the SHBP, neither the Georgia General Assembly nor the Board of Community Health has waived its sovereign immunity. Thus no action either in law or in equity, can be brought or maintained against the State of Georgia, the Board of Community Health, or any other department or political subdivision of the State of Georgia to recover any money under this Plan. In like fashion, no suit may be maintained against any officials or Employees of these bodies if the ultimate financial responsibility would have to be borne by public Funds from the General Treasury, the health benefit Funds or elsewhere.

(a) The Board of Community Health, however, does reserve the right to maintain any suits, either in its own name, or through its officials, Employees, or agents, which it deems necessary to the administration of the SHBP, including actions to recover money from participants, beneficiaries, agents, Employees, officials, or any other person.

(b) The Board of Community Health reserves the right to modify its Benefits, Coverages, and eligibility requirements at any time, subject only to reasonable advance notice to its Members. When such a change is made, it will apply as of the effective date of the modification to any and all charges which are incurred by Members from that date forward, unless otherwise specified by the Board of Community Health.

(c) The Administrator is authorized to act as interpreter of the terms and conditions of the Plan.

(4) **Non-duplication of Benefits and Subrogation.** The Plan will not duplicate payments for medical expenses made under third-party personal-injury-protection contracts nor will it duplicate payments made as the result of any litigation. The Plan will be subrogated to any right of recovery that a Member has against a person or organization where medical expenses were incurred as a result of injuries suffered because of alleged negligence or misconduct. In any case where the primary plan provides for subrogation for third-party liability and this Plan would be determined to be secondary, benefits under this Plan shall

be reduced to the amount that would have been paid under the secondary provisions of this Plan.

(5) **Recovery of Benefit Overpayments.** The Administrator shall seek repayment for any benefits paid to any individual, corporation, firm, or other entity who or which is not qualified, in the opinion of the Administrator, to receive benefits from the Plan. The Administrator shall establish procedures for collecting the overpayments, duplicate payments, or wrong payee payments. The procedures may include, but are not limited to, establishing installment payments, withholding future benefit payment, or filing suit or garnishment.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.10
Authority: O.C.G.A. Secs. 20-2-881 to 20-2-885, 20-2-887, 20-2-911 to 20-2-915, 45-18-1*et seq.*, Health Insurance Portability and Accountability Act of 1996 (HIPAA), Social Security Act.
History. Original Rule entitled "Plan Benefits" adopted. F. Apr. 18, 2005; eff. May 8, 2005.
Repealed: New Rule of same title adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.
Amended: F. Sept. 28, 2007; eff. Oct. 18, 2007.
Amended: F. Aug. 20, 2008; eff. Sept. 9, 2008.
Repealed: New Rule of same title adopted. F. Apr. 14, 2010; eff. May 4, 2010.

Rule 111-4-1-.11. Claims.

(1) **Filing Claims.** The Administrator shall coordinate the procedures for filing claims with the TPA. Such procedures may not establish a liability period greater than the maximum liability period set forth below. Claim forms shall be designed and printed for the Member's and providers' use when appropriate.

(2) **Maximum Liability Period.** All Claims of Benefits must be presented in writing to the Administrator or TPA in accordance with the procedures established by the Administrator and the TPA, which procedures may not permit payment of claims submitted after twenty-four (24) calendar months following the month of service in which the service was rendered. If any Claim for Benefits is presented to the Administrator or TPA after two (2) years from the date the service was rendered, benefits will not be owed or paid.

(3) **Unclaimed or Uncased Claim Checks.** All drafts issued on behalf of the Plan shall be void if not presented and accepted by the drawer's bank within six (6) calendar months of the date the draft was drawn. If the payee or Subscriber does not present the draft or request a reissue of the draft for a period of seven (7) years from the date the draft was drawn, the draft will be void and funds retained in the appropriate trust Fund.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.11
Authority: O.C.G.A. Sec. 20-2-881, 20-2-884, 20-2-890, 20-2-911, 20-2-917, 45-18-2, 45-18-6, 45-18-11.
History. Original Rule entitled "Health Maintenance Organizations" adopted. F. Apr. 18, 2005; eff. May 8, 2005.
Repealed: New Rule entitled "Claims" adopted. F. Jan. 22, 2007; eff. Feb. 11, 2007.
Repealed: New Rule of same title adopted. F. Apr. 14, 2010; eff. May 4, 2010.

Rule 111-4-1-.12. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.12
Authority: O.C.G.A. Secs. 20-2-881, 20-2-890, 20-2-911, 20-2-917, 45-18-2, 45-18-11.
History. Original Rule entitled "Claims" adopted. F. Apr. 18, 2005; eff. May 8, 2005.
Repealed: F. Jan. 22, 2007; eff. Feb. 11, 2007.

Rule 111-4-1-.13. Georgia Retiree Health Benefit Fund.

(1) **Functions, Duties and Responsibilities of the Board of Community Health.** The Board shall establish the Georgia Retiree Health Benefit Fund (GRHBF). The Board in its official capacity shall be the GRHBF's trustee. The Board shall annually review Other Post Employment Benefits (OPEB) liability. The Board shall determine Annual Required Contributions (ARC), which may not be the same as employer and employee contribution rates. The Board shall also determine annual employer and employee contribution rates. The Board shall collect employee and employer contributions and deposit the contributions into the GRHBF. The Board may utilize the investment services of the Employee Retirement System, Division of Investment Services to invest a portion of the GRHBF for long-term investments. No member of the Board or employee of the Department shall have any personal interest in the gains or profits from any investment made by the Board or use the assets of the GRHBF in any manner, directly or indirectly, except to make such payments as may be authorized by the Board or by the Commissioner as the executive officer of the Board.

(a) **Establish and Design Plan.** The Board is authorized to establish the GRHBF to collect employee and employer contributions for OPEB. The Board shall account for employee and employer contributions by each pension plan, as delineated at 111-4-1-.01(50), separately.

(b) **Promulgate Regulations.** The Board is authorized to adopt and promulgate rules and regulations for the effective administration of the GRHBF.

(c) **EstablishContributionsonBehalf of Retirees.** The Board shall establish by Resolution, contributions by public school teacher retirees, retired public school employees, retired State employees, and any other Annuitant listed at 111-4-1-.01(50) and shall deposit those contributions into the GRHBF. The Board shall consider the actuarial estimates of OPEB in establishing the contributions.

(d) **Establish Employer Rates.** The Board shall establish by Resolution, OPEB employer contribution rates and shall deposit those contributions into the GRHBF.

(2) **Functions, Duties and Responsibilities of the Commissioner.** The Commissioner in his or her official capacity shall be the Administrator of the GRHBF and shall be the custodian of the GRHBF.

(a) **Administer Regulations and Policies.** The Commissioner shall administer the GRHBF consistent with Board regulation and policy. The Department shall contract with the Division of Investment Services of the Teachers Retirement System of Georgia and the Employees' Retirement System of Georgia with respect to GRHBF investments. The Department shall maintain all necessary records regarding the GRHBF in accordance with generally accepted accounting principles. The Department shall collect all moneys due to the GRHBF and shall pay any administrative expenses necessary and appropriate for the operation of the GRHBF from the GRHBF.

(b) **Annual Report.** The Department shall prepare an annual report of GRHBF activities for the Board, the House Appropriations Committee, and the Senate Appropriations Committee. Such reports shall include, but not be limited to, audited financial statements. The reports shall contain the most recent information reasonably available to the Department reflecting the obligations of the GRHBF, earnings on investments, revenue and expenses by pension plan, and such other information as the Board deems necessary and appropriate. This report shall reflect activity on a state fiscal year basis. The Department shall be entitled to any information that it deems necessary and appropriate from a retirement system, as delineated at 111-4-1-.01(50), so that the provisions of Code Section 45-18-103 may be fulfilled.

(c) **Regulations.** The Commissioner shall recommend to the Board amendments to the regulations, submit the approved regulations to appropriate filing entities, cause all regulations to be published, and provide a copy to the Employing Entities.

(d) **Provide Notice of OPEB Employer Contribution.** The Commissioner shall provide notice and certification of the required OPEB employer contribution rate to each of the Employing Entities and the Department of Education on or before June 1st of each year.

(3) **Duties and Responsibilities of Employing Entity.** Each Employing Entity is responsible for complying with these regulations. It shall be the responsibility of State agencies to make contributions to the GRHBF, subject to appropriations, in accordance with the OPEB employer contribution rate established by the Board. It shall be the responsibility of all other Employing Entities to make contributions to the GRHBF in accordance with the OPEB employer contribution rates established by the Board in addition to the employer contributions required to be made to the GRHBF for the health plan as determined from fiscal year to fiscal year.

(a) **Deduct Enrolled Member Premium Amounts.** The Employing Entity shall withhold the contribution rate as approved by the Board.

(b) **Remit Employer Contributions.** The Employing Entity shall calculate and remit the appropriate OPEB employer contribution.

Cite as Ga. Comp. R. & Regs. R. 111-4-1-.13
Authority: O.C.G.A. Secs. 20-2-898, 20-2-926, 45-18-21, 45-18-100 to 45-18-105.
History. Original Rule entitled "Georgia Retiree Health Benefit Fund" adopted. F. Oct. 15, 2007; eff. Nov. 4, 2007.

Chapter 111-5. REPEALED.

Subject 111-5-1. REPEALED.

Rule 111-5-1-.01. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.01
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Definitions" adopted. F. June 13, 2006; eff. July 3, 2006.
Amended: F. Aug. 26, 2009; eff. Sept. 15, 2009.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.02. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.02
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Administration of the Program" adopted. F. June 13, 2006; eff. July 3, 2006.
Amended: F. Aug. 26, 2009; eff. Sept. 15, 2009.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.03. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.03
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Health Care Provider Eligibility" adopted. F. June 13, 2006; eff. July 3, 2006.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.04. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.04
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Volunteers" adopted. F. June 13, 2006; eff. July 3, 2006.
Amended: F. Aug. 26, 2009; eff. Sept. 15, 2009.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.05. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.05
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Patient Selection and Referral" adopted. F. June 13, 2006; eff. July 3, 2006.

Amended: F. Aug. 26, 2009; eff. Sept. 15, 2009.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.06. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.06
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Eligibility" adopted. F. June 13, 2006; eff. July 3, 2006.
Amended: F. Aug. 26, 2009; eff. Sept. 15, 2009.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.07. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.07
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Covered Services" adopted. F. June 13, 2006; eff. July 3, 2006.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.08. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.08
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Contracts" adopted. F. June 13, 2006; eff. July 3, 2006.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.09. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.09
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Notice Requirements" adopted. F. June 13, 2006; eff. July 3, 2006.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.10. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.10
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Patient Records" adopted. F. June 13, 2006; eff. July 3, 2006.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.11. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.11
Authority: O.C.G.A. § 31-2A-6.

History. Original Rule entitled "Sovereign Immunity" adopted. F. June 13, 2006; eff. July 3, 2006.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.12. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.12
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Legal Actions" adopted. F. June 13, 2006; eff. July 3, 2006.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.13. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.13
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Complaints" adopted. F. June 13, 2006; eff. July 3, 2006.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Rule 111-5-1-.14. Repealed.

Cite as Ga. Comp. R. & Regs. R. 111-5-1-.14
Authority: O.C.G.A. § 31-2A-6.
History. Original Rule entitled "Department Reports" adopted. F. June 13, 2006; eff. July 3, 2006.
Amended: F. Aug. 26, 2009; eff. Sept. 15, 2009.
Repealed: F. Sep. 20, 2013; eff. Oct. 10, 2013.

Chapter 111-8. HEALTHCARE FACILITY REGULATION.

Subject 111-8-1. RULES AND REGULATIONS FOR ADULT DAY CENTERS.

Rule 111-8-1-.01. Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated (O.C.G.A.) § 49-6-80*et seq.*, the "Adult Day Center for Aging Adults Licensure Act."

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.01
Authority: O.C.G.A. § 49-6-80.
History. Original Rule entitled "Authority" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.02. Title and Purposes.

These rules shall be known as the Rules and Regulations for Adult Day Centers. The purposes of these rules are to provide for licensing and inspection of adult day centers which provide adult day care services and/or adult day health services to three or more adults, and to establish the minimum standards for the operation of adult day centers. It is the intent of these rules to promote, safeguard and protect the well-being of adults participating in adult day care who need such services.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.02
Authority: O.C.G.A. § 49-6-80.
History. Original Rule entitled "Title and Purposes" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.03. Exemptions.

These rules and regulations shall not apply to the following:

(1) Individuals or organizations operating an adult day center without receiving compensation as a condition of the participant's receiving such services;

(2) Individuals or organizations that provide services for compensation to only one or two participants;

(3) Programs which provide day habilitation and treatment services exclusively for developmentally disabled persons; and

(4) Respite care services programs, provided the program meets all parts of the definition for a respite care services program as outlined in section 111-8-1-.04(hh).

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.03
Authority: O.C.G.A. § 49-6-82.
History. Original Rule entitled "Exemptions" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.04. Definitions.

(1) In these rules, unless the context otherwise requires, the words and phrases set forth herein shall mean the following:

(a) "Abuse" means any intentional or grossly negligent act or series of acts or intentional or grossly negligent omission to act which causes injury to a participant, including but not limited to assault or battery, failure to provide treatment or care, or sexual harassment.

(b) "Activities of daily living" means bathing, shaving, brushing teeth, combing hair, toileting, dressing, eating, grooming, taking medications, and transfers and/or ambulation.

(c) "Adult" means a person 18 years or older or an emancipated minor.

(d) "Adult day care (ADC)" means the provision of a comprehensive plan of services that meets the needs of aging adults as defined in paragraph (g) of these definitions under a social model, as defined in paragraph (ll) of these definitions. This term shall not include programs which provide day habilitation and treatment services exclusively for individuals with developmental disabilities.

(e) "Adult day center" or "center" means a facility serving aging adults that provides adult day care or adult day health services, as defined in paragraphs (d) and (f) of these definitions, for compensation to three or more persons. Adult day centers may operate in more than one location if classified and approved by the Department as a mobile adult day center. This term shall not include a respite care services program.

(f) "Adult day health services (ADHS)" means the provision of a comprehensive plan of services that meets the needs of aging adults under a medical model as defined in paragraph (v) of these definitions. This term shall not include programs which provide day habilitation and treatment services exclusively for individuals with developmental disabilities.

(g) "Aging adults" means persons 60 years of age or older or mature adults below the age of 60 whose needs and interests are substantially similar to persons 60 years of age or older who have physical or mental limitations that restrict their abilities to perform the normal activities of daily living and impede independent living.

(h) "Assistance with self-administration" means staff can provide assistance as outlined in Rule 111-8-1-.19.

(i) "Capacity" means the number of participants for which a center has been licensed to provide care and services at any given time.

(j) "Days" means calendar days, not workdays, unless otherwise noted in the text.

(k) "Department" means the Georgia Department of Community Health.

(l) "Dietitian" means a registered dietitian, with current registration by the Commission on Dietetic Registration of the American Dietetic Association; and a licensed dietitian, with current licensure by the Georgia Board of Examiners of Licensed Dietitians.

(m) "Direct care staff" means any individual who provides direct services to participants, including, but not limited to the Director, a licensed nurse, the activities director, aides, and volunteers.

(n) "Director" means the person designated by the governing body as responsible for the overall operation of a center.

(o) "Disaster preparedness plan" means a written document which identifies potential hazards or events, that should they occur, would cause an emergency situation at the center; and proposes, for each identified emergency situation, a course of action so as to minimize the threat to health and safety of the participants.

(p) "Exploitation" means an unjust or improper use of another person or the person's property through undue influence, coercion, harassment, duress, deception, false representation, false pretense, or other similar means for one's own personal advantage.

(q) "Facility" means an adult day center, unless otherwise specified.

(r) "Governing body" means the Board of Trustees, the partnership, the corporation, the association, or the person or group of persons who maintain and control the center and who are legally responsible for the operation of the center.

(s) "Individual plan of care" means a document describing the participant's needs, services to be provided by the adult day center and, for adult day health services, identification of the therapeutic service provider who will deliver the required services, the expected outcomes and frequency of re-evaluation of the plan.

(t) "Licensed practical nurse (LPN)" means a person who provides care relating to the maintenance of health and prevention of illness under the supervision of a physician, dentist, podiatrist or registered nurse (RN).

(u) "Long-term care facility" means any skilled nursing home, intermediate care home, personal care home or assisted living community licensed by the Department.

(v) "Medical model" means a comprehensive program that provides adults with the basic social, rehabilitative, health and personal care services needed to sustain the essential activities of daily living and to restore or maintain optimal capacity for self-care. Such program of care shall be based on individual plans of care and shall be provided for less than 24 hours per day.

(w) "Mobile adult day center" means a program of services offered by an adult day center which utilizes a designated staff that travels from one central location to off-site locations to provide adult day services as described in these rules. The mobile adult day center transports the necessary staff and/or volunteers, participant records, supplies and program materials to each off-site location for the provision of services. The services offered by a mobile adult day center may either be adult day care services or adult day health services, or both, and are offered four days per week or less at any one location.

(x) "Neglect" means a failure to act or omission to act that caused or may cause physical harm, emotional injury or death.

(y) "Nurse" means a registered nurse (RN) or licensed practical nurse (LPN) licensed in the state of Georgia.

(z) "Nursing services" means services provided by licensed nursing personnel and may include therapy services. Nursing services may also include observation, promotion and maintenance of health, dressing changes, prevention of illness and disability, management of health care during acute and chronic phases of illness, guidance and counseling of individuals and participants' representatives, administration of medications and referral to physicians, other health care providers, and community resources when appropriate.

(aa) "Participant" means an adult receiving services in the adult day center.

(bb) "Physician's orders" means an order that is signed and dated by a medical doctor (MD), doctor of osteopathy (DO) or other person(s) authorized by law who is licensed to practice medicine in the state of Georgia.

(cc) "Primary caregiver" means the one identified relative or other person in a relationship of responsibility, such as an agent under a valid durable power of attorney for health care or health care agent under a valid advance directive for health care, who has assumed the primary responsibility for the provision of care needed to maintain the physical or mental health of an aging adult, who lives in the same residence with such individual, and who does not receive financial compensation for the care provided.

(dd) "Proxy caregiver" means an unlicensed person who has been determined to have the necessary knowledge and skills acquired through training by a licensed healthcare professional to perform documented health maintenance activities, including specialized procedures, for an individual with a disability who has delegated to the designated proxy caregiver the performance of such health maintenance activities through execution of a written informed consent by the individual with a disability or a person legally authorized to act on behalf of such individual with a disability.

(ee) "Registered nurse (RN)" means a person currently licensed by the Georgia Board of Nursing or successor entity to practice professional nursing.

(ff) "Representative" means anyone that the participant identifies as having authority to make decisions on his or her behalf.

(gg) "Resident" means any person receiving treatment or care in a long-term care facility.

(hh) "Respite care services program" means a program for aging adults who can function in a group setting and who can feed and toilet themselves with or without the assistance of a personal aide accompanying them and which:

1. Is operated by a nonprofit organization;

2. Provides no more than 25 hours of services per week;

3. Is managed by a director who has completed an adult day care services training and orientation program approved by the Department;

4. Is staffed primarily by volunteers; and

5. Has as its sole purpose to provide primary caregivers of aging adults with relief from normal caregiving duties and responsibilities.

(ii) "Restraint" means any manual or physical device, material, or equipment attached or adjacent to the participant's body that the individual cannot remove easily which restricts freedom or normal access to one's body or a drug or medication when it is used as a restriction to manage the participant's behavior or restrict the participant's freedom of movement and is not standard treatment or dosage for the participant's condition.

(jj) "Serious injury" means an injury requiring emergency medical intervention or treatment by medical personnel, either at an urgent care facility, at an emergency room or a medical office.

(kk) "Social activities" means therapeutic, educational, cultural enrichment, recreational, and other activities on site or in the community in a planned program to meet the social needs and interests of the participant.

(ll) "Social model" means a program that addresses primarily the basic social and recreational activities needed to be provided to aging adults, but also provides, as required, limited personal care assistance, supervision, or assistance essential for sustaining the activities of daily living. Such programs of care shall be based on individual plans of care and shall be provided for less than 24 hours per day.

(mm) "Staff" means, as appropriate to their roles and responsibilities, all people who provide supervision, care, treatment, and services in the center including permanent, temporary, and part-time employees, as well as contracted individuals and health profession students. The definition of staff does not include licensed independent practitioners who are not paid employees, contract employees or volunteers.

(nn) "Standard Precautions" means a system of precautions or set of guidelines designed to reduce exposure to and transmission of microorganisms from both recognized and unrecognized sources of potential infections.

(oo) "Volunteer" means an individual who performs or offers to perform a service for the center out of his/her own free will and without payment.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.04
Authority: O.C.G.A. § 49-6-82*et seq*.
History. Original Rule entitled "Definitions" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.05. Application for a License.

(1) Unless exempted in section 111-8-1-.03, no person, partnership, entity, corporation, or association, whether operated for profit or not for profit, shall operate an adult day center without first obtaining a valid license from the Department.

(2) A license issued under these rules shall not be assignable or transferable.

(3) Unless exempted in section 111-8-1-.03, no entity or person shall use terms in its business name or marketing materials to imply or indicate that it is an adult day center unless the entity or person holds a valid license issued by the Department.

(4) A separate application and license is required for each adult day center.

(5) During the application process, the governing body shall provide the following:

(a) A completed application for a license on forms provided by the Department.

(b) An application and license fee as approved by the Board of Community Health based upon the type of services provided;

(c) Proof of the legal right to occupy the property where the adult day center is housed;

1. Proof of ownership or right of occupancy may include a warranty deed, lease agreement or bill of sale; or

2. Written permission from the owner of the premises authorizing the adult day center to operate exclusively within a designated space is permissible where the adult day center provides services in a donated space or does not own or lease the premises where services are provided;

(d) A floor sketch of the facility showing windows, doors, room measurements, and the location of the adult day center facilities and any other services provided on the premises;

(e) A completed affidavit of personal identification;

(f) In the case of corporations, partnerships, and other entities authorized by law, the applicant shall provide a copy of its certificate of incorporation or other acceptable proof of its legal existence and authority to transact business within the State of Georgia;

(g) Documentation from the local authority having jurisdiction over fire safety or by the State Fire Marshal that the center is in compliance with all applicable fire safety regulations. Such documentation shall be dated within the six (6) months preceding the date of the application;

(h) Documentation of approval for water source and sewage disposal system from the local authority for water and/or sewage;

(i) Documentation from local zoning authorities that the center is in compliance with local zoning codes;

(j) A list of the locations of any additional adult day centers operated by the governing body;

(k) If vehicle transportation services are provided by the center, the center shall submit the following:

1. Proof of insurance coverage for property damage, uninsured motorists and bodily injury for the vehicle which transports participants; and

2. Proof of current vehicle registration.

(l) For a mobile adult day center, a list of all locations where services are provided. If the mobile adult day center provider also operates a standard freestanding adult day center, the name and address of that center shall also be included on the application.

(6) Local zoning and other local requirements regarding the proper location and establishment of adult day centers must be addressed by the applicant with the responsible local officials.

(7) All adult day centers which are required to be licensed and operating as of the effective date of these rules shall make application to the Department for a license within 90 days of the initial effective date of these rules. Such centers may continue to operate without

disruption until such time as the Department has made a determination of compliance or noncompliance with these rules and regulations.

(8) A license shall be issued to the governing body of the adult day center disclosed in the application for licensure and proof of ownership documents.

(9) The adult day center shall annually submit a license renewal fee in the amount approved by the Board of Community Health.

(10) Knowingly making any verbal or written false statement of material fact in connection with the application for a license or supplying false or misleading information shall constitute grounds for denial or revocation of a license.

(11) **Fees.** The Department shall require the payment of application fees, license fees, license renewal fees or other similar fees relating to the licensure of adult day centers in amounts approved by the Board of Community Health. Fees are nonrefundable except as provided in Chapter 111-8-25.

(12) All application fees and license fees shall be submitted and made payable to the Department of Community Health.

(13) **Mobile adult day centers**.

(a) Each license issued to a mobile adult day center shall enable the licensee to provide services at no more than five (5) off-site locations.

(b) Each off-site location where the mobile adult day center provides services must be listed on the mobile adult day center's application for a license.

(c) If an applicant proposes to operate a regular adult day center as well as a mobile adult day center, there shall be a separate license fee for each type of center.

(d) Providers applying for operation of a mobile adult day center shall demonstrate compliance with all rules and regulations applicable to the types of services provided.

(e) All off-site facilities used by mobile adult day center providers shall be in compliance with all applicable regulations for physical plant and safety standards as indicated in section 111-8-1-.10 and the fire safety standards set forth in 111-8-1-.09.

(14) Following evidence of substantial compliance with these rules and regulations and any provisions of law applicable to the operation of the adult day center, the Department may issue a license.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.05
Authority: O.C.G.A. § 49-6-83.

History. Original Rule entitled "Application for License" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.06. License Requirements.

(1) The governing body of each adult day center shall obtain a valid license from the Department prior to beginning operation. To be eligible for a license, the center must be in substantial compliance with the applicable rules and regulations.

(2) The adult day center's capacity shall be determined by the floor space available for participant activity, as described in 111-8-1-.10(1)(f), and the occupancy load determined by the local authority having jurisdiction over fire safety or the State Fire Marshal. The license shall state the maximum number of participants per day who may receive services at the center. Adult day centers shall schedule and provide services to participants in such a manner that it does not exceed its licensed capacity.

(3) The license shall be displayed in a prominent place on the premises where the adult day center programs are operated.

(4) Licenses are not transferable from one governing body to another or from one adult day center location to another.

(5) A license shall no longer be valid and shall be returned to the Department when the adult day center ceases to operate, changes locations, the ownership changes, the governing body is significantly changed, or the license is suspended or revoked. At such time a license is no longer valid, it shall be returned to the Department.

(6) Each change of ownership, change of location, addition of another location, change in name, change in the maximum number of participants per day or a change in the scope of services provided shall be reported to the Department along with an application from the proposed new owners or lessees for a new license.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.06
Authority: O.C.G.A. § 49-6-83.
History. Original Rule entitled "License Requirements" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.07. Governing Body.

(1) Each adult day center or mobile adult day center shall have a clearly identified governing body which shall be empowered and responsible for determining all policies and procedures and ensuring compliance with these rules and regulations.

(2) The governing body shall be responsible for compliance with the requirements of O.C.G.A. §§ 49-6-81 through 49-6-86, and with applicable administrative rules and

regulations of the Department, including but not limited to all applicable statutes, rules and regulations regarding disclosure of ownership.

(3) The governing body shall certify in its application the name of the Director who has been designated as responsible for the overall management of the center and for carrying out the rules and policies adopted by the governing body.

(4) The governing body shall notify the Department in writing immediately when there is a change in the Director.

(5) Each adult day center owned or operated by the same governing body shall have a designated Director who is available on-site during operating hours.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.07
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Governing Body" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.08. Administration.

(1) Prior to being granted a license, each adult day center shall develop written policies and procedures outlining the responsibilities of center staff, management and volunteers. The policies and procedures shall at a minimum include the following:

(a) A description of the types of services provided by the center including whether the center provides adult day care, adult day health services or both, characteristics of the participants that the center expects to serve and an Alzheimer's Disclosure Form as applicable, in compliance with O.C.G.A. § 31-8-182, *et seq.*

(b) A description of the number and qualifications of staff and/or volunteers who will provide the services; and whether the services will be provided by center staff and/or volunteers or a contract provider;

(c) A description of the center's days and hours of operation;

(d) The center's policy for fees for service, including the daily charge; any additional fees for specific services, goods, or incidental supplies that are not included in the daily charge (e.g. personal hygiene products, transportation, bathing assistance, personal care assistance, etc.); and the method for notifying participants or their representatives of any changes or adjustments in fees;

(e) The center's policy for refunds;

(f) The center's policies and procedures for accepting voluntary contributions as compensation from or on behalf of participants;

(g) The procedure for documenting any serious or unusual incidents occurring at the center which would affect the health, safety or welfare of participants including procedures for obtaining needed care and procedures for informing participants' representatives and/or legal guardian(s), of any such incidents or major changes in general functioning or medical condition of the participant;

(h) An explanation of how emergency medical situations will be handled at the center, including how participants and representatives are informed of the procedures for dealing with emergency medical situations;

(i) The procedure for implementing standard precautions;

(j) A policy and procedure to assure that no staff member, volunteer, visitor, contractor or any other person may be on the premises of the center during the hours of operation if the person exhibits: symptoms of illness, a communicable disease transmitted by normal contact, or behavior which gives reasonable concern for the safety of the participants and others;

(k) A policy for the proper storage, handling and documentation regarding medications where assistance with self-administration is offered and/or medications are administered by a licensed nurse;

(l) A non-smoking policy or a statement that the center has designated an appropriate outside area for smoking;

(m) A description of the criteria for voluntary and involuntary discharge of a participant from the center, and the time frame for notifying the participant and/or participant's representative prior to an involuntary discharge;

(n) A policy for addressing and resolving complaints made by participants, the participant's representative, family or other interested person(s) within a reasonable time not to exceed seven (7) business days, including providing information to such person(s) about appropriate local, county and/or state agency contacts;

(2) Each center shall establish core hours and days of operation during which services are available.

(3) Each center shall maintain an organizational chart, illustrating the lines of authority and communication within the center.

(4) Each center shall ensure that participants and their representatives, if any, shall receive at least 30 days written notice prior to any substantive changes in the participant agreement or fees for service.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.08
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Administration" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.09. Disaster Preparedness, Fire Safety and Emergencies.

(1) In a format provided by the Department, each center shall complete and submit for approval a disaster preparedness plan that contains a set of procedures for responding to internal and external disasters or emergency situations.

(2) The disaster preparedness plan shall identify the staff position responsible for implementing the plan, obtaining necessary emergency medical attention or intervention for participants, and coordinating with the local emergency management agency.

(3) A standardized format shall be used throughout the plan that clearly describes how the emergency procedures should be carried out for each potential disaster. The emergency procedures should answer the questions of "who, what, when, where, and how," and allow the center to be ready to act effectively and efficiently in an emergency situation.

(4) The plan shall contain a section that outlines the frequency of rehearsal and the procedures to be followed during rehearsal. Each aspect of the plan must be rehearsed on an annual basis.

(5) Each center shall forward a copy of the plan to the local emergency management agency.

(6) Each center shall review and update its disaster preparedness plan as needed, but at a minimum on an annual basis.

(7) Each center shall maintain the following records and make them available to authorized Department employees upon request:

   (a) A copy of the disaster preparedness plan and any subsequent changes thereto, which shall also be available for immediate access by center staff;

   (b) Records of rehearsals of the disaster preparedness plan to include the names of all participants, staff and volunteers participating in the rehearsals; and

   (c) Records of incidences, which required implementation of the disaster preparedness plan, including a written incident report and a written critique of the performance under the plan.

(8) Each center shall notify the Department within one business day when an emergency situation occurs which dictates implementation of the disaster preparedness plan. Such notification to the Department may initially be verbal and shall be followed-up in writing within three business days.

(9) **Fire Safety.** Adult day centers shall ensure that facilities where services are provided meet all applicable standards for fire and safety requirements. Fire safety must be observed at all times.

(a) The building must be kept in good repair; electrical, heating and cooling systems must be maintained in a safe manner. Electrical appliances, devices and lamps must be used in a manner that prevents overloaded circuits. Any extension cords in excess of six (6) feet must be shielded or protected and shall not be used in lieu of permanent wiring.

(b) Each center must develop and conspicuously post throughout the center an emergency evacuation plan.

(c) Fire drills shall be conducted at least quarterly and all staff and participants shall participate in the drills. Drills shall be held at expected and unexpected times and under varying conditions to simulate the unusual conditions that can occur in an actual emergency. Documentation of the fire drills shall be maintained by the center and shall include the date and time of such drills, the staff and participants included in the drill, and the actual evacuation time.

(d) Storage items must be arranged to minimize fire hazard. Gasoline, volatile materials, paint, and similar products must not be stored in the building housing participants unless approved in writing by the local fire marshal.

(e) Outside areas designated for smoking shall have ashtrays of noncombustible material and safe design.

(f) Portable fire extinguishers shall be maintained in operable condition at all times, inspected once a year by a qualified technician, and shall be labeled indicating the condition and date of last inspection.

(g) Each center shall be equipped with a sufficient number of smoke detectors, operated by house current or hardwired into the center's electrical service. Center staff shall consult local fire safety authorities to determine the appropriate number and placement of the smoke detectors.

(h) The use of unvented heaters, open flame heaters or portable space heaters is prohibited.

(i) The Department may require an appropriate fire safety inspection of any center at any time, including, but not limited to, when the physical plant undergoes a substantial change, such as repairs, renovations, or additions, or the Department has reason to believe that fire safety violations exist and that participants may be at risk.

(10) **Emergency Procedures.** Each center shall establish written emergency policies and procedures. Emergency procedures shall include at least the following:

(a) A written plan and/or agreement for emergency care;

(b) A written plan and/or agreement for emergency transportation;

(c) An easily located file for each participant containing at least the following:

1. Name and telephone number of the participant's physician;
2. Hospital preference;
3. Insurance information;
4. Medications and allergies;
5. Current diagnoses and history;
6. Name and telephone number of emergency contact;
7. Copy of any Georgia Advance Directive for Health Care; and
8. Photograph (for participant identification).

(d) A written plan for notification of local law enforcement when a participant has been missing for more than thirty (30) minutes.

(11) The Department may suspend any requirements of these rules and the enforcement of any rules where the governor of the state of Georgia has declared a public health emergency.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.09
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Disaster Preparedness, Fire Safety and Emergencies" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015

Rule 111-8-1-.10. Physical Plant Health and Safety Standards.

(1) **General.** The adult day center shall be constructed, arranged, and maintained so as to provide adequately for the health, safety, access, and well-being of the participants.

(a) Each center shall have a standard telephone, not a pay telephone or cellular telephone, on the premises which is immediately accessible during the center's hours of operation. A list of emergency telephone numbers for fire, ambulance, police, poison control and 911 shall be posted at each telephone.

(b) Each center shall provide adequate, safe and sanitary facilities appropriate for the services provided by the center and for the needs of the participants. All centers shall be accessible to and usable by physically disabled individuals and shall meet all applicable regulations for access for the handicapped.

(c) The adult day center shall be in compliance with all building codes and other applicable codes.

(d) Each center shall provide adequate lighting for participant activities and safety.

(e) Each center shall be adequately ventilated at all times by either mechanical or natural means to provide fresh air and the control of unpleasant odors.

(f) There shall be adequate floor space in the center to safely and comfortably accommodate the number of participants for all activities and services provided by the center. Centers shall provide at least 35 feet of usable floor space for each participant, exclusive of passageways, bathrooms, lockers, storage rooms, staff rooms, and other areas not used for participant activities.

(2) **Facilities.** Center facilities shall consist of, but not be limited to, the following:

(a) Bathrooms;

(b) Dining areas;

(c) Kitchen areas;

(d) Rest area(s) as needed by the participants;

(e) Activity areas for recreation and leisure time;

(f) A private area for the provision of first aid, assistance with activities of daily living, and counseling services when provided, or as necessary for other services required by participants; and

(g) An adult day center may be co-located at a licensed long-term care facility provided that both the center and the long-term care facility are meeting the needs of the adult day participants and the long-term care facility residents, maintaining their required staffing ratios, and respecting the rights of the residents of the long-term care facility to privacy and the quiet enjoyment of their residence.

(3) **Furnishings.** Each center shall provide sufficient furniture for use by participants, which provide comfort and safety, and are appropriate for an adult population with physical limitations, visual and mobility limitations and cognitive impairments. Furnishings shall be maintained in good condition, intact, and functional.

(a) Each center shall provide clean, comfortable seating with support meeting the needs for each participant.

(b) Each center shall provide table space sufficient to seat all participants for dining at one time.

(c) Dining areas and furnishings shall be arranged to accommodate participants using wheelchairs.

(d) Rest areas shall be furnished with a bed and mattress, recliner, sofa, or chair with back and arm support.

(e) Furnishings and décor shall reflect non-institutional settings.

(f) Adult day centers co-located within a licensed long-term care facility may not use residents' rooms or furnishings for adult day care participants.

(4) **Bathrooms.** There shall be adequate bathroom facilities to meet the needs of participants.

(a) At a minimum, there shall be not less than one toilet for every 12 participants or fraction thereof;

(b) Bathrooms and fixtures shall be accessible to participants with disabilities, function properly, and be maintained in a sanitary and odor free condition;

(c) Multiple toilets in the same room shall have individual stalls with doors which can be closed;

(d) Each bathroom shall be equipped with waste receptacles which are emptied and cleaned regularly; and

(e) Doors to all bathrooms must be equipped with closure devices which can be opened from the outside, in case a participant experiences difficulty and needs staff assistance.

(5) **Bathing Facilities.** A minimum of one bathing unit shall be provided in each adult day health center and in adult day care centers that provide assistance with bathing.

(a) The bathing unit, when in use, shall not interfere with the accessibility to bathroom facilities by other participants;

(b) Each tub or shower shall be in an individual room or enclosure that provides space for the private use of the bathing fixture, for bathing, drying and dressing, for the participant and staff; and

(c) Tubs and/or showers for participant use must have non-slip bottoms or floor surfaces, either installed or applied to the surface.

(6) **Environment/Sanitation.** The building shall be clean and in good repair, free from litter, extraneous materials, unsightly or injurious accumulations of items and free from pests and vermin.

(a) Waste, trash and garbage shall be removed from the premises at regular intervals. Excessive accumulations are not permitted.

(b) Floors, walls and ceilings must be structurally sound, maintained, cleaned, repaired and/or painted when needed.

(c) All outside refuse containers shall have tight fitting lids left in closed position. Containers shall be maintained in a clean and serviceable condition.

(7) **Temperature Conditions.** Each center shall provide an adequate central heating and cooling system or its equivalent at ranges that are consistent with the individual health needs and comfort of participants. The temperature range shall be maintained between 70 degrees Fahrenheit and 85 degrees Fahrenheit in all rooms used by the participants.

(8) **Outdoor Areas.** Adult day centers that provide outdoor activities shall have a safe, secure, and suitable outdoor recreation or relaxation area that includes a shaded area for participants that is designed to meet the needs of participants.

(a) The outdoor area shall be connected to, a part of, controlled by, and directly accessible from the center; and

(b) The outdoor area shall be suitably furnished with seating appropriate to the needs of the participants.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.10
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Physical Plant Health and Safety Standards" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.11. Supplies.

(1) Each center shall supply soap at the sinks, toilet tissue at each commode, and single use towels or mechanical hand dryers in each bathroom.

(2) Each center shall stock and maintain in a single location first aid supplies to treat minor burns, cuts, abrasions, and accidental poisonings. Staff shall assure that supplies with expiration dates are replaced in a timely manner to avoid expiration. The first aid supplies shall include the following:

(a) Thermometer;

(b) Band aids, tape and gauze;

(c) Antiseptic and antibiotic solutions; and

(d) Syrup of ipecac (to be used only if so instructed by the Georgia Poison Control Center).

(3) **Adult Day Health Centers.** In addition to the above, adult day health care centers shall maintain the equipment and supplies listed below in a safe, clean and usable condition:

(a) Scales;

(b) Sterile dressing materials;

(c) Blood pressure equipment;

(d) Stethoscope;

(e) Tub-shower chair/bench;

(f) Wheelchair; and

(g) Anti-bacterial ointment or spray.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.11
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Supplies" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015

Rule 111-8-1-.12. Services.

(1) The scope of services provided or arranged by the center shall be based on the written description of the program.

(a) Adult day centers may provide a social model adult day care program or a medical model adult day health care program, which are differentiated by the intensity and scope of service delivery.

(b) Each model or program shall comply with all the general licensing standards as well as the program specific requirements outlined herein.

(2) **Core Services.** Core services provided by all centers shall include at a minimum the following:

(a) Supervision commensurate with the needs of the participants;

(b) Social and leisure activity programming which takes into consideration individual differences in health and functioning, lifestyle, ethnicity, religious affiliation, values, experiences, needs, interests, abilities and skills;

(c) Individual and group activities that encourage creativity, social interaction, and physical activity appropriate to each participant's functional status and abilities; and

(d) Nutrition, for all centers open for more than four (4) hours per day.

(3) **Optional Services.** Optional or additional services that may be arranged for or provided by the adult day center include the following:

(a) Transportation; and

(b) Assistance with the self-administration of medications.

(4) **Adult Day Health Services.** In addition to the above core services, centers that provide adult day health services shall provide an ongoing program of therapeutic activities designed to meet, in accordance with the assessment or reassessment, the physical, mental and psychosocial well-being of each participant. The activity program shall be multifaceted and reflect each individual's needs, abilities, and interests and include the following:

(a) Nursing services;

(b) Health monitoring;

(c) Medication administration;

(d) Physical therapy;

(e) Occupational therapy; and

(f) Speech therapy.

(5) **Individual Plan of Care.** The services provided by the center shall be in accordance with the participant's individual plan of care.

(a) The individual plan of care shall be completed by the Director or his/her designee, implemented within three business days of admission, and shall include the following:

1. Signature of the participant or representative as evidence of their involvement;

2. A review of the participant's functional abilities and disabilities, personal habits, likes and dislikes, medical condition and any other information helpful to developing the plan;

3. A statement of the activities and services the center will provide in order to meet the participant's needs and preferences;

4. The expected outcomes and the frequency of reevaluation of the plan;

5. The participant's usual travel arrangements to and from the site, the usual time for arriving and leaving, and any plan for using transportation services; and

6. The participant's usual times of arrival and departure not to exceed 14 hours in a 24 hour period.

   In addition to the above, for adult day health care centers, the individual plan of care shall also include:

7. The frequency and intensity of services to be provided; and

8. Identification of the therapeutic service provider who will provide any therapeutic services;

(b) The plan shall be reviewed and updated at least bi-annually or more often as warranted by changes in the participant's functioning, health condition, preferences or services. Changes shall be documented in the participant's record; and

(c) For adult day health services, the center shall document at least quarterly how each participant is responding to the individual plan of care.

(6) The center shall have a written agreement with any agency, program, or other service provider that provides essential services not provided directly by and otherwise the responsibility of the center. This written agreement shall include the nature and extent of the services provided and shall be updated annually. The center shall ensure that such services comply with the requirements of these rules.

(7) If the center uses animals as part of the program of activities, any such animals shall be tolerant of people on the premises, and be currently inoculated against rabies, if applicable. Documentation of immunizations for all animals that live onsite or are provided by the center shall be maintained at the center.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.12
Authority: O.C.G.A. § 49-6-81.

History. Original Rule entitled "Services" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.13. Staffing.

(1) **Core Requirements.** Each adult day center shall have as many staff and/or volunteers on duty at all times as may be needed to properly safeguard the health, safety and welfare of the participants, as required by these regulations. At a minimum the following shall be observed:

(a) Each center shall have a Director who is responsible for the day to day operation of the center and in the absence of the Director, a staff member shall be designated to supervise the center.

(b) Each center shall have at least one staff member who has current certification in first aid and cardiopulmonary resuscitation ("CPR") shall be in the center at all times.

(c) Each center shall identify which staff person is responsible for directing activities for the center.

(d) Each center shall provide appropriately qualified staff and/or volunteers in sufficient number to meet the needs of the participants and implement the participant's individual plan of care. At a minimum, adult day centers shall provide a staff and/or volunteer to participant ratio of no less than 1:8. The staffing ratio refers to the staff providing direct services to participants and therefore excludes such employees as clerical or office workers and maintenance or food service staff.

(e) Each center shall maintain a monthly work schedule showing that the center has planned for adequate coverage and shall document actual coverage by date, name, and hours worked.

(f) Each center shall ensure sufficient staffing to promptly and safely evacuate all participants in the event of an emergency. The center must adjust staffing as necessary based on the number of non-ambulatory participants at the center.

(2) **Adult Day Health Centers.** In addition to the requirements above, adult day health centers shall provide the following staffing:

(a) A registered nurse (RN) who shall assess participant's physical and mental health needs. The RN is responsible for the development and supervision of the participant's individual plan of care within three business days of admission.

If the center employs the services of a licensed practical nurse (LPN), the center shall ensure that the LPN is supervised by an RN as required by O.C.G.A. § 43-

26-1*et seq.* The LPN shall be available by phone, pager and/or email when not on site at the center.

The nurse shall:

1. Monitor and record participant's vital signs as needed;
2. Observe participant's functional levels and note any changes in physical condition;
3. Monitor medications brought into the center and observe participants for effectiveness and possible side effects;
4. Teach self-care activities and encourage participant's self-care;
5. Assist participants with medications when indicated;
6. Coordinate each participant's individual plan of care with the physician and other service agencies;
7. Notify the participant's primary health care provider and personal representative of changes in the participant's condition;
8. Supervise the provision of and teach other adult day health personnel to perform assist participants with activities of daily living; and
9. Document the participant's status in the participant's record.

(b) Appropriately qualified staff to perform skilled therapies, e.g. physical therapy, occupational therapy, and speech therapy, as identified in the participant's individual plan of care.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.13
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Staffing" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.14. Personnel.

(1) All adult day centers shall maintain written personnel policies and procedures which address at least the following:

(a) The hiring, training, and supervising of staff members; and

(b) The use, nature and extent of volunteer services, including a screening procedure to select volunteers with appropriate skills to work with the participants, or otherwise assist the center.

(2) Prior to hiring, the center shall search the Georgia Nurse Aide Registry to determine if an individual is designated in the registry as having abused, neglected or exploited a resident or consumer of a facility.

(a) If the employee or applicant has resided in another state, that state's nurse aide registry shall be searched prior to hiring.

(b) If the individual represents that they are certified or licensed, there shall be evidence in the file of the individual having a current license or certification that is not restricted.

(c) Each center shall search the Georgia Board of Nursing website to determine if a prospective nursing employee has been cited for disciplinary actions.

(d) A center shall not utilize a person to provide services who is listed in the Georgia Nurse Aide Registry, another state's Nurse Aide Registry and/or state licensing/certification boards as having abused, neglected or exploited a resident or consumer of a facility or having their license or certification restricted.

(e) For all staff and volunteer positions, employment and criminal background checks shall be conducted prior to employment. The center shall not employ nor use as volunteers persons with criminal histories which include the abuse, neglect, or exploitation of any disabled or aging adult.

(3) **Training.** The Director shall be responsible for ensuring that any person working in the center as an employee or under contract receives work-related training acceptable to the Department within the first ninety (90) days of employment. However, for centers providing services prior to the initial effective date of these rules, the centers shall have until March 1, 2015 to have all such staff who were hired prior to the initial effective date of these rules certified in first aid and cardiopulmonary resuscitation. The center shall ensure that at least one staff member who has completed the minimum training requirements be present in the center at all times.

(a) Work-related training for employees shall at a minimum include the following:

(1) Orientation to the rules and regulations contained in this chapter, and to the center's policies and procedures;

(2) Evidence of current certification in cardiopulmonary resuscitation where the training course required return demonstration of competency;

(3) Training in standard precautions, infection control and latex safety;

(4) Training in identifying participants who may be victims of elder abuse or self-neglect;

(5) Training in participants' rights including the prevention and reporting of suspected abuse, neglect or exploitation;

(6) Training in protecting the confidentiality of participant information and records;

(7) Training on the nature of influenza and the role of vaccination in controlling its spread to those persons having direct participant contact;

(8) Training in diversity and cultural sensitivity;

(9) Training on Alzheimer's disease and other dementias including communicating and responding to behaviors; and

(10) Medication training for the unlicensed staff that are providing assistance with or supervision of self-administration of medications to capable participants. The medication training must be conducted with an appropriate curriculum for providing medication assistance and include at least the following topics:

i. The center's medication policy and procedures, including actions to take if concerns regarding participant's capacity to self-administer medications are identified;

ii. How to read prescription labels including common abbreviations;

iii. Providing the right medication to the right participant at the right time in the right amount and the right way including how to measure various medications;

iv. Actions to take when concerns regarding medications are identified;

v. Infection control procedures relative to providing assistance with medications;

vi. Proper medication storage and disposal;

vii. Recognition of side effects and adverse reactions for the specific medications;

viii. Understanding the common classifications of medications, typical side effects and adverse reactions and medications for which

unlicensed staff may never provide assistance with or supervision of self-administration; and

ix. Proper documentation and record keeping using the Medication Assistance Record.

(b) **Adult Day Health Centers.** In addition to the training requirements above in 3(a), centers that provide adult day health services shall provide training on the laws governing administration of prescribed medications.

(c) **Volunteers.** The Director is responsible for ensuring that all volunteers receive training in accordance with the services they provide in the center. At a minimum, all volunteers shall receive training in the following:

(1) Identifying abuse, neglect and exploitation and the applicable reporting requirements; and

(2) Participant rights.

(4) **Staff Records.** Each center shall maintain personnel records for each employee and volunteer who provides direct care to participants. Each employee shall have access to his/her personnel record. Individual personnel records on all staff members shall contain at least the following:

(a) A complete application for employment or volunteer services;

(b) References, which may be documented as oral references or letters of reference;

(c) Copy of current license or certificate, as required for the position, including a valid driver's license for persons providing transportation services;

(d) Staff development records, to include, but not limited to evidence of current certification in CPR and first aid as well as evidence of training for staff; and

(e) Evidence of having conducted background screenings as required by these rules in regards to the staff member or volunteer.

(5) **Health Requirements.** All staff and volunteers who provide direct care to participants shall have received a report of physical examination by an authorized healthcare professional within twelve months prior to employment, sufficiently comprehensive to include at least the following:

(a) Documentation that the employee/volunteer is free of signs and symptoms of communicable diseases; and

(b) Evidence that all staff/volunteers are free of active tuberculosis based upon the results of a negative tuberculin skin test or chest x-ray within twelve months prior to employment.

(6) **Education/License Requirements.**

(a) The adult day center shall employ staff qualified by training or experience to perform all aspects of the position for which they are hired.

(b) **Adult Day Health Centers.** In addition to the above, adult day health centers shall ensure the following:

1. Directors shall have a bachelor's degree or at least four years experience in a health or human services or related field and shall have demonstrated ability to perform all aspects of the position;

2. Nurses shall have a current Georgia license to practice as a nurse; and

   All contract professionals, i.e. social workers or occupational, physical, or speech therapists, shall be licensed or certified, as required by law.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.14
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Personnel" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.15. Admission.

(1) **Admission.** Each adult day center shall admit individuals based on the center's comprehensive description of the types of services to be provided by the center and shall only admit individuals for whom the center can meet the participant's needs.

(2) Prior to the provision of services, the Director or his/her designee shall have at least one in-person interview with the applicant and/or representative to assess the applicant's needs and suitability of the program and shall obtain the following:

(a) A statement indicating any contraindications or limitations to the individual's participation in center activities;

(b) Evidence that the participant is free of active tuberculosis based upon the results of a negative tuberculin skin test or chest x-ray within 12 months prior to admission;

(c) A signed participant agreement;

(d) Any other information as required for the participant's care.

(3) The Director or his/her designee shall search the National Sex Offender Registry website maintained through the Department of Justice and draft any resulting safety plan for participants, staff and visitors.

(4) In addition to the above, centers that provide assistance with or administration of medications shall obtain documentation of the participant's over the counter and prescription medications.

(5) **Adult Day Health Centers.** In addition to the above, adult day health centers shall obtain documentation of the following:

(a) A medical examination report signed by a physician, nurse practitioner or physician assistant, completed within six months prior to admission that includes recommendations for care, diet, and medical, nursing, health or supportive services which may be needed; and

(b) Physician's orders for any therapies, when applicable.

(6) At admission the center shall ensure that the participant and representative receive a copy of the following:

(a) The center's pertinent policies and procedures required to be provided in the participant agreement; and

(b) Participant's rights information.

(7) **Participant Agreement.** Upon admission to the center, staff shall complete and the participant or their representative shall sign a written agreement. The agreement shall include the following:

(a) A disclosure statement that describes the center's range of care and services;

(b) Specific services to be provided to the participant by the center;

(c) A current statement of all fees and daily, weekly or monthly charges and any additional fees for specific services, goods, or incidental supplies that are not included in the daily charge;

(d) Days and hours of participant attendance not to exceed 14 hours in a 24 hour period;

(e) Arrangements for reimbursement and payment;

(f) Identification of and authorization for third party payors, if applicable;

(g) Any non-financial obligations of the participant and his/her family, such as a commitment by the participant to attend the center a specified number of days per week;

(h) Admission and discharge criteria;

(i) The center's refund policy;

(j) Schedule of holidays when the center is closed; and

(k) Announcement procedures for unexpected closing of the center due to disaster or severe weather.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.15
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Admission" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.16. Records.

(1) **Participant Records.** An individual file for each participant shall be established and maintained at the adult day center and shall include the following:

(a) The participant's full name, address, telephone number, date of birth, marital status, and living arrangement;

(b) At least two emergency contacts to include name, address, telephone number, and relationship to participant;

(c) Name, address and telephone number of the participant's primary health care provider;

(d) A signed participant agreement;

(e) Any powers of attorney, guardianship orders, or any other documents which identify authorized representatives of the participant, if applicable;

(f) All individual plans of care including updates;

(g) Copies of all signed authorizations for the center to receive and provide confidential information on the participant, if applicable;

(h) Signed authorization for the participant to receive emergency medical care from any licensed medical practitioner, if such emergency care is needed by the participant;

(i) A medical examination report conducted within six months prior to admission or within thirty (30) days after admission, and updated annually, signed by a licensed physician, physician's assistant or nurse practitioner;

(j) A statement signed by the participant or representative acknowledging receipt of center policies;

(k) An activity participation record for each participant;

(l) Medication Assistance Records; and

(m) A record of incidents, accidents, injuries, illnesses and emergencies involving the participant.

(2) **Adult Day Health Centers.** In addition to the above, adult day health centers shall maintain the following records:

(a) Progress notes including the written report of staff discussions, conferences, consultation with family or other interested parties; and

(b) Evaluation of a participant's progress, and any other information regarding a participant's situation.

(3) **Center Records.** The center shall maintain the following center records:

(a) Copies of activities schedules;

(b) Copies of menus served to participants, if applicable;

(c) Monthly fees collected and fees to be collected;

(d) A daily record of attendance of participants by name; and

(e) A written record of all serious or unusual incidents affecting participants, employees or volunteers of the center.

(4) All records shall be retained for a minimum of three years.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.16
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Records" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.17. Participant Rights.

(1) The following rights shall be guaranteed and cannot be waived by the participant or his or her representative:

(a) The right to be treated as an adult, with respect and dignity;

(b) The right to participate in a program of services and activities that promotes positive attitudes on one's usefulness and capabilities;

(c) The right to be free from physical, mental, sexual and verbal abuse, neglect, and exploitation;

(d) The right to be free from actual or threatened physical or chemical restraints;

(e) The right to be encouraged and supported in maintaining one's independence to the extent that conditions and circumstances permit, and to be involved in a program of services designed to promote personal independence;

(f) The right to self-determination within the day care setting, including the opportunity to:

1. Participate in developing one's plan of care;

2. Decide whether or not to participate in any given activity;

3. Be involved to the extent possible in program planning and operation;

4. Refuse to participate in treatment, activities or services at the center;

5. The right to be cared about in an atmosphere of sincere interest and concern in which needed support and services are provided;

6. The right to privacy and confidentiality;

7. The right to be made aware of the grievance process;

8. The right to file a complaint with the Healthcare Facility Regulation Division, including the complete address and phone number of the Division, whenever the participant believes that services are not being delivered in accordance with these rules;

9. The right to view inspection reports on the facilities compliance on the Department's web site; and

10. The right to review personal records.

(2) Each participant shall be provided at the time of admission a copy of the participant rights.

(3) Each participant shall receive care and services which shall be adequate, appropriate and in compliance with applicable state laws and regulations

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.17
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Nutrition" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.18. Nutrition.

(1) All adult day centers operating for more than four (4) hours a day and/or operating during regularly scheduled mealtimes shall ensure that a nutritious meal is provided to each participant in attendance.

(2) Snacks and fluids shall be available and offered to meet the participant's nutritional and fluid needs. At a minimum, a mid-morning and mid-afternoon snack shall be offered daily to participants.

(3) Meals and snacks provided by the center shall be planned to keep sugar, salt and cholesterol intake to a minimum.

(4) **Adult Day Health Centers.** In addition to the above, adult day health centers shall ensure the following:

(a) A meal shall meet at least one-third of an adult's daily nutritional requirement as specified by the Dietary Guidelines for Americans;

(b) A therapeutic diet shall be provided when prescribed in writing by a physician, physician's assistant or nurse practitioner;

(c) Menus shall be approved by a dietitian or RN;

(d) A dietitian or RN shall provide written techniques to staff on basic and special nutritional needs and proper food handling techniques and the prevention of food borne illness; and

(e) If therapeutic diets are prepared by center staff, such staff shall have training in planning and preparing therapeutic diets or shall provide documentation of previous training and education sufficient to assure ability to prepare meals in accordance with a physician's order.

(5) Food services for adult day centers licensed to care for 24 or more participants per day are subject to the provisions of the Rules and Regulations of the Department of Human Services for Food Service, Chapter 290-5-14 *et seq.* and any local health ordinances. Such a center must obtain a valid food service permit.

(6) Adult day centers licensed to care for fewer than 24 participants per day are not required to obtain a food service permit, but shall meet the following requirements:

(a) Each center preparing and providing meals shall have a properly equipped kitchen;

(b) Each center shall store, prepare, distribute, and serve food under sanitary conditions with generally accepted and recognized food service standards to prevent foodborne illness;

(c) All foods served to participants must originate from a reputable source;

(d) All perishable foods shall be stored at such temperatures as will protect against spoilage;

(e) All foods while being stored, prepared, or served shall be protected against contamination and be safe for human consumption;

(f) All foods must be cooked, maintained, stored, and served at appropriate temperatures;

(g) Refrigerator temperatures shall be maintained at or below 41 degrees Fahrenheit and freezers at 0 degrees Fahrenheit; and

(h) Non-disposable dishes, glasses and silverware shall be properly cleaned by pre-rinsing and scraping, washing, sanitizing and drying.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.18
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Nutrition" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.19. Medications.

(1) All medications required by a participant in an adult day center that does not employ a licensed RN, LPN or proxy caregiver shall be self-administered by the participant.

(2) Centers that provide assistance with medication without employing a licensed RN, LPN or proxy caregiver may do so to the following extent:

(a) Staff may remind participants of the time to take medication;

(b) Staff may check the dosage according to the container label; and

(c) Staff may physically assist a participant in opening or pouring the medication.

(3) Adult day centers that employ the services of an RN, LPN or a proxy caregiver may have the RN, LPN or proxy caregiver administer medications provided such medication

administration is performed in accordance with all applicable laws and regulations. For proxy caregivers, please review the Rules and Regulations for Proxy Caregivers used in Licensed Healthcare Facilities, Chapter 111-8-100.

(4) The center shall maintain a Medication Assistance Record of all medications, prescription and over-the-counter, that are supervised by staff or administered by RNs, LPNs or proxy caregivers. The Medication Assistance Record must include:

(a) The name of the medication;

(b) Dosage; and

(c) Date, time and signature of the staff person who assists the participant or administers the medications to the participant.

(5) Participants shall have the right to refuse any and all medications. The center's Director or staff providing medication assistance shall report such incidents to the participant's family and/or representative and documented on the Medication Assistance Record. The center shall record each instance of medication refusal by a participant in the participant's individual record and on the Medication Assistance Record.

(6) The center shall have the right to not accept or to discharge a participant who refuses assistance with medications if the center reasonably feels that the participant cannot safely possess and control his/her medications.

(7) All medications in the center shall be stored securely and in a manner to prevent spoilage, dosage errors, administrative errors, and inappropriate access.

A participant may keep possession of medications needed for frequent or emergency use. The center shall store all medications that require refrigeration in a locked container in the refrigerator.

(8) All medications shall be in the original pharmacy-dispensed container with a proper label and directions attached.

(9) Medications by injection, including but not limited to insulin, shall be administered by a nurse or proxy caregiver if the participant is unable to self-administer the medication.

(10) A nurse in an adult day health center shall monitor the medication regimen for all participants. He/she shall:

(a) Evaluate the health status of the participant by identifying symptoms of illness and/or changes in mental and/or physical health status;

(b) Make recommendations to the family or primary health care provider regarding any medication needs or other health needs requiring follow up; and

(c) Follow up on previous recommendations.

(11) At the end of the program day, or when the shift ends, the nurse shall count all controlled substances and sign the controlled substance book. If the nurse on duty at the next shift or at the beginning of the next program day is not present during the above counts, he/she shall count all controlled substances and sign the controlled substance book immediately after beginning the work period. Any discrepancies in count shall be reported immediately to the Director.

(12) Unused or discontinued prescription medications are the property of the participant and shall be given to the participant and/or the representative, whenever possible.

(13) Any unused or discontinued prescription medications that are left with a center shall be disposed in accordance with applicable Georgia laws.

(14) The Director, the activities director or a center nurse must immediately report to the representative any unusual reactions to medications or treatments.

(15) **Bio-Medical and Hazardous Waste.** The storage and disposal of bio-medical and hazardous wastes must comply with applicable federal, state and local rules and/or standards.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.19
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Medications" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.20. Transportation.

(1) The center may provide transportation and/or assist in arranging transportation services for participants.

(2) When transportation is provided to participants through center-operated vehicles, the operation of each vehicle shall comply with all applicable state and federal regulations relative to both driver and vehicle.

(3) Where the center contracts for transportation services, the center shall require that the contractor provide proof of insurance and current vehicle registration.

(4) When the adult day center provides transportation, the following requirements shall be met to ensure the health and safety of the participants:

(a) Each person transported shall have a seat in the vehicle;

(b) Vehicles used to transport participants shall be equipped with seatbelts;

(c) Participants shall be required to use seatbelts while being transported;

(d) Each vehicle shall have a first aid kit, along with fire extinguisher and safety triangles;

(e) The driver or attendant shall be trained in first aid procedures which include but are not necessarily limited to the following:

1. Care during a seizure;

2. Basic first aid; and

3. CPR;

(f) The driver or attendant shall have medical and emergency information in the vehicle for participants being transported;

(g) All transportation vehicles shall be equipped with a device for two-way communication;

(h) The transportation vehicle shall be in safe operating condition; and

(i) Each vehicle which transports participants shall have a trip roster which contains the addresses of the participants and the emergency contact phone numbers for each participant.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.20
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Transportation" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.21. Procedures for Change in Condition.

(1) In case of an accident or adverse change in a participant's condition or adjustment, the center shall immediately obtain needed care and notify the representative or emergency contact.

(2) The center shall immediately investigate the cause of an accident or injury involving a participant and take necessary steps to prevent recurrence.

(3) A record of incidents, accidents, injuries, illnesses and emergencies involving the participant shall be maintained in the participant's file.

(4) Accidents. In an emergency situation where the participants are subject to an imminent and substantial danger that only immediate transfer or discharge will relieve, the center

shall transfer or arrange for the transfer of the participant to another health facility or call 911 for emergency medical assistance.

(5) The center shall document in the participant's file the reasons for such emergency transfer and shall immediately inform the participant's guardian and other persons of the participant's choice regarding such transfer and the place where the participant is to be transferred.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.21
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Immediate Transfer, Discharge and Death" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.22. Immediate Transfer, Discharge and Death.

(1) **Immediate Transfer.** In case of emergency, such as acute illness, if family or the participant's representative cannot be reached, a signed release shall be on file stating that the participant may be sent to the nearest hospital emergency room for treatment.

(2) **Discharge.** Each participant agreement shall include a written procedure for handling discharge of the participant that complies with these rules.

(a) Each participant and/or representative shall be given 14 days written notice if the participant is to be discharged from the center for other than emergency reasons.

(b) During a participant's placement in a center, the participant agreement required by Rule 111-8-1-.15(7) regarding plans for discharge shall be adjusted according to the participant's circumstances.

(c) Emergency discharges are authorized when the health, safety and welfare of the participant or other participants at the center may be endangered by the participant's further placement in the center.

(3) **Death.** Upon the death of a participant while in the center, local law enforcement shall be immediately notified in addition to the participant's representative and/or family members, other medical personnel. The Department shall be notified within 24 hours.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.22
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Immediate Transfer, Discharge and Death" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.23. Reporting Requirements.

(1) **Serious Incidents.** All adult day centers shall maintain records and submit on a timely basis reports required by the Department.

(2) On forms provided by the Department, no later than the next business day, the adult day center shall report whenever any of the following serious or unusual incidents involving a participant occurs or center has reasonable cause to believe that an incident involving a participant has occurred at the center or off-site during the provision of services:

(a) Any death of a participant;

(b) Any rape of a participant;

(c) Any serious injury to a participant that requires medical attention;

(d) Any suspected abuse, neglect or exploitation of a participant; and

(e) Any time a participant cannot be located and the participant has been missing for more than thirty (30) minutes.

(3) Reports of participant incidents shall include:

(a) The name of the adult day center, the name of the Director, and a contact telephone number for information related to the report;

(b) The date of the incident and the date the adult day center became aware of the incident;

(c) The type of incident, with a brief description of the incident; and

(d) Any immediate corrective or preventive action taken by the adult day center to ensure against the replication of the incident.

(4) The adult day center shall conduct an internal investigation of any of the serious or unusual incidents listed in subparagraph (2) of this rule and shall complete and retain on-site a written report of the results of the investigation within five (5) business days of the discovery of the incident. The complete report shall be readily available to the Department for inspection and shall contain at least the following:

(a) An explanation of the circumstances surrounding the incident, including the results of a root cause analysis or any other system analysis;

(b) Any findings or conclusions associated with the review; and

(c) A summary of any actions taken to correct identified problems associated with the incident and to prevent recurrence of the incident, and also any changes in procedures or practices resulting from the investigation.

(5) **Other Incidents Requiring Report.**

(a) The adult day center shall report to the Department whenever any of the following events involving adult day center operations occurs or when the adult day center becomes aware that it is likely to occur, to the extent that the event is expected to cause or causes a significant disruption of care for adult day center participants:

1. An external disaster or other community emergency situation which causes a complete disruption in services; or

2. An interruption of services vital to the continued safe operation of an adult day center, such as telephone, electricity, gas, or water services.

(b) The adult day center shall make a report of the event not later than the next business day from when the reportable event occurred or from when the adult day center has reasonable cause to anticipate that the event is likely to occur. The report shall include:

1. The name of the adult day center, the name of the Director, and a contact telephone number for information related to the report;

2. The date of the event, or the anticipated date of the event, and the anticipated duration, if known;

3. The anticipated effect on care and services for adult day center participants; and

4. Any immediate plans the adult day center has made regarding participant management during the event.

(6) Where the Department determines that a rule violation related to any self-reported incident or event has occurred, the Department shall initiate a separate complaint investigation of the incident. The complaint investigation report and the report of any rule violation compiled by the Department arising either from the initial report received from the adult day center or an independent source shall be subject to disclosure in accordance with applicable laws.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.23
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Reporting Requirements" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.24. Quality Assurance.

(1) Adult day centers shall develop and implement an annual quality improvement plan to evaluate and improve the effectiveness of the program's operation and services to ensure continuous improvement in service delivery. The plan shall include the parties to be

involved and the areas which will be addressed. A formal evaluation shall be conducted at regular intervals, but at least annually.

(2) The evaluation process shall include:

(a) A review of the existing program including serious incidents and corrective actions taken;

(b) Satisfaction survey results or comments and complaints received from staff, participants and/or participant's representatives;

(c) Program modifications made in response to changing needs of participants; and

(d) Proposed program administrative improvements.

(3) The center shall prepare a written report which summarizes the evaluation findings, improvement goals and implementation plan.

(4) Findings of the quality improvement evaluation shall be utilized to correct identified problems, revise adult day center policies, and improve the care of participants.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.24
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Quality Assurance" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.25. Infection Control.

(1) Each adult day center shall develop and implement policies and procedures that address infection control issues in all components of the adult day center. These policies and procedures shall be based on accepted standards of infection control and shall address at least the following:

(a) Hand hygiene;

(b) Cleaning, disinfecting, and sanitizing participant areas;

(c) Isolation precautions;

(d) Handling, transport, and disposal of medical waste or bodily fluids;

(e) Center requirements for communicable disease health screening, including tuberculosis surveillance and any recommended immunizations;

(f) Use of personal protective equipment and exposure reporting/follow-up;

(g) Work restrictions for staff with potentially infectious diseases;

(h) Evaluation of the participant related to infection control risks;

(i) Outbreak investigation procedures;

(j) Dietary practices;

(k) Reporting of communicable diseases, as required by law; and

(l) Standard precautions.

(2) **Adult Day Health Centers.** In addition to the above, adult day health center shall develop and implement policies and procedures that address infection control issues regarding the following:

(a) Wound care;

(b) Urinary tract care;

(c) Respiratory therapy;

(d) Enteral therapy; and

(e) Infusion therapy.

(3) The infection control program shall be evaluated as needed, but at least annually to ensure the effectiveness of the program related to the prevention of the transmission of infections to participants and staff.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.25
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Infection Control" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.26. Inspections by Department Staff.

(1) The Department is authorized and empowered to conduct complaint investigations and periodic on-site inspections of any center when determined necessary.

(2) Prior to licensure and periodically thereafter, the Department shall inspect each adult day center to ensure that the center is providing adequate care to its participants and is in compliance with all applicable rules and regulations.

(3) An application for a license or the issuance of a license by the Department constitutes consent by the applicant, the proposed holder of the license and the owner of the premises for the Department's representative, after displaying proper identification to any center

staff, to enter the premises at any time during operating hours for the purpose of inspecting the center to determine compliance with these rules.

(a) The adult day center staff, facilities, and participants shall be accessible during all hours of operation to properly identified representatives of the Department for inspections and investigations relating to the adult day center's license.

(b) For the purposes of any inspection, investigation, or survey conducted by the Department, the adult day center shall provide to properly identified representatives of the Department meaningful access to all books, records, papers, or other information related to the licensing of the adult day center.

(4) Knowingly making any verbal or written false statement of material fact in connection with any inspection or investigation or supplying false or misleading information is grounds for denial or revocation of a license.

(5) The Department may exempt a center from periodic inspections if such center has been certified or accredited by an entity recognized and approved by the Department if such entity uses standards that are substantially similar to those established by the Department. A center seeking exemption from inspection shall be required to submit to the Department documentation of certification or accreditation, including a copy of its most recent certification or accreditation inspection report, which shall be maintained by the Department as a public record.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.26
Authority: O.C.G.A. § 49-6-85.
History. Original Rule entitled "Inspections by Department Staff" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.27. Variances and Waivers.

(1) A center may request a waiver or variance of a specific rule by application on forms provided by the Department. The Department may grant or deny the request for waiver or variance at its discretion. If the waiver or variance is granted, the Department may establish conditions that must be met by the adult day center in order to operate under the waiver or variance. Waivers or variances may be granted with conditions of the following:

(a) **Variance.** A variance may be granted by the Department upon a showing by the applicant that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application would cause undue hardship. The applicant must also show that adequate standards exist for affording protection for the health, safety, and care of participants, and these existing standards would be met in lieu of the exact requirements of the rule or regulation.

(b) **Waiver.** The Department may dispense altogether with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, and care of the participants, or by demonstrating that the purpose of the statute on which the underlying rule is based can be or has been achieved by other specific means and that strict application of the rule(s) would create a substantial hardship for the applicant.

(c) **Experimental Waiver or Variance.** The Department may grant a waiver or variance to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant that the intended protections afforded by the rule or regulation in question are met and that the innovative approach has the potential to improve service delivery.

(2) Waivers and variances granted by the Department shall be for a time certain, as determined by the Department.

(3) Waivers and variances granted to an adult day center shall be recorded and shall be available to the public through posting to the State's rules waiver register.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.27
Authority: O.C.G.A. § 49-6-81 and § 31-2-7.
History. Original Rule entitled "Variances and Waivers" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.28. Enforcement and Penalties.

An adult day center that fails to comply with licensing requirements contained in these rules, the Rules and Regulations for the Use of Proxy Caregivers, Chapter 111-8-100 as applicable and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25, is subject to civil and administrative actions brought by the Department to enforce licensing requirements as provided by law and rules. Such actions will be initiated in compliance with the Georgia Administrative Procedures Act, O.C.G.A. § 50-13-1*et seq.*, O.C.G.A. § 31-2-11 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.28
Authority: O.C.G.A. §§ 49-6-84, 31-2-7, 31-2-8, 43-26-12 and 50-13-1*et seq.*
History. Original Rule entitled "Enforcement and Penalties" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 111-8-1-.29. Severability.

In the event that any rule, sentence, clause, or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portion thereof. The remaining rules or portions of rules shall remain in full

force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-1-.29
Authority: O.C.G.A. § 49-6-81.
History. Original Rule entitled "Severability" adopted. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Subject 111-8-4. AMBULATORY SURGICAL TREATMENT CENTERS.

Rule 111-8-4-.01. Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Ambulatory Surgical Treatment Centers" means any institution, building, or facility, or part thereof, devoted primarily to the provision of surgical treatment to patients not requiring hospitalization, as provided under provisions of O.C.G.A. § 31-7-1(4)(c). Such facilities do not admit patients for treatment which normally requires overnight stay, nor provide accommodations for treatment of patients for period of twenty-four (24) hours or longer;

(b) "Governing Body" and/or "Management" means the Board of Directors and/or Trustees, the partnership, the corporation, the association, or the person or group of persons who maintain and control the operation of the ambulatory surgical treatment center and who are legally responsible for its operation;

(c) "Center" means an ambulatory surgical treatment center as defined in these rules and regulations;

(d) "Board," unless otherwise indicated, shall mean the Georgia Board of Community Health;

(e) "Commissioner" means the Commissioner of the Georgia Department of Community Health or his designee;

(f) "Department" means the Georgia Department of Community Health;

(g) "General Anesthesia" means any drug, element or other material administered to eliminate all sensation and which, when administered, is accompanied by a state of unconsciousness;

(h) "Licensee" means the person or body to whom the license or permit is issued and who is held responsible for compliance with all required rules, regulations, and minimum standards;

(i) "Permit" or "license" means an authorization granted by the Department to an applicant to operate an ambulatory surgical treatment center providing one or more types or classifications of services;

(j) "Provisional Permit" means an authorization granted by the Department to an applicant to operate an ambulatory surgical treatment center on a conditional basis to allow a newly established center a reasonable but limited period of time to demonstrate that operational procedures are in satisfactory compliance with these rules and regulations, or to allow an established and operating center a specified length of time to comply with these rules and regulations, provided said center shall first present a plan of improvement which is acceptable to the Department;

(k) "Plan of Improvement" means a written plan submitted to the Department by the person or persons responsible for the center, and acceptable to the Department. The plan shall identify the existing areas of noncompliance of the facility, together with the proposed procedures, methods and period of time to correct the areas of noncompliance;

(l) "Professional Staff" means the group of persons or body appointed by the Governing Body to provide patient services, and who require special licensure or registration. Normally, the professional staff will be restricted to currently licensed medical, dental, and podiatrist practitioners. Other personnel, for example, registered nurses, may be appointed to the professional staff to assist the practitioners in the development, interpretation, and enforcement of patient care policies;

(m) "Practitioner" means a physician, dentist, or podiatrist;

(n) "Physician" means an individual who is currently licensed to practice medicine, surgery or osteopathy in the State of Georgia, under the Georgia Medical Practice Act, O.C.G.A. § 43-34-20*et seq.*;

(o) "Dentist" means any person who is currently licensed to practice dentistry in the State of Georgia, under provisions of the Georgia Dentist and Dental Hygienists Act, O.C.G.A. § 43-11-1*et seq.*;

(p) "Podiatrist" (Chiropodist) means any person who is currently licensed to practice podiatry (chiropody) in the State of Georgia, under provisions of the Georgia Podiatry Act, O.C.G.A. § 43-35-1*et seq.*;

(q) "Registered Nurse," "Registered Professional Nurse," or "R.N." means a person who is currently licensed to practice as a licensed registered nurse under provisions of O.C.G.A. § 43-26-1*et seq.*;

(r) "Licensed Practical Nurse" or "L.P.N." means a person currently licensed to practice as a licensed practical nurse under provisions of O.C.G.A.§ 43-26-30*et seq.*;

(s) "Private Office(s)," "Office(s)," and/or "Treatment Rooms" means any area or place established and maintained by a currently licensed individual practitioner, professional

association, or group practice of such practitioners, in his/her/their private individual or private group practice, in which he/she/they primarily see(s), consult(s) with, examine(s), and/or treats private patients on a regular and on-going basis, and in the operation of which such currently licensed practitioners have full control of all financial, administrative, and professional arrangements with said patients;

(t) "Hospital" means any facility which meets the requirements of and is currently licensed as a hospital under Georgia Laws and rules and regulations pertaining thereto;

(u) "Procedure Room" means any room or area of the ambulatory surgical treatment center in which surgical procedures are performed;

(v) "Patient" means any individual who receives medical/surgical treatment in facilities governed by these regulations;

(w) "Qualified Counselor" means a person who assists the professional staff by talking with and informing patients regarding expectations and probable outcomes associated with services in an ambulatory surgical treatment center, and who possesses the following minimum qualifications: at least a bachelor's degree from an accredited college or university in nursing, psychology or social work, or in some related field, or who has special training in counseling which is deemed acceptable by the Department; provided, however, that any such counselor shall function only under the direct supervision of the responsible practitioner.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.01
Authority: O.C.G.A. §§ 31-2-4*et seq.*, and 31-7-1 *et seq.*
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.02. Exemptions.

The following types of health care facilities are exempt from the requirements of these regulations:

(a) currently licensed hospitals, or a facility as specified in 111-8-4-.03(12);

(b) a practitioner's private offices or treatment rooms in which a practitioner primarily sees, consults with, and treats patients;

(c) facilities owned and operated by the Federal Government.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.02
Authority: O.C.G.A. §§ 31-2-7 and 31-7-1*et seq.*
History. Original Rule entitled "Exemptions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.03. Organization and Administration.

(1) Each ambulatory surgical treatment center shall be organized with an identifiable governing body that establishes the objectives, sets the policies and assumes full legal responsibilities for the overall conduct of the center and for compliance with all applicable laws and regulations pertaining to the center. The membership of the governing body shall be identified in the application to the Department for licensure.

(2) The ownership of the center shall be fully disclosed in the application to the Department. This disclosure shall include the names and addresses of all corporate officers and any person(s) having a five percent (5.0%) or more financial interest.

(3) The governing body of the center shall be responsible for appointing the professional staff and shall establish effective mechanisms for quality assurance and to ensure the accountability of the center's medical and/or dental staff and other professional personnel.

(4) The organizational objectives of the ambulatory surgical treatment center shall be clearly stated in the procedures and policies of the governing body and on the application for licensure.

(5) The governing body shall inform the Department of the name(s) of the administrator(s) to whom the responsibility for the day-to-day management of the center is delegated, including the implementation of rules and policies adopted by the governing body.

(6) Each center shall be at all times under the immediate personal and daily supervision and control of the administrator or his designated representative, whose authority, duties and responsibilities shall be defined in writing and which shall be available to the Department upon request.

(7) The Department shall be notified with a new application, or written amendment to the current application, when there are changes in location, ownership, management or operational objectives.

(8) Individual patients shall be discharged within twenty-four (24) hours of admission, in an ambulatory condition which will not endanger their continued well-being, or shall be transferred to a licensed hospital or other treatment facility. There shall be written procedures and assigned responsibilities for implementing such procedures, including provisions for transportation. Patients requiring emergency services shall be accompanied by a member of the professional staff of the center.

(9) Each center shall have an organized professional staff which is responsible for the development of patient care policies and procedures and for maintaining the level of professional performance through a continuing program of staff education, review and evaluation of patient care.

(10) Each center shall at all times have a professional director designated by the governing body, who shall be responsible for the direction and coordination of all professional aspects of the center programs.

(11) The practitioners applying for staff privileges shall be required to sign an agreement to abide by the staff bylaws and required State laws and rules and regulations.

(12) Nothing in these rules and regulations shall prevent a licensed hospital from organizing and providing an ambulatory surgical treatment service as a part of a licensed hospital under the controlling authority of a hospital board, so long as all hospital licensure standards are met and the provided services are included in the application under which the hospital license is granted.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.03
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Organization and Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.04. Classification of Services.

Each ambulatory surgical center, when applying for a permit shall designate the type(s) or classification(s) of services to be provided in or by the center. These classifications may include, but are not necessarily limited to the following: general surgery; eye, ear, nose, and throat; plastic surgery; oral and maxillofacial; obstetrical-gynecological; oncological; ophthamological; and urological. Provided, however, that any facility providing labor and delivery services must meet the requirements of Rules and Regulations for Hospitals, Maternity and Obstetrical and Newborn Services, Rule 111-8-40-.34 or as later revised. The permit for a single ambulatory surgical treatment center may cover one or more types of services. Each ambulatory surgical treatment center shall provide only those services listed on the face of its permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.04
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Classification of Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.05. Application for Permits.

(1) Any person or persons responsible for the operation of an ambulatory surgical treatment center as defined and classified in these regulations, or who may hereafter propose to establish and operate such an institution, shall submit an application to the Department for a permit to operate said institution using forms provided by the Department. No such institution shall be operated in Georgia without a valid permit which shall be displayed in a conspicuous place within the center.

(2) The applicant for a permit to operate an ambulatory surgical treatment center shall submit a completed application with character references and a certification that the applicant is

able and willing to comply with the minimum standards for an ambulatory surgical treatment center and with the rules and regulations lawfully promulgated. Each application shall be accompanied by a statement from the local (city or county) fire safety authority stating that an inspection has been made of the premises and that state and local fire safety requirements have been met.

(3) The application shall include full and complete information concerning the name and address of the applicant and the classification(s) of services to be provided; the ownership of the property and operation; in case a center is organized as a corporation, the names and addresses of each officer and director of the corporation; in case the center is organized as a partnership, the names and addresses of each partner; the identity of the professional director of the facility; the days and hours the center is normally operated; and any other information which the Department may require.

(4) Ambulatory surgical treatment centers are subject to review by the Department, pursuant to the Georgia Certificate of Need Law. Evidence of completion of this review shall be made a part of the application for a permit.

(5) Plans for ambulatory surgical treatment centers shall be submitted to the Department for review and approved in three stages of development:

(a) schematic drawings;

(b) design-development drawings; and

(c) final working drawings and specifications.

(6) A permit shall be issued to the person or persons named only for the premises listed on the application for licensure.

(7) Permits are not transferable or assignable.

(8) Changes in ownership shall be subject to notice requirements as specified in O.C.G.A.§ 31-6-40.1. Each planned change of ownership or lease shall be reported to the Department thirty (30) days prior to such change with an application being submitted from the proposed new owners for a new permit.

(9) Separate applications and permits are required for centers maintained in separate premises, even though they are owned or operated by the same person(s), business or corporation, and may be doing business under the same title.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.05
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-6-40.1 and 31-7-1 *et seq.*
History. Original Rule entitled "Application for Permits" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.06. Permits.

(1) Following inspection and classification of the institution for which application for a permit has been made, the Department may issue a permit or a provisional permit or refuse to reissue or continue a permit or provisional permit. Each permit or provisional permit shall indicate the classifications of services to be provided and patient capacity of the center.

(2) Permits issued shall mean that the Department grants authorization to the governing body of the applicant institution to operate an ambulatory surgical treatment center and signifies compliance with these rules and regulations. Permits issued shall remain in force and effect until revoked or suspended.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.06
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Permits" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.07. Provisional Permits.

Provisional permits may be issued for a limited period specified by the Department based on an acceptable written plan for correcting one or more deficiencies (plan of correction) found during an inspection; provisional permits issued shall remain in force and effect for such limited period of time as specified by the Department, unless earlier revoked due to prevailing circumstances which are not acceptable to the Department. Centers which are established and operating prior to adoption of these rules and regulations may be considered for extension of a provisional permit when needed to meet physical plant standards. If the Department's decision is that a deficiency is of such nature that it would jeopardize the life of a patient, a provisional permit will not be issued.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.07
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Provisional Permits" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.08. Inspections.

(1) The ambulatory surgical treatment center shall be available at all reasonable and/or scheduled operating hours for observation and examination by properly identified representative of the Department.

(2) The governing body shall notify the Department of the anticipated opening date of a newly constructed center in order that a preopening licensure inspection of the center may be conducted to determine compliance with these rules and regulations.

(3) The administrator or his representative shall accompany the Department representative on all tours of inspection and shall sign the completed checklist.

(4) Each center shall be periodically inspected to determine whether the center is continuing to meet these requirements or is making satisfactory progress on approved plans of correction.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.08
Authority: O.C.G.A. § 31-2-8.
History. Original Rule entitled "Inspections" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.09. Professional Services.

(1) All services provided by or in the center shall be provided by persons who are currently licensed to perform the services they render when such services require licensure or registration under the laws of the State of Georgia. There shall be a sufficient number of qualified staff members to adequately provide for patient needs based on services provided and the number of patients served.

(2) Each center shall have a professional director who shall be a practitioner currently licensed in Georgia, and who shall be responsible for the direction and coordination of all medical aspects of the center program.

(3) General anesthesia shall be administered by an anesthesiologist, a physician anesthetist, an oral surgeon, or a certified R.N. anesthetist under the direction and responsibility of a currently licensed physician with training and experience in anesthesia, as specified in Georgia Code 84-10A. After administration of a general anesthetic, patients shall be constantly attended (at bedside) by a person qualified as above or by an R.N. until reactive and able to summon aid.

(4) All nursing services shall be under the supervision of a registered nurse (R.N.). Each center shall have a sufficient number of currently licensed nurses present and on duty to attend to patients at all times patients are receiving treatment or recovering from treatment up to and including the time of discharge. Additional staff shall be on duty and available to assist the professional staff to adequately handle routine and emergency patient needs.

(5) Each center shall establish written procedures for emergency services which will insure that a professional staff member who has been trained in emergency resuscitation procedures shall be on duty at all times when there is a patient receiving treatment or recovering from treatment, up to and including the time of discharge.

(6) The written procedures shall provide that an appropriate practitioner be designated on call and available to provide timely response to emergencies which may occur with any patient in the center.

(7) Each center shall have a hospital affiliation agreement and/or the medical staff must have admitting privileges or other acceptable documented arrangements to insure the necessary

backup for medical complications. The center must have the capability to transfer a patient immediately to a hospital with adequate emergency room services.

(8) Each center will have effective policies and procedures for handling infection control and for recording complications which occur during or after surgery, which includes a reporting mechanism for patients who develop infections or postoperative complications after discharge.

(9) Either prior to, or at the time of admission, each patient who is admitted to the center without an appointment with a specified practitioner shall be provided (in writing) with the name, address and phone number of the practitioner who is serving him/her. The practitioner or a qualified counselor designated by the practitioner, shall explain the surgical and medical procedures, its potential complications, and postoperative complications and other alternatives to surgery; this shall be confirmed by the patient who shall sign an informed consent form as provided under O.C.G.A. § 31-9-1*et seq.* Prior to dismissal, each patient shall be provided with both verbal and written instructions for posttreatment care and procedures for obtaining emergency care, if needed during the period of recuperation.

(10) All ancillary supportive health or medical services such as radiological services, pharmaceutical services, or clinical laboratory services provided in or by the center shall be in accordance with applicable rules and regulations of the State of Georgia.

(11) Each center shall establish policies for patient care and procedures for maintaining these policies.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.09
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Professional Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.10. Physical Plant and Operational Standards.

The following minimum physical plant and operational standards shall be met by an applicant or licensee as a prerequisite for the issuance and continuance of a permit to operate an ambulatory surgical treatment center. The failure of any licensee to comply with the minimum standards may result at any time in the denial, revocation, or suspension of licensure to operate an ambulatory surgical treatment center, pursuant to provisions of O.C.G.A. § 31-2-8, and these rules and regulations.

(a) Rooms and/or areas shall be planned and provided with sufficient space and equipment to provide for patient and visitor waiting area; presurgical examination and treatment; procedure rooms; patient recovery; and staff and administrative areas.

(b) The physical plant of the center shall meet all Federal, State and local laws, codes, ordinances, and regulations which apply to its location, construction, maintenance and operation.

(c) Equipment, electrical appliances, wiring, elevators, heating and cooling systems, surgery rooms and special service areas shall be constructed so as to assure the safety of all occupants. It shall be the responsibility of the governing body to assure that the center is in a safe condition at all times and that a fire inspection record is maintained on equipment, systems, and areas that may present a hazard to occupants.

(d) Except where additional requirements are specified herein, or are required by State or local ordinances or regulations, the construction of an ambulatory surgical treatment center shall meet the requirements for Health Care or Business Occupancies as specified in Chapter 10 and/or Chapter 13, as applicable, of the 1976 Life Safety Code, as currently adopted and amended by regulations of the Georgia Safety Fire Commissioner, Chapter 120-3-3, March 1, 1979, and subsequent revisions thereto.

(e) Entrances for patients shall be connected to the public right-of-way by a hardsurfaced, unobstructed walkway in good repair. Handicapped patients confined to a wheel chair or otherwise impaired shall be able to access the center building without climbing any stairs or steps. A ramp with handrails over existing stairs or steps may be utilized in meeting this requirement. A hard-surfaced, unobstructed road or driveway for use by ambulances or other emergency fire or police vehicles shall run from at least one entrance of the building to the public right-of-way. The doorway of such entrance shall be immediately adjacent to the road or driveway.

(f) Ambulatory surgical services provided in multistory buildings shall be accessible by an elevator of adequate size to accommodate date a standard wheeled litter patient and two attendants. A stairway or ramp of adequate dimensions shall be available for transfer of a patient in case of power failure.

(g) All procedure rooms shall be constructed, equipped, and maintained to assure the safety of patients and personnel. The following requirements shall apply within the patient treatment/procedure rooms and adjoining areas:

1. Procedure rooms shall be designed and located to prevent traffic through them to any other part of the center;

2. The walls and floors in procedure rooms shall be of material that will permit frequent washing and cleaning;

3. Sterilizing equipment shall be provided within the center and shall be convenient to the procedure rooms;

4. Staff dressing rooms and scrubup facilities shall be convenient to the procedure rooms, and shall include a knee or elbow operated scrub sink, soap dispenser, and brushes;

5. An equipment cleanup area with adequate plumbing, including a sink with counter, shall be provided outside the procedure room;

6. Enclosed storage facilities for sterile supplies and equipment shall be provided within the procedure areas;

7. Scrub clothing worn by personnel outside the procedure area shall be changed before returning to the procedure area;

8. Locations using flammable anesthetic agents shall comply with the following:

   (i) Floors, furniture and equipment in operating rooms shall be of electrically conductive material. Conductive flooring shall extend into contiguous rooms and at least ten (10) feet into the entrance traffic area.

   (ii) Clean conductive footwear testing device shall be maintained in the procedure rooms.

   (iii) An anesthesia supply and equipment storage room shall be provided within the procedure area.

   (iv) Separate storage enclosures shall be provided for flammable gases and combustion supporting gases. Such enclosures shall be constructed of building material with a fire resistive rating of at least one hour and shall not communicate directly with anesthetizing locations or each other. Air shall be adequately exhausted by gravity or spark proof forced ventilation from the flammable storage enclosure to the exterior of the building at a rate of not less than two (2) changes per hour. Storage enclosures for combustion supporting gases of less than 1500 cubic feet cylinder capacity need not be vented to the outside. Flammable materials such as fabrics, rubber and wood shall not be stored in these enclosures.

   (v) Clothing generating large amounts of static electricity shall be prohibited in the procedure rooms.

9. Locations using flammable anesthetic agents shall be identified by prominently posted signs at all entrances to the procedure room and within the location signifying the type of anesthetics used.

(h) Toilet facilities shall be accessible to patients from the treatment, examining and recovery areas. Convenient handwashing facilities shall be provided for both staff and patients, and shall be provided with soap, disposable towels and dispensers. The use of common towels is prohibited.

(i) Emergency life support equipment shall be available for immediate use, in patient treatment areas. Such equipment shall include, but not necessarily be limited to the

following: suction, IV fluids, oxygen, needles, intracatheters, medications, and ventilatory equipment such as ambu bags, oral and nasal airways and endotracheal tubes. Facilities providing general anesthesia shall also have a defibrillator and tracheotomy equipment and supplies.

(j) All medical gases shall be stored in accordance with Bulletin 56A of the National Fire Protection Association.

(k) All plumbing shall be designed and installed in accordance with State laws and local ordinances.

(l) The center shall be arranged and organized in such a manner as to ensure the comfort, safety, hygiene, privacy, and dignity of patients treated therein.

(m) Equipment for sterilizing instruments and supplies shall be conveniently located and of adequate capacity for the workload. Records shall be maintained to assure quality control, including date, time and temperature of each batch of sterilized supplies and equipment.

(n) Medicines shall be stored in a conveniently located cabinet with lock, and only licensed persons shall have access.

(o) Clean and soiled utility rooms shall be arranged and provided with equipment necessary for proper patient care, including sterilizers, storage cabinets and work counters.

(p) Each center shall provide one or more recovery rooms or areas staffed by qualified personnel. The recovery area shall be adequate for the numbers of patients scheduled. Separate recovery areas and/or cubicle curtains shall be provided for patient privacy, when appropriate.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.10
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Physical Plant and Operational Standards" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.11. Personnel.

(1) The governing body shall appoint an administrator who is responsible for the day-today management and operation of the center.

(2) The administrator shall designate an individual to act for him in his absence in order to provide the center with administrative direction at all times.

(3) All center personnel shall be currently licensed to perform the services they render when such services require licensure or registration under the laws of the State of Georgia.

(4) Each center shall require that each employee receives a health examination upon employment and a policy shall provide for follow-up examinations. The examination shall be in sufficient detail, including pertinent laboratory and x-ray data, to assure that the employee is physically and mentally qualified to perform the job to which he is assigned.

(5) There shall be a separate personnel folder maintained for each employee. This file shall contain all personnel information concerning the employee, including the application and qualifications for employment, physical examination (including laboratory and x-ray reports, if applicable), job description and attendance record.

(6) Fire and internal disaster drills shall be conducted at least quarterly and the results documented. There shall be an ongoing program of continuing education for all personnel concerning aspects of fire safety and the disaster plan for moving personnel and patients to safety, and for handling patient emergencies.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.11
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Personnel" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.12. Records.

(1) A full-time employee shall be designated responsible for establishing and maintaining medical records required to be kept by these rules and regulations.

(2) Medical records containing sufficient information to validate the diagnosis and to establish the basis upon which treatment is given shall be maintained on each patient.

Contents of individual medical records shall normally contain the following at least:

(a) Admission and discharge data:

1. Name, address, birth date, sex, marital status, race, etc.
2. Date and time of admission.
3. Date and time of discharge.
4. Admitting diagnosis.
5. Final diagnosis.
6. Procedures or operations performed.

7. Condition on discharge.

8. Attending practitioner's signature.

(b) History and physical examination data:

1. Personal medical history (including all current medication that the patient is taking).

2. Family medical history.

3. Physical examination.

4. Psychiatric examination (if applicable).

(c) Treatment data:

1. Practitioner's orders.

2. Progress notes.

3. Nurse notes.

4. Medication.

5. Temperature-Pulse-Respiration (Graphic Chart; surgical purposes only).

6. Special examination(s) and reports (include x-ray and lab reports).

7. Signed informed consent form.

8. Operation record.

9. Anesthesia record (if applicable).

10. Consultation record (if applicable).

11. Tissue findings when performed.

12. Where dental services are rendered, a complete dental chart with dental diagnosis, treatment, prescription and progress notes shall be part of the clinical record.

(3) All orders on patients shall be signed by the practitioner giving them; admitting diagnosis (purpose of admission) shall be recorded prior to or at the time of admission.

(4) Medical records shall be preserved as original records, microfilms or other usable forms and shall be such as to afford a basis for complete audit of professional information. Centers shall retain all medical records, at least until the sixth anniversary of the patient's discharge. In the case of patients who have not attained majority at the time of the discharge, centers shall retain such records at least six (6) years after patient reaches age of majority. In the event a center shall cease operation, the Department shall be advised of the disposition and/or location of said records.

(5) The center shall collect, retrieve and annually summarize data from the medical record so that it may provide the Department with the following medical statistical information including:

(a) Number of visits by patients.

(b) Number of patients seen.

(c) Basis of treatment (clinical diagnosis and/or problem for which the patient was treated).

(d) Types and number of operative procedures performed.

(e) Age distribution of patients.

(f) Complications and emergencies.

(g) Number of times a patient was transferred from the center to a hospital.

(h) Pathological diagnosis.

(6) Patient records shall be current and shall be entitled to the same protection as provided for any medical records under Georgia law.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.12
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Records" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.13. Administrative Area and Waiting Rooms.

(1) Each center shall provide administrative space and facilities for admitting patients and other service, such as telephone and information office files and supplies, patients' personal belongings, medical records and files.

(2) A waiting room area shall be provided with a seating capacity to accommodate the number of patients and others of the public normally present in the facility at one time.

(3) The center shall have adequate and conveniently located toilets and handwashing facilities for its staff, employees, out-patients and visiting personnel.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.13
Authority: O.G.C.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Administrative Area and Waiting Rooms" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.14. Clinical Laboratory Services.

(1) Laboratory services utilized by an ambulatory surgical treatment center shall be consistent with requirements of the Clinical Laboratory Licensure Law, O.C.G.A. § 31-22-1*et seq*., and applicable amendments and regulations, which provide for clinical laboratory services to be either licensed under Rules and Regulations of the State of Georgia, Chapter 111-8-10, or to be exempt from licensure as specified in the Clinical Laboratory Licensure Law. If exemption is claimed, the application shall state the name(s) of the practitioner(s) responsible for the operation of the clinical laboratory and there shall be an affidavit by the physician that he/she is responsible for the laboratory claims and the exemption.

(2) All removed tissues shall be examined immediately by the practitioner, whose findings shall be recorded in the patient's records, in addition to reports of pathologic examinations which may be obtained later.

(3) Laboratory services shall be provided for each patient, consistent with accepted medical practice and the conditions and needs of the patient. Laboratory reports shall be made a part of patient records.

(4) A system shall be established for the collection of information and all postoperative surgical complications and infections.

(5) The center shall report to the Department all communicable diseases detected or reported for patients.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.14
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-7-1 *et seq.* and 31-22-1 *et seq.*
History. Original Rule entitled "Clinical Laboratory Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.15. Housekeeping, Laundry, Maintenance and Sterile Supplies.

(1) Each center shall provide sufficient space and equipment and ensure that housekeeping and maintenance is sufficient to keep the center and equipment in a clean and tidy

condition and state of good repair. Proper maintenance shall be provided as necessary to correct, prevent, or adjust faulty equipment and/or correct other undesirable conditions.

(2) Laundry service shall be provided. Separate space and facilities shall be provided for receiving, sorting and storing soiled laundry, and for sorting, storing and issuing of clean laundry, if reusable items are utilized.

(3) There shall be adequate space and facilities for receiving, packaging and proper sterilizing and storage of supplies and equipment, consistent with the services to be provided.

(4) Special precaution shall be taken to ensure that sterile instruments and supplies are kept separate from non-sterile instruments and supplies. Sterilization records shall be kept and sterile items shall be dated and utilized, based on established procedures.

(5) A recognized method of checking sterilizer performance shall be adopted.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.15
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Housekeeping, Laundry, Maintenance and Sterile Supplies" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.16. Drug Storage and Dispensing.

Each center shall provide adequate space and equipment and staff to assure that drugs are stored and administered in compliance with State and Federal laws and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.16
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Drug Storage and Dispensing" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.17. Blood Supply and Storage.

Each center which provides service for which blood is needed, shall provide separate refrigeration for the storage of blood and shall have a written agreement with a source for meeting its blood needs. If blood is retained overnight, such refrigeration shall be equipped with a temperature alarm device, and shall be tied in on an automatic emergency electrical power system. In all cases, refrigeration equipment shall be provided with a temperature recording device or the temperature shall be checked and recorded each day of use.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.17
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-7-1 *et seq.* and 31-22-1 *et seq.*
History. Original Rule entitled "Blood Supply and Storage" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.18. X-Ray.

All X-Ray facilities in the center shall be registered with and meet the requirements of rules and regulations of governing radiological health as promulgated by the Department. X-Rays and x-ray reports shall be made a part of the patient's record.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.18
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-7-1 *et seq.* and 31-13-1 *et seq.*
History. Original Rule entitled "X-Ray" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.19. Electrical Power.

(1) All electrical work and equipment shall be designed and installed in accordance with State and local laws and ordinances.

(2) All areas of the center shall have sufficient artificial lighting for designated purpose.

(3) Centers which utilize general anesthesia shall provide an emergency electrical system so controlled, that, after interruption of the normal electric power supply, an acceptable auxiliary power source is available and capable of being brought into use within ten seconds with sufficient voltage and frequency to reestablish essential in-house services and other emergency equipment needed to effect a prompt and efficient transfer of patients to an appropriate licensed hospital, when needed.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.19
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Electrical Power" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.20. Sanitation and Waste Disposal.

(1) All centers shall provide facilities for maintaining sanitary standards throughout the premises, as well as for water supply, sewerage, garbage and refuse, disposal systems. Such facilities shall meet local and State regulations.

(2) All garbage, trash and waste shall be stored and disposed of in a manner, by approved methods, that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents.

(3) Arrangements shall be made for proper disposal of all contaminate and/or infection dressings and surgical and obstetrical waste.

(4) Effective means shall be provided at all outside doors, windows and other openings to the center to prevent entrance and harborage of flies, other insects and rodents.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.20
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Sanitation and Waste Disposal" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.21. Advertising.

Any advertising of the services provided in or by ambulatory surgical treatment center shall include the full name of the center and its Georgia license number, as shown on the face of the permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.21
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Advertising" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.22. Waiver of Rule.

The Department may waive any rule for a stated period of time when it is shown that the specific rule is not applicable or when a waiver is needed to permit experimentation and demonstration of new and innovative approaches to the delivery of services which will not jeopardize the health and safety of the patients, staff or others utilizing the center. Results of such experimentation and demonstration projects shall be submitted to the Department as prescribed by the plan under which the waiver is approved. The Department shall maintain a record of and make available to interested persons information on all waivers granted under this rule.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.22
Authority: O.C.G.A. § 31-2-7.
History. Original Rule entitled "Waiver of Rule" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.23. Enforcement.

An ambulatory surgical treatment center which fails to comply with these rules and regulations shall be subject to revocation of its permit or provisional permit and/or other sanctions provided by law. The enforcement and administration of these rules and regulations shall be as prescribed in O.C.G.A. §§ 31-5-8, 31-5-9 and 31-2-8 which includes provision for:

(a) the misdemeanor penalty for violation of rules and regulations promulgated under this Title;

(b) injunctive relief under appropriate circumstances; and

(c) the due process requirements of notice, hearing and appeals.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.23
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-7-1 *et seq.* and 50-13-1 *et seq.*

History. Original Rule entitled "Enforcement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-4-.24. Applicability of Regulations.

These regulations are applicable only to ambulatory surgical treatment centers and the services provided therein, and expressly do not modify or revoke any of the provisions of the published rules of the Department of Community Health, Chapter 111-8-40 (Rules and Regulations for Hospitals) or of revisions which may be made to said regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.24
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-7-1 *et seq.*
History. Original Rule entitled "Applicability of Regulations" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Oct. 14, 2022; eff. Nov. 3, 2022.

Rule 111-8-4-.25. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions thereof shall remain in full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Board of Community Health to establish rules and regulations that are constitutional and enforceable so as to safeguard the health and well-being of the people of the State.

Cite as Ga. Comp. R. & Regs. R. 111-8-4-.25
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Severability" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-5. ANATOMICAL GIFTS.

Rule 111-8-5-.01. Legal Authority.

The legal authority for this chapter, unless otherwise noted, is "The Georgia Anatomical Gift Act," O.C.G.A. § 44-5-140.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.01
Authority: O.C.G.A. §§ 31-2-5, 31-2-6, 31-2-7 and 44-5-140*et seq.*
History. Original Rule entitled "Legal Authority" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.02. Organization and Purpose.

The purpose of these rules is to establish the requirements of "The Georgia Anatomical Gift Act" as it applies to the practices, procedures and criteria for making and routinely requesting anatomical gifts in hospitals.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.02
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Organization and Purpose" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.03. Definitions, Unless Otherwise Indicated.

(1) "Anatomical Gift" or "Gift" means a donation of all or part of a human body to take effect upon or after death.

(2) "Bank or Storage Facility" means an organ procurement organization or any other entity licensed or approved in the State of Georgia as a tissue bank, eye bank, or clinical laboratory which procures, stores, or processes human tissue designed to be used for medical purposes in human beings.

(3) "Decedent" means a deceased individual and includes a stillborn infant or fetus.

(4) "Department" means the Georgia Department of Community Health.

(5) "Document of gift" means a donor card, a statement attached to or imprinted on a motor operator's or chauffeur's license, a will, or other writing used to make an anatomical gift.

(6) "Donee" means the person that receives an anatomical gift.

(7) "Donor" means an individual who makes a gift of all or part of his body.

(8) "Enucleator" means an individual who is authorized to remove eyes.

(9) "Eye Bank" means a facility which is maintained and operated for the extraction, removal, care, storage, preservation, and use of human eyes or parts thereof for purposes of sight preservation or restoration, medical education, instruction pertaining to sight preservation, or restoration, or research and which is licensed by the Department for such purposes.

(10) "Hospital" means a hospital licensed, accredited, or approved under the laws of any state, although not required to be licensed under state laws, and includes hospitals operated by the United States government or by the state or a subdivision thereof.

(11) "Hospital Administrator" means the person in charge of a hospital.

(12) "Organ" means any heart, lung, pancreas, kidney, or liver.

(13) "Organ Procurement Organization" means an organization located in the State of Georgia that is designated by the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services under the end stage renal disease facility regulations to perform or coordinate the performance of all of the following services:

(a) procurement of donated kidneys;

(b) preservation of donated kidneys;

(c) transportation of donated kidneys; and

(d) maintenance of a system to locate prospective recipients of procured organs. An organ procurement organization may also perform those services for extrarenal vital organs and includes any organization certified by the federal Department of Health and Human Services as an organ procurement organization.

(14) "Part" means organs, tissues, eyes, bones, arteries, blood and other fluids, and any other portions of a human body. The term "part" also means a heart pacemaker.

(15) "Person" means an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust partnership or association, or any other legal entity.

(16) "Physician" or "Surgeon" means a physician or surgeon licensed or authorized to practice under the laws of any state.

(17) "State" means any state, district, commonwealth, territory, insular possession, and any other area subject to the legislative authority of the United States of America.

(18) "Technician" means an individual authorized by a bank or storage facility to remove or process an anatomical gift, excluding the removal of organs for transplantation.

(19) "Tissue Bank" means a facility which provides through its ownership or operation for the storage of human or animal tissues designed to be used for medical purposes in human beings and which is licensed by the department as a clinical laboratory.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.03
Authority: O.C.G.A. §§ 31-1-6, 31-22-1(2), 31-23-1(1), 44-5-140*et seq.*
History. Original Rule entitled "Definitions, Unless Otherwise Indicated" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.04. Permissible Donees and Purposes of Anatomical Gifts.

The following persons may become donees of anatomical gifts for the purposes stated:

(a) Any hospital, surgeon, or physician, for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation;

(b) Any accredited medical or dental school, college, or university for education, research, advancement of medical or dental science, or therapy;

(c) Any bank or storage facility, for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation; or

(d) Any specified individual, for therapy or transplantation needed by him.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.04
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Permissible Donees and Purposes of Anatomical Gifts" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.05. Permissible Donors.

(1) Any individual who is 18 years of age or older and of sound mind may give all or any part of his body for any purposes specified in Rule .04 of this Chapter, the gift to take effect upon death.

(2) The parents, legal guardians, or other persons authorized or obligated to dispose of the body may, unless otherwise directed by a will, give all or any part of the body of a person who is under 18 years of age for any purpose specified in Rule .04 of this Chapter, the gift to take effect upon death.

(3) Persons listed at Rule .07(1)(c)1. and .07(1)(c)2. of this Chapter may give all or any part of a decedent's body for any purposes specified in Rule .04 of this Chapter.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.05
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Permissible Donors" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.06. Hospital Admissions.

(1) Upon admission to any hospital, a person, at his request, may make an expression of his intention regarding the disposition of his body. Such expression shall be deemed to be sufficient notice under O.C.G.A. § 44-5-140 and this Chapter not to be contravened by opposition from persons listed in Rule .07(1)(c)1. and .07(1)(c)2. of this Chapter.

(2) Hospitals shall assure that written policies and procedures are established, implemented, and maintained for recording such expressions and effective appropriate dispositions in accordance with the expressed intentions of the persons who make the requests.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.06
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Hospital Admissions" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.07. Routine Requests on or Before the Occurrence of Death in Hospitals.

(1) All hospitals shall establish, implement, and maintain written policies and procedures for requesting anatomical gifts on or before the occurrence of death in hospitals. The primary purpose of such policies and procedures shall be to inform persons specified in Rule .07(1)(c)1. and .07(1)(c)2. of their options of making anatomical gifts when previous expressed intentions have not been made either upon admission to the hospital or by document of gift. Such policies and procedures shall include a written agreement with a bank or storage facility and shall, at a minimum, include the following provisions:

(a) Screening and Identification of Potential Donors. Before initiating requests for anatomical gifts it must be determined that the body or parts are suitable for donation pursuant to the criteria at Rule .10 of this Chapter.

(b) Procedures for Notifying Bank or Storage Facilities of Potential Donors. If it is determined that a body or parts are suitable for donation, the hospital administrator or designated representatives shall contact the concerned bank or storage facility. However, such notification shall only be made in the absence of actual notice of contrary indications by the decedent, or in the absence of actual notice of opposition by a member of the same or prior classes specified in Rule .07(1)(c)1. and .07(1)(c)2. of this Chapter, and when persons in such prior classes are not available.

(c) Procedures for Making Requests. Actual request for donations must be made by the notified bank or storage facility and shall only be made if consent would yield a suitable donation. However, hospitals may enter into written cooperative agreements with one or more bank or storage facilities, under which agreements designated hospital staff, including physician or surgeons, may make requests as the authorized agents or representatives of the bank or storage facility. Such requests, whether made by hospital staff or the notified bank or storage facility, shall be made in the following manners:

1. For individuals 18 years of age or older, any of the following persons, in order of priority stated, may be requested to give all or any part of the decedent's body for any purposes specified in Rule .04 of this Chapter.

(i) any person having the power to permit an anatomical gift of all or part of the body of the decedent if such power is granted pursuant to a health care agency created under Chapter 32 of Title 31, the Georgia Advance Directive for Health Care Act.

(ii) the spouse;

(iii) an adult son or daughter;

(iv) either parent;

(v) an adult brother or sister;

(vi) a grandparent;

(vii) a guardian of the person of the decedent at the time of his death other than a guardian ad litem appointed for such purpose; or

(viii) any other person authorized or under obligation to dispose of the body.

2. For individuals under 18 years of age, any of the following persons, in order of priority stated, may be requested to give all or any part of the decedent's body for any purposes specified in Rule .04 of this Chapter.

(i) both parents;

(ii) if both parents are not readily available and no contrary indications of the absent parent are known, one parent;

(iii) if the parents are divorced or legally separated, the custodial parent;

(iv) in the absence of the custodial parent, when no contrary indications of the absent parent are known, the noncustodial parent;

(v) if there are no parents, any grandparent;

(vi) if there are no parents readily available or any grandparents, the legal guardian; or

(vii) any other person authorized or obligated to dispose of the body.

3. Consent or refusal must be obtained from persons in the highest priority class available.

4. Consent shall be made by a document signed by the person making the gift or by his telegraphic, recorded telephonic, or other recorded message.

(d) Recordkeeping. The hospital administrator or designated representative shall record in a book any notification to a concerned bank or storage facility about a potential donor; whether, if appropriate, a request for a consent to a gift was made; whether or not consent was granted; and the name of the person granting the consent and his or her relationship to the decedent.

(2) Persons authorized in Rule .07(1)(c)1. and .07(1)(c)2. of this Chapter may make the gift after or immediately before death.

(3) If during the process of a routine request, the donee has actual notice of contrary indications by the decedent or actual notice that a gift made by a member of a class is opposed by a member of the same or prior class listed at Rule .07(1)(c)1. and .07(1)(c)2. of this Chapter, then the donee shall not accept the gift.

(4) In the absence of a specification by a decedent or a person authorized in Rule .07(1)(c)1. and .07(1)(c)2. to give all or part of the decedent's body, any bank or storage facility that becomes the donee of any part of the decedent's body shall give preference to potential recipients of that donation of such body part, other than an organ of the decedent, who are residents of Georgia if: the donation is medically acceptable to the potential recipients who are residents of Georgia; potential recipients who are residents of other states are not in greater need of the donation than potential recipients who are residents of Georgia; and the requisite medical procedure required for the potential recipient to receive the donation will be performed in Georgia.

(5) A gift of all or part of a body authorizes any examination necessary to assure medical acceptability of the gift for the purposes intended.

(6) The rights of the donee created by the gift are paramount to the rights of others except nothing in these rules shall restrict the power of a coroner or medical examiner to limit an anatomical gift of all or part of a person's body when a medical examiner's inquiry is required of that person's death pursuant to O.C.G.A. § 45-16-24 and nothing in these rules shall restrict legal prescribing powers and duties with respect to autopsies.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.07
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Routine Request on or Before the Occurrence of Death in Hospitals" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.08. Certain Physicians not to Participate in Removing or Transplanting Parts.

(1) The following physicians shall not participate in the procedures for removing or transplanting parts:

(a) The physician who becomes a donee;

(b) The attending physician of the donor at his death or, if there is no attending physician, the physician who certifies the death.

(2) However, a document of gift may designate the surgeon or physician who shall carry out the appropriate procedures. In the absence of a designation or if the designee is not available, the donee or other person authorized to accept the gift may employ or authorize any surgeon or physician for the purpose. A physician or surgeon so designated, employed, or authorized to carry out such procedures may authorize any other person to perform such procedures if such person is:

(a) so trained in those procedures;

(b) so authorized by the appropriate bank or storage facility to perform those procedures; and

(c) any of the following:

1. a physician's assistant;

2. a registered professional nurse;

3. a licensed professional nurse;

4. a technician; or

5. when the procedure involves only the human eye, an enucleator.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.08
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Certain Physicians Not to Participate in Removing or Transplanting Parts" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.09. Delivery of Donations from Receiving Hospitals to Permissible Donees.

Hospitals shall establish, implement, and maintain appropriate hospital policies and procedures for assisting bank or storage facilities or other permissible donees in the delivery of donations to potential recipients. Such assistance shall include the use of available hospital services, equipment, and supplies. Hospitals shall be reimbursed by the donee for reasonable charges incurred in the provision of such assistance.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.09
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Delivery of Donations from Receiving Hospitals to Potential Recipients" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.10. Suitability of Anatomical Gifts.

(1) A gift authorizes any examination necessary to assure medical suitability of the gift for the intended purposes. The suitability of anatomical gifts shall be determined by attending physicians or surgeons and may be made in conjunction with applicable types of banks or storage facilities. Factors which must be considered in determining suitability shall include age, etiology of death, length of cardiac arrest, and infection or disease. All determinations shall be based upon existing, acceptable medical criteria related to the specific donation and its purpose, as established by the United Network for Organ Sharing, the Southeastern Organ Procurement Foundation, the Organ Procurement and Transplant Network, the American Association of Tissue Banks, and the Eye Bank Association of America, respectively. Hospitals shall be reimbursed by the donee for reasonable charges incurred in doing necessary laboratory work for donor evaluations and suitability determinations when the donee has requested the laboratory work, regardless of whether the donee receives an anatomical gift.

(2) Any permissible donee shall subject or have subjected all human body parts, or the potential donors of such parts, to a HIV test prior to making such parts available for use in the body of another human being. No parts found to be infected or no other parts of a donor found to be infected shall be used in the body of another human.

(3) Unless used for medical research, all HIV infected tissue or organs retrieved from a donor shall be incinerated.

(4) When a human body part or a donor is determined to be HIV infected, the permissible donee that provided or provided for the testing shall:

   (a) Provide personal and confidential notification to a living donor from whose body the part was removed if the donee's records identify where the donor is located.

   (b) Provide personal and confidential notification to any known physician licensed in Georgia of a deceased donor; such physician shall then have the sole discretion to determine whether to notify the persons who executed the gift or any other persons who were at risk of being infected with HIV by the decedent.

(5) In a medical emergency constituting a serious threat to the life of a potential recipient of blood, if blood that has been subjected to the HIV testing as required by Rule .10(2) is not available, the testing otherwise required by Rule .10(2) shall not be required regarding such blood.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.10
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Suitability of Anatomical Gifts" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Rule 111-8-5-.11. Training.

(1) Persons making requests for anatomical gifts shall relate to donors and families in a sensitive and caring manner and shall have received suitable training in the following areas:

(a) psychological and emotional considerations when dealing with bereaved families;

(b) social, cultural, ethical and religious factors affecting attitudes toward donations;

(c) procedures for declaring death and collecting and preserving organs, tissues and/or other body parts, and how these procedures are to be explained to decedents' families.

(d) general medical concepts and issues in organ, tissue, and eye donations;

(e) procedures for notifying and involving banks or storage facilities;

(f) procedures for recording the outcome of requests.

(2) Any cooperative agreement between a hospital and bank or storage facility developed in accordance with Rule .07(1) of this Chapter shall include provisions for suitable training of appropriate hospital staff by the bank or storage facility. Such training shall be provided to any staff members designated to request anatomical gifts.

Cite as Ga. Comp. R. & Regs. R. 111-8-5-.11
Authority: O.C.G.A. § 44-5-140*et seq.*
History. Original Rule entitled "Training" adopted. F. Feb. 19, 2013; eff. Mar. 11, 2013.

Subject 111-8-7. RULES AND REGULATIONS FOR BIRTH CENTERS.

Rule 111-8-7-.01. Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Administrator" means the individual who is responsible for the day to day management of the center.

(b) "Birth Center", "Birthing Center" or "Center" means a facility, other than the laboring woman's legal residence, which admits persons for the purpose of childbearing and which facility has not been classified and licensed by the Department as a hospital.

(c) "Birth Room" means any room within a center which is provided as an area where births take place.

(d) "Certified Nurse Midwife" means an individual who is a Registered Nurse currently licensed in the State of Georgia and who is also certified by the American College of Nurse Midwives.

(e) "Department" means the Georgia Department of Community Health.

(f) "General Anesthesia" means any drug, element or other material which is administered to eliminate all sensation and which, when administered, is accompanied by a state of unconsciousness.

(g) "Governing Body" or "Management" means the board of directors, trustees, partnership, corporation, association, or person or group of persons who maintain and control the operation of the center and who are legally responsible for its operation.

(h) "Hospital" means any facility which meets the requirements of and is currently licensed as a hospital under the provisions of OCGA Chapter 31-7, Article 1, and is in compliance with all rules and regulation of the Department pertaining to Maternity, Obstetrics and Newborn services.

(i) "Local Anesthesia" means any drug which, when administered, provides localized temporary loss of sensation, but not accompanied by a state of unconsciousness.

(j) "Low Risk Patient" means an individual who:

1. is in general good health with uncomplicated prenatal course;

2. is participating in an ongoing prenatal care and education program;

3. has no major medical problems;

4. has no significant signs or symptoms of hypertension, toxemia, hydramnios, abruptio placenta, chorioamnionitis, malformed fetus, multiple gestation, intrauterine growth retardation, fetal meconium, fetal distress, alcoholism, or drug addiction, Rh or other blood group antigen sensitization;

5. has no history of fetal wastage or premature delivery;

6. has no previous significant obstetrical complications likely to recur, nor previous uterine wall surgery or Caesarean section;

7. has parity under six unless a justification for a variation is documented by clinical staff;

8. is not a nullipara of greater than thirty six years of age;

9. is not less than sixteen years of age at onset of pregnancy;

10. is appropriate for a setting where anesthesia is limited to local infiltration of the perineum, or a pudendal block, and analgesia is limited;

11. while in active labor:

    (i) demonstrates no significant signs, or symptoms, or evidence of anemia, significant hypertension, placenta previa, malpositioned fetus or breech;

    (ii) is progressing normally;

    (iii) is without prolonged ruptured membranes; and

    (iv) is not in premature labor.

12. is not postmature.

(k) "Patient" means any woman who receives antepartum, intrapartum and postpartum care, or any newborn who receives medical care, in facilities governed by these regulations.

(l) "Permit" or "License" means an authorization granted by the Department to the Governing Board to operate a birth center.

(m) "Physician" means an individual who is currently licensed to practice medicine in the State of Georgia and is board certified or board eligible in obstetrics, family practice or pediatrics.

(n) "Plan of Correction" means an acceptable written plan submitted to the Department by the person or persons responsible for the center and which states proposed procedures and methods to correct the areas of non-compliance within an acceptable time frame.

(o) "Practitioner" means a physician or a certified nurse midwife.

(p) "Professional Staff" means the group of physicians, certified nurse midwives, other registered nurses, licensed practical nurses and other health professionals who require special licensure, certification or registration, who provide patient services at the center.

(q) "Provisional Permit" means an authorization granted by the Department to operate a birth center on a conditional basis in order to allow a newly established center a reasonable but limited period of time, as determined by the Department, to demonstrate that operational procedures are in satisfactory compliance with these rules and regulations, or to allow an

established and operating center a specific length of time to comply with these regulations, provided said center shall first present an acceptable plan of correction.

(r) "Regional Anesthesia" means any drug, element or other material which, when administered, is accompanied by temporary sectional loss of sensation.

(s) "Special Care Capability" means availability of on-site equipment for use in providing emergency care to adult and newborn patients.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.01
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Definitions" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.02. Application for Permits.

(1) The governing body shall submit an application to the Department for a permit using forms provided by the Department. No center shall be operated in Georgia without a valid permit which shall be displayed in a conspicuous place within the center. Failure or refusal by the governing body of any facility existing at the time these rules become effective to file an application for a permit within ninety (90) days shall constitute a violation of law and shall be dealt with as provided by law.

(2) The applicant for a permit to operate a birth center shall submit a completed application and a certification that the applicant is able and willing to comply with the minimum standards for a birth center and with the rules and regulations lawfully promulgated. Each applicant shall be responsible for complying with applicable fire safety laws and shall present evidence of such compliance, prior to receiving a permit.

(3) The application shall include complete information concerning the name and address of the applicant and the services to be provided; the ownership of the property and operation; if organized as a corporation, the names and addresses of each officer and members of the board of directors of the corporation; if organized as a partnership, the names and addresses of each partner; the identity of the medical director of the facility; and any other information which the Department may require.

(4) The applicant shall submit evidence of approval from the State Health Planning and Development Agency, as a part of the application to the Department for a permit.

(5) Plans for birth centers shall be submitted to the Department for review and approval in two stages of development:

(a) schematic drawings; and

(b) final working drawings and specifications.

(6) A permit shall be issued to the person or persons named only for the premises listed on the application for licensure.

(7) Permits are not transferable or assignable.

(8) Changes in ownership shall be subject to prior review and approval as required by the Department. Each planned change of ownership or lease shall be reported to the Department at least sixty (60) days prior to such change along with an application from the proposed new owners for a new permit.

(9) The Center shall file a new application, prior to change in ownership or location. A written amendment to the current application shall be filed when there is a change in management or operational objectives.

(10) Separate applications and permits are required for centers maintained in separate premises, even though they are owned or operated by the same person(s), business or corporation, and may be doing business under the same title.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.02
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Application for Permits" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.03. Permits.

(1) Following inspection and evidence of compliance with these regulations, the Department may issue a permit. Each permit shall indicate the classifications of services to be provided and patient capacity of the center.

(2) Permits issued shall remain in force and effect until revoked or suspended for failure to comply with these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.03
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Permits" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.04. Provisional Permits.

Provisional permits may be issued by the Department for a time specific period based on an acceptable written plan for correcting deficiencies (plan of correction) found during an inspection. Provisional permits may be revoked by the Department due to prevailing circumstances which are not acceptable to the Department. Centers which are established and operating prior to adoption of these rules and regulations may be issued provisional permits when additional time is needed to meet physical plant standards.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.04
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Provisional Permits" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.05. Inspections.

(1) The center shall be open at all reasonable hours for observation and examination by properly identified representatives of the Department.

(2) The governing body shall notify the Department of the anticipated opening date of a newly constructed center in order that a pre-opening licensure inspection of the center may be conducted to determine compliance with these rules and regulations.

(3) The administrator (or a designated representative) shall accompany the Department representative on all tours of inspection and shall sign the completed inspection report.

(4) The center may be inspected at the discretion of the Department to determine whether it is continuing to meet these requirements or is making satisfactory progress in accordance with approved plans of correction.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.05
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-5-21; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Inspections" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.06. Organization and Administration.

(1) The birth center shall be organized with an identifiable governing body which is responsible for establishing objectives and policies and which assumes full legal responsibilities for the overall conduct of the center, including compliance with laws and regulations pertaining to the center. The governing body and its membership shall be identified in the application for licensure.

(2) The ownership of the center shall be fully disclosed in the application. This disclosure shall include the names and addresses of all corporate officers and any person(s) having a five percent (5.0%) or more financial interest in the center.

(3) The governing body shall be responsible for professional staff appointments, shall establish effective mechanisms for quality assurance, and shall ensure the accountability of the professional staff.

(4) The organizational objectives of the center shall be clearly stated in the policies and procedures of the center.

(5) The governing body shall appoint an administrator and shall notify the Department of such person's name.

(6) The center shall be at all times under the personal and daily supervision and control of the administrator (or a designated representative) whose authority, duties and responsibilities shall be defined in writing. This information shall be available to the Department on request.

(7) The center shall be available for occupancy twenty-four (24) hours per day, with professional staff on call at all times.

(8) Criteria for admission to the center shall be clearly identified in the center's policies. The admission policy shall be submitted with the application for licensure. At a minimum, admission criteria shall include a provision that only low-risk patients will be admitted and that there will be no discrimination according to race.

(9) Each patient shall be provided with a copy of the fee schedule and policy regarding payment.

(10) Admissions to the center shall be restricted to low-risk patients who have received antepartum care in accordance with the facility's policies. The center's policies and procedures regarding management of complications shall be explained by a staff physician or certified nurse midwife.

(11) The center shall have written policies and procedures for antepartum, intrapartum, postpartum and newborn care including physician consultation, referral, transfer and transport to the hospital and registration of vital records. A written procedure shall be established to maintain these policies.

(12) The center shall have a written policy regarding visitation or attendance during the birth process.

(13) The mother and newborn shall be discharged within twenty-four (24) hours after delivery, in a condition which will not endanger the well-being of either the mother or newborn, or shall be transferred to a licensed hospital. The mother and newborn will be discharged in the care of another responsible adult who will assist in their transport from the birth center.

(14) The center shall have an organized professional staff which is responsible for the development of patient care policies and procedures and for maintaining the level of professional performance through a continuing program of staff education, and review and evaluation of care. Records of staff attendance at educational programs shall be maintained.

(15) The center shall have a medical director who is a physician, designated by the governing body, who shall be responsible for the direction and coordination of all professional aspects of the center's program.

(16) Practitioners applying for center privileges shall sign an agreement to abide by the center's policies and procedures.

(17) The center shall have specific policies and procedures for infection control, which include a mechanism for reporting to the Department those infections which develop within six (6) weeks after discharge of the patient from the center, using forms provided by the Department.

(18) The center shall submit annually to the Department a statistical summary of morbidity and mortality data on forms supplied by the Department.

(19) Nothing in these rules and regulations shall prevent a licensed hospital from organizing and providing a birth center as an integral part of its facility, so long as the provided services are included in the application under which the hospital license is granted.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.06
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Organization and Administration" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.07. Transfer and Transport Capability.

(1) Each birth center shall have a written agreement with a hospital(s) which is licensed to provide obstetrical services, for emergency care. Each physician practicing in the birth center shall have admitting privileges at the back-up hospital.

(2) Each birth center shall have a written agreement with the emergency back-up hospital for acceptance and examination of laboratory specimens to expedite treatment, prior to formal admission procedures.

(3) The center shall have the capability to transfer and transport the adult and/or newborn patients to the contract hospital within thirty (30) minutes of initiation of transfer procedure to the arrival on the obstetric/newborn service of the hospital. Documentation of each transfer shall be maintained by the center to substantiate to the Department that it has met this requirement.

(4) The center shall have a written contract with a licensed ambulance service which will assure timely response.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.07
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Transfer and Transport Capability" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.08. Professional Services.

(1) All services provided by or in the center shall be performed by persons who are appropriately licensed or certified to perform such services in accordance with the laws of the State of Georgia. There shall be qualified staff members to provide for patient needs. At least one physician, certified nurse midwife or registered nurse shall be present at all times that the facility is open whenever a patient (mother or new born) is in the facility.

(2) All services shall occur within a health care system which provides for medical consultation, collaborative management or referral.

(3) All intrapartal services shall be under the direct supervision of a physician or a certified nurse midwife. At least one other member of the professional staff shall also be present at each delivery.

(4) The center shall establish written policies and procedures for emergency services to patients and shall require each professional staff member to receive instruction in emergency treatment of adult and infant patients, upon employment and at least annually thereafter.

(5) Each medical staff member shall have admitting privileges or a written agreement with a staff physician to provide services at the contract hospital. Documentation to show compliance with this requirement shall be maintained in the center.

(6) Definite means of identification shall be applied to every infant immediately after birth. Such identification shall remain on the infant until discharged. The permanent records of each newborn shall include footprints.

(7) The center shall have written policies and procedures to ensure (a) metabolic screening of all newborns within one week of age, (b) assessment of newborn status, including Apgar score at one and five minutes, (c) prevention of eye infection, (d) umbilical cord care, and (e) periodic observation and assessment after birth until the infant's condition is stable. These policies shall be developed in consultation with a pediatrician.

(8) Policies, procedures and facilities shall be provided for proper collection, storage and laboratory testing of cord blood for necessary studies on Rh Negative and O Positive mothers and a supply of Rhogam or other appropriate treatment material shall be readily available for use when needed.

(9) Prior to discharge, each newborn shall be examined by a physician.

(10) Verbal and written instructions shall be provided for observation and care of both the mother and newborn after discharge.

(11) A joint conference involving physicians, nurses, representatives of administration and other health personnel responsible for obstetric and newborn care shall be conducted at least quarterly to discuss morbidity and mortality. All fetal and newborn deaths and transfers occurring within the interval since the previous conference shall be reviewed. Minutes shall be kept of the meetings and shall be available to the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.08
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Professional Services" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.09. Personnel.

(1) The center shall require that each employee receives a health examination up on employment. The examination shall be in sufficient detail, including pertinent laboratory and tuberculosis screening, to assure that the employee is able to perform assigned tasks. The center shall have a policy for monitoring the health status of employees.

(2) There shall be a separate personnel folder maintained for each employee. This personnel file shall contain all pertinent information concerning the employee, including the application for employment and qualifications for employment, verifications of physical examinations, job description and a copy of current Georgia license for those required to be licensed.

(3) There shall be an on-going program of continuing education for all personnel. This shall include aspects of fire safety and the disaster plan for moving personnel and patients to safety and for handling patient emergencies.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.09
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Personnel" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.10. Health Services Information System.

(1) The birth center shall establish and maintain an organized health services information system for the collection, processing, maintenance, storage and retrieval of information concerning health services received by the patient.

(2) An individual medical record shall be maintained within the system for each patient, and shall include the following data:

(a) Identification-name, address, identifying number, date of first visit, age or birth date, sex, marital status, occupation, telephone number, and name and telephone number of a person to contact in event of an emergency;

(b) An initial health evaluation including a chronological record of past medical history, drug use profile, personal and family history and results of physical examinations, including laboratory and x-ray reports;

(c) A health care plan which includes information regarding each visit;

(d) Clinical diagnosis or impression, studies ordered, treatment given, disposition, recommendations, and instructions to patient, complete with a progress note for each follow-up visit.

(3) The system shall be kept current and available to staff or agencies authorized to use the system.

(4) Medical records shall be preserved as original records, microfilms or other usable forms and shall be such as to afford a basis for complete audit of professional information. Centers shall retain all medical records or shall assure that they are maintained in a manner acceptable to the Department at least until the sixth anniversary of the patient's discharge. In the case of patients who have not attained majority at the time of the discharge, centers shall retain such records for at least six (6) years after the patient reaches age of majority. In the event a center shall cease operation, the Department shall be advised of the location of said records.

(5) Sufficient space and equipment for record processing, storage and retrieval shall be provided.

(6) Policies and procedures shall be written and implemented to assure organization and continuous maintenance of the health information system.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.10
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Health Services Information System" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.11. Clinical Laboratory Services.

If laboratory services are provided on site, the laboratory shall be licensed under the provisions of the Georgia Laboratory Licensure Law of 1970, O.C.G.A. Chapter 31-22, and applicable rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.11
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1; O.C.G.A. Chapter 31-22.
History. Original Rule entitled "Clinical Laboratory Services" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.12. Drug Storage and Administration.

(1) Each center shall provide adequate space and equipment and staff to assure that drugs are stored and administered in compliance with State and Federal laws and regulations.

(2) No drugs shall be dispensed at the facility unless pharmacy regulations are met.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.12
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Drug Storage and Administration" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.13. Food Service.

If food services are provided, the facility must comply with Georgia Laws and Food Services Rules and Regulations of the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.13
Authority: O.C.G.A. Chapter 26-2, Article 13; O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Food Service" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.14. Anesthesia.

General or regional anesthesia shall not be utilized in a birth center. Local or pudendal anesthesia is permitted.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.14
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Anesthesia" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.15. Physical Plant and Operational Standards.

The following minimum physical plant and operational standards shall be met:

(a) The center shall provide sufficient space and equipment for patient and visitor waiting area, examination and treatment rooms, birth rooms, special care capability, and for staff and administrative areas. Birthrooms shall each have at least 100 square feet of area, exclusive of bathroom, toilet or entry way, and be designed and located to prevent traffic through them to any other part of the center.

(b) The Department may deny the center a permit if it does not comply with Federal, State and local laws, codes, ordinances, and regulations which apply to its location, construction, maintenance and operation.

(c) It shall be the responsibility of the governing body to assure that the center is in a safe condition at all times, and that a fire inspection record is maintained on equipment, systems, and areas that may present a hazard to occupants.

(d) Fire and internal disaster drills shall be conducted at least quarterly and the time of the drill and results documented.

(e) In addition to requirements specified herein, and those required by local ordinances or regulations, the construction of a birth center shall meet the requirements of the Georgia Safety Fire Commissioner, Chapter 120-3-3,* March 1, 1979, and subsequent revisions thereto. Applications for licensure shall be accompanied by written evidence that these requirements have been met.

(f) Entrances for patients shall be connected to the public right-of-way by a hard-surfaced, unobstructed walkway in good repair. Access for handicapped individuals shall be provided at a minimum of one entrance. A hard-surfaced, unobstructed road or driveway for use by ambulances or other emergency vehicles shall run from at least one entrance of the building to the public right-of-way. The doorway of such entrance shall be immediately adjacent to the road or driveway. If such doorway is not on the same level as the road, a ramp shall provide a continuous, unobstructed plane to the entrance.

(g) Services provided in multi-story buildings shall be accessible by an elevator of adequate size to accommodate a standard wheeled litter patient and two attendants. Multi-story buildings will be considered to have met this requirement when patients are located only on ground level floors with outside exits. A stairway or ramp of adequate dimensions shall be available for transfer of patients in case of power failure.

***EDITORIAL NOTE:** A copy of said Chapter 120-3-3, Rules and Regulations of the Safety Fire Commissioner, was filed with former Chapter 290-5-41 and is on file with same in the Office of Secretary of State.

(h) The birth center shall be constructed, equipped, and maintained to assure the safety of patients and personnel. The following requirements shall apply within the center:

1. Birth rooms shall be designed and located to prevent traffic through them to any other part of the center.

2. The walls and floors of birth rooms, examination rooms and staff dressing and scrub areas shall be of material that will permit frequent washing and cleaning.

3. Staff dressing rooms and scrub facilities shall be convenient to the birth rooms, and shall include a knee, elbow, wrist or foot operated sink soap dispenser and brushes.

4. Toilet and handwashing facilities shall be accessible to patients from the birth room. Convenient handwashing facilities shall be provided for both staff and patient and shall be provided with soap dispenser and individual or disposable towels. The use of common towels is prohibited

5. The center shall be arranged and organized in such a manner as to ensure the comfort, safety, hygiene, privacy and dignity of patients treated therein.

6. A clean up room for equipment shall be provided.

7. The center shall have an audible alarm system with control switches in all birth rooms which can be activated during an emergency.

8. The center shall have special care capability which includes but is not necessarily limited to the following, for both adults and infants: resuscitation equipment, intravenous solutions, drugs, oxygen, suction, infant stethoscope and transfer isolette. Such emergency equipment shall be provided on each floor on which patients are served.

9. Each birth room shall have an infant resuscitation tray with a laryngoscope, positive pressure bag and mask and endotracheal tubes.

(i) The center shall provide space and facilities for administrative activities, including offices, medical records and other files and storage of supplies.

(j) A waiting room and patient admissions area(s) shall be provided. There shall also be space for storage of personal belongings of staff, patients and visitors.

(k) The center shall have adequate and conveniently located toilets and handwashing facilities for its staff, employees, patients and visitors.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.15
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Physical Plant and Operational Standards" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.16. Housekeeping, Laundry, Maintenance and Sterile Supplies.

(1) The center shall ensure that housekeeping and maintenance is adequate to maintain the center and equipment in a clean condition and state of good repair. An equipment clean-up area with adequate plumbing, including a sink with counter, shall be provided within the center.

(2) Laundry service shall be provided either in house or by contractual arrangement. Separate space and facilities shall be provided for receiving, sorting and storing soiled laundry and for the sorting, storing and issuing of clean laundry, if reusable items are utilized.

(3) There shall be adequate space and facilities for receiving, packaging and proper sterilization end storage of supplies and equipment consistent with the services to be provided.

(4) Special precaution shall be taken to ensure that sterile instruments and supplies are kept separate from nonsterile instruments and supplies. Equipment for sterilization of instruments and supplies shall be conveniently located and of adequate capacity for the

workload. Records shall be maintained to assure quality control, including, date, time and temperature of each batch of sterilized supplies and equipment. Sterilization performance shall be checked and records shall be kept. Sterile items shall be dated and utilized, based on established procedures.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.16
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Housekeeping, Laundry, Maintenance and Sterile Supplies" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.17. Electrical Power.

(1) All electrical work and equipment shall be designed and installed in accordance with State and local laws and ordinances.

(2) All areas of the center shall have sufficient artificial lighting, for designated purposes.

(3) All centers shall have an alternative lighting source for emergency use in the event of a power failure.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.17
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Electrical Power" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.18. Sanitation and Waste Disposal.

(1) The center shall maintain sanitary conditions throughout the premises. This shall include the water supply, sewerage, and solid waste disposal systems. Such facilities shall meet local and State regulations.

(2) All garbage, trash and waste shall be stored and disposed of in a manner that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents.

(3) Obstetrical wastes and contaminated materials shall be disposed of by incineration or other means acceptable to the Department.

(4) Effective means shall be provided at all outside doors, windows and other openings to the center to prevent the entrance and harborage of flies, other insects and rodents.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.18
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Sanitation and Waste Disposal" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.19. Advertising.

Any advertising of the services provided in or by a birth center shall be truthful and shall include the full name of the center and its Georgia license number, as shown on the face of the permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.19
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Advertising" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.20. Waivers and Variances.

(1) The Department upon application may grant variances or waivers of specific rules and regulations as provided for in O.C.G.A. Section 31-2-7(b), when it has been shown that the rule or regulation is not applicable or to allow experimentation and demonstration of new and innovative approaches to delivery of services.

(2) The Department may exempt classes of facilities from regulation as provided for in O.C.G.A. Section 31-2-7(c), when regulation would not permit the purpose intended or the class of facilities is subject to similar requirements under other rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.20
Authority: O.C.G.A. § 31-2-7; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Waivers and Variances" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.21. Enforcement.

A birth center which fails to comply with these rules and regulations shall be subject to denial of a permit, revocation of its permit or provisional permit and other sanctions provided by law. The enforcement and administration of the rules and regulations: shall be as prescribed in O.C.G.A. Chapter 31-7, Enforcement and Administrative Procedure, which includes provision for:

(a) the misdemeanor penalty for violation of rules and regulations promulgated under this Title;

(b) injunctive relief under appropriate circumstances;

(c) the Inspection Warrant; and

(d) the due process requirements of notice, hearing and appeals.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.21
Authority: O.C.G.A. § 31-2-4; O.C.G.A. Chapter 31-5; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1; O.C.G.A. Chapter 50-13.

History. Original Rule entitled "Enforcement" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-7-.22. Applicability of Regulations.

These regulations are applicable to any building or facility which is or shall be classified by the Department of Community Health as a birth center and the services provided there in, and expressly do not modify or revoke any of the provisions of the published rules of the Department of Community Health, Chapter 111-8-40 (Rules and Regulations for Hospitals) or of revisions which may be made to said regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.22
Authority: O.C.G.A. §§ 31-2-4, 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Applicability of Regulations" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.
Amended: F. Oct. 14, 2022; eff. Nov. 3, 2022.

Rule 111-8-7-.23. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions there of shall remain of full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Board of Human Resources to establish rules and regulations that are constitutional and enforceable so as to safeguard the health and well-being of the people of the State.

Cite as Ga. Comp. R. & Regs. R. 111-8-7-.23
Authority: O.C.G.A. § 31-2-4; O.C.G.A. § 31-7-1; O.C.G.A. Chapter 31-7, Article 1.
History. Original Rule entitled "Severability" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Subject 111-8-9. BLOOD LABELING.

Rule 111-8-9-.01. Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Act" means "The Blood Labeling Act" (O.C.G.A. § 31-24-1*et seq.*);

(b) "Person" means any individual, blood bank, clinical laboratory, hospital, firm, corporation or any other entity;

(c) "Department" means the Georgia Department of Community Health;

(d) "Board" means the Board of Community Health;

(e) "Clinical Laboratory" means a single facility for the biological, microbiological, serological, immunological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body, for the diagnosis of, recommendation of treatment of, or for the purpose of providing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, man; the term "clinical laboratory" shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its component parts as well as tissue banks which store human or animal tissues designed to be used for medical purposes in human beings.

(f) "Director" means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including supervision of procedures for testing and the reporting of results;

(g) "Blood" means whole human blood, packed red blood cells, blood platelets, concentrated leukocytes, and blood plasma. It does not include blood derivatives manufactured or processed for industrial use.

(h) "Donation" means any transaction involving the person from whom blood is withdrawn, whether he presents himself for the withdrawal of blood on his own initiative or on the initiative of another person, in which he receives no consideration other than credit through blood assurance programs or other intangible benefits.

(i) "Purchase" means any transaction involving the person from whom blood is withdrawn, whether he presents himself for the withdrawal of blood on his own initiative or on the initiative of another person, in which he receives a monetary consideration in any form. Time off from work granted by an employer for the purpose of giving blood shall not be considered a direct monetary consideration.

(j) "Industrial use" means a use of blood in which the blood is modified by physical or chemical means to produce derivatives for therapeutic or pharmaceutic biologicals and laboratory reagents or controls.

(k) "Transfusion" means a use of blood in which the blood is administered to a human being for treatment of sickness or injury.

Cite as Ga. Comp. R. & Regs. R. 111-8-9-.01
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-1*et seq.*
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-9-.02. Criteria for Donor Selection.

No blood may be withdrawn from any individual in this State for transfusion or industrial use unless he qualifies to be a blood donor under the laws of this State. Criteria for donor selection

shall conform to those required in accordance with provisions of the act providing for the control and operation of clinical laboratories (O.C.G.A. § 31-22-1*et seq.*) and the Rules and Regulations as adopted and promulgated thereunder entitled "Rules and Regulations for Licensure of Clinical Laboratories".

Cite as Ga. Comp. R. & Regs. R. 111-8-9-.02
Authority: O.C.G.A. §§ 31-2-3, 31-2-5 and 31-2-7.
History. Original Rule entitled "Criteria for Donor Selection" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-9-.03. Labeling for Containers of Blood; Certificates for Out-of-State Blood.

(1) It shall be the responsibility of the licensed laboratory director to assure the legal requirement that every unit of blood drawn from an individual and any components derived by physical processes (including plasmapheresis for transfusions and blood for auto transfusions), shall have affixed to each container of such blood or components, a label which indicates whether the blood was obtained by purchase or donation. The label must be affixed prior to bleeding of the donor. The label shall meet the following specifications:

(a) Labels shall state that content is "Blood From Paid Donor" or "Blood From Volunteer Donor".

(b) Labels must be affixed in a prominent position, in such manner as not to obscure any other necessary identifying labels, and using non-toxic permanent type adhesive which is non-leachable through plastic blood bag.

(c) If incorporated into the product label, the wording must be easily read, with block lettering in size described below:

(d) If a separate label is used, such label must be:

1. No less than 3/8 inch by 1¼ inch in overall size;

2. With black letters on an orange background; and

3. Using bold Helvetica or similar block letters, capital height no less than five (5) points in size. See example below.

BLOOD FROM BLOOD FROM

VOLUNTEER DONOR PAID DONOR

(e) If blood is received from out-of-state with individual labels which meets the above specifications, it need not have an additional label applied.

(2) The director of any blood bank who receives blood from a federally licensed blood bank in another state shall be responsible for acquiring a certificate from the out-of-state blood bank certified by its director, indicating which blood units in each shipment were acquired by "donation" or "purchase" as defined in these regulations. If he holds a certificate which certifies that the blood was received by donation, he may label such blood as donated blood. If he cannot obtain such a certificate, he shall label each unit of blood as blood acquired by purchase. In those instances where the supplying out-of-state blood bank draws blood exclusively from volunteer donors, only one certificate per year, acquired in advance, will be required.

(3) The certificate accompanying each shipment of blood or the single annual certificate shall be signed by the Director in whose name the blood bank is federally licensed or an individual authorized by him and so recorded.

(4) All certificates from out-of-state blood banks shall be retained by the receiving Georgia bank for at least five years.

(5) All costs for both certificates and labels shall be borne by the blood bank involved.

Cite as Ga. Comp. R. & Regs. R. 111-8-9-.03
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-1*et seq.*
History. Original Rule entitled "Labeling of Containers of Blood; Certificates for Out-of-State Blood" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-9-.04. Unlabeled Blood, Medical Record, Removal of Label.

(1) No person may administer blood, transfer, or offer to transfer, blood or blood components for transfusion purposes by any type of transaction unless the container of such blood is labeled as required by these regulations. The label may not be removed before or during the administration of the blood or blood components.

(2) A record must be maintained in the blood bank to identify the source of each unit as by "donation" or "purchase".

(3) The identification numbers of the unit(s) of blood transfused shall be recorded in the patient's medical record by the person authorized to administer the blood. Records accompanying each unit of blood or blood products leaving a Blood Bank shall indicate whether such unit was acquired by donation or purchase.

Cite as Ga. Comp. R. & Regs. R. 111-8-9-.04
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-5.
History. Original Rule entitled "Unlabeled Blood, Medical Record, Removal of Label" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-9-.05. Blood and Blood Components: Industrial Uses.

Blood and blood components, including salvage plasma, may be used and transferred for industrial uses without regard to whether its original acquisition was by purchase or donation.

Cite as Ga. Comp. R. & Regs. R. 111-8-9-.05
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-5.
History. Original Rule entitled "Blood and Blood ComponentsIndustrial Uses" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-9-.06. Administration.

Determination of fulfillment of these requirements shall be made by the Department of Community Health as a part of, and using the procedures of the Act providing for the control and operation of clinical laboratories (O.C.G.A. § 31-22-1*et seq.*).

Cite as Ga. Comp. R. & Regs. R. 111-8-9-.06
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-7.
History. Original Rule entitled "Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-9-.07. Punishment for Violations.

Any person violating the provisions of the Act on which these Rules are based shall be guilty of a misdemeanor and upon conviction thereof shall be punished as for a misdemeanor.

Cite as Ga. Comp. R. & Regs. R. 111-8-9-.07
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-24-8.
History. Original Rule entitled "Punishment for Violations" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-9-.08. Enforcement.

The administration and enforcement of these rules and regulations shall be in accordance with the provisions of the Act providing for the control and operation of clinical laboratories (O.C.G.A. § 31-22-1*et seq.*), and in compliance with the applicable minimum requirements as prescribed by the Georgia Administrative Procedure Act (O.C.G.A. § 50-13-1*et seq.*).

Cite as Ga. Comp. R. & Regs. R. 111-8-9-.08
Authority: O.C.G.A. §§ 31-2-5, 31-2-7, 31-2-8 and 50-13-1*et seq.*
History. Original Rule entitled "Enforcement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-10. LICENSURE OF CLINICAL LABORATORIES.

Rule 111-8-10-.01. Legal Authority.

The legal authority for this chapter is found in Chapters 2, 7 and 22 of Title 31 of the Official Code of Georgia Annotated.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.01
Authority: O.C.G.A. §§ 31-2-5*et seq.*, 31-7-1 *et seq.* and 31-22-1 *et seq.*
History. Original Rule entitled "Legal Authority" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.02. Purpose.

The purpose of these rules is to implement the requirements of Chapter 22 of Title 31 of the Official Code of Georgia Annotated pertaining to the licensure of clinical laboratories and the qualifications and performances of laboratory personnel.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.02
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Purpose" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.03. Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning here in after respectively ascribed to them:

(a) **Analyte** means a substance or constituent for which the laboratory conducts testing;

(b) **Board** means the Board of Community Health of the State of Georgia;

(c) **Clinical Laboratory** means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis of, recommendation of, treatment of, or for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings; the term "Clinical Laboratory" shall include specimen collection stations and blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its component parts unless such human blood and its component parts are intended as source material for the manufacture of biological products and regulated by the Center for Biologics Evaluation and Research (CBER) within the federal Food and Drug Administration; the term "Clinical Laboratory" shall include tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings. The term 'clinical laboratory' shall not include laboratories which are nondiagnostic only and regulated pursuant to the federal Clinical Laboratory Improvement Amendments (CLIA) whose sole function is to perform examination of human blood or blood components intended as source material for the manufacture of biological products.

(d) **CLIA-exempt state** means a state where the Centers for Medicare & Medicaid Services (CMS) has determined that the state has enacted laws/rules relating to laboratory requirements that are equal to or more stringent than CLIA requirements. All laboratories subject to state licensure will be considered as "CLIA exempt" where the state has been determined to be CLIA exempt;

(e) **Commissioner** means the Commissioner of the Department of Community Health of the State of Georgia;

(f) **Department** means the Georgia Department of Community Health;

(g) **Director** means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including supervision of procedures for testing and the reporting of results;

(h) **Evaluation Program** means a state-conducted or state-approved proficiency testing program;

(i) **Facility** means a building, structure, institution, place, or entity, which may be fixed or mobile;

(j) **Laboratory Advisory Council** means the Clinical Laboratory, Blood Bank and Tissue Bank Committee authorized and required by law and appointed by the Board;

(k) **Laboratory Test** means any examination and/or manipulation performed on a specimen produced by the human body, by procedures such as phlebotomy or blood diverted from a normal or life-sustaining circulatory path, or in vivo testing of body fluids for the purpose of diagnosis, treatment, monitoring or the assessment of the health of human beings;

(l) **Limited specialty laboratory** or **limited laboratory specialty** means a clinical laboratory, or part of a clinical laboratory, in which testing is restricted (limited) to a designated category or subcategory, including but not necessarily limited to the following examples: cytology, histology, tissue banking, special chemistries (radio bioassay, blood gases, toxicology, etc.), cytogenetics and histocompatibility;

(m) **Other Personnel** means non-technical personnel who may be employed in the laboratory such as aides, clerks, etc. These persons may assist laboratory technical staff, but do not themselves qualify as technical staff or perform tests;

(n) **Person** means any individual, firm, partnership, association, corporation, the State or any municipality or other subdivision thereof, or any other entity whether organized for profit or not;

(o) **Pertinent Laboratory Experience** means full time or equivalent work in a clinical laboratory, directing, supervising or performing tests in all categories, or, when limited to laboratory specialty(ies), work is restricted to that category/subcategory;

(p) **Plan of Correction** means a written plan submitted by the laboratory director, owner, or other controlling authority, for approval by the Department. The plan shall identify the existing noncompliance of the laboratory and the proposed procedures, methods, means and reasonable period of time needed to correct the noncompliance;

(q) **Point of Care Technician** means a medical professional person subject to these rules, who has received special training in point of care testing as defined by these rules. Medical professional staff authorized to perform point of care testing are limited to registered professional nurses, certified nurse practitioners, licensed practical nurses, certified respiratory care professionals, physician assistants, certified paramedics, certified emergency medical technicians, perfusionists, laboratory technologists, laboratory technicians and certified cardiovascular technologists, radiologic technologists certified by a professional credentialing organization approved by the Department, and phlebotomists, certified by a professional credentialing organization approved by the Department;

(r) **Point of Care Testing** means testing performed in the immediate proximity of the patient. All point of care testing must be approved by and under the supervision of a Georgia-licensed laboratory, unless the test site meets the requirements for exemption. All such point of care testing shall be approved only in the specialties for which the laboratory holds a license. Testing shall be limited to procedures which meet all current Georgia rules for quality control, quality assurance and Point of Care Testing personnel requirements. Point of Care Testing is exclusive of screening and monitoring tests;

(s) **Quality Assurance** means a comprehensive process used by the laboratory to prevent and control errors that may occur at any interval from the time a test is ordered until it is reported and charted;

(t) **Quality Control Program** means those quality control requirements established for clinical laboratories as provided in applicable federal law and regulations and in Georgia law and regulations;

(u) **Screening and Monitoring Tests.** Screening tests mean those simple laboratory tests, approved by the Board as screening tests, used to aid in the detection of previously undiagnosed conditions. Monitoring tests mean those simple laboratory tests, approved by the Board as monitoring tests, with performance characteristics (accuracy and precision) that allow the tests to be used for evaluation of the status of previously diagnosed conditions and/or for evaluation of response to medical management;

(v) **Specimen Collection Station** means a place or entity, without regard to location, that either collects specimens directly from patients or brings specimens together after collection for the purpose of forwarding them either intrastate or interstate to a licensed/certified clinical laboratory for examination;

(w) **Specimen Collector and/or Phlebotomist** means any person who has been trained in procedures requiring understanding and skills in the procurement of specimens for clinical laboratory analysis in Clinical Chemistry, Hematology, Immunohematology,

Microbiology, and Immunology/Serology and who works under the general supervision of the laboratory director, supervisor or technologist;

(x) **Supervisor** means an assistant to the director and a person with special scientific skills, who, under the general supervision of a clinical laboratory director, supervises technical personnel;

(y) **Technician** means any person other than the clinical laboratory director, supervisor, technologist, or trainee who functions under the supervision of a clinical laboratory director, supervisor, or technologist and performs only those clinical laboratory procedures which require limited skill and responsibility and a minimal exercise of independent judgment as described in 111-8-10-.06(5)(a). The degree of supervision by the clinical laboratory director, supervisor, or technologist of a technician shall be determined by the director, supervisor, or technologist based on:

1. The complexity of the procedure to be performed;
2. The training and capability of the technician; and
3. The demonstrated competence of the technician in the procedure being performed;

(z) **Technologist** means a person who performs clinical laboratory procedures which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisor, in only those specialties or subspecialties in which they are qualified by education, training, experience, and certification.

(aa) **Trainee** means a person who is enrolled in an accredited training program or who, in a limited laboratory specialty(ies) for which there is no accredited training program available, trains under the supervision of a director, supervisor, or technologist qualified in the specialty(ies), but does not report actual patient test results without prior supervisory approval.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.03
Authority: O.C.G.A. § 31-22-1 et seq.
History. Original Rule entitled "Definitions. Amended" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Jan. 27, 2017; eff. Feb. 16, 2017.
Amended: F. Mar. 19, 2018; eff. Apr. 8, 2018.

Rule 111-8-10-.04. License.

(1) Clinical Laboratory License.

(a) No clinical laboratory shall be operated without a license issued pursuant to these rules and regulations and without a licensed director. All laboratory activities, which are not specifically exempted by these regulations, must be performed in a

license laboratory. Provided, however, a facility or part of a facility in which laboratory testing is done may qualify for exemption from personnel requirements when only specific tests or techniques, designated by the Department and used for screening and monitoring purposes only, are performed, and the facility or part of the facility is under the supervision of the laboratory as outlined in Rule 111-8-10-.16.

(b) A license shall be issued by the Department to a clinical laboratory after all requirements for licensure are met.

(c) A provisional license may be issued as an authorization to operate a clinical laboratory for a limited and specified period of time under the following conditions:

1. After a review of an application and on-site inspection of a new laboratory has indicated that the laboratory has the potential to meet required standards and appears to be in substantial compliance with the requirements of these rules and regulations; or

2. An inspection or review of a licensed laboratory reveals only correctable deficiencies for which an acceptable plan of correction has been provided to Licensure of Clinical Laboratories Chapter 111-8-10 the Department and where the deficiencies do not constitute imminent hazards to patients or to laboratory personnel.

(d) A license shall authorize the performance of one or more categories, subcategories and/or test procedures and shall be valid for one year from the date of issue unless sooner canceled, suspended or revoked. Renewal of a license is subject to continued conformance with all rules and regulations.

(e) A license shall specify the names of the owner and director, categories and subcategories of tests, and the location of the laboratory. The laboratory license must be displayed at all times in view of the public.

(f) A license shall be valid only for the clinical laboratory (as defined at 111-8-10-.03(c)) at the stated location and shall not be subject of sale or transfer to any premises other than those for which it was issued. Should the laboratory change its location, or ownership, a new application shall be made.

(g) Laboratory licenses shall be maintained current and changes in categories/subcatogories of tests or off site locations shall not be implemented without prior notification to and approval by the Department.

(h) Specimen collection stations which have a parent clinical laboratory which is licensed by the State of Georgia may be considered by the Department to be a part of that laboratory; but subject to all other applicable regulations.

(2) **Director's License.**

(a) A director's license shall be issued by the Department to persons meeting the requirements stated in these rules and regulations. Applications for licensure or renewal as a director shall be made on a form provided by the Department accompanied by the non-refundable fee, and provide pertinent information as deemed necessary by the Department.

(b) The director's license shall be maintained current and changes in the required information shall be reported to the Department when they occur. Application shall be made and approved by the Department prior to assumption of duties as a laboratory director.

(c) Any licensed laboratory director who is convicted, pleads guilty or nolo contendere or receives first offender treatment under the laws of this state, the United States, or any other state of any criminal offense involving the manufacture, distribution, trafficking, sale, or possession of a controlled substance or marijuana shall notify the Department of the conviction within ten days following the conviction, plea or first offender treatment.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.04
Authority: O.C.G.A. §§ 16-13-111 and 31-22-1*et seq.*
History. Original Rule entitled "License" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.05. Fees.

(1) Each original application for licensure and each application for annual renewal for a clinical laboratory shall be accompanied by the non-refundable fee set by the Board. These fees as determined by the Board shall be applicable to a ll laboratories. Each screening and monitoring approval shall pay a non-refundable processing and inspection fee as set by the Board.

(2) A non-refundable fee set by the Board shall accompany each application and renewal for licensure as a clinical laboratory director. Each license or renewal shall be valid for two years, unless suspended or revoked, or voluntarily terminated.

(3) Changes in fees and/or development of additional fee schedules may be established by the Board, without formal change in the rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.05
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Fees" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.06. Laboratory Personnel Requirements, Personnel Qualifications and Personnel Records.

(1) **Laboratory Personnel Requirements**:

(a) **General**. The laboratory shall perform tests in only those categories, subcategories or procedures for which it is licensed and for which there is either a director, supervisor, or technologist having minimum qualifications as outlined for Clinical Laboratory Technologists in Rule 111-8-10-.06(4). (Special personnel requirements for donor screening and plasmapheresis and whole blood donor centers are outlined in Rule 111-8-10-.28). In addition, the following criteria shall be minimum personnel qualifications for the supervision of the categories and subcategories below:

1. Clinical Chemistry, Hematology, Immunohematology, Microbiology, Clinical Immunology and Serology: Supervisory requirements for these categories are those requirements for Clinical Laboratory Supervisor, outlined in Rule 111-8-10-.06(3).

2. Exfoliative Cytology. For the purpose of these rules, exfoliative cytology is defined as that part of laboratory science dealing with the examination of cells obtained from human body fluids, surfaces, tissues, and other sources. This service must be provided by either a licensed physician who is certified or eligible for certification in anatomic pathology or cytopathology by the American Board of Pathology or the American Osteopathic Board of Pathology or by applicants who have a doctoral degree and whose special field is cytology. Unless the physician/Ph.D. also serves as cytology general supervisor, the supervisor must meet the minimum qualifications outlined in Rule 111-8-10-.06(3)(b)5 or current federal regulations of § 353 of the Public Health Service Act and Title 42 U.S.C. 263 a, whichever is more stringent.

3. Anatomic Pathology. For the purpose of these rules, anatomic pathology is defined as the examination and diagnosis of human tissues whether removed during life or after death. It deals with the morphologic study of normal or abnormal structure of tissues. For the purpose of these rules, this definition includes performance of all autopsies including medical-legal, and forensic autopsies. The laboratory director, if not so qualified, shall engage the services of a licensed physician who is certified or eligible for certification in an anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

4. Oral Pathology. For the purpose of these rules, oral pathology is defined as a branch of anatomic pathology (see (a)3. above). The laboratory director, if not qualified in oral pathology, shall engage the services of a licensed physician who is certified or eligible for certification in anatomic pathology

by the American Board of Pathology or the American Osteopathic Board of Pathology or those of a dentist, licensed in the State of Georgia, who is certified or eligible for certification by the American Board of Oral Pathology.

5. Radiobioassay. For the purposes of these rules, radiobioassay is defined as the diagnostic in vivo study involving administration of radioactive materials to a human subject (with the exclusion of organ scanning). Laboratories performing tests in radiobioassay must have a director or supervisor who is a physician working in Georgia in the field of radiobioassay at the time of the adoption of these rules and regulations or is qualified and trained in nuclear medicine or radioisotopic pathology and/or is certified or eligible for certification by the American Board of Nuclear Medicine or the subspecialty of radioisotopic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology. If not so qualified, the laboratory must engage the services of one so qualified:

   (i) In vitro studies of organs, tissues, or fluids, using radioactive materials are considered in the licensed category of Clinical Chemistry (special) and may be handled by those appropriately qualified in this area.

   (ii) For both in vivo and in vitro studies, all users of radioactive material must comply with Georgia "Rules and Regulations for Radioactive Material", Chapter 290-5-23.

6. Qualifications for test areas not included in above general categories may be established as Department policy.

(b) **Directors**. Each licensed laboratory shall be under the direction of a licensed laboratory director whose responsibilities and qualifications are outlined in Rule 111-8-10-.06(2). The director may delegate Point of Care Testing oversight to qualified laboratory supervisors; however, such delegation must be in writing. In addition, delegation of authority does not relieve director of responsibilities as outlined in these regulations regarding Point of Care Testing.

(c) **Supervisors.** With the exception of a laboratory in which the director also qualifies and serves as supervisor, each laboratory shall have one or more supervisors who serve as assistants to the laboratory director and whose responsibilities are outlined in Rule 111-8-10-.06(3). Such personnel must spend an adequate amount of time in the laboratory to supervise the performance of the work in the laboratory and must be readily available at other times for on-site or telephone consultation.

(d) **Technologists and Technicians**. Each laboratory shall engage the services of a sufficient number of clinical laboratory technologists, and/or clinical laboratory technicians to meet the workload demands including prompt performance, reporting and record-keeping of test results, quality control and proficiency testing.

(e) **Point of Care Technicians.** Each point of care testing site subject to state licensure shall utilize medical professional staff, as defined in these rules to perform such testing.

(f) **Specimen Collectors and Phlebotomists.** A laboratory may employ specimen collectors and/or phlebotomists whose responsibilities are outlined in Rule 111-8-10-.06(7).

(g) **Other Personnel.** No person may perform laboratory tests within a licensed laboratory unless they qualify as a trainee, technician, technologist, supervisor, or director as defined in these rules. Other personnel may be employed in the laboratory such as aides, clerks, etc. These persons may assist the laboratory technical staff, but do not themselves qualify as technical staff, perform patient testing or operate clinical analyzers.

(h) **Personnel Records:**

1. Personnel records shall be kept current. They shall include a complete resume of each employee's training, experience, duties, competency evaluation and date or dates of employment. Personnel forms shall be submitted to the Department in a timely manner.

2. The laboratory is responsible for maintaining written documentation (in the personnel file of each employee performing testing) which demonstrates that the employee meets the personnel qualifications as set forth in these rules.

(2) **Licensed Laboratory Directors.**

(a) Responsibilities and general requirements:

1. Each licensed clinical laboratory shall be under the direction of a licensed laboratory director who is responsible for the operation of the laboratory at all times, who must spend an adequate amount of time in the laboratory to administer the technical and scientific operation of the laboratory, is responsible for the proper performance and reporting of laboratory findings, and is responsible for adequate staffing by qualified laboratory personnel, their in-service training and work assignment.

(i) There must be documentation completed by the laboratory director or supervisor, of competency to perform testing by an individual initially before patient testing is performed and not less than annually, thereafter, unless test methods or instruments change, in which case the director or supervisor is responsible for completing a new competency validation on the individual(s) before test results can be reported. Competency is to be measured against an established performance standard as defined by the laboratory director. Methods for validation of competency for each procedure must include:

(I) Direct observation of test performance through the testing of previously analyzed specimens and internal blind samples or external proficiency testing samples previously run and recorded. Testing samples may not be labeled as competency evaluation material, but must be treated as patient samples for routine processing;

(II) Review of test results from tests performed as a part of the competency assessment;

(III) Assessment of response to problems or situations related to the procedure;

(IV) Review of documentation of critical incidents related to the individual's performance of the procedure;

(V) Response to written or oral questions related to the procedures and, if applicable to the individual's responsibilities;

(VI) Assessment of the performance of calibration, and review of records pertaining to quality control and instrument maintenance.

(ii) The laboratory director may delegate the responsibility for competency assessment to other directors or supervisors in the laboratory meeting the qualifications described in 111-8-10-.06(2) and 111-8-10-.06(3).

(iii) The licensed laboratory director shall ensure that no individual performs any laboratory procedure independently without first having demonstrated competency for the procedure as described above in 111-8-10-.06(2)(a)1. (i).

(iv) When a director will be continuously absent for more than four weeks, arrangements must be made for a qualified substitute licensed director.

2. In addition to responsibilities outlined at 111-8-10-.06(8)(a) and (b) of these rules, the director is responsible for ensuring that all testing is instituted and conducted in a manner that complies with all applicable rules. The director, in consultation with appropriate medical staff, shall prepare an internal needs assessment for point of care testing which shall include evaluation of patient benefits and criteria for establishing the necessity of such testing. The assessment shall also include an evaluation of proposed methodologies for tests to be performed. The director is responsible for terminating testing in cases where there is consistent non-compliance with applicable rules or substandard performance.

3. There must be a written plan of action for how patient testing and reporting is handled when either laboratory or point of care testing fails. The director must ensure that, when recommended by the manufacturer, all screening tests performed must have confirmatory tests performed in a timely manner. The director must also ensure that the laboratory is enrolled and successfully participates in an approved proficiency testing program and that each Point of Care Testing area either enroll and successfully participate in an approved proficiency testing program *or* successfully participate in an approved program subscribed to by the responsible laboratory. Point of Care Testing methods, analyzers, or test areas must be challenged the number of times a year as is consistent with the requirement for clinical laboratories under state and/or current federal regulations. The director may delegate his or her authority, to assure that all applicable state regulations are met, to a supervisor that is qualified as defined in these rules and regulations.

4. Each licensed clinical laboratory must be served by a licensed clinical laboratory director, (permitted to direct no more than five clinical laboratories at a given time), on a full time or regular part-time basis. However, no licensed clinical director (Restricted) shall be permitted to direct more than one clinical laboratory at a given time.

(b) Qualifications:

1. Each licensed clinical laboratory in Georgia shall be directed by a licensed clinical laboratory director who qualifies under either (i), (ii), (iii), (iv), or (v) below, and whose practice is to be restricted according to the subparagraph under which he/she qualifies.

(i) **Licensed Clinical Laboratory Director.** A licensed clinical laboratory director must hold a license to practice medicine and surgery pursuant to Chapter 34 of Title 43 of the Official Code of Georgia Annotated, or a Georgia license to practice dentistry, or hold an earned doctoral degree in biology, microbiology, chemistry or related fields, and must either be certified or eligible for certification by one of the following:

(I) The American Board of Pathology or the American Board of Osteopathic Pathology in Clinical and/or Anatomic Pathology;

(II) The American Board of Oral Pathology;

(III) The American Board of Medical Microbiology;

(IV) The American Board of Clinical Chemistry;

(V) The American Board of Bioanalysists [Clinical Laboratory Director (CLD) and/or Bioanalyst Clinical Laboratory Director (BCLD)]; or

(VI) The American Board of Medical Laboratory Immunology; or

(VII) Qualified by other combinations of pertinent laboratory training and experience, in one or more of limited laboratory specialties, which are acceptable to the Department.

(ii) **Licensed Clinical Laboratory Director (Restricted**). In recognition that certain laboratories, due to varying circumstances, have difficulty providing a laboratory director qualified under the requirements above, the clinical laboratory director's license (restricted) is authorized for issuance to new applicants who are physicians or possess an earned doctoral degree and who are qualified as laboratory supervisors under Rule 111-8-10-.06(3)(b)1. or (b)2., and who meet the following requirements:

(I) The person will serve as director of only one laboratory at a given time;

(II) The served laboratory employs not more than ten full-time technical employees (supervisors, technologists, and

technicians) or equivalent number of part-time technical employees; and

(III) The laboratory must also employ a qualified full-time or regular part-time clinical laboratory supervisor or pathologist.

(iii) **Licensed Clinical Laboratory Director (Plasmapheresis and/or Whole Blood Donor Centers).** The director of a plasmapheresis and/or whole blood donor center shall be a physician licensed in Georgia, who is qualified by training and/or experience in blood banking and/or plasmapheresis procedures and who shall be responsible for the medical, technical and clerical services, including special services such as phlebotomy for autologous transfusion, and special pheresis technique.

(iv) **Licensed Clinical Laboratory Director (Specimen Collection Station).** Each specimen collection station which is not a part of a parent clinical laboratory that is licensed by the State of Georgia must have a licensed clinical laboratory director. The director of a Specimen Collection Station shall be a person who is licensed to practice medicine in Georgia, or who holds an earned doctoral degree in biology, microbiology, chemistry or a related field and have pertinent clinical laboratory experience related to specimen collection.

(v) A person, who at the time of adoption of these regulations holds a current Georgia license as a clinical laboratory director, may renew the license and continue to function with same or similar duties and responsibilities upon application and payment of license fee. Persons who qualify under this provision but who are inactive for two (2) consecutive years must meet current requirements. Provided, further, that individuals and laboratories so concerned must meet all other standards of performance required by law and accompanying rules and regulations.

2. In addition to the directorship of the clinical laboratory, the director may participate in actual laboratory work only in those areas in which qualified by training and experience. For those categories in which the director is not qualified, a supervisor must be employed who is qualified in accordance with Rule 111-8-10-.06(3) to perform and/or supervise those procedures independently.

3. The person serving as a hospital laboratory director must be a member of the hospital medical staff.

(3) **Laboratory Supervisor**.

(a) **Responsibilities and general requirements.** With the exception of a laboratory in which the director also serves as supervisor, each laboratory must have an adequate number of qualified personnel who are assistants to the director, and who, under his/her general direction may function as supervisors, depending upon the size of the laboratory and diversity of the laboratory testing. A supervisor must be available for two-way communication within 30 minutes during all hours of operation, for the purpose of supervising technical personnel. For Point of Care Testing areas, the responsible supervisor must be qualified at a minimum under subparagraph (3)(b)4 of this rule. In addition, the supervisor of the testing area must be available for two-way communication within 30 minutes during all hours of operation. The supervisor is responsible for developing a quality control and quality assurance program for each test area that is equal to or more stringent than current federal and applicable state requirements. No Point of Care Testing area may be operated without a qualified supervisor.

(b) **Qualifications.** A supervisor shall meet one of the following minimum requirements:

1. Hold a license to practice medicine and surgery pursuant to Chapter 34 of Title 43 of the Official Code of Georgia Annotated and have at least two years of pertinent laboratory experience; or

2. Hold a doctoral degree from an accredited institution with a chemical, physical, or biological science as the major subject and have at least two years of pertinent laboratory experience; or

3. Hold a master's degree from an accredited institution with a major in one of the chemical, physical or biological sciences, allied health science or laboratory management, and have at least three years of pertinent laboratory experience as a technologist as outlined in Rule 111-8-10-.06(4)(b) of these rules and regulations; or

4. Qualify as a clinical laboratory technologist under Rules 111-8-10-.06(4)(b)1., 2., 3. or 4. and have at least four years of pertinent laboratory experience as a technologist as outlined in Rule 111-8-10-.06(4)(b); or

5. In the limited specialty laboratory or limited laboratory specialty(ies), the supervisor must meet one of the above conditions or, if restricted to the category or subcategory, must meet one of the following:

(i) Hold a master's degree with a major in a chemical, physical, or biological science, allied health science, or laboratory management; be a graduate of an accredited program in the specialty and have at least two years pertinent laboratory experience in the specialty as technologist; or

(ii) Hold a bachelor's degree in the specialty; or a degree with a major in chemical, physical, or biological sciences and be a graduate of a program in the specialty accredited by an agency accepted by the Department, or have one year of training in a clinical laboratory environment; and have at least three years of pertinent laboratory experience in the specialty as a technologist; or

(iii) Qualify as a technologist under Rule 111-8-10-.06(4)(b)6. (i) and have at least four years of pertinent laboratory experience in the specialty as a technologist.

(iv) A cytology supervisor must be a physician licensed to practice medicine in Georgia, and be certified in anatomic pathology by the American Board of Pathology, or the American Osteopathic Board of Pathology, and be licensed by the Department as a laboratory director.

(v) A cytotechnologist general supervisor must meet the requirements of Rule 111-8-10-4(b)6. (iii) and have 3 years full time experience as a cytotechnologist in a clinical laboratory.

(vi) A histocompatibility supervisor must be a pathologist who is board certified in anatomical and clinical pathology, a licensed physician or doctor of osteopathy with four years experience in histocompatibility, or a Ph.D. with two years general immunology and two years histocompatibility experience.

(vii) The histopathology supervisor must be a licensed physician or doctor of osteopathy, and be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, and licensed by the Department as a laboratory director.

(viii) The histotechnologist general supervisor must have formal training, be certified by an approved crediting agency and have two years of pertinent experience.

6. Persons who have been continuously engaged as laboratory supervisors in Georgia since July 1, 1970, are exempt from the personnel qualifications listed above. Persons who initially qualified under this provision and who become inactive for two (2) consecutive years for any reason must meet current requirements. Provided, further, individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(4) **Technologist.**

(a) **Responsibilities and general requirements.** Technologists, under general supervision, exercise independent judgment to perform and report findings proficiently for clinical laboratory tests. In the case of technologists who are qualified only in limited laboratory specialties, work as a technologist shall be limited to those respective specialties in which qualified.

(b) **Qualifications.** Each technologist shall successfully complete a certification examination from the American Society for Clinical Pathology (ASCP), the American Medical Technologists (AMT), the National Credentialing Agency for Laboratory Personnel (NCA), the American Association of Bioanalysts (AAB), or another agency approved by the Department, and shall meet one of the following requirements, listed in 1. through 7. below:

1. Successful completion of a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university; or

2. Successful completion of three years of academic study (a minimum of 135 quarter hours or equivalent) in an accredited college or university and the successful completion of a course of training of at least 12 months in a school of medical technology accredited by an agency recognized by the Council for Higher Education Accreditation (CHEA) or the U.S. Department of Education; or

3. Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical, or biological sciences, and have at least one year of pertinent laboratory experience or training accepted by the Department; or

4. Successful completion of 135 quarter hours in an accredited college or university, including 24 quarter hours of chemistry, 24 quarter hours of biology, and 5 quarter hours of mathematics, (thirty quarter hours of the total, with a minimum of fifteen in science, must be at the third or fourth

year level), and have at least two years of pertinent laboratory experience; or

5. Successful completion of a full course of study which meets all academic requirements for an associate's degree in medical technology from an accredited college or university, or successful completion of two years of academic study (a minimum of 90 quarter hours or equivalent) in an accredited college or university which included at least 20 quarter hours of lecture and laboratory courses in chemical, physical, or biological sciences acceptable toward a major in science, with at least three years of pertinent laboratory experience; or graduation from high school and successful completion of a formal technician training course which is accredited by an accrediting agency accepted by the Department with at least four years of pertinent laboratory experience; or

6. In the limited specialty laboratory or limited laboratory specialty(ies), a technologist is restricted to the category or subcategory of testing authorized to be performed in the limited laboratory, and must have satisfactorily completed either:

   (i) Ninety (90) quarter hours in an accredited college or university with at least 20 quarter hours in science and one year of pertinent laboratory experience or training accepted by the Department; or

   (ii) At least two years of pertinent laboratory experience as a technician under the supervision of a director qualified in the specialty, or a one-year formal training program accepted by the Department in the specialty; or

   (iii) Cytotechnologists must be certified by specialty examination by the American Society for Clinical Pathology (ASCP), or another agency approved by the Department; or

   (iv) Histotechnologists must have formal training and specialty certification by the American Society for Clinical Pathology (ASCP) or another agency acceptable to the Department.

7. Persons who possess the technologist qualifications under provisions (b)1. through 6. above and have recently moved into the state or have recently completed the academic and training/experience requirements may be temporarily classified once as technologists for eighteen (18) months to afford the persons an opportunity to successfully complete an approved qualifying examination.

8. Persons who have been continuously engaged as technologists in Georgia since July 1, 1970, are exempt from the personnel qualifications listed above. Persons who initially qualified under this provision but become inactive for two consecutive years must meet current requirements. Provided further, that individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(c) **Technologist allowable testing.** Technologists shall be permitted to independently perform all laboratory procedures for which the technologist has been trained and demonstrated competency as described under 111-8-10-.06(2)(a)1. (i). Where the technologist chooses to delegate the performance of any test requiring more than limited skill and responsibility and exercise of independent judgment as described in 111-8-10-.06(5)(c):

1. The delegating technologist shall ensure that the individual to whom the testing has been delegated meets at a minimum the qualifications described in 111-8-10-.06(5)(b) and has documented competency for performance of the test as described in 111-8-10-.06(2)(a)1. (i);

2. The delegating technologist shall be responsible for the accuracy of the test results; and

3. The delegating technologist shall ensure that a qualified technologist is available onsite or by telephone for consultation regarding the testing or for review of results; and

4. In those cases where a qualified technologist is not available on site during the performance of the delegated test, but is only available on call, the performance of those tests shall only be delegated to an individual who has completed a technician-level certification test approved by the Department, has completed a full course of study which meets all academic requirements for an associate's degree in medical technology from an accredited college or university, and has completed a minimum of two years of pertinent full time laboratory experience, one year of which experience has been obtained in the laboratory where they will be performing the delegated test.

(5) **Technician**.

(a) **Responsibilities and general requirements.** The laboratory must employ a sufficient number of qualified technicians to meet the workload demands, and they must function under the direct supervision of a technologist, supervisor or director. The decision regarding the degree of supervision necessary shall be determined by consideration of the complexity of the procedure, the training and capability of the technician, and the demonstrated competency of the technician in the procedure to

be performed. The determination of the degree of supervision under which the technician performs any type of laboratory testing must be documented in the technician's job description and personnel record. In the case of technicians who are qualified only in limited laboratory specialties, work as a technician shall be limited to those respective specialties in which qualified.

1. For any testing performed by a technician, there must be documentation in the technician's personnel record of training and competency testing of the technician to perform the test.

2. Documentation of the test and reporting of results must be retained, for the purpose of supervisory review, for all testing performed independently by a technician.

(b) **Qualifications.** Each technician shall successfully complete a certification examination from the American Society for Clinical Pathology (ASCP), the American Medical Technologists (AMT), the National Credentialing Agency for Laboratory Personnel (NCA), the American Association of Bioanalysts (ABB), or another agency approved by the Department and shall meet one of the following requirements listed in 1. through 4. below:

1. Has earned an associate's degree in medical laboratory technology; or successful completion of two years of academic study (a minimum of 90 quarter hours or equivalent) in an accredited college or university which included at least 20 quarter hours of lecture and laboratory courses in chemical, physical, or biological sciences acceptable toward a major in science and have at least one year of pertinent laboratory experience or training accepted by the Department; or

2. Graduation from high school and successful completion of a formal technician training course which is accredited by an accrediting agency accepted by the Department; or

3. Graduation from high school and subsequent to graduation has obtained two years of pertinent laboratory experience in a clinical laboratory of a hospital, a health department, university, or in an independent clinical laboratory; or

4. For persons who possess the technician qualifications under provisions above and have recently moved into the state or completed the academic and/or training requirements, they may be temporarily classified once as technicians for eighteen (18) months to afford them an opportunity to successfully complete an approved qualifying examination.

5. Persons who have been continuously engaged as technicians in Georgia since July 1, 1970 are exempt from personnel qualifications listed above. Persons who initially qualified under this provision but become inactive for

two consecutive years for any reason must meet current requirements. Provided, further, individuals and laboratories so concerned must meet all other standards of performance required by this law and applicable rules and regulations.

(c) **Technician allowable testing.** Technicians shall be permitted to perform tests requiring limited skill and responsibility and a minimal exercise of independent judgment, and for which the technician has demonstrated competency as described in 111-8-10-.06(2)(a)1. (i), to include:

1. CLIA waived tests;
2. Complete blood count (CBC) utilizing automated/semi-automated methods with internal support systems;
3. Routine chemistries utilizing automated/semi-automated methods with internal support systems; and
4. Coagulation studies utilizing automated methods.

(6) **Trainee**. A trainee is a person who is enrolled in an accredited training program, or who, in a limited laboratory specialty(ies) for which there is no accredited training program, works and trains under the direct supervision of a qualified director, supervisor, or technologist qualified in the specialty(ies), but does not report actual patient test results without prior supervisory review. A person may function as a trainee for the duration of the formal approved training program or for a maximum period of 24 months.

(7) **Specimen Collector and/or Phlebotomist.** The laboratory may employ specimen collectors, qualified by training and/or experience approved by the laboratory director, to perform, under general supervision, collection procedures requiring understanding and skills in the procurement of specimens for clinical laboratory analysis. Documentation of qualifying training and/or experience must be available in the laboratory's personnel files. The collector may also perform exempt screening and monitoring tests as outlined in Rule 111-8-10-.16 of these regulations. Phlebotomists certified by the American Society for Clinical Pathologists (ASCP), the American Medical Technologists (AMT), the National Healthcareer Association (NHA), the National Center for Competency Testing (NCCT), the American Association of Bioanalysts (ABB), or another professional credentialing organization that has been approved by the Department, may perform Point of Care Testing in accordance with these rules.

(8) **Point of Care Technician.**

(a) **Responsibilities and general requirements.** Point of Care technicians must function under the supervision of a laboratory director and/or supervisor appointed

by the director. These technicians must complete all training requirements as outlined in subparagraph (b) of this rule.

(b) **Qualifications:**

1. Professional background. Point of Care technicians must have one of the following medical professional backgrounds: licensed registered nurse, certified nurse practitioner, licensed practical nurse, certified respiratory care professional, physician assistant, perfusionist, certified paramedic or certified emergency medical technician, radiologic technologist, certified cardiovascular technologist certified by a professional credentialing organization approved by the Department, medical technologist and medical technician qualified by these rules, or a phlebotomist certified by a professional credentialing organization approved by the Department.

2. Training. The laboratory director is responsible for determining and maintaining documentation of an individual's credentials which qualify him or her to perform Point of Care Testing. The director may delegate this responsibility to a qualified supervisor. The documentation of qualifications to perform point of care testing must include the following: training, licensure, certification or other medical professional background information as well as competency certification documentation. In all cases, an individual must be trained and his or her competency verified prior to the director or supervisor allowing the individual to perform patient testing. Such training must include, at a minimum, proper specimen collection and handling, proper use of test instruments, proper storage, handling and preparation of test kits/reagents, quality control, quality assurance, remedial action and record keeping. Training must also include troubleshooting to the extent that results will not be reported when instrument or quality control problems arise.

(9) **Other Personnel.** Other personnel may be employed in the laboratory, such as aides, clerks, etc. These persons may assist laboratory technical staff in the performance of non-clinical tasks, but do not qualify as technical staff, perform technical tests or operate testing devices.

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Amended: F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-10-.07. Application.

(1) Applications for licensure of clinical laboratories shall be made on forms provided by the Department and shall indicate from the following list, those categories, subcategories and/or procedures for which the facility requests licensure:

(a) Clinical Chemistry;

1. Routine;

2. Urinalysis;

3. Special (includes Radiobioassay, Blood Gases, Medical Toxicology, Therapeutic Drug Monitoring, Immunohistochemistry, etc.)

(b) Hematology;

(c) Immunohematology (including Group/Type/Crossmatch, Antibody Screen/Identification, Storage, Transfusion Services, Pheresis/ Components, Donor Services (autologous, general), Histocompatibility.

(d) Microbiology;

1. Bacteriology (Level I - Direct microscopic examination of smears; Level II - Primary culture, report no growth and refer growth for identification; Level III - Culture and Identification and/ or Sensitivity Testing);

2. Mycobacteriology (Level I - Direct microscopic examination of smears for acid fast organisms; Level II - Primary culture, report no growth and refer growth for identification; Level III - Culture, Identification and/or Sensitivity Testing);

3. Mycology (Level I - Direct microscopic examination for fungi; Level II - Primary culture, report no growth and refer growth for identification; Level III - Culture, Identification and/or Sensitivity Testing);

4. Parasitology; and

5. Virology.

(e) Clinical Immunology and Serology:

1. Syphilis;

2. Non-syphilis;

3. Viral Serology;

4. HIV (Screening/Confirmation).

(f) Pathology;

1. Exfoliative Cytology;
2. Anatomic Pathology; and
3. Oral Pathology.

(g) Radiobioassay.

(h) Tissue Banking.

(i) Cytogenetics.

(j) Inherited Metabolic Disorder Testing of Newborns.

(k) Specimen Collection Station(s).

(l) Point of Care Testing.

(m) Other: (ART, andrology, molecular genetics).

(2) If a facility provides any laboratory testing services it must apply for and obtain one or more appropriate laboratory licenses (or screening and monitoring approvals) as needed to cover all laboratory services provided and must meet all requirements of these regulations. Where testing beyond the scope of authorized laboratory services is performed, these additional tests must be obtained from a duly licensed laboratory that meets all requirements of these regulations or from an out-of-state laboratory holding a current federal certificate for laboratory testing.

(3) The application for licensure in the category of specimen collection station shall be made on forms provided by the Department, and shall indicate the name and address of the laboratory or laboratories to which specimens are submitted for testing.

(4) Application for screening and monitoring approvals shall be made on forms provided by the Department and shall provide pertinent information as deemed necessary by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.07
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Application" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.08. Sanitation and Safety.

(1) **General.** All laboratories shall be well lighted, maintained in a clean, neat, orderly and professional manner, and operated in a manner which will prevent undue physical, chemical, or biological hazards to its employees or other members of the community, and shall meet local and state sanitation and safety regulations:

(a) Adequate lighting shall be provided for the work area at bench top level.

(b) Syringes, needles, lancets, or other bloodletting devices capable of transmitting infection from one person to another shall be of a disposable type or shall be cleaned and sterilized before use, in accordance with accepted sterilization procedures.

(2) **Sanitary Facilities.** All laboratories shall have suitable sanitary facilities, including toilet and hand washing facilities, within the premises. New installations and major renovations completed after the effective date of these rules shall include hand washing and toilet facilities for visitors and patients, separate from those provided for employees.

(3) **Garbage and Rubbish Disposal.** All laboratories shall provide facilities for maintaining sanitary standards, including water supply, sewage, garbage and refuse disposal, throughout the laboratory structure and premises. Such facilities shall meet local and state regulations, and shall be maintained in a clean and orderly manner. Cultures and specimens shall be discarded in an appropriate manner.

(4) **Safety.** Laboratory locations and facilities must conform to local and state building and safety and fire codes and ordinances where applicable. There shall be sufficient space, equipment and facilities to perform the services provided by the laboratory with reasonable accuracy and safety:

(a) Work involving the licensed subcategories of mycobacteriology (Levels II or III), mycology (Levels II or III), and appropriate virology shall be performed under a biological safety cabinet with a rating of Class IIA/B3. Safety cabinets shall exhaust filtered air directly to the outside when a recirculation air conditioning system is used. Laboratories utilizing a single pass ventilation system with their safety cabinet may exhaust air back into the laboratory. All laboratory procedures which involve liberation of large amounts of toxic, corrosive or explosive substances shall be performed under a fume hood that has a face velocity of 100 feet per minute and an independent exhaust system;

(b) Cylinders of compressed gas shall be properly secured by restraining chains, brackets or other materials that are sufficiently strong to support the weight of the cylinder;

(c) Flammable or combustible liquids shall be in containers not larger than one liter, in safety cans, in cabinets suitable for storage of flammable or combustible liquids or must otherwise comply with the requirements established by the state fire marshal; flammable liquids requiring refrigeration shall be stored in an

Underwriters' Laboratory labeled explosion-proof refrigerator or otherwise comply with the requirements established by the state fire marshal;

(d) Laboratories utilizing corrosive materials or solutions shall have an appropriately located safety spray hose or shower;

(e) Each plumbing fixture shall be provided with air gap or vacuum breaker where necessary to eliminate back-siphoning hazards.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.08
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Sanitation and Safety" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.09. General Quality Control Requirements.

Each laboratory shall establish and follow written policies and procedures for a quality assurance program, comprehensive in scope and specific to that laboratory. The program shall monitor and evaluate the ongoing and overall quality of the total testing process from specimen collection to reporting of test results. The program shall identify and correct problems, assure the accurate, reliable and prompt reporting of test results and assure adequacy and competency of laboratory staff. Written procedures shall be revised when evaluation results indicate the need. There must be documentation of the ongoing quality assurance program as well as corrective action taken when necessary. The laboratory director is responsible for ensuring that the following quality controls are employed for all clinical testing authorized under the laboratory's license:

(a) Preventive maintenance, periodic inspection or testing for proper operation of equipment and instruments, based on but not limited to manufacturers' instructions. The laboratory must confirm the effectiveness of its preventive maintenance program;

(b) Each quantitative method shall be validated prior to placing into routine use. Such validation shall include reportable range, sensitivity, specificity, accuracy and precision. Documentation of validation shall be maintained for the period the method is used, or for at least two years, whichever is longer;

(c) Evaluation of reagents and volumetric equipment;

(d) Maintenance of documentation verifying that test systems perform according to laboratory specification; such documentation must be available to the authorized persons ordering or receiving test results, and to the Department; the laboratory must establish its reference range for each method before reporting patient test results;

(e) Establishment and employment of policies/procedures for remedial action to be taken in response to quality control outside acceptable limits, equipment or methodology performance outside established operating limits, test results outside acceptable limits,

tests not performed within laboratory established time frames, proficiency test results outside acceptable limits or errors detected in reported patient results;

(f) Adequacy of space, ventilation, facilities, equipment, instruments, and methods of performance of the procedures or categories of procedures for which a license application is filed or granted; proper lighting for accuracy and precision; convenient location of essential utilities; monitoring of temperature controlled spaces and equipment to assure proper performance of equipment and storage of specimens, tissues, reagents and supplies; the evaluation of analytical measuring devices, with respect to all critical operating characteristics, and the laboratory shall not report test results unless such operating characteristics are within defined acceptable ranges;

(g) Labeling of all reagents and solutions to indicate identity, and when significant, titer, strength or concentration, recommended storage and preparation or expiration date, and other pertinent information. Material of substandard reactivity, expired, or deteriorated materials may not be used;

(h) Availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a category, of laboratory manuals or other complete written descriptions and instructions (properly designated and dated to reflect an initial and periodic review by the current director) relating to the current analytical methods, specimen processing procedures, reagents, control and calibration procedures, microscopic examinations, remedial action procedures, limitations in methodologies, pertinent literature references and the date each procedure was placed into use. Textbooks may be used as supplements to such written descriptions but may not be used in lieu thereof;

(i) Written approval by the director of any and all changes in laboratory procedures; a copy of each procedure must be retained for two years after the procedure has been discontinued;

(j) Maintenance and availability to laboratory personnel, and to the Department, of records, reflecting dates, and where appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation, and alternative test methods;

(k) Written materials designed to provide instruction for proper collection, labeling, preservation and transportation of specimens to assure accurate results suitable for clinical interpretation.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.09
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "General Quality Control Requirements" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.10. Quality Control for Microbiology.

Chemical or biological solutions, reagents, and antiserum shall be tested and inspected as prescribed by the Department for reactivity and deterioration. Discs and systems used in antibiotic susceptibility testing are checked for deterioration and proper reactivity, using approved reference organisms.

(a) **Bacteriology, Mycobacteriology and Mycology.** Staining material shall be tested for intended reactivity by weekly application to smears of microorganisms with predictable staining characteristics, with the exception of fluorochrome acid fast stains, which must be checked each day of use. Each batch of media shall be tested before or concurrently with use with selected organisms to confirm required growth characteristics selectivity, enrichment, and biochemical response. The laboratory may use commercial manufacturers' quality control checks of media if the laboratory has documentation to verify that the manufacturer meets the National Committee for Clinical Laboratory Standards (NCCLS) requirements for media quality control. Each day of use the laboratory must test direct antigen detection systems using positive and negative control organisms that evaluate both the extraction and reaction phases.

(b) **Parasitology.** A reference collection of slides, photographs, or gross specimens of identified parasites shall be available in the laboratory for the appropriate comparison with diagnostic specimens. A calibrated ocular micrometer shall be used for determining the size of ova and parasites, if size is a critical factor. Staining material shall be tested for intended reactivity, using a fecal sample control that will demonstrate staining characteristics, whenever a new lot number of reagent is opened or once a month, whichever comes first;

(c) **Virology.**

1. Systems for the isolation of viruses and reagents for their identification shall be available to cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.

2. Records shall be maintained which reflect the systems used, and the reactions observed. In tests for the identification of viruses, controls shall be employed which will identify erroneous results.

3. Physical facilities and safety cabinets must be adequate and appropriate for the extent of testing offered.

4. There must be a written procedure in place and utilized by the laboratory for the proper disposal of infectious materials and biohazardous waste.

5. Host systems must be checked for sensitivity to viral agents and sterility.

6. Continuous cell lines must be checked for bacterial/fungal contamination as appropriate.

7. Storage requirements and expiration dates must be observed and recorded.

8. Diluents must be checked for sterility and pH.

9. Records must be kept of cell types, passage number, source, lot numbers and media used for growth and maintenance.

10. In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

11. Inoculated cultures must be checked for cytopathic effect at appropriate intervals.

12. Records must be kept of all quality control and quality assurance for as long as required under current federal regulations or not less than two years, whichever is more stringent.

13. If serodiagnostic tests for viral diseases are performed, requirements for quality control as specified for serology and immunology shall apply as listed at 111-8-10-.09(4).

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.10
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Quality Control for Microbiology" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.11. Quality Control for Serology/Immunology.

(1) Serologic and immunologic tests on unknown specimens shall be run concurrently with a positive control serum of known titer or controls of graded reactivity plus a negative control in order to detect variations in reactivity levels. Controls for all test components shall be employed to ensure reactivity and uniform dosage. Test results shall not be reported unless the redetermined pattern of the control is obtained.

(2) Each new lot of reagent shall be tested with one of known acceptable reactivity, or with known control sera before or concurrent with the new lot of reagent being placed into routine use.

(3) Equipment, glassware, reagents, controls and techniques for tests for syphilis shall conform to manufacturers' specifications, where applicable.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.11
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Quality Control for Serology/Immunology" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.12. Quality Control for Clinical Chemistry.

(1) The laboratory must verify (validate) that each method or testing system functions in the laboratory as specified by the manufacturer. Verification includes reportable range, accuracy, sensitivity and specificity. Verification studies must be done upon introduction of a new methodology; a laboratory may not report test results beyond or below its own established range.

(2) Calibration, or calibration verification must be performed:

   (a) According to manufacturer specifications, or every six months, whichever is sooner;

   (b) When a complete change of reagents (except where all reagents are packaged together) occurs;

   (c) When major preventive maintenance or replacement of a critical part occurs;

   (d) When controls begin to reflect an unusual trend or are consistently outside acceptable ranges; or

   (e) At least every six months.

(3) Each quantitative assay procedure shall be rechecked at least once each day of testing (24-hour period) except for blood gases, which must be rechecked each shift (see (7) below); rechecks must be conducted using two levels of calibrators, controls, standards, or a combination of these materials.

(4) Limits for standards and reference samples shall be recorded and shall include the course of action to be instituted when the results are outside the acceptable limits for each lot number of controls. Manufacturer's limits may be used only if they are verified by the laboratory.

(5) For urinalysis, the laboratory shall use a positive control each day of patient testing, which checks the reactivity of each constituent for which qualitative tests are reported.

(6) Counting equipment used for in vitro radioassay determination shall be checked for stability at least once each day of use with radioactive standards or reference sources. Records which document the routine precision of each method, automated or manual, and its recalibration scheduled, shall be maintained. At least one standard and one reference sample (control) shall be included with each run (ad defined by guidelines) of unknown specimens.

(7) For blood gas analysis, a two point calibration must be performed and documented each shift; a third point verification must be run using a separate material from that used in the two point check; for blood gas analyzers which include other chemistries (electrolytes,

glucose, bun, etc.) the quality control requirements are outlined under Rule 111-8-10-.09 and .09(5).

(8) For co-oximetry, preventive maintenance shall follow manufacturer's guide lines except where regulations are more stringent; a hemoglobin control shall be performed each day of testing. The calibration of the instrument shall be checked weekly unless required more frequently by the manufacturer.

(9) Drug screens for medical purposes must contain a standard which contains all drugs to be identified by the method used, or for which the laboratory reports, per each plate or run. The control must go through all phases of testing including extraction, unless technology that is more current has been approved by the Department. Positive qualitative tests must be confirmed by a quantitative method, if required or recommended by the manufacturer.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.12
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Quality Control for Clinical Chemistry" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.13. Quality Control for Immunohematology.

Those clinical laboratories which provide for the collection, processing or storage of human blood and its components shall provide methods for the selection of blood and component donors as well as for the collection, storage, processing and transfusion of blood and its components, and shall ensure that the blood and component donation will not be detrimental to the donor and also protect, as far as possible, the recipient of the human blood or any of its components from infectious disease known to be transmissible by blood. The methods used shall conform to the following:

(a) **Selection of donor:**

1. On the day of donation, the donor shall be evaluated in order to protect the donor and the recipient of the donation. At a minimum, the following shall be used in the evaluation of the donor and records shall be retained.

2. The minimum age for donation is seventeen (17) years; the maximum age for a donor is left to the discretion of the director of the facility providing the donor is in good health.

3. Minimum weight for routine donation shall not be less than 110 lbs. (50 kg) with a maximum of 525 ml. of blood removed per donation; individuals weighing less than 110 lb. (50 kg) may donate relative to the volume collected; in this event, the volume of anticoagulant must be considered. Any recent unexplained weight loss (e.g., more than 4.5 gk. or 10 lbs) should be evaluated by the donor's physician.

4. The volume of donation shall not exceed 545 ml in an eight week period; donation of whole blood must be deferred for at least 48 hours after apheresis.

5. The systolic blood pressure shall be no higher than 180mm of mercury, and the diastolic blood pressure must be no higher than 90 mm of mercury.

6. Pulse rate shall be between 50 and 100 beats per minute. Prospective donors with pathogenic cardiac irregularities must be deferred.

7. Donor hemogoblin or hematocrit must be determined prior to donation by a method acceptable to the Department; donors with a hemoglobin less than 12,5g/dL or a hematocrit less than 38% must not be considered for donation.

8. Prospective donors with chronic or acute illness must be evaluated by a physician prior to donation.

9. Routine donation must be deferred for six months after the conclusion of a pregnancy.

10. Prospective donors on therapeutic drugs must be evaluated by a physician prior to donation to protect the donor and the recipient.

11. The donor temperature (oral) shall not exceed 37.5 degrees C. (99.6 degrees F.).

(b) **Donor deferral:**

1. Abnormal behavior: a prospective donor shall not appear to be under the influence of alcohol or any illegal substance.

2. The site of venipuncture shall be free of lesions; evidence of drug abuse shall indefinitely exclude the potential donor. At a minimum, both arms shall be inspected for parenteral drug use.

3. A history of syphilis or gonorrhea shall exclude the potential donor for a period of not less than six months after treatment of the disease.

4. Potential donors who have received blood, blood components, derivatives, or other human tissue known to be a possible source of blood borne pathogens shall be excluded as donors for a period of not less than 12 months.

5. Potential donors who have taken medication known to alter platelet function within the previous three days, shall be evaluated as to the impact on the patient who is to receive the platelets from this donor and that such donor is to be the sole source of the platelets.

6. Immunizations and vaccinations: Donors shall be evaluated for the impact of the immunizations and vaccinations on the donation in accordance with general accepted standards of practice. At a minimum the following actions shall be taken:

   (i) Potential donors who have received toxoids and killed viral, bacterial, and rickettsial immunizations and/or vaccinations may be considered as a donor if symptom-free and afebrile.

   (ii) Potential donors who received human diploid cell rabies shots may be considered if symptom-free and afebrile, unless the vaccine was given following an animal bite; the exclusion period for this event shall be no less than one year.

   (iii) Potential donors shall be deferred after receiving the following vaccinations:

      (I) Live attenuated viruses such as measles, rubella(a), mumps (oral), or yellow fever shall be deferred for a period of not less than two weeks.

      (II) German measles (rubella) shall be deferred for a period of not less than four weeks.

      (III) Hepatitis B Immune Globulin (HBIG) shall be deferred for a period of not less than twelve months.

7. Infectious diseases requiring indefinite deferral:

   (i) Those potential donors with a history of hepatitis B after the age of eleven, or those who have been confirmed positive for hepatitis B surface antigen (HBsAg) or those who have had a repeatedly reactive test for antibodies to hepatitis B core (anti-HCc) on more than one occurrence.

   (ii) Those potential donors with a present or past clinical history of infection with hepatitis C virus (HCV), human T-cell lymphatic virus (HTLV) or human immunodeficiency virus (HIV);

   (iii) Those potential donors (male) who have had sex with another male since 1977;

   (iv) Those potential donors who have had sex for money;

   (v) Those potential donors who were born or emigrated from a country where heterosexual activity is thought to play a major role in the transmission of HIV-2 infection.

8. Deferral of potential donors having had contact with potential viral pathogens, application of a tattoo, mucus membrane exposure to blood, exposure to blood or other body fluid through non-sterile skin penetration, non-casual contact with another person positive for hepatitis B surface antigen (HGsAg) or HIV, or being incarcerated in a correctional institution for more than 72 hours, shall be not less than twelve months.

9. Malaria:

   (i) Potential donors diagnosed as having malaria must be excluded for a period of not less than 3 years after becoming asymptomatic;

   (ii) A potential donor coming from a country considered endemic for malaria must be excluded for a period of not less than 3 years;

   (iii) Potential donors who are permanent residents of a country in which malaria is not considered endemic, but who has traveled to a malaria endemic country must be excluded for a period of not less than 12 months, and they must be asymptomatic at the time of donation;

   (iv) Malaria restrictions may not apply, if the donor is only donating plasma and the red cells are not used for transfusion purposes.

10. Other protozoan diseases: Potential donors with a history of Babesios is or Chagas' disease shall be deferred indefinitely.

(c) **Donor Information.** Potential donors must be informed and sign a consent form. This information/form must contain, at least, information relative to the potential danger of donation, the significance of blood-borne pathogens, and post-phlebotomy care. The donor must be given the opportunity to confidentially request that his/ her donation not be used for transfusion. A physician associated with the collecting facility must establish a means to notify donors of any significant abnormality detected during predonation evaluation or laboratory test results.

(d) **Autologous donor blood.** If a donation is only for autologous purposes, the donor requirements may be reduced, however, no donation shall be collected for an individual with a systemic infection. The unit must be labeled "autologous use only". Autologous units must be stored under the same requirements as banked blood. However, the autologous units must be segregated from the regular banked blood and blood components. The facility must be licensed by the FDA for the collection and storage of autologous donations.

1. The facility must have policies and procedures for the selection of donors, the collection, processing (testing), storage and disposition of autologous donations.

2. The ABO group and Rh type on these units to be transfused must be determined.

3. Test for HBsAg, HIV-1, anti-HIV-1, anti-HIV-2, anti-HCV, anti-Hbc and a serological test for syphilis must be performed by the collecting facility prior to being transfused in another facility. The unit must be labeled positive for any positive test results.

4. The transfusing facility and the physician must be informed of any abnormal test results. Prior to autotranfusion, the ABO group and Rh type of the donor and recipient must be confirmed.

5. Autologous units must be labe led "autologous donor" and "for autologous use only".

(e) **Therapeutic donations:**

1. Therapeutic bleeding, to include hemapheresis, can only be performed with the written approval of the patient's physician and must be approved by the director of the laboratory.

2. There shall be written policies and procedures for performing the phlebotomy.

3. Records must be retained to document patient identification, diagnosis, and type of therapeutic procedure performed, extracorporeal blood volume, nature and volume of component removed, quality control of measuring device, any occurrence of adverse reactions to medication, disposition of the blood, and the unit shall be labeled "not for transfusion".

(f) **Reagent quality control.** All reagents must conform to FDA regulations and manufacturer's instructions must be followed.

1. ABO antisera must be quality controlled with a positive control each day of use.

2. Rh antisera and reagent cells must be quality controlled with a negative control each day of use; the negative control may be deleted if indicated by the manufacturer.

3. Other antisera must be quality controlled with a positive and negative control each day of use.

4. Anti human globulin sera must be quality controlled with a positive and negative control each day of use.

5. Antibody screening cells must be quality controlled with a positive control each day of use.

6. Each bottle of reagents used in testing must be evaluated in the quality control program on the day of use.

(g) **Transfusion services.** It is the responsibility of the laboratory director to assure that the needs of the physicians responsible for the diagnosis, management, and treatment of patients are met in reference to blood, blood components, blood products and blood bank testing services.

(h) **Preparation of blood components.** The process of component preparation must be sterile and a closed system is preferred.

1. If a closed system is not employed or the seal is broken, components stored between 1- 6° C shall have an expiration date of 24 hours.

2. All components must be traceable through identification numbers and lot numbers.

3. For red blood cells, the unit must contain the type of anticoagulant/ preservative used in the collection.

   (i) Red blood cells and deglycerolized red cells designated for freezing, must be frozen within six days of collection.

   (ii) Rejuvenated red blood cells: following rejuvenation, the cells may be washed and transfused within 24 hours or deglycerolized and frozen; the label on the unit of blood after rejuvenation must indicate the rejuvenating solutions.

   (iii) Irradiated red blood cells: for red blood cells which have received at least 500 cGy irradiation, the dose shall be a minimum of 2,500 cGy targeted to the midpoint of the canister; if free-standing irradiation is used, or to the center midplane of an irradiation field if a respiratory instrument is used; the method used for irradiation must be monitored at least annually to verify the delivered cGy.

4. Plasma components. Fresh frozen plasma - removed from a single donor must be stored at -18° C; if collected in CPD, CPD.2, OR CPDA-1, the plasma must be frozen within 8 hours of collection; if collected in ACD, the plasma must be frozen within 6 hours of collection. The freezing process must protect the plasma from chemical alteration.

   (i) Cryoprecipated antihemophilic factor (AHF) must be thawed at 1-6° C, separated from the plasma and stored frozen within one hour; there must be a method to monitor the amount of AHF and fibrinogen harvested. For platelets and platelet pheresis, a method to determine the concentration of platelets must be established and followed. When leukocyte reduction is a consideration, there shall be a method to determine the leukocyte contamination.

   (ii) For granulocyte pheresis, a method shall be established and followed to monitor the concentration of the component.

(iii) When any blood components are mixed/pooled, any plasma alloantibodies must be compatible with red cell antigens.

(i) **Testing of donor blood.** Prior to transfusion, the testing laboratory must perform, at a minimum, the following tests on donor blood:

1. ABO group must be performed by testing the red cells with anti-A and anti-B, and by testing the serum or plasma for expected antibodies to A1 and B red blood cells.

2. Rh type must be determined with anti-D; if the anti-D is negative, a test for weak D must be performed; both tests must be negative in order for the unit to be labeled D negative; the donor's previous record must be checked relative to ABO and Rh, and any discrepancy must be resolved.

3. Testing for unexpected red cell antibodies: serum or plasma from donors with a history of transfusion or pregnancy must be tested for the presence of clinically significant antibodies; if any such antibody(s) is detected, it must be identified, if the blood is to be transfused, and the blood and its components labeled with the identity of the antibody(s).

4. Testing to prevent disease transmission: All blood for transfusion must be tested for HBsAg, anti-HBC, anti-HTLV, HIV-1-Ag, anti-HIV-1, anti-HIV-2, anti-HCV, and with a serological test for syphilis; blood should not be transfused prior to completion of testing; in the event of prior transfusion, follow up investigation must be documented and the recipient's physician must be notified if the unit was found to be positive for any or all of those markers.

(j) **Blood labeling.** The label on a unit of blood or blood component must identify the original unit and any component, or component modification; the label must be clear, eye-readable, and may be machine readable; handwritten labels must be legible and in permanent ink; prior to labeling, a review to reveal units not to be issued shall be completed; the labeling process must include a second check to determine if an error has occurred in the labeling; this check must verify ABO, expiration date, and other appropriate labels on the unit as well as components. An appropriate label must be affixed, should modification be made to the component.

1. Unit identification. A unique identifier must be assigned to each unit by the collection facility; such identification may not be removed or altered by subsequent facilities; other facilities may affix another unique identifier which must identify the facility; no more than two unit identifications may appear on the unit at a given time.

2. Labeling at collection or preparation. At the time of collection for whole blood, and at the time of preparation for components, the unit must be labeled as to whether it is whole blood, a component, or an intended component, unique identification, type

of anticoagulant (not required for frozen, deglycerolized, rejuvenated, or washed blood cells); for platelets, low volume red blood cells, fresh frozen plasma, pooled components, or components prepared by apheresis, the approximate volume must appear on the container, sedimenting agent (if any), and the identification of any facility collecting or modifying the blood component.

3. Labeling prior to use. The final container label must indicate at least the following information:

   (i) Temperature of storage, expiration date/time, if appropriate, identification of the facility preparing the final component, ABO group, Rh type and interpretation of unexpected antibody test, when positive, and instructions for the transfusionist, at a minimum; to properly identify intended recipient, the statement "This product may transmit infectious agents. Caution: Federal law prohibits dispensing without a prescription."

   (ii) The type of donor: i.e., volunteer, paid or autologous.

   (iii) Name of anticoagulant, except for components, prepared by hemapheresis, and type of cells, i.e., frozen, deglycerolized, rejuvenated or washed red cells.

4. Irradiated blood and components must be labeled as such, along with the name of the facility performing the irradiation.

5. CMV negative red blood cells or cellular components to be issued to a CMV negative recipient must be labeled CMV-negative.

6. Labeling for pooled components: In addition to the labeling requirements under "labeling at collection or preparation" and "prior to use", the label for pooled components must contain the following: name of pooled component, final volume of pooled component, name of facility preparing the pooled component, and unique identification of pooled component. The following information must appear either on the label or on the attached tag:

   (i) Number of units in the pool.

   (ii) ABO group and Rh type in the pool (-Rh is not required for cryoprecipitate).

   (iii) The record must contain the unique identification for each unit in the pool as well as the collecting facility.

7. Labeling of blood bags must meet FDA regulations (21 CFR 606 Subpart G).

(k) **Storage.** Refrigerators in which blood and blood components are stored must provide a uniform temperature. Blood and blood components must be stored within an acceptable temperature range.

1. Refrigerators, freezers, incubators, and other storage areas must have a continuously monitored record of the temperature; in those areas not continuously monitored, the temperature must be monitored and documented each four hours of storage.

2. Refrigerators and freezers used for the storage of blood and blood components must be equipped with an audible alarm, set to activate at a temperature to allow proper action to be taken before the blood and components reach unacceptable temperatures.

3. The alarm system used with liquid nitrogen storage must be set in such a manner as to alert personnel of an unsafe level of liquid nitrogen.

4. Blood and red blood cells must be transported in a manner to ensure a temperature of 1-10°C.

5. Components stored at 20-24° C.

6. Components stored in a frozen state must be transported to assure that they remain in the frozen state.

(l) **Expiration of blood and blood components.** Provided that FDA approved collection methods, solutions, labeling practices, storage, transportation and equipment are used, the expiration date that appears on the label must be followed under ordinary situations. In order to consider this the expiration date, the closed system under which the unit was collected must not have been compromised; dating periods must follow FDA regulations (21 CFR 610.5B).

(m) **Apheresis.** At a minimum, the following policies and procedures must be available and followed when blood or a blood component is to be returned to the donor in a timely manner to assure that only the donor's blood or blood component is re infused to the donor:

1. Only 0.9% USE injectable sodium chloride may be mixed with the blood as a diluent.

2. Donor must provide an informed consent.

3. A licensed physician must be responsible for the apheresis procedure and must assure donor care.

4. Only sterile, pyrogen-free, non-toxic containers and additives which are compatible with the contents may be employed (those approved by the FDA).

5. For apheresis performed for the purpose of transfusion (i.e., platelet, AHF, granulocytes), there must be policies and procedures to evaluate the recovery with the recipient's needs considered; those products not meeting the established criteria must not be transfused without additional evaluation.

6. The procedures employed must assure the safe reinfusion of blood and avoid possible air embolism.

7. Any adverse reactions must be documented and medical advice must be rendered.

(n) **Plasmapheresis.** The donor criteria for an occasional (not to exceed one donation in a four-week period) donation shall be the same as those for a whole blood donor.

1. When plasmapheresis occurs more frequently than once every four weeks, FDA regulations 21 CFR 600- 660 must be followed; for those donations not following this regulation, the donor must have a physical on the day of donation and a physician must request the donation and take responsibility for any undesirable outcome.

2. Cells shall be returned to the donor before collecting a second unit or within 2 hours of the initial phlebotomy; no more than 500 ml. of whole blood shall be removed at one time, or 1000 ml. for transfusion (or within 24 hours), unless, the donor's weight exceeds 176 lbs., in which case the amount shall be 600 ml. or 1200 ml. respectively.

3. If the pheresis is performed using an automated instrument, the amount of plasma collected shall not exceed the amount approved by the FDA for the instrument in use.

(o) **Compatibility Testing.** Requests for transfusion and samples from the recipient must contain sufficient information for positive identification of the recipient; the facility must establish policies to determine minimum criteria for recipient identification; these policies and procedures must contain provisions for emergency situations; the minimum acceptable information must be the patient's name (first and last) and an identification number, if not addressed in the emergency policy; any discrepancy must be resolved prior to testing. The facility must do the following as appropriate:

1. Recipient specimen labeling policies and procedures must be established by the facility. These policies and procedures must provide a method of positive recipient identification on the specimen, a unique identification between the recipient, the specimen(s), and the blood or components to be prepared for the patient, assure that the specimen is labeled at the time of collection in the presence of the recipient, and assure a method to identify and document the specific identity of the individual collecting the specimen. Should there by any discrepancy in the specific identification system, it must be resolved prior to testing.

2. The transfusion service must confirm the ABO group of all whole blood and red blood cells as well as the Rh type using a sample obtained from the attached segment. Any discrepancy in group and/or type must be reported to the collecting facility and the unit must be quarantined until notification from the collecting agency. This verification must be completed prior to release for transfusion. A label must be affixed to the unit indicating group and type confirmation.

3. Each blood specimen consisting of one or more tubes to be used in testing for the transfusion of whole blood and/or red blood cells must be tested for ABO group and Rh type. A screen for unexpected antibodies to red blood cell antigens must be performed. If the transfusion is to take place more than three days in the future, the specimen must be recollected and re-screened for antibodies to red blood cell antigens if:

   (i) The patient has been transfused in the preceding three months with blood or components containing red blood cells;

   (ii) The patient has been pregnant in the preceding three months or;

   (iii) The patient history is not certain or unavailable.

4. ABO group must be determined using the red cells with anti-A and anti-B reagents. The serum or plasma must be tested using known A1 and B cells to determine the presence of expected antibodies to A1 and B cells. Any discrepancy must be resolved.

5. Rh typing must be determined using anti-D reagents. A control system must be employed, if indicated by the manufacturer of the anti-D reagent.

6. Screening for unexpected antibodies in the recipient's specimen must be conducted. This screen must be capable of detecting clinically significant antibodies and must include a 37º that are not pooled. With documentation of equivalent sensitivity, an alternative screening method may be employed. A control system using red blood cells sensitized with IgG must be applied to each test interpreted as negative. When a licensed test system is employed that does not allow the addition of IgG-sensitized cells, controls shall be used as recommended by the manufacturer.

7. Prior to release for transfusion of whole blood or red blood cells, the transfusion history or the patient must be reviewed in order to detect a possible error.

8. Except in cases of emergency, a sample of the recipient's serum or plasma must be crossmatched against a sample from the donor cells from a specimen attached to the unit of whole blood or red blood cells. The crossmatch must have the ability to demonstrate ABO incompatibility and clinically significant antibodies to red blood cell antigens and must include an antiglobulin test. If no clinically significant antibodies to red blood cell antigens are detected and the patient's history does not

indicate a clinically significant antibody, then only serologic testing to detect ABO incompatibility is required.

9. A computer system that has been validated by the facility to prevent the release of ABO incompatible blood and blood components, may be used in place of a serologic crossmatch, provided that the system contains donor information to include the donor number, the component name, ABO group, and Rh type of the component and the interpretation of the ABO confirmatory test. The system must contain the recipient's ABO group and Rh type.

   (i) There must be a method to verify correct entry of data prior to release of blood or components. The system must alert the user to discrepancies between the donor unit labeling and the blood group confirmatory test interpretation and to ABO incompatibilities between the recipient and the donor unit.

   (ii) There must be documentation of initial training for those individuals using the system, and of annual training thereafter. After initial training, annual training may be limited to upgrades and/or changes in the computerized system. The facility must maintain a back-up program to implement in the event of failure or malfunction of the computerized system to assure uninterrupted service.

(q) **Selection of blood and blood components for transfusion:**

1. Recipients should receive ABO group specific whole blood of ABO group compatible red blood cells.

2. Whole blood and red blood cells must lack the red blood cell antigen when the recipient demonstrates the presence of a clinically significant, unexpected antibody(s) to a specific red blood cell antigen(s). In addition, the donor unit must lack the red blood cell antigen(s) when the recipient's history indicates the presence of a clinically significant antibody(s) directed toward a specific antigen.

3. Fresh frozen plasma should be ABO compatible, whenever possible.

4. The donor plasma in platelet preparations must be ABO compatible when the recipient is an infant. Red blood cells and granulocytes shall be ABO compatible with the recipient's plasma.

5. Each facility must have written and utilized policies and procedures for the release of blood and blood components for transfusion purposes.

6. When a recipient has received a volume of blood approximating his/her total blood volume in a 24-hour period, the compatibility testing procedure may be

abbreviated. This is at the discretion of the director of the laboratory. There must be written policies and procedures for the laboratory personnel to follow.

7. Where recipients are under four months of age, the ABO group, using anti-A, anti-B, and the Rh type, using anti-D must be performed on the infant. For the antibody screen, serum or plasma from the infant or infant's mother may be used. If the initial red blood cell antibody screen is negative, it is not required to crossmatch donor red blood cells for the initial or subsequent transfusions for the duration of that hospitalization. If the initial antibody screen is positive for clinically significant red blood cell antibodies, the infant must be transfused with red blood cells that are negative for the corresponding antigen or are compatible by antiglobulin crossmatch.

8. In the case of massive or exchange transfusion, only blood drawn to be hemoglobin S negative should be transfused.

(q) **Issuance and transfusion of blood and blood components.** At the time of release for transfusion, the donor unit must be labeled as specified in the facility's policy. The information must include, at a minimum, the recipient's name (first and last), identification number, donor unit number, and compatibility test interpretation, if performed. There must be a mechanism to identify the intended recipient and requested blood component at the time of issue. The transfusion record for each unit of blood, blood component or pooled component must contain the intended recipient's name, identification number, ABO group, and if required, the Rh type, the interpretation of the compatibility tests, if performed, and the date of transfusion. Following the transfusion, the record must be made part of the patient's medical record. A sealed specimen from the recipient and the donor must be maintained at 1- 6ºC for a period of seven days post transfusion.

1. Blood must be inspected immediately before issuance. If it appears abnormal, the unit must not be transfused.

2. Blood that has been returned to the blood bank must not be reissued unless the container closure has not been disturbed, and blood has not been allowed to warm above place and followed to assure that temperature ranges are not exceeded. The record must indicate that the blood has been reissued, and that it has been inspected prior to being reissued.

3. At least one sealed segment of integral donor tubing must remain attached to the container. Those segments removed may be reattached, if the identification number on them are identical to the segment(s) that remain attached.

4. When the requesting physician indicated with a signed statement, that a delay in transfusion could be detrimental to the patient, the blood may be released prior to the completion of the tests that are performed to reduce the transmission of infectious diseases as well as the compatibility testing. In that event, recipients

whose ABO group can be determined (excluding the recipients' history) may receive ABO group specific or ABO group compatible red blood cells or whole blood. The unit must be labeled in a conspicuous manner to indicate that the compatibility testing was not performed at the time of release. Standard compatibility tests should be completed promptly on those units signed out as "uncrossmatched". All requirements relative to the labeling of specimens to assure positive identification must not be ignored during the collection, release, or the transfusion of blood during an emergency. After completion of required testing, the laboratory must notify the recipient's phys icia n and the laboratory director, if a test result could effect the health and safety of the recipient.

(r) **Transfusion complications.** The facility must establish policies and procedures to assure that any transfusion complication is investigated. These policies and procedures must have a mechanism to detect errors in reporting, and evaluation of suspected complications of transfusion. All such investigations must be evaluated with a written interpretation by the laboratory director. The collection facility must be notified, if the complication appears to be attributed to the donor or the processing of the unit. Fatal transfusion reactions must be reported to the FDA, the collecting facility, and the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.13
Authority: O.C.G.A. § 31-22-1*et seq*.
History. Original Rule entitled "Quality Control for Immunohematology" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.14. Quality Control for Hematology.

Instruments used in hematological examination of specimens shall be recalibrated, retested or reinspected, as appropriate, each day of use. Each procedure shall be recalibrated or rechecked each shift of use with standards or controls covering the entire range of expected values, unless required more frequently by the manufacturer or federal laboratory regulations. Tests such as the hematocrit and one-stage prothrombin time test shall be run in duplicate except as specified in published guidelines. Standard deviation, coefficient of variation, or other statistical estimates of precision shall be determined by the laboratory. All control materials used to satisfy the control requirement must have documented established limits.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.14
Authority: O.C.G.A. § 31-22-1*et seq*.
History. Original Rule entitled "Quality Control for Hematology" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.15. Quality Control for Exfoliative Cytology; Histopathology; and oral Pathology.

(1) **Exfoliative Cytology.**

(a) The laboratory must establish and document an annual evaluation of the number of cytology cases examined, the number of specimens processed by type, the number of cases reported by diagnosis, including the number of cases reported as unsatisfactory for diagnosis, the number of gynecologic cases where cytology and available histology are discrepant, and the number of cases where histology results were unavailable for comparison. The evaluation must also include the number of gynecologic cases where the rescreen of a negative or normal test results in a reclassification to a premalignant or malignant diagnosis.

(b) The laboratory must evaluate the case reviews of each person examining slides against the overall statistical values, document the reasons for deviations, and corrective actions taken, if needed.

(c) The laboratory must develop and implement procedures to detect inadequately prepared slides, assuring no diagnosis is reported on such cases. Such procedures must include a plan for promptly notifying referring physicians of inadequately prepared slides. The report must clearly distinguish specimens, or smears, or both, that are unsatisfactory for diagnosis interpretation. Documentation of unsatisfactory specimens and notifications must be retained by the laboratory for a minimum of five years.

(d) The laboratory director or supervisor qualified in cytology or cytotechnology shall rescreen for proper staining and correct interpretation at least a ten percent random sample of gynecological smears which have been interpreted to be in one of the benign categories by personnel not processing director or supervisor qualifications. The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information. Records of initial examination and rescreening must be available. Rescreening must be performed prior to reporting.

(e) No laboratory shall assign or permit an individual engaged in the evaluation of cytology preparations by non-automated microscopic technique to examine more than one hundred (one patient per slide, gynecologic or non-gynecologic, or both) slides in a twenty-four hour period. This limit represents an absolute maximum number of slides in any twenty-four hour period, unless slide preparations are made using automated, semiautomated, or other liquid-based slide preparatory techniques resulting in cell dispersion over one-half or less of the slide area, in which case the slide counts as one-half slide, if examined by nonautomated microscopic technique. The maximum number of one hundred slides shall be examined in not less than an eight-hour period. Recognizing individual differences in abilities, the laboratory must establish the maximum number of slides (not to exceed the 100 slide limit) each individual may screen in a twenty-four hour period, and records must be available to document that each individual's workload

limit is reassessed at least every six months and adjusted, when necessary. For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an eight hour workday basis, a period of eight hours must be used to prorate the number of slides that may be examined by using the following formula:

number of hours examining slides X 100 / 8

(f) Records shall be maintained by the laboratory of the total number of slides examined by cytotechnologist during each twenty-four and eight hour period. It shall be the responsibility of each laboratory to maintain records of the number of slides read on and off the premises of the laboratory by cytotechnologists when such slides are assigned by that laboratory. All slides must be read on the premises of the licensed laboratory unless referred to another licensed laboratory.

(g) All gynecological smears interpreted to be in the "suspicious" or "positive" categories by cytotechnologists shall be confirmed by the laboratory director or supervisor, who is qualified in Exfoliative Cytology as specified in Rule 111-8-10-.06(1)(a)2. or (3)(b), and who shall personally sign all such suspicious or positive reports. All nongynecological cytological preparations, positive and negative, shall be reviewed by such a director or supervisor qualified in cytology. All slides for exfoliative cytology must be retained as long as required by applicable federal law and regulations, but not less than five years from the date of examination.

(h) The laboratory must review, for each patient with premalignant or malignant gynecologic cytology results, all gynecologic cytology specimens received within the previous five years, if available. If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report.

(2) **Histopathology and Oral Pathology.** Special stains on tissue sections must be checked for intended reactivity by use of positive preparations, and results of reactions must be documented. Stained slides and tissue blocks shall be retained as long as required by applicable federal law and regulations, but not less than ten years for slides or two years for tissue blocks. Remnants of tissue specimens shall be retained in a fixative solution until those portions submitted for microscopy have been examined and a diagnosis made by a pathologist.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.15
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Quality Control for Exfoliative Cytology; Histopathology; and Oral Pathology" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.16. Quality Control for Tissue Banks.

Tissue banks which procure, store, or process human or animal tissue designed to be used for medical purposes in human beings shall conform to the procurement, storage and processing requirements listed in this section. The tissue bank must maintain donor and patient recipient records and communications. These records must be retained for not less than seven years after the distribution of the tissue material. These records shall be evaluated and reviewed by the director to ensure the suitability of the donated tissue for its intended use. Records must include the following:

(a) Each step in collection, preparation, testing, storage and distribution of the tissue must be documented concurrent with the performance of each step.

(b) Records must be legible and indelible and must include dates of testing, testing results, interpretations, assigned expiration date, if applicable, and the identity of the person performing the work.

(c) Donor identification and documentation of the pathological and microbiological evaluation of the donor shall be recorded.

(d) Each tissue and any component must be given a generic designation and a unique identification number which shall be used as the lot number throughout the collection, processing, distribution and utilization processes.

(e) All records concerning donor history, tissue processing and any other details deemed necessary (within the bounds of medical-legal and donor confidentiality) shall be available to authorized personnel upon request.

1. An adverse reaction file must be maintained.

2. An accurate inventory of all tissues (unprocessed, processed, and distributed) must be maintained.

3. There must be verification of step by step procedures under which tissue is procured, processed, tested and stored. Final disposition of the transplanted tissue must be recorded.

(f) Air drains, surfaces and water faucets shall include periodic sampling to ensure the tissue bank environment is maintained.

(g) The tissue bank shall have a system to prevent unauthorized entry either by physical configuration and/or an adequate security system.

(h) Procedures for recruiting donors shall be established and approved by appropriate officials.

(i) Permission to obtain tissues from living or non-living donors shall be documented through informed consent. Tissue banks must comply with Georgia Rules and Regulations for Anatomical Gifts, Chapter 111-8-5, as may be applicable.

(j) Tissues shall be processed by procedures which are appropriate for the type of tissue and the manner in which it is retrieved. Processing shall not change the physical properties of the tissues.

(k) Tissue preservation and types of storage containers shall ensure that the biological and biochemical properties are retained.

(l) Tissues shall be sent only to licensed and approved facilities that have accepted responsibility for proper handling and use. There shall be an agreement for notifications of the tissue bank if tissues are received in defective packaging, have been removed from sterile containers but not used, or have been lost. The following criteria for distribution must be met:

1. Transportation methods shall maintain proper environmental conditions during transit.

2. Excess product remaining after use shall be discarded unless the tissue bank retains control of the product and the product remains sterile.

3. Upon receipt of tissue, a record shall be made of its description, date received, and the tissue supplier and, if applicable, expiration dates.

4. Tissue shall not be dispensed without a documented order from the physician or other authorized health professional, and records of the person to whom this tissue was dispensed, and the integrity of the container and label.

(m) Records must be retained indefinitely to permit tracing of any tissue from the donor to all recipients or other final dispositions. Records must include the following:

1. Receipt, storage, and transportation information;

2. Identity of the source facility;

3. Type of tissue and the numeric or alphanumeric identification;

4. Name(s) of the recipient(s);

5. Personnel who prepared the tissue for dispensing;

6. Personnel who dispensed the tissue;

7. Personnel who accepted the tissue for use;

8. Dates of dispensing and transportation;

9. Identification of the ordering physician or other authorized health professional;

(n) Storage temperature records must be retained for five years.

(o) Container labels must include:

1. Name of product;
2. Name and address of tissue bank; and
3. Tissue identification number.

(p) Package labels must include:

1. Product name;
2. Name and address of the tissue bank;
3. Unique tissue identification number;
4. Expiration date of contents, if applicable;
5. Method of sterilization, if applicable;
6. Preservation and concentration or "no preservative" if preservative presents a safety factor;
7. Number of containers, if applicable;
8. Amount of product by weight;
9. Storage and handling instructions, including recommended storage temperature and special handling instructions relative to the product;
10. Sensitizing substances known to be present;
11. Antibiotics added during processing: type and calculated amount;
12. Product source, if a factor in safety of administration; and
13. A statement that the tissue donor was tested for HIV antibody and Hepatitis B surface antigen (HBsAg) using FDA approved tests and found to be nonreactive.

(q) Final container shall be packaged in a manner that ensures the integrity and sterility of the contents.

(r) A product insert must accompany all tissues.

(s) There shall be written procedures for tissue recall and notification of recipient centers of possible tissue contamination, errors detected in the processing, preparation or distribution process or other factors which may render the tissue unsuitable for its intended application.

(t) Standard nomenclature and units of measure shall be used to describe tissues and the processing they have undergone.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.16
Authority: O.C.G.A. § 31-22-1*et seq*.
History. Original Rule entitled "Quality Control for Tissue Banks" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.17. Quality Control for Sperm Banks/Embryology and Assisted Reproductive Technology (ART).

(1) **Sperm Banks.** Facilities collecting semen specimens shall comply with the following:

(a) Sperm banks shall be staffed with personnel trained in the most current methods of cryobanking and who meet the personnel requirements of these rules.

(b) Records must contain a donor release and a complete history.

(c) Donor semen shall have specific identification codes for use during the freezing and storage processes. Codes shall in no way be linked to the donor or the recipient.

(d) Donor history shall include the following:

1. Interview;

2. Examination including personal, physical, sexual and genetic histories;

3. Examination of semen to ensure viability and motility, freedom from infection and/or foreign cells and freezing survival capabilities.

(e) Semen specimens shall be collected at the sperm bank and processing shall be initiated within one hour of collection. Test results and measurements shall be initiated within one hour of collection. Test results and measurements shall be documented concurrent with evaluation.

(f) An appropriate method of cryopreservation shall be chosen which ensures maximum viability and freedom from contamination. Documentation shall be available which validates the method chosen.

(g) Storage and handling instructions shall be made available to the requesting physician. Such instructions shall include handling and disposition of unused specimen. Donor semen shall not be refrozen or redistributed.

(2) **Assisted Reproductive Technology (ART).** Facilities providing ART shall comply with the following:

(a) The laboratory director must meet requirements at Rule 111-8-10-.06(2)(b) of these regulations; in addition, the director must have two years of documented experience in a laboratory performing ART procedures, have documented training of at least six months in an embryo laboratory which includes performing, at a minimum, each ART laboratory procedure 60 times. Included in the responsibilities of the director of the laboratory performing these procedures shall be:

1. To establish and monitor a program to ensure that aseptic conditions are maintained in the laboratory;

2. To assure that procedure manuals meet requirements at Rule 111-8-10-.09(2)(h);

3. Establish and monitor a quality assurance program that meets requirements at Rule 111-8-10-.06(3)(a), as applicable.

(b) An ART supervisor shall meet the requirements at Rule 111-8-10-.06(3)(b)1., 2., 3., or .06(4)(b)1., or 3., and have documented training which includes performing, at a minimum, each ART laboratory procedure sixty (60) times.

1. An ART supervisor must be accessible to laboratory personnel when ART procedures are performed, either on-site or via electronic means; and

2. An ART supervisor may perform director responsibilities as authorized, in writing, by the director.

(c) A reproductive biologist in an ART must meet the requirements for director, supervisor, or meet the following:

1. Requirements at Rule 111-8-10-.06(4)(b)1., or 3.;

2. Have documented ART training for laboratory procedures; and

3. Training must include the performance of ART procedures at least 30 times under director and constant supervision.

(d) In addition to meeting all safety requirements at Rule 111-8-10-.08, an ART laboratory must also:

1. Be located in a secure place with access limited to authorized personnel;

2. Conduct laboratory activities under aseptic conditions; and

3. Use no radioisotopes in the laboratory where ART procedures are performed.

(e) In addition to meeting all quality assurance requirements at Rule 111-8-10-.09, an ART laboratory must also:

1. Verify that materials which come in contact with sperm, oocytes, and embryos have been tested and found to be non-toxic to the sperm, oocytes and embryos;

2. Ensure patient confidentiality throughout the testing phase; and

3. Require that an authorized person's request for testing must be written or electronic; and that an oral request must be followed within 24 hours by a written or electronic request.

(f) In addition to meeting all quality control requirements, as applicable, at Rule 111-8-10-.09, an ART laboratory must also:

1. Have documented criteria for assessment of oocyte morphology, maturity, fertilization, and embryo quality;

2. Document the insemination schedule relative to oocyte maturity;

3. Document volume, numbers, and quality of sperm used for insemination of each oocyte;

4. Document disposition of oocytes with an abnormal number of pronuclei; disposition of excess oocytes; and

5. Document critical time periods for various procedures.

(g) In addition to meeting specimen, reporting and records requirements at Rules 111-8-10-.11, .12, and .13, an ART laboratory must also:

1. Keep records for the pre- and post-washing and concentration for insemination, the outcome of insemination and culture, and quality of all embryos at transfer, and the identity of testing personnel;

2. Use a reliable tracking method for cryopreserved specimens;

3. Use permanent labeling of containers; and

4. Assure that records are indelible and legible, retained for two years on-site and for ten years beyond the date of final disposition or disposal of all specimens obtained during each patient's ART cycle.

(h) If the ART laboratory ceases operation, it must make provisions for records to be maintained for the required time frames.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.17
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Quality Control for Sperm Banks/Embryology and Assisted Reproductive Technology (ART)" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.18. Quality Control for Specimen Collection Stations.

(1) A laboratory supervisor or designated supervisory qualified staff must make monthly on-site visits to specimen collection stations.

(2) Collection stations drawing specimens must have a written agreement with a designated person possessing medical emergency treatment skills to be available/on call during all hours of specimen collection.

(3) Procedure manuals for specimen collection stations must include procedures for:

(a) Proper collection of specimen;

(b) Types of specimens collected;

(c) Storage and handling of specimens;

(d) Proper identification and labeling of specimens;

(e) Instructing facilities forwarding specimens to the collection station, including criteria for unsatisfactory specimens; and

(f) Forwarding reports to the appropriate physician when reports are returned to the collection station.

(4) Accession records for specimen collection stations shall indicate the following:

(a) Patient name;

(b) Requesting physician;

(c) Test requested;

(d) Date of specimen collection;

(e) Date of referral to testing laboratory; and

(f) Date results are received back from reference laboratory.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.18
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Quality Control for Specimen Collection Stations" adopted. F. Feb. 20, 2013; eff.

Mar. 12, 2013.

Rule 111-8-10-.19. Quality Control for Cytogenetics.

(1) Each laboratory performing cytogenetics procedures shall engage the services of a sufficient number of testing personnel who meet the requirements as noted in Rule 111-8-10-.06. In addition, the laboratory must document the competency of testing personnel in the areas of collection, handling, preparation and processing of various specimens, appropriate culture techniques for specimens submitted, proper techniques for setting up cell cultures and harvesting specimens, proper techniques of chromosome banding and staining, maintenance and use of microscopes, photographic and computer-generated imaging techniques and equipment, chromosome analysis including knowledge of normal and abnormal morphology, general laboratory skills, quality control, and understanding of general principles of genetics.

(2) Each cytogenetics laboratory must comply, at a minimum, with ma nfacturers' instructions except where applicable regulations are more stringent, when using reagents and equipment and must document all quality control activities.

(a) The laboratory must define and follow specific criteria for receiving specimens and for handling unacceptable specimens.

(b) The laboratory must establish and follow a maintenance schedule and must document routine maintenance and function checks on all instruments. Microscopes must have a sufficiently high resolution for examination of slides. The hoods used for processing and handling cultures must be designed to keep contaminants out, checked periodically to ensure that the filters are functioning properly and that the airflow meets specifications and protect employees.

(c) The laboratory must perform an acceptable quality control performance check on routine and fluorescent stains (the method must check the timing that is critical to the staining process). Corrective action must be documented, if staining time has to be adjusted. Reagents (purchased, made in-house or aliquoted) must be properly labeled, and include content and quantity, concentration or titer, storage requirements, date prepared or received, date placed in service and expiration date.

(d) For in-house culture media, an acceptable method of checking the pH, sterility, contamination and ability to support growth must be in place. The sterility of each lot or shipment of commercial media must be checked when received.

(e) The laboratory must establish procedures and follow the appropriate incubation period for cell cultures to achieve active cell division. Incubation time may vary for each diagnostic area. There must be a monitoring system in place to detect power failure which may affect the incubation phase.

(f) The laboratory must define and document chromosome analysis failure rates, maintain records of causes of failures and investigate cultures that failed.

(g) The laboratory must establish (based on standardized methods) the minimum number of cells examined for X and Y chromatin counts, fragile X, complete metaphases or other applicable analysis performed.

(h) Critical limits must be established for appropriate tests and records must identify the appropriate person to be notified if results do not fall within established limits.

(3) The laboratory must maintain records that indicate the media used, reactions observed, number of chromosomes counted for each metaphase spread, quality of banding, and resolution to support the final results and number of karyotypes for each individual. Records must also be maintained of confirmatory testing on all atypical results, of at least two cells karotyped for each use, and two cultures for each specimen type.

(4) The laboratory must establish guidelines, based on appropriate standards for setting time limits on signing out final reports. Preliminary reports must be submitted within a reasonable length of time as established by the laboratory. Laboratory reports must include type of banding used, number of cells counted and analyzed microscopically, number of cells from which photographic or computerized karotypes were prepared, band resolution, preliminary report results, a narrative report of clinical pathology interpretation of the laboratory findings, diagnosis and identification of testing personnel. The current International System of Human Cytogenetic Nomenclature (ISCN) or other standard nomenclature recognized industrywide, must be used correctly in the final report. The results of tests performed must be reviewed and signed out by the director.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.19
Authority: O.C.G.A. § 31-22-1*et seq*.
History. Original Rule entitled "Quality Control for Cytogenetics" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.20. Quality Control for Screening and Monitoring Tests.

(1) Facilities performing only screening and monitoring tests shall establish a training program with written guidelines and must keep documentation of the training of those personnel designated for performance of specific tests.

(2) Quality control procedures for screening and monitoring tests shall be performed for each test, if available. Controls and control frequency shall be according to published guidelines. Only tests approved by the Department may be performed; a list of approved tests shall be available from the Department. Proficiency testing is required for all tests, where such is available and graded.

(3) Results of exempt screening and monitoring tests, including all quality control records, shall be maintained separate from the patient's medical record for two years. The records must include the test date, time, patient's first and last name or unique identifier, test site, control/calibration results, lot numbers of reagents/controls, and identification of testing personnel.

(4) Reports of test results provided to non-physicians shall contain a statement which recommends that the results of the test be reviewed by a physician or that medical advice be obtained.

(5) The results of the tests shall be clearly identified as being performed by a nonlicensed facility and shall be displayed in a manner which will clearly differentiate them from results of a licensed laboratory.

(6) Screening test results which indicate abnormal conditions shall be noted with a recommendation that the abnormal results be confirmed by a definitive laboratory test performed in a licensed laboratory.

(7) Safety instruction using CDC's universal precaution guide lines for handling blood and instructions for packaging, labeling and disposal of potentially infectious waste materials and sharps, must be available to and practiced by the facility personnel.

(8) Each facility, performing whole blood cholesterol, HDL or other approved screening procedures, shall establish a training program with written guidelines and retain documentation of the training of those personnel designated for performing these procedures. The training shall include all areas of the testing process including the use of the instrument.

(a) Prior to performing cholesterol testing, the facility must evaluate the procedure for accuracy and precision. Maintenance and testing for proper operation of any analyzers shall be performed with the frequency specified by the manufacturer.

(b) Two levels of control must be performed at the beginning of each day of testing and one level of control must be performed if testing equipment is moved from site to site.

(c) Maintenance, quality control, current procedure manuals and test participant records shall be available at each test site or with each instrument in use.

(d) The screening facility shall recommend referrals for further cholesterol testing in accordance with the National Cholesterol Education Program (NCEP) published guidelines.

(e) Reports shall show the name, telephone number, street address, city and state of the screening facility/agency. The screening facility/agency shall provide privacy for blood sampling and confidential counseling about test results.

(f) Each screening entity shall have a medical review officer who is licensed to practice medicine in Georgia. This officer may authorize testing.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.20
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Quality Control for Screening and Monitoring Tests" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.21. Quality Control for Histocompatibility.

(1) Mechanical refrigerators and freezers with recording thermometers must have an audible alarm that is monitored 24 hours a day. If liquid nitrogen is used for storage of frozen cells, the level of liquid nitrogen in the cell freezers must be monitored periodically. Sera and reagents must be stored at an acceptable temperature range. Reagents, solutions, culture media, controls, calibrators or other materials must be labeled to indicate identity and when significant, titer, strength or concentration, recommended storage requirements, preparation and expiration date and other pertinent information. Reagents typing area (locally constructed trays) must indicate source, bleeding date, identification number and volume remaining.

(2) The laboratory must have available and follow written policies and procedures regarding specimen collection:

(a) Requisitions must include patient's first and last name or unique identifier, name and address of the authorized person who ordered the test, date and time of specimen collection and source of specimen.

(b) All specimens must be properly identified and easily retrievable. Blood samples must be labeled with the patient's first and last name or unique identifier, date of collection, and must be obtained in a manner which does not compromise aseptic techniques.

(3) The laboratory must maintain a system to ensure reliable specimen identification and document each step in the processing and testing of patient specimens. If "chain of custody" is a requirement, the laboratory must maintain records of the "chain of custody" of the sample, the phlebotomist who collected the sample, documentation to identify each specimen, and a signature to verify information submitted.

(a) Computer assisted analysis and all reports must be reviewed and verified by the supervisor or director. Records may be saved in a computer file if back-up files are maintained to ensure against loss of data.

(b) The laboratory must, at least once a month, give each individual performing tests a characterized specimen as an unknown to verify his or her ability to reproduce results.

(4) Records of the results for each individual must be maintained for a minimum of two (2) years. In addition, the laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another licensed/ certified laboratory in order to validate interlaboratory reproducibility.

(a) The laboratory must maintain records of each result, including preliminary reports, for at least two (2) years. Worksheets must clearly identify the subject whose cells were tested, the typing sera used, date of test and the person performing the test. For each cellserum combination, the results must be recorded in a manner which indicates the approximate percent of cells killed.

(b) Membranes or autoradiography from nucleic acid analysis must be retained as a permanent record.

(c) For marrow transplantation, the donor must give his/her informed consent before blood is taken for typing and before the donor is placed on a list of donors available to be called. Donor records for marrow transplantation must be maintained so that donors can be rapidly retrieved according to HLA type. The report must contain the date of collection, name, street address, city and state of the testing facility, patient's name or unique identifier, date of testing, date of final report, test results, control values and normal ranges where appropriate, interpretation, and signature of the director or his/her designee.

(5) Renal and Bone Marrow Transplantation. The laboratory must have established policies for selecting appropriate patient samples for crossmatching, preparing donor lymphocytes for crossmatching, and reporting crossmatch results; having available results of final crossmatches before an organ or tissue is transplanted, documenting efforts to obtain specimens for all potential transplant recipients at initial typing, for periodic screening, for pre-transplantation crossmatch and following sensitizing events such as transfusion and transplant loss. If transplantation is deferred, a new serum sample must be obtained from the patient at monthly intervals, screened for antibodies and stored in the frozen state for possible use in crossmatch tests. Serum used for crossmatching must be tested undiluted and with one or more dilutions. Crossmatching must use techniques documented to have increased sensitivity in comparison with the basic microlymphocytotoxicity test such as prolonged incubation, washing or augmentation with antiglobulin or flow cytometry. Final crossmatches performed prior to transplantation must utilize a serum sample collected within the past 48 hours before transplant if the recipient has class I lymphocytotoxic antibodies or has had a recent sensitizing event, otherwise, a serum collected within seven days may be used. Donors and recipients must be ABO and Rh typed according to blood bank standards.

(a) The laboratory must HLA type all potential transplant recipients and organ donors, and follow a policy that establishes when antigen redefinition and retyping are required.

(b) The laboratory must have and follow criteria for the preparation of lymphocytes for HLA-A, B and DR typing; select typing reagents which are made in-house or purchased commercially, assignment of HLA antigens and assure that reagents used for typing recipients and donors are adequate to define all major and International Workshops HLAA, B and DR specificities for which reagents are readily available.

(6) Potential transplant sera must be screened for HLA-A, B and DR antibodies with a suitable lymphocyte panel on sera collected, at the time of the recipient's initial HLA typing and thereafter, following sensitizing events and upon request. A suitable cell panel, which contains all the major HLA specificities and common splits for screening patient sera, must be used.

(7) Transfusion and Non-Renal Transplantation. All requirements specified in (5)(a) must be met.

(a) The laboratory must check each typing tray using positive and negative control sera and must use positive controls for specific cell types (i.e., T cells, B cells and monocytes) when applicable. Controls must be used to monitor the test components and each phase of the test system to ensure an acceptable performance for each compatibility test, i.e., mixed lymphocyte cultures, homozygous typing cells for DNA analysis.

(b) Compatibility tests for cellularly-defined antigens must use techniques such as the mixed lymphocyte culture test, or homozygous typing cells for DNA analysis. If the laboratory uses immunologic reagents such as antibodies or complement to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the methods must be verified with appropriate controls.

(8) Non-Renal Solid Organ Transplantation. The results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior screening, except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provide d by the patient's physician to the laboratory.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.21
Authority: O.C.G.A. § 31-22-1*et seq*.
History. Original Rule entitled "Quality Control for Histocompatibility" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.22. Quality Control for Flow Cytometry.

(1) A standard, consisting of latex beads or other uniform particles, shall be run to insure proper focusing and alignment of all lenses in the path, and for both the existing light source and signal (light scatter, fluorescence, etc.) detectors. The results of optical focusing/ alignment must be recorded each day.

(2) A threshold value for acceptable optical standardization shall be established for all relevant signals for each instrument and the focusing procedure repeated until these values are achieved or surpassed. If a particular threshold value cannot be attained, a written protocol for instituting corrective action must be available and used.

(3) A fluorescent standard, for each fluorochrome to be used, shall be run to insure adequate amplification of the fluorescent signal(s) each day of use and after any maintenance or adjustment of the instrument. This standard may be incorporated in the beads or other particles used for optical standardization or may be a separate bead of fixed cell preparation. If acceptable fluorescence separation cannot be attained, a written protocol instituting corrective action must be available and used.

(4) When performing analyses using two or more fluorochromes simultaneously, an appropriate procedure must be used to compensate for "spill over" into the other fluorescence detectors.

(5) For laser based instruments, the current input (amps) and laser light output (milliwatts), at the normal operating wavelength measured after the laser is peaked and normal operating power set, must be recorded as part of a daily quality control record.

(6) The use time of instruments with mercury fluorescent lamps must be recorded. Lamps must be replaced when the allowable use limit has been reached.

(7) The laboratory must run a positive and negative control each day of patient testing. The negative controls should include normal serum from a healthy individual. The positive control (using appropriate dilutions) should react with cells representing all HLA types (i.e., pulled high PRA sera).

(8) Each laboratory must establish and document its own threshold with multiple normal sera for discriminating positive crossmatches. For significant change in protocol, instrumentation, or software, the characterization of the positive threshold must be repeated.

(9) For internal labeling, the method used to allow fluorochrome labeled antibodies to penetrate the cell membrane must be documented as effective.

(10) Whether analyzed directly or fixed prior to analysis, labeled cells must be analyzed within a time period demonstrated by the laboratory to avoid significant loss of any cell sub-population or total cell numbers. Test samples must be analyzed within the same period, after staining, as the control samples.

(11) If analysis will be based on a population of cells selected by flow cytometry "gating" on size or density parameters, or selected depletion or enrichment techniques, control stains must be run for each test individual to detect the presence of contaminating cells in the selected population (i.e., monocyte contamination of lymphocytes gated by forward angle or forward angle vs. 90 degree light scatter must be detected with a monocyte specific marker antibody). For cell surface labeling, a method must be used to determine the proportion of viable cells in the population of counted cells (i.e., thidium bromide staining, CD45 staining). If this value falls below an established laboratory threshold, an appropriate reanalysis of specific measurements must be done.

(12) Conclusions about abnormal proportions of abnormal cell surface marker shall only be drawn in comparison with local control data obtained with the same instrument, reagents and techniques. Conclusions about leukemia/lymphoma classification shall be based on local or published reference data. Determination of percent positives must take into consideration the results of the negative control reagent.

(13) The specificity of monoclonal antibodies shall be verified by the published and/or manufacturer's documentation and, whenever possible, verified locally through tests with appropriate control cells prepared and tested by the same analysis. The quantities of reagents used for each test sample must be determined by the manufacturers from published data and, whenever possible, should be verified locally by appropriate titration procedures.

(14) Terminology used must be defined and/or must conform to nomenclature recommended/approved by the most recent International Workshop of Differentiation Antigens of Human Leukocytes or other appropriate scientific organizations.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.22
Authority: O.C.G.A. §§ 31-22-1, 31-22-4.
History. Original Rule entitled "Quality Control for Flow Cytometry" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.23. Evaluation.

The Department shall conduct a clinical laboratory performance evaluation (proficiency testing) program with the following requirements:

(a) All clinical laboratories shall enroll and successfully participate in a Department approved proficiency testing program. Point of Care testing areas shall be enrolled or participate in approved proficiency testing programs subscribed to by the responsible laboratory. No proficiency testing agency will be Department-approved unless it meets current requirements found in Title 42 U.S.C. Section 263 a.

(b) In addition, the Department may require the clinical laboratory to analyze test samples submitted or authorized by the Department and to report on the results of such analysis.

(c) Laboratories shall enroll in one or more representative segments of approved proficiency testing programs, if available, based upon the categories, subcategories and/or procedures for which a license is issued, and shall have copies of the results sent to the Department. External proficiency testing is not required for blood, tissue, and/or plasmapheresis donor screening procedures.

(d) Proficiency testing must be conducted in the laboratory being evaluated, by regular employees of that laboratory and in the same manner as patient testing. If a laboratory is found to have intentionally sent proficiency testing samples to another laboratory for analysis prior to receiving results back from the testing agency, it shall have its license revoked for a minimum of one year or a period that is equal to or more stringent than current federal law and regulations and, shall be subject to other appropriate sanctions as provided for in Chapter 111-8-25 of the Georgia Rules and Regulations for General Licensing and Enforcement Requirements; all records of proficiency testing must be retained and available for inspection for a period of not less than two years.

(e) Proficiency testing performance standards must be consistent with current federal requirements unless the Department elects to require more stringent standards.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.23
Authority: O.C.G.A. §§ 31-2-8 and 31-22-1*et seq.*
History. Original Rule entitled "Evaluation" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.24. Specimens Examined.

(1) A licensed clinical laboratory shall examine human specimens only at the request of a licensed physician, dentist or other person authorized by law to use the findings of laboratory examinations.

(2) All specimens accepted by a licensed laboratory shall be tested on the premises, unless forwarded to another licensed clinical laboratory.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.24
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Specimens Examined" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.25. Reporting.

The results of a test performed by a licensed clinical laboratory shall be reported only to (or as directed by) a licensed physician, dentist, or other authorized person requesting the test. Such reports shall include the name of the director and the name and street address of the clinical laboratory in which the test was performed. When a test is performed in a reference laboratory, the director, name and address of the laboratory performing the test must be clearly identified in the report.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.25
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Reporting" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.26. Records.

Records of all clinical laboratory services, including records of laboratory test requests and reports, shall be retained by the laboratory for as long as required by federal law and regulations, and:

(a) For general laboratory records and quality control records, kept at least two (2) years,

(b) For records of immunohematology and cytology, kept at least five (5) years, and

(c) For records of surgical pathology, kept at least ten (10) years.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.26
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Records" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.27. Reports to the Department.

(1) Clinical laboratories shall report to the Department evidence of selected infectious diseases on forms provided by the Department.

(2) Clinical laboratories making such reports concerning infectious diseases shall not be held liable for having violated a trust or confidential relationship. The reports shall be deemed confidential and not subject to public inspection.

(3) Reports of Serious Incidents/Events. The laboratory shall report to the Department the following incidents:

   (a) Fatal transfusion reactions or transfusion complications affecting the patients;

   (b) Laboratory testing errors which have resulted in the death or serious injury to a patient or employee;

   (c) Significant interruptions in service vital to the continued safe operation of the facility, such as the loss of electricity, gas or water services.

(4) The laboratory shall make the initial report of the serious incident/ event within twenty-four (24) hours or by the next regular business day from when the reportable event occurred, or from when the laboratory has reasonable cause to believe that the reportable

event has occurred. The initial report shall be received by the Department in confidence and shall include at least the following:

(a) The name of the laboratory;

(b) The date of the event or the anticipated event and the duration of the incident, if known;

(c) Any immediate corrective actions that the laboratory has taken or expects to take.

(5) Within forty-five (45) days following the resolution of the event, the laboratory shall prepare a written report which includes a root cause analysis on systems and processes associated with the event to identify those improvements that are within the control of the laboratory that will be made to help prevent similar occurrences. The complete report shall be available to the Department for inspection at the facility. The laboratory is not required to complete a written report or a root cause analysis on interruptions in service for which the laboratory did nothing that contributed to the interruption in service.

(6) The Department will hold the initial self-report concerning the reportable serious incident/event in confidence and not release it to the public. However, where the Department determines that a rule violation related to the reported serious incident/event has occurred, the Department will initiate a separate complaint investigation of the incident. The separate complaint investigation report and survey results concerning the serious incident/event will not be kept confidential.

(7) Where a licensed laboratory is operated as an organized service of the licensed hospital, the laboratory may comply with the requirements for reporting serious incidents/events set forth in this rule by submitting its reports to the Department through the hospital- wide peer review committee, so long as the reports are made in a timely manner. Only one self-report of each serious incident/event is required to be made for the licensed laboratory that is operating within a licensed hospital.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.27
Authority: O.C.G.A. §§ 31-7-15 and 31-22-1*et seq.*
History. Original Rule entitled "Reports to the Department" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.28. Plasmapheresis and Whole Blood Donor Centers.

Clinical laboratories, including independent plasmapheresis and whole blood donor centers, which provide a system for the collection, processing or storage of human blood and/or its components shall provide methods for the selection of donors as well as methods for the collection, storage, processing, and transfusion, which shall ensure that the donation will not be detrimental to the donor and also protect (as far as possible) the recipient of human blood or any of its components from infectious disease known to be transmissible by blood.

(a) Special Personnel Requirements. In addition to the general personnel requirements outlined elsewhere in these Rules and Regulations, the following special personnel requirements are established:

1. Requirements for Directors and/or Physicians:

   (i) In a whole blood, plasmapheresis or other blood component donor center, the director shall meet at least the requirements of Rule 111-8-10-.06(2)(b)1.

   (ii) In a whole blood, plasmapheresis or other blood component donor center, the director and any other physician employed must be licensed in the State of Georgia and comply with all provisions of the Georgia Laboratory Licensure Law and associated regulations, and with all applicable federal regulations, specifically those provisions regarding physician requirements. The director shall be responsible, at all times, for all phases of operation.

2. Requirements for Other Personnel:

   (i) Donor Selection (Screening) Area. The donor screening area shall be staffed with trained personnel with no lesser qualification than that of Licensed practical Nurse (LPN), Clinical Laboratory Technician or an equivalent level of training or experience. Every screener must be trained to recognize abnormalities, (i.e., blood pressure, pulse, etc.). Careful evaluation must be conducted by a skilled interviewer (based on the outline for donor selection published by the American Association of Blood Banks) to eliminate most donor reactions. A Clinical Laboratory Technologist or a licensed Registered Nurse (RN) must be assigned responsibility for supervision of the screening area, including such procedures as total protein, hemoglobin and hematocrit testing performed there.

   (ii) Blood Collection (Phlebotomy) Area.

      (I) The supervisors in the phlebotomy area must be persons who have a minimum of three months training and experience in a plasmapheresis or blood donor center and who are qualified as either a Registered Nurse or a Clinical Laboratory Technologist, Licensed Practical Nurse, or a Certified Physician's Assistant. One person of such qualifications must be employed for one (1) to twelve (12) donors being processed at one time.

      (II) The phlebotomists in the phlebotomy area must be persons who have a minimum of one month training in a plasmapheresis or blood donor center and who meet no lesser qualifications in phlebotomy and/or reinfusion than that of Licensed Practical Nurse (LPN), Clinical Laboratory Technician, or equivalent level of training and/or experience. A phlebotomist must be employed for one to six donors being processed on automated equipment, for manual

processing there must be one phlebotomist for one to four donors being processed at a time, with a minimum of two phlebotomists in the phlebotomy area whenever any donors are processed. (The phlebotomy supervisors may also serve as phlebotomists).

(iii) Laboratory Testing Area. Personnel in the laboratory area of all whole blood, plasmapheresis or other blood component donor centers must meet qualifications required for any licensed clinical laboratory.

(iv) Other Personnel. Other personnel may be employed or used in the center, such as aides, clerks, volunteer workers, etc. These persons may assist technical staff, but shall not themselves perform technical laboratory duties.

(b) **Proficiency Testing Requirements.** Rule 111-8-10-.23 outlines proficiency testing requirements for hematology, immunohematology, syphilis serology, HIV testing and hepatitis testing. External proficiency testing is not required for blood, tissue and/or plasmapheresis donor screening procedures such as specific gravity, hematocrits, dipstick tests and serum proteins. This exemption from external proficiency testing does not, however, exempt such facilities from quality control requirements, inspection and licensure.

(c) **Documentation of Reactions.** The records system of the facility must maintain documentation of all reactions. Adequate reporting and recording forms must be available and used.

(d) **Blood Labeling and Associated Records.** In addition to labeling required as a part of good laboratory practices, it shall be the responsibility of the licensed laboratory director to comply with Chapter 24 of Title 31 of the Official Code of Georgia Annotated and Rules and Regulations for Blood Labeling, Chapter 111-8-9.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.28
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Plasmapheresis and Whole Blood Donor Centers" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.29. Exemption of Specific Screening and Monitoring Tests.

A facility or part of a facility in which laboratory testing is performed may apply and qualify for exemption from personnel requirements for specific screening and monitoring tests or techniques, as approved and published by the Board.

(a) The Department shall establish guidelines for the exempted screening and monitoring tests, which shall include adequate provisions for (1) personnel, (2) quality control, (3) reporting, (4) record keeping and (5) safety. The guidelines and list of tests or techniques will be periodically reviewed and published by the Department.

(b) Screening and monitoring approvals shall be issued by the Department and shall be valid for one year or a limited and specified time.

(c) Approvals, renewal of approvals or continuation of approvals are subject to continued conformance with the published guidelines, as determined by the Department. If approval is not granted, the laboratory testing is subject to clinical laboratory licensure.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.29
Authority: O.C.G.A. §§ 31-2-7 and 31-22-1*et seq.*
History. Original Rule entitled "Exemption of Specific Screening and Monitoring" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.30. Inspection and Plans of Correction.

(1) Employees and agents of the Department shall have the right of entry into the premises of the laboratory during all hours of operation and full access to all records, reports and documents relevant to the licensure status of the laboratory as determined by the Department.

(2) Licensed laboratories shall submit to inspection by CMS or CMS agents as a condition of licensure, and failure to submit to such inspection shall constitute grounds for suspension or denial of the State license.

(3) A laboratory subject to CMS inspection is authorized and required by the Department to release to CMS or CMS agents all records and information required by CMS in the course of the inspection.

(4) The Department shall make periodic inspections of every clinical laboratory, at its discretion. The frequency of inspection shall take into consideration the compliance record of the laboratories, e.g., the laboratory personnel, proficiency testing performance, and the number or seriousness of deficiencies reported on or since the last on-site inspection.

(5) The director or the laboratory supervisor in charge of the laboratory in the director's absence shall be present during each inspection of the laboratory. In the case of hospital laboratories, the hospital administrator or the administrator's designee shall be available for interview at the opening and close of inspection.

(6) None of the inspections performed by the Department nor any reports generated by the Department shall relieve the licensee from its duty to maintain the safety of its equipment, the work place, or to ensure safe and accurate laboratory testing.

(7) **Plan of Correction.** If as a result of an inspection, violations of these licensing rules are identified; the laboratory will be given a written report of the inspection which identifies the rules violated. The laboratory shall submit to the Department a written plan of correction in response to the report of inspection, which states what the laboratory will do, and when, to correct each of the violations identified. The laboratory may offer an explanation or dispute the findings or violations in the written plan of correction, so long as an acceptable plan of correction is submitted within ten days of the facility's receipt of the written report of inspection. The laboratory shall comply with its plan of correction.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.30
Authority: O.C.G.A. § 31-22-1*et seq.*
History. Original Rule entitled "Inspections and Plans of Correction" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.31. Exemptions.

These rules and regulations shall not apply to:

(a) Clinical laboratories operated by the Medical College of Georgia, the Emory University School of Medicine, Mercer University School of Medicine, Morehouse School of Medicine, or any other medical schools in Georgia, or the United States Government;

(b) Clinical laboratories operated and maintained exclusively for research and teaching purposes involving no patient or public health services;

(c) Clinical laboratories operated by duly licensed physicians exclusively in connection with the diagnosis and treatment of their own patients; or

(d) Pharmacists duly licensed in Georgia practicing in accordance with O.C.G.A. § 26-4-4 as it pertains to the performing or capillary blood tests and the interpretation of the results of those tests as a means to screen for or monitor disease risk factors and facilitate patient education. The capillary blood tests allowed under this exemption shall be limited to those capillary blood tests available to and for use by the public without licensure of the user of the test.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.31
Authority: O.C.G.A. §§ 26-4-4 and 31-22-9.
History. Original Rule entitled "Exemptions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.32. Variances and Waivers.

The Department, upon application or petition, may grant variances and waivers to these rules and regulations (after review and advice of Laboratory Advisory Council) when it is shown that the rule and regulation should not be applied as written, because strict application would cause undue hardship and that adequate standards affording protection of health, safety and care exist and will be met in lieu of the exact requirements, or that the purpose of the rule is met through equivalent standards affording equivalent protection of health, safety and care, or to allow experimentation or demonstration of new and innovative approaches to delivery of services, where the approach has the potential to improve service delivery and the intended protections afforded by the rule are being met.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.32
Authority: O.C.G.A. § 31-2-7.
History. Original Rule entitled "Variances and Waivers" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.33. Enforcement.

(1) The administration and enforcement of these rules and regulations shall be in accordance with Chapters 2, 5 and 22 of Title 31 of the Official Code of Georgia Annotated and Chapter 13 of Title 50 of the Official Code of Georgia Annotated and the Rules and Regulations General Licensing and Enforcement Requirements, Chapter 111-8-25.

(2) A Clinical Laboratory and/or Clinical Laboratory Director License may be denied, revoked, suspended, limited or renewal denied for:

(a) Making false statements of material information on an application for a license or any other documents required by the Department;

(b) Permitting unauthorized persons to perform technical procedures or to issue or sign reports;

(c) Demonstrating incompetence in the performance or reporting of clinical laboratory examination and procedures;

(d) Performing a test for or rendering a report to a person not authorized by law to receive such services;

(e) Referring a specimen for examination to a clinical laboratory in this state which has not been licensed or exempted under Chapter 22 of Title 31 of the Official Code of Georgia Annotated or, if not in this state, certified under all applicable federal law and associated rules and regulations;

(f) Making a report on clinical laboratory work actually performed in another clinical laboratory without designating the director and the name and address of the clinical laboratory in which the test was performed.

(g) Lending the use of the name of the licensed clinical laboratory or its personnel to an unlicensed clinical laboratory;

(h) Violating or aiding in the violation of any provision of Chapter 22 of Title 31 of the Official Code of Georgia Annotated, or these rules and regulations;

(i) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.

(3) Upon being notified of a conviction, plea, or first offender treatment of a licensed laboratory director involving the manufacture, distribution, trafficking, sale, or possession of a controlled substance or marijuana, the Department shall suspend or revoke the license of such individual as follows:

(a) Upon the first conviction, the licensed individual shall have his or her license to direct a clinical laboratory suspended for a period of not less than three months, provided, however, that in the case of a first conviction, plea, or first offender treatment for a misdemeanor the Department shall be authorized to impose a lesser sanction or no sanction upon the licensed individual, and

(b) Upon the second or subsequent conviction, the licensed individual shall have his or her license to direct a clinical laboratory revoked. The failure of a licensed laboratory director to notify the Department of a conviction as required in subsection C of Rule 111-8-10-.04(2) shall be considered grounds for revocation of his or her license to direct a clinical laboratory.

(c) A licensed laboratory director sanctioned under the foregoing subsections (a) or (b) may be entitled to reinstatement of his or her license to direct a clinical laboratory upon successful completion of a drug abuse treatment and education program approved by the Department.

(4) The operation or maintenance of an unlicensed clinical laboratory in violation of Chapter 22 of Title 31 of the Official Code of Georgia Annotated and these rules may be declared a nuisance, inimical to the public health, welfare, and safety. The Commissioner may bring an action for an injunction to restrain such violation or to enjoin the future operation or maintenance of any such clinical laboratory until compliance with Chapter 22 of Title 31 of the Official Code of Georgia Annotated and these rules has been demonstrated to the satisfaction of the Department. (5) Any person who violates any provision of Chapter 22 of Title 31 of the Official Code of Georgia Annotated or any of the rules and regulations promulgated thereto shall be guilty of a misdemeanor.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.33
Authority: O.C.G.A. §§ 16-13-110*et seq.*, 31-2-8 and 31-22-1 *et seq.*
History. Original Rule entitled "Enforcement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-10-.34. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions thereof shall remain in full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part thereof.

Cite as Ga. Comp. R. & Regs. R. 111-8-10-.34
Authority: O.C.G.A. § 31-22-1*et seq*.
History. Original Rule entitled "Severability" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-12. RULES AND REGULATIONS FOR CRIMINAL BACKGROUND CHECKS.

Rule 111-8-12-.01. Legal Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated (O.C.G.A.) § 31-7-350 et seq. (effective Oct. 1, 2019).

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.01
Authority: O.C.G.A. §§ 31-2-5, 31-2-7, 31-7-360.
History. Original Rule entitled "Legal Authority" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.02. Title and Purpose.

These rules, known as the Rules and Regulations for Criminal Background Checks, establish the minimum standards for the Georgia Long-term Care Background Check Program for conducting criminal background checks of owners, applicants for employment, administrators, onsite managers, directors and direct access employees at certain facilities.

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.02
Authority: O.C.G.A. § 31-7-350 et seq.
History. Original Rule entitled "Title and Purpose" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.03. Definitions.

In these rules, unless the context otherwise requires, the terms set forth herein shall mean the following:

(1) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, or mental anguish. Such term includes the

deprivation by an individual of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Such term includes verbal abuse, sexual abuse, physical abuse, and mental abuse, including abuse facilitated or enabled through the use of technology.

(2) "Conviction" means a finding or verdict of guilty or a plea of guilty regardless of whether an appeal of the conviction has been sought.

(3) "Crime" means commission of:

(a) Any of the following offenses:

1. A violation of O.C.G.A. § 16-5-70;

2. A violation of O.C.G.A. § 16-5-101;

3. A violation of O.C.G.A. § 16-5-102;

4. A violation of O.C.G.A. § 16-6-4;

5. A violation of O.C.G.A. § 16-6-5;

6. A violation of O.C.G.A. § 16-6-5.1; or

7. A violation of O.C.G.A. § 30-5-8;

(b) A felony violation of:

1. Chapter 5, 6, 8, 9, or 13 of O.C.G.A. Title 16;

2. O.C.G.A. § 16-4-1;

3. O.C.G.A. § 16-7-2; or

4. O.C.G.A. § 31-7-12.1; or

(c) Any other offense committed in another jurisdiction which, if committed in this state, would be deemed to constitute an offense identified in this paragraph without regard to its designation elsewhere.

(4) "Criminal background check" means a search of the criminal records maintained by the Georgia Crime Information Center and the Federal Bureau of Investigation to determine whether an owner, applicant for employment, or employee has a criminal record.

(5) "Criminal record" means any of the following:

(a) Conviction of a crime;

(b) Arrest, charge, and sentencing for a crime when:

1. A plea of nolo contendere was entered to the crime:

2. First offender treatment without adjudication of guilt was granted to the crime; or

3. Arrested and charged for a crime if the charge is pending, unless the time for prosecuting such crime has expired pursuant to Chapter 3 of Title 17;

(c) Such term shall not include an owner, applicant for employment, or employee for which at least ten years have elapsed from the date of his or her criminal background check since the completion of all of the terms of his or her sentence; provided, however, that such ten-year period or exemption shall never apply to any crime identified in subsection 0) of O.C.G.A. § 42-8-60.

(6) "Department" means the Department of Community Health of the State of Georgia, its agents and employees.

(7) "Direct access" means having, or expecting to have, duties that involve routine personal contact with a patient, resident, or client, including face-to-face contact, hands-on physical assistance, verbal cuing, reminding, standing by or monitoring or activities that require the person to be routinely alone with the patient's, resident's, or client's property or access to such property or financial information such as the patient's, resident's, or client's checkbook, debit and credit cards, resident trust funds, banking records, stock accounts, or brokerage accounts.

(8) "Employee" means any individual who has direct access and who is hired by a facility through employment, or through a contract with such facility, including, but not limited to, housekeepers, maintenance personnel, dieticians, and any volunteer who has duties that are equivalent to the duties of an employee providing such services. Such term shall not include an individual who contracts with the facility, whether personally or through a company, to provide utility, construction, communications, accounting, quality assurance, human resource management, information technology, legal, or other services if the contracted services are not directly related to providing services to a patient, resident, or client of the facility. Such term shall not include any licensed healthcare provider, including, but not limited to physicians, dentists, nurses, and pharmacists who are licensed by the Georgia Composite Medical Board, the Georgia Board of Dentistry, the Georgia Board of Nursing, or the State Board of Pharmacy.

(9) "Facility" means:

(a) A personal care home required to be licensed pursuant to O.C.G.A. § 31-7-12;

(b) An assisted living community required to be licensed pursuant to O.C.G.A. § 31-7-12.2;

(c) A private home care provider required to be licensed pursuant to O.C.G.A. § 31-7-301;

(d) A home health agency required to be licensed pursuant to O.C.G.A. § 31-7-151;

(e) A hospice required to be licensed pursuant to O.C.G.A. § 31-7-173;

(f) A nursing home, skilled nursing facility, or intermediate care home required to be licensed pursuant to O.C.G.A. § 31-7-1 et seq.; or

(g) An adult day center required to be licensed pursuant to O.C.G.A. § 49-6-83.

(10) "Fingerprint records check determination" means a satisfactory or unsatisfactory determination by the department based upon fingerprint based national criminal history information.

(11) "GCIC" means the Georgia Crime Information Center established under Article 2 of Chapter 3 of Title 35.

(12) "License" or "Permit" means the document issued by the department to authorize a facility to operate.

(13) "Owner" in the context of a nursing home or intermediate care home means an individual who is not an "excluded party" as such term is defined in O.C.G.A. § 31-7-3.3, otherwise such term means an individual or any person affiliated with a corporation, partnership, or association, who has 10 percent or greater ownership interest in a facility and who performs one or more of the following:

(a) Purports to or exercises authority of a facility;

(b) Applies to operate or operates a facility;

(c) Maintains an office on the premises of a facility;

(d) Resides at a facility;

(e) Has direct access at a facility;

(f) Provides direct personal supervision of facility personnel by being immediately available to provide assistance and direction when such facility services are being provided; or

(g) Enters into a contract to acquire ownership of a facility.

(14) "Records check application" means fingerprints in such form and of such quality as prescribed by GCIC under standards adopted by the Federal Bureau of Investigation and a records search fee to be established by the department by rule and regulation, payable

in such form as the department may direct to cover the cost of obtaining a criminal background check.

(15) "Registry check" means a review of the nurse aide registry provided for in O.C.G.A. § 31-2-14, the state sexual offender registry, and the List of Excluded Individuals and Entities as authorized in Sections 1128 and 1156 of the federal Social Security Act, as it existed on February 1, 2018, or any other registry useful for the administration of, or mandated under, these rules.

(16) "Satisfactory determination" means a written determination that an individual for whom a criminal background check was performed was found to have no criminal record.

(17) "Unsatisfactory determination" means a written determination that an individual for whom a criminal background check was performed was found to have a criminal record.

(18) "Willful" means acting deliberately, not that there is an intention to inflict injury or harm.

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.03
Authority: O.C.G.A. §§ 31-7-351, 31-7-355.
History. Original Rule entitled "Definitions" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.04. Registry and Professional Licensing Board Checks.

(1) Prior to a criminal background check required by these rules, the facility shall perform a registry check of the owner, administrator, onsite manager, director, and employees. If an individual has not resided in this state for at least two years, the facility shall conduct registry checks of each state in which the individual resided for the previous two years, as represented by such individual or as otherwise determined by the facility.

(2) If the subject of the criminal background check is a licensed healthcare professional or is required to hold a professional license as a qualification for the position, a query of available information maintained by the Georgia Composite Medical Board, the Secretary of State, or other applicable licensing boards shall be conducted prior to a criminal background check to determine that such individual has a professional license and is in good standing.

(3) If the individual appears on a registry or has a professional license that is not in good standing, the facility must comply with the Rule 111-8-12-.06.

(4) Except as provided in subsection (c) of O.C.G.A. § 31-7-359, nothing in these rules shall be construed to limit the responsibility or ability of a facility to screen owners, applicants for employment, administrators, onsite managers, directors or employees through additional methods.

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.04
Authority: O.C.G.A. §§ 31-7-352, 31-7-354.
History. Original Rule entitled "Registry and Professional Licensing Board Checks" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.05. Records Check Application.

(1) A records check application shall be required:

(a) For each owner, upon application for a new license;

(b) For each owner, upon application for a change of ownership;

(c) For each administrator, onsite manager or director of a facility, upon application for employment or prior to placement in the position;

(d) For each direct access employee, upon application for employment or prior to placement in the position; and

(e) For existing owners, administrators, onsite managers, directors and direct access employees, on or before January 1, 2021.

(2) In lieu of a records check application, the facility may submit documentation, satisfactory to the department, that the individual has received a satisfactory determination within the immediately preceding 12 months (provided the prior satisfactory determination was issued on or after October 1, 2019) or at any time prior if the individual's fingerprints have been retained under authority of O.C.G.A. § 35-33-3(a)(1)(f).

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.05
Authority: O.C.G.A. §§ 31-7-353, 31-7-354.
History. Original Rule entitled "Records Check Application" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.06. Employment Prohibition; Grace Period; Personnel Files; Notice.

(1) Except for the Grace Period described in paragraph (3) below, an individual required to submit to a registry check and criminal background check shall not be employed by, contracted with, or allowed to work as an employee at a facility, or to serve as an administrator, onsite manager or director of the facility, if:

(a) The individual appears on a registry check;

(b) There is a substantiated finding of neglect, abuse, or misappropriation of property by a state or federal agency pursuant to an investigation conducted in accordance with 42 U.S.C. Section 1395i-3 or 1396r as it existed on February 1, 2018;

(c) The individual's professional license, if applicable, is not in good standing; or

(d) The facility receives notice from the department that the individual has been found to have an unsatisfactory determination as a result of a criminal background check.

(2) An individual whose professional license is not in good standing may be employed by a facility in a position wherein his or her duties do not require professional licensure, so long as he or she has a satisfactory determination.

(3) **Grace Period**

(a) **During pending criminal background checks.** While a criminal background check is pending, the facility may permit an individual to have direct access to residents for a period not to exceed 30 days, provided that the individual is under the direct supervision of a staff member who has a satisfactory determination or otherwise meets the requirements of these rules.

At the end of 30 days, if no background check determination has been issued by the department and the individual is working at the facility, the facility shall ensure that the individual does not have direct access to residents. The 30-day grace period shall not apply to placement of an administrator, onsite manager or director; the facility shall not appoint any individual to serve as an administrator, onsite manager or director while the background check for that individual is pending. In order for facilities subject to federal regulations that require background screening before employment to utilize the 30-day grace period, the facility first must obtain a GCIC state criminal history record check comparison of data with information other than fingerprints in order to verify that the individual has not been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law.

(b) **During administrative appeals.** Unless prohibited under federal regulations, the facility may retain a current director, administrator, onsite manager or employee who has an unsatisfactory determination during the period of his or her administrative appeal.

(4) **Personnel file.** A personnel file for each employee shall be maintained by the facility. Such files shall be available for inspection by the department but shall otherwise be maintained to protect the confidentiality of the information contained therein and shall include, but not be limited to, evidence of each employee's satisfactory determination, registry check, and licensure check, if applicable.

(5) **Notice to applicants.** Each application form provided by a facility to an applicant for employment shall conspicuously state the following: "FOR THIS TYPE OF EMPLOYMENT, STATE LAW REQUIRES A NATIONAL AND STATE BACKGROUND CHECK AS A CONDITION OF EMPLOYMENT."

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.06
Authority: O.C.G.A. §§ 31-7-354; 31-7-355, 31-7-357.
History. Original Rule entitled "Employment Prohibition; Grace Period; Personnel Files; Notice" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.07. Ownership Prohibition.

When the department determines that an owner has an unsatisfactory determination as a result of a criminal background check or has appeared on a registry check, the department shall notify such owner of the ineligible status for ownership and shall take the necessary steps to revoke the facility's license or refuse to issue a license if an application is pending.

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.07
Authority: O.C.G.A. § 31-7-358.
History. Original Rule entitled "Ownership Prohibition" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.08. Background Checks Initiated by the Department.

The department may require a criminal background check on any facility owner, administrator, onsite manager, director or employee during the course of an abuse investigation involving such individual or if the department receives information that such individual was arrested for a crime. In such instances, the department shall require the owner or employee to furnish two full sets of fingerprints which the department shall submit to GCIC together with appropriate fees collected from the owner or employee.

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.08
Authority: O.C.G.A. § 31-7-355.
History. Original Rule entitled "Background Checks Initiated by the Department" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.09. Enforcement and Penalties.

The department shall impose a civil monetary penalty fine in the amount of the lesser of $10,000.00 or $500.00 for each day that a violation of these rules occurs. The daily civil monetary penalty fine shall be imposed only from the time the facility knew or should have known that it employed an individual with a criminal record and until the date such individual's employment is terminated.

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.09
Authority: O.C.G.A. § 31-7-356.
History. Original Rule entitled "Enforcement and Penalties" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.10. Contested Results and Appeals.

(1) An owner, applicant for employment, employee, administrator, onsite manager or director may:

(a) Obtain information concerning the accuracy of his or her criminal record, and the department shall refer such individual to the appropriate state or federal law enforcement agency that was involved in the arrest or conviction;

(b) Challenge the finding that he or she is the true subject of the results from a registry check, and the department shall refer such individual to the agency responsible for maintaining such registry; and

(c) Appeal his or her disqualifying unsatisfactory determination pursuant to O.C.G.A § 31-7-358.

(2) Applicants for employment, employees, administrators, onsite managers or directors who received an unsatisfactory determination or whose name appears on a registry check conducted pursuant to these rules shall be eligible to appeal such determination pursuant to Chapter 13 of title 50, the "Georgia Administrative Procedure Act." In a hearing held pursuant to this paragraph, the hearing officer shall consider in mitigation the length of time since the crime was committed, the absence of additional criminal charges, the circumstances surrounding the commission of the crime, and other indicia of rehabilitation.

(3) Owners

(a) The department's unsatisfactory determination of an owner or any action by the department revoking or refusing to grant a license based on such determination, shall constitute a contested case for purposes of Chapter 13 of Title 50, the "Georgia Administrative Procedure Act," except that any hearing required to be held pursuant thereto may be held reasonably expeditiously after such determination or action by the department.

(b) In a hearing held pursuant to subparagraph (1)(c) above, the hearing officer shall consider in mitigation the length of time since the crime was committed, the absence of additional criminal charges, the circumstances surrounding the commission of the crime, other indicia of rehabilitation, the facility's history of compliance with the regulations, and the owner's involvement with the licensed facility in arriving at a decision as to whether the criminal record requires the denial or revocation of the license to operate the facility. When a hearing is required, at least 30 days prior to such hearing, the hearing officer shall notify the

office of the prosecuting attorney who initiated the prosecution of the crime in question in order to allow the prosecuting attorney to object to a possible determination that the conviction would not be a bar for the grant or continuation of a license as contemplated under these rules. If objections are made, the hearing officer shall take such objections into consideration.

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.10
Authority: O.C.G.A. §§ 31-7-354, 358.
History. Original Rule entitled "Contested Results and Appeals" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Rule 111-8-12-.11. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions thereof shall remain in full force and effect as if such rule or portions thereof so determined, declared or adjudicated invalid or unconstitutional were not originally part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-12-.11
Authority: O.C.G.A. §§ 31-2-5, 31-2-7, 31-7-360.
History. Original Rule entitled "Severability" adopted. F. Aug. 14, 2019; eff. Sept. 3, 2019.

Subject 111-8-13. RULES AND REGULATIONS FOR THE GEORGIA CAREGIVER REGISTRY.

Rule 111-8-13-.01. Legal Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated §§ 31-7-380 et seq.

Cite as Ga. Comp. R. & Regs. R. 111-8-13-.01
Authority: O.C.G.A. §§ 31-7-380 et seq.
History. Original Rule entitled "Legal Authority" adopted. F. Nov. 30, 2021; eff. Dec. 20, 2021.

Rule 111-8-13-.02. Title and Purpose.

These rules, known as the Rules and Regulations for the Georgia Caregiver Registry, establish the minimum standards for the Georgia Caregiver Registry which allows employers who are family members or guardians of elderly persons to conduct an employment eligibility determination for an applicant or employee who will provide personal care services for the employer's family members or wards.

Cite as Ga. Comp. R. & Regs. R. 111-8-13-.02
Authority: O.C.G.A. § 31-7-380.
History. Original Rule entitled "Title and Purpose" adopted. F. Nov. 30, 2021; eff. Dec. 20, 2021.

Rule 111-8-13-.03. Definitions.

In these rules, unless the context otherwise requires, the terms set forth herein shall mean the following:

(a) "Applicant" means an individual applying to provide personal care services to an elderly person in a residence or location not licensed by the Department.

(b) "Caregiver Registry" means the database established by the Department to provide private family employers with access to employee or applicant eligibility determinations.

(c) "Criminal Background Check" means a search of the criminal records maintained by the Georgia Crime Information Center (GCIC) and the Federal Bureau of Investigation to determine whether an applicant or employee has a criminal record.

(d) "Department" means the Department of Community Health.

(e) "Elderly Person" means an individual who is 65 years of age or older.

(f) "Employee" means any individual who is providing personal care services to an elderly person in a residence or location not licensed by the Department.

(g) "Employer" means an individual who is considering an applicant or has hired an employee for a family member or ward.

(h) "Family Member" means an individual with a close familial relationship, including, but not limited to, a spouse, parent, sibling, or grandparent.

(i) "Personal care services" means home care, health care, companionship, or transportation and includes, but is not limited to, providing assistance with bathing, eating, dressing, walking, shopping, fixing meals, and housework.

(j) "Records Check Application" means fingerprints in such form and of such quality as prescribed by GCIC under standards adopted by the FBI and a records search fee, payable in such form as the Department may direct to cover the cost of obtaining a criminal background check.

(k) "Registry Check" means a review of the nurse aide registry provided in O.C.G.A § 31-2-14, the state sexual offender registry, and the List of Excluded Individuals and Entities as authorized in Sections 1128 and 1156 of the federal Social Security Act, as it existed on February 1, 2018, or other registry useful for the administration of these rules as specified by the Department.

(l) "Ward" means an elderly person for whom a guardian has been appointed pursuant to O.C.G.A. § 29-1-1 et seq.

Cite as Ga. Comp. R. & Regs. R. 111-8-13-.03
Authority: O.C.G.A §§ 31-7-381, 31-7-386.
History. Original Rule entitled "Definitions" adopted. F. Nov. 30, 2021; eff. Dec. 20, 2021.

Rule 111-8-13-.04. Use of the Georgia Caregiver Registry.

(1) The Georgia Caregiver Registry will enable employers who are family members or guardians of elderly persons in Georgia to obtain an employment eligibility determination for applicants or employees who are providing personal care services to the employer's family members or wards.

(2) The Caregiver Registry shall be used solely for those applicants or employees that offer personal care related services to an elderly person that is an employer's family member or ward in the State of Georgia. Personal care services performed pursuant to these rules shall not be performed at facilities licensed by the Department.

(3) The use of the Georgia Caregiver Registry is voluntary and not required by state or federal law.

(4) The Georgia Caregiver Registry shall not be used by facilities licensed by the Department, or other entities, or individuals who are not employers, as defined in this rule, to determine a person's employment status or for any other purpose.

(5) DCH will allow employers to use the Georgia Caregiver Registry to inquire about the eligibility status of an applicant or current employee as if they were applying to work or working in one of the facilities licensed under O.C.G.A. § 31-7-351(8) if the following requirements are met:

   (a) the applicant or employee agrees to such request,

   (b) the applicant or employee provides his or her fingerprints as set forth in O.C.G.A. Article 14, Chapter 7, Title 31; and

   (c) the applicant or employee provides written consent to the inclusion of the results in the Georgia Caregiver Registry.

(6) If the requirements in Section 111-8-13-.04(5)(a)-(c) are satisfied, DCH shall issue a written eligibility determination to the applicant or employee. The employer shall be responsible for all employment decisions made based on the eligible or ineligible employment determination. Any fees associated with such check shall be paid by the employer, applicant, or employee.

(7) Should the applicant or employee refuse to include the results of their criminal background check into the Georgia Caregiver Registry then the Department shall not issue a determination as defined in O.C.G.A. §§ 31-7-351(15) and (16).

Cite as Ga. Comp. R. & Regs. R. 111-8-13-.04
Authority: O.C.G.A. §§ 31-7-380, 31-7-382, 31-7-383.
History. Original Rule entitled "Use of the Georgia Caregiver Registry" adopted. F. Nov. 30, 2021; eff. Dec. 20, 2021.

Rule 111-8-13-.05. Appeals of Ineligibility Determinations.

(1) If an applicant or employee receives an ineligible determination notice by the Department and wishes to appeal the ineligible determination, the applicant or employee must appeal by requesting an appeal in writing within ten (10) days of receipt of the notice. The applicant or employee must submit their request in writing to the Department at 2 Peachtree St., N.W., 5th Floor, Atlanta, Georgia 30303.

(2) An applicant or employee who receives an ineligible determination or whose name appears on a registry check conducted pursuant to these rules shall be eligible to appeal such determination pursuant to Chapter 13 of Title 50, the "Georgia Administrative Procedure Act." In a hearing held pursuant to this paragraph, the hearing officer shall consider in mitigation the length of time since the crime was committed, the absence of additional criminal charges, the circumstances surrounding the commission of the crime, and other indicia of rehabilitation.

Cite as Ga. Comp. R. & Regs. R. 111-8-13-.05
Authority: O.C.G.A. §§ 31-7-360, 31-7-384.
History. Original Rule entitled "Appeals of Ineligibility Determinations" adopted. F. Nov. 30, 2021; eff. Dec. 20, 2021.

Rule 111-8-13-.06. Severability.

In the event that any rule, sentence, clause, or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions of rules shall remain in full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-13-.06
Authority: O.C.G.A. §§ 31-2-5, 31-2-7, 31-7-386.
History. Original Rule entitled "Severability" adopted. F. Nov. 30, 2021; eff. Dec. 20, 2021.

Subject 111-8-16. DISASTER PREPAREDNESS PLANS.

Rule 111-8-16-.01. Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Approved Plan" means a Disaster Preparedness Plan which has been found by the Department to meet the requirements of these regulations;

(b) "Board" means the Georgia Board of Community Health;

(c) "CDC" means the U.S. Centers for Disease Control and Prevention;

(d) "Commissioner" means the Commissioner of the Georgia Department of Community Health or his designee;

(e) "COVID-19" means coronavirus disease 2019;

(f) "Department" means the Georgia Department of Community Health;

(g) "Direct care staff person" means any employee, facility volunteer, or contract staff who provides to residents:

1. Any personal services, including but not limited to, medication administration or assistance, assistance with ambulation and transfer, and essential activities of daily living such as eating, bathing, grooming, dressing, and toileting; or

2. Any other limited nursing services, as defined in subsection (b) of Code Section 31-7-12.

(h) "Disaster Preparedness Plan" or "Plan" means a written document which identifies, (1) potential hazards or events, that should they occur, would cause an emergency situation at the facility; and (2) proposes, for each identified emergency situation, a course of action so as to minimize the threat to health and safety of the patients or residents;

(i) "Facility" means any institution subject to licensure under the provisions of O.C.G.A. Chapter 31-7, Article 1; which is not exempted from the requirements of these rules and regulations;

(j) "Governing Body" means the Board of Directors or trustees, partnership, corporation, association, person or persons who are legally responsible for the facility's operation.

(k) "Long-term care facility" means a personal care home with 25 or more beds, an assisted living community, or a nursing home licensed by the Department.

(l) "SARS CoV-2" means Severe Acute Respiratory Syndrome Coronavirus 2, the strain of coronavirus that causes the COVID-19 disease.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.01
Authority: O.C.G.A. §§ 31-7-3(c), 31-7-12.
History. Original Rule entitled "Definitions" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Mar. 19, 2018; eff. Apr. 8, 2018.
Amended: F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.02. Exemptions.

The following facilities are exempt from these rules and regulations:

(a) Facilities classified and licensed by the Department as: "Family Personal Care Homes", "Freestanding Emergency Care Centers", "Home Health Agencies", and "Specimen Collection Center" or "Health Testing Facilities."

(b) Institutions operated exclusively by the federal government or by any of its agencies.

(c) Public health services operated by the state, its counties or municipalities.

(d) Health care facilities, other than nursing homes, which are certified by the Centers for Medicare and Medicaid Services (CMS) for participation in the Medicare program. All licensed nursing homes shall remain subject to these rules.

(e) Any health care facility accredited by a CMS-approved Accreditation Organization (AO), as long as the facility's accreditation status is maintained. Facilities losing accreditation shall immediately be subject to these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.02
Authority: O.C.G.A. §§ 31-2-4 (1982 Supp); 31-7, Article 1.
History. Original Rule entitled "Exemptions" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Mar. 19, 2018; eff. Apr. 8, 2018.
Amended: F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.03. Disaster Preparedness Plan.

(1) Unless specifically exempted in Rule 111-8-16-.02 every facility shall have a Disaster Preparedness Plan which meets the requirements of Rule 111-8-16-.04. Disaster Preparedness Plan rehearsals shall be regularly conducted with a minimum of two rehearsals in each calendar year.

(2) The governing body shall be responsible for the development of the plan. The governing body shall designate those individual(s) within the facility who have primary responsibility for rehearsal and implementation of the plan.

(3) The facility shall designate staff to participate in the healthcare coalition for their region, as designated by the Department of Public Health (DPH). Participation in the coalition shall include:

(a) Initiation and maintenance of an account with the web-based emergency operations center managed by DPH or its contractor, agent or designee;

(b) Evidence of participation, at least annually, in communication drills with the coalition and/or attendance at coalition meetings; and

(c) Evidence of contact, at least annually, with the local emergency management agency coordinator for the area in which the facility is located.

(4) The facility shall review the plan at least annually and make appropriate updates. The Department shall require a revised plan under the following circumstances:

(a) A 10% or greater increase in the number of patients or residents at the facility;

(b) A change in evacuation strategy that requires different contractual arrangements for the facility;

(c) Additions or major renovations to the physical plant of the building; or

(d) Technological advancements which provide new warning and communications systems or sources.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.03
Authority: O.C.G.A. § 31-7-3(c).
History. Original Rule entitled "Disaster Preparedness Plan" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Mar. 19, 2018; eff. Apr. 8, 2018.

Rule 111-8-16-.04. Content of Plan.

(1) The plan shall contain a section in which the unique needs of the facility's residents are identified and assessed.

(2) The plan shall contain a section which identifies the emergency situations to be addressed by the plan. As a minimum the following emergency situations shall be addressed:

(a) fire;

(b) explosion;

(c) unanticipated interruption of each utility used by the facility; i.e., electricity, gas, other fuel, water, etc.;

(d) loss of air conditioning or heat; and

(e) damage to physical plant resulting from severe weather, i.e., tornadoes, ice or snowstorms, etc. Other emergencies or hazards may be included in the plan.

(3) For each of the emergencies identified in subsection (2) above, the plan shall include a set of emergency guidelines or procedures. A standardized format should be used throughout the plan that clearly describes how the emergency procedures should be carried out. The emergency procedures should answer the questions of "who, what, when, where, and how", and allow the facility to be ready to act effectively and efficiently in an emergency situation.

(4) The written procedures referred to in subsection (3) above should address as a minimum: assignment of responsibility to staff members; care of the residents; notification of attending physicians and other persons responsible for the resident; arrangements for transportation and hospitalization; availability of appropriate records; alternate living arrangements; and emergency energy sources.

(5) The plan must contain a section that outlines the frequency of rehearsal and the procedures to be followed during rehearsal. The rehearsal should be as realistic as possible and designed to check the following:

(a) knowledge of facility staff regarding their responsibility under the plan;

(b) the reliability of individuals or community agencies or services that are listed in the plan as resources to be called upon in the event of an emergency. However, the quest for realism in the rehearsal of the plan should not require the actual movement of non-ambulatory patients/residents nor those whose physical or mental condition would be aggravated by a move.

(6) When portions of the facility's plan are contingent on services or resources of another agency, facility, or institution, the facility shall execute a written agreement with the other party or parties acknowledging their participation in the plan. Such agreement(s) shall be made a part of the plan.

(7) Long-term care facilities shall include in the plan a pandemic plan for influenza and other infectious diseases which conforms to CDC standards and contains the following minimum elements:

(a) Protocols for surveillance and detection of epidemic and pandemic diseases in residents and staff;

(b) A communication plan for sharing information with public health authorities, residents, residents' representatives or their legal surrogates, and staff;

(c) An education and training plan for residents and staff regarding infection control protocols;

(d) An infection control plan that addresses visitation, cohorting measures, sick leave and return-to-work policies, and testing and immunization policies; and

(e) A surge capacity plan that addresses protocols for contingency staffing and supply shortages.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.04
Authority: O.C.G.A. §§ 31-7-3(c), 31-7-12.5.
History. Original Rule entitled "Content of Plan" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.05. Special Requirements for Long-Term Care Facilities.

Each Long-term care facility shall:

(1) Inform its residents and their representatives or legal surrogates by 5:00 P.M. the next calendar day following the occurrence of either a single confirmed infection of COVID-19 or another airborne infectious disease identified by the department or the CDC as a threat to public health, or three or more residents or staff with new-onset of respiratory symptoms occurring within hours of each other. Such information shall:

(a) Not include personally identifiable information;

(b) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and

(c) Include any cumulative updates for residents and their representatives or legal surrogates at least weekly or by 5:00 P.M. the next calendar day following the occurrence of any subsequent confirmed infection of COVID-19, or whenever three or more residents or staff with new onset of respiratory symptoms occurs within 72 hours of each other;

(2) Maintain a minimum of a seven-day supply of protective masks, surgical gowns, eye protection, and gloves sufficient to protect all residents and staff based on CDC guidance and with consideration given to any widespread supply shortages documented by the facility or known to the department;

(3) Maintain and publish for its residents and their representatives or legal surrogates policies and procedures pertaining to infection control and mitigation within their facilities and update such policies and procedures annually; and

(4) On or before September 28, 2020, ensure that each resident and direct care staff person has received an initial baseline molecular SARS CoV-2 test as outlined by the CDC.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.05
Authority: O.C.G.A. §§ 31-7-3(c), 31-7-12.5, 31-7-12.6.
History. Original Rule entitled "Records" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013
Amended: New title "Special Requirements for Long-term Care Facilities." F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.06. Records.

The facility shall maintain the following records and make them available to authorized Department employees upon request:

(a) a copy of the plan and any subsequent changes thereto;

(b) records of rehearsals of the plan;

(c) records of incidences which required implementation of the plan.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.06
Authority: O.C.G.A. § 31-7-3(c).
History. Original Rule entitled "Scope of Regulations" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: New title "Records." F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.07. Scope of Regulations.

The rules as contained in this chapter expressly do not modify or revoke the provisions of any of the other rules of the Department of Community Health which have been or will be promulgated under the authority of O.C.G.A. Chapter 31-7, Article 1.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.07
Authority: O.C.G.A. § 31-7, Article 1.
History. Original Rule entitled "Notice to the Department" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: New title "Scope of Regulations." F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.08. Notice to the Department.

When an emergency situation occurs which dictates implementation of the plan and results in injury or loss of life, the Department shall be notified within 24 hours. Such notification may be

verbal. In other emergency situations which dictate implementation of the plan a record shall be made including a written incident report and a written critique of the performance under the plan. These records shall be filed with the plan and made available to the Department during inspections of the facility.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.08
Authority: O.C.G.A. § 31-7-3(c).
History. Original Rule entitled "Waivers and Variances" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: New title "Notice to the Department." F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.09. Waivers and Variances.

The Department, upon petition, may grant variances or waivers of specific rules and regulations as provided for in O.C.G.A. § 31-2-7 when it has been shown that the rule or regulation is not applicable or to allow experimentation and demonstration of new and innovative approaches to the delivery of services, or the center has met the intended purpose of the rule through equivalent standards, provided that the granting of the variance or waiver will not jeopardize the health, safety or care of the residents. The Department may establish conditions which must be met by the facility in order to operate under the variance or waiver.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.09
Authority: O.C.G.A. §§ 31-2-7, 31-7-3(c).
History. Original Rule entitled "Enforcement" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: New title "Waivers and Variances." F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.10. Enforcement.

A facility which fails to comply with these rules and regulations shall be subject to revocation of its permit or provisional permit and/or other sanctions provided by law. The enforcement and administration of these rules and regulations shall be as prescribed in O.C.G.A. Chapter 31-5, Enforcement and Administrative Procedure, which includes provisions for:

(a) the misdemeanor penalty for violation of rules and regulations promulgated under Title 31;

(b) injunctive relief under appropriate circumstances; and

(c) the due process requirements of notice, hearing and appeals.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.10
Authority: O.C.G.A. §§ 31-5, 31-7, Article 1.
History. Original Rule entitled "Severability" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: New title "Enforcement." F. Oct. 19, 2020; eff. Nov. 8, 2020.

Rule 111-8-16-.11. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof, and such remaining rules or portions thereof shall remain of full force and effect, as if such rules or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Board of Community Health to establish rules and regulations that are constitutional and enforceable so as to safeguard the health and well-being of the people of the State.

Cite as Ga. Comp. R. & Regs. R. 111-8-16-.11
Authority: O.C.G.A. § 31-7-3(c).
History. Original Rule entitled "Severability" adopted. F. Oct. 19, 2020; eff. Nov. 8, 2020.

Subject 111-8-19. RULES AND REGULATIONS FOR DRUG ABUSE TREATMENT AND EDUCATION PROGRAMS.

Rule 111-8-19-.01. Legal Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated (O.C.G.A.) Sec. 26-5-1*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.01
Authority: O.C.G.A. § 26-5-1*et seq.*
History. Original Rule entitled "Legal Authority" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.02. Title and Purposes.

These rules shall be known as the Rules and Regulations for Drug Abuse Treatment and Education Programs. The purpose of these rules is to provide minimal requirements for the licensing and inspection of drug abuse treatment and education programs, not subject to regulation as licensed hospitals, or approved Emergency, Receiving, Evaluation and/or Treatment (ERET) services or licensed Narcotic Treatment Programs monitored by the State Methadone Authority.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.02
Authority: O.C.G.A. § 26-5-1*et seq.*
History. Original Rule entitled "Title and Purposes" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.03. Definitions.

In these rules, unless the context otherwise requires, the words and phrases set forth herein shall mean the following:

(a) "Ambulatory Detoxification Program" means a program for the medical management and other support for processes associated with the physical process of withdrawal from drugs in a non-residential setting. Persons treated in this setting are without unusual or significant medical risks or behavioral problems.

(b) "Behavior management" means those principles and techniques used by a facility to assist a client in facilitating self-control, addressing inappropriate behavior, and achieving positive outcomes in a constructive and safe manner. Behavior management principles and techniques shall be used in accordance with the client's treatment plan, written policies and procedures governing service expectations, treatment goals, safety, security, and these rules and regulations.

(c) "Branch" means a part-time (operating less than five days per week) substance abuse program at a site or location different from the location of the licensed program, yet which is operated as a part of the licensed program and is not separately licensed.

(d) "Department" means the Department of Community Health, acting through the Division of Healthcare Facility Regulation, or its successor.

(e) "Drug abuse treatment and education program" or "program" means any system of treatment or therapeutic advice or counsel provided for the rehabilitation of drug dependent persons and shall include programs offered in residential and/or nonresidential settings.

(f) "Drug dependent person" means a person who is in imminent danger of becoming dependent upon or addicted to the use of drugs or who habitually lacks self-control as to the use of drugs or who uses drugs to the extent that his health is substantially impaired or endangered or his social or economic function is substantially disrupted.

(g) "Drugs" means any substance defined as a drug by federal or Georgia law or any other chemical substance which may be used in lieu of a drug to obtain similar effects, with the exception of alcohol and its derivative.

(h) "Emergency safety interventions" means those behavioral intervention techniques that are authorized under an approved emergency safety intervention plan and are utilized by properly trained staff in an urgent situation to prevent a client from doing immediate harm to self or others.

(i) "Emergency safety intervention plan" means the plan developed by the facility utilizing a nationally recognized, department-approved, evidence-based, training program for emergency safety intervention. The plan shall clearly identify the emergency safety interventions staff may utilize and those that may never be used.

(j) "Final Adverse Finding" means

1) the issuance of a ruling by the Commissioner of the Department of Community Health on any appeal from a decision of a state administrative law judge or hearing examiner pursuant to a contested case involving the imposition of a sanction;

2) when a decision of the state administrative law judge or hearing examiner becomes final by operation of law because no appeal is made to the Commissioner of the Department of Community Health;

3) where the parties to a contested case dispose of the case by settlement; or

4) where a facility does not contest within the allotted time period a sanction imposed by the department.

(k) "Governing body" means the county board of health, the partnership, the corporation, the association, or the person or group of persons who maintains and controls the program and who is legally responsible for the operation.

(l) "Inspection" means any examination by the department or its representatives of a provider, including but not necessarily limited to the premises, staff, persons in care, and documents pertinent to initial and continued licensing so that the department may determine whether a provider is operating in compliance with licensing requirements or has violated any licensing requirements. The term inspection includes any survey, monitoring visit, complaint investigation, or other inquiry conducted for the purposes of making a compliance determination with respect to licensing requirements. Such examinations are generally unannounced.

(m) "License" means the official permit issued by the department which authorizes the holder to operate a drug abuse treatment and education program for the term provided therein.

(n) "Manual hold" means the application of physical force, without the use of any device, for the purpose of restricting the free movement of a client's body. A manual hold does not include briefly holding the client without undue force to calm or comfort the client, holding the client by the hand or by the shoulders or back to walk the client safely from one are to another where the client is not forcefully resisting the assistance, or assisting the client in voluntarily participating in activities of daily living.

(o) "Mechanical restraint" means a device attached or adjacent to the client's body that is not a prescribed and approved medical protection device, and that he or she cannot easily remove, that restricts freedom of movement or normal access to his or her body.

(p) "Narcotic Treatment Program" means a program for chronic heroin or opiate-like drug users that administers narcotic drugs under physicians' orders either for detoxification purposes or for maintenance treatment in a rehabilitative context. This program is licensed according to rules promulgated by the department.

(q) "Outpatient Drug Treatment Program" means a non-residential program staffed by professional and paraprofessional persons that provides drug treatment or therapeutic services, primarily counseling and other supportive services for drug dependent persons, and is not classified as an ambulatory detoxification program or Specialized Day Treatment Program.

(r) "Parent program" means the licensed program that develops and maintains administrative controls of Subunits and Branches of the program.

(s) "Residential Sub-Acute Detoxification Program" means a residential program for drug dependent persons which includes the medical management and other support for processes associated with the physical withdrawal from drugs in a residential setting, staffed by professional and paraprofessional persons, which is not in a licensed hospital or approved ERET facility.

(t) "Residential Intensive Treatment Program" means a residential program staffed by professional and paraprofessional persons which provide highly structured treatment and therapeutic activities that focus on stabilization, abstinence, and skills required for recovery; are not classified as a residential sub-acute detoxification program.

(u) "Residential Transitional Treatment Program" means a residential program which provides therapeutic services to drug dependent persons, who are transitioning to the community or to other treatment modalities, and who, typically, lack a stable living situation and require variable levels of therapeutic services.

(v) "Seclusion" means the involuntary confinement of a client away from other clients, due to imminent risk of harm to self or others, in a room or an area from which the client is physically prevented from leaving.

(w) "Specialized Day Treatment Program" means a non-residential program for drug dependent persons staffed by professional and paraprofessional persons that provides structured treatment or therapeutic services, utilizing activity schedules as part of its operational method; it is not classified as an ambulatory detoxification or outpatient drug treatment program.

(x) "Special Program" means a program that provides therapeutic services to drug dependent persons which does not fit into existing program classifications.

(y) "Subunit" means a full-time program for drug dependent persons operated semiautonomously in a different location from the Parent program, which may provide different modalities of services, and must independently meet the licensing requirements and shall be separately licensed.

(z) "Time out" means a behavior management technique that involves the brief separation of a client from the group or setting where the client is experiencing some behavioral or emotional distress, not to exceed twenty (20) minutes, designed to de-escalate the

emotionally charged condition of the client. During "time-out" a client's physical freedom of movement is not restricted.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.03
Authority: O.C.G.A. § 26-5-1*et seq.*
History. Original Rule entitled "Definitions" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.04. Governing Body.

Each licensed program shall have a clearly identified governing body. The chairperson or chief executive officer of the governing body shall complete a statement of responsibility on behalf of the governing body acknowledging the governing body's responsibility for the operation of the program in accordance with these rules in connection with any application for a license on a form provided by the department. If a program is individually owned, then the owner(s) will complete the statement of responsibility.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.04
Authority: O.C.G.A. § 26-5-1*et seq.*
History. Original Rule entitled "Governing Body" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.05. Licenses.

No governing body shall operate a drug abuse treatment and education program in the state without first obtaining a license or provisional license. A licensed program may offer one or more of the program services described in these rules.

(a) License. A license will be issued, upon presentation of evidence satisfactory to the department, that the program is in compliance with these rules and all applicable federal and state laws for the handling and dispensing of drugs, and all state and local health, safety, (including fire, sanitation, building) and zoning requirements. A license shall remain in force and effect for a period determined by the department unless sooner suspended or revoked by the department. Such license shall describe each type of service and program that the licensee is authorized to provide. Any changes in authorized services and programs shall be reported to the department. The department will determine whether a new license is required.

(b) Provisional license. A provisional license may be issued for a period not to exceed 90 days to a program that has substantially complied with all requirements for a regular license. Provisional licenses shall be renewed at the discretion of the department only in cases of extreme hardship and in no case for longer than 90 days. The obligations and conditions of a provisional license shall be the same as those of a license unless otherwise provided for by the department. Such provisional license shall describe each type of service and program that the licensee is authorized to provide. Any changes in authorized

services and programs shall be reported to the department. The department will determine whether a new license is required.

(c) Qualifications Requirement. In order to obtain or retain a license or provisional license, the administrator of the program and its employees must be qualified, as defined in these rules, to administer or work in a program. However, the department may require additional reasonable verification of the qualifications of the administrator and employees either at the time of application for a license or provisional license or at any time during the license period whenever the department has reason to believe that an administrator or employee is not qualified under these rules to administer or work in a program.

(d) License is nontransferable. A license or provisional license to operate a program is nontransferable for a change of location or governing body. Each license or provisional license shall be returned to the department in the following cases: changes in location, governing body, program closure or the license is suspended or revoked.

(e) Exclusions. The following types of entities are not subject to these specific rules:

1. Narcotic Treatment Programs which are licensed/monitored by the State Methadone Authority;

2. Licensed hospitals not operating separate and distinct drug abuse treatment programs as classified by the department;

3. Approved Emergency Receiving, Evaluation and/or Treatment (ERET) facilities which have been licensed or approved by the department and are not operating drug abuse treatment programs as classified by the department;

4. Licensed individual professionals operating in compliance with their state practice acts but do not offer or purport to offer "Drug Abuse Treatment and Education Programs.

5. Organizations or persons that provide supportive services (i.e. residence, transportation, and etc.) to drug dependent persons but do not offer or purport to offer "Drug Abuse Treatment and Educational Programs." Support services under the direct control of licensed programs must be a part of the licensed program.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.05
Authority: O.C.G.A. §§ 26-5-6 to 26-5-11, 26-5-14, 31-2-4.
History. Original Rule entitled "Licenses" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.06. Accreditation.

The department may issue a license to a program that provides proof of accreditation by an accreditation agency approved by the department, if the accreditation agency's requirements are substantially equivalent or more stringent than the requirements of these rules. The license may

be issued without an on-site visit by the department, however, the department reserves the right to inspect accredited programs on a sample validation basis or whenever there is reason to believe that the requirements of these rules are not being met. Provided however, any denial, suspension, or revocation of such accreditation shall result in similar licensure actions, and the governing body shall be required to apply for a new license. For purpose of this rule, proof of accreditation shall require a copy of the program's most recent accreditation report together with any supplemental recommendations or reports. Such reports shall be submitted to the department whenever received by a program or whenever requested by the department.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.06
Authority: O.C.G.A. §§ 26-5-6, 26-5-10, 31-2-4, 37-1-22, 37-7-3.
History. Original Rule entitled "Accreditation" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.07. Applications.

(1) An application for a license to operate a drug abuse treatment and education program shall be submitted to the department on forms provided by the department, as well as requested updating information, and shall include assurances satisfactory to the department that the program is in compliance with all applicable federal and state laws for the handling and dispensing of drugs, with professional practice acts, and all state and local health, safety, sanitation, building, and zoning requirements.

(2) False or Misleading Information. An application for a license must be truthfully and fully completed. In the event that the department has reason to believe that an application has not been completed truthfully, the department may require additional verification of the facts alleged. The department may refuse to issue a license where false statements have been made in connection with an application or any other documents required by the department.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.07
Authority: O.C.G.A. §§ 26-5-6, 26-5-8.
History. Original Rule entitled "Applications" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.08. Inspections and Plans of Corrections.

(1) The department is authorized and empowered to conduct onsite inspections of any program to verify compliance with these rules. A program shall permit any authorized department representative to enter upon and inspect any and all program premises which, for the purposes of these rules, shall include access to all parts of the facility, staff, persons in care, and documents pertinent to initial and continued licensure, including but not limited to all clinical records maintained on clients. Failure to permit entry and inspection shall constitute noncompliance or violation of this rule and, subject to notice of an opportunity for a hearing, may result in the denial of any license applied for or the

suspension or revocation of a license or provisional license. Inspections are generally unannounced, and may occur at any time the department deems necessary.

(2) If as a result of an inspection, violations of these licensing rules are identified, the program will be given a written report of the inspection which identifies the rules violated. The program must submit a written plan of correction in response to the report of inspection which states what the program will do when to correct each of the violations identified. The program may offer any explanation or dispute the findings of violations in the written plan of correction so long as an acceptable plan of correction is submitted within ten days of the receipt of the written report of inspection. Failure to submit an acceptable plan of correction may constitute cause for the department to deny a license or suspend or revoke a license.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.08
Authority: O.C.G.A. §§ 26-5-6, 26-5-13, 26-5-14.
History. Original Rule entitled "Inspections and Plans of Corrections" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013

Rule 111-8-19-.09. Administration.

(1) Program Purpose. A licensed program shall develop and implement written policies and procedures that specify its philosophy, purpose, and program orientation. Such policies and procedures shall identify the types of drug abusers and the ages of the clients that it serves, including referral sources. When the program serves persons with special needs, the description shall explain how these special needs will be met.

(2) Program Operations. A licensed program shall develop and implement written policies and procedures for operations to include:

(a) A description of the range of treatment and services provided by the program to be reviewed annually and updated as needed, specifying which American Society of Addiction Medicine (ASAM) levels of care will be offered, what services will be provided directly by the program, and what services are provided in cooperation with available community or contract resources;

(b) The process for intake, assessment, admission, treatment planning, and evaluation of treatment;

(c) Discharge summaries and aftercare plans;

(d) The protection of client's rights and confidentiality of client records;

(e) The appropriate use of behavior management and emergency safety interventions; and

(f) When the program administers medications, policies and procedures related to medication administration.

(3) Administrator. The governing body of the program shall designate an administrator who shall be authorized to manage the program. The clinical director may serve as the administrator.

(4) Clinical Director. The governing body of the program shall designate a clinical director who is responsible for all treatment services provided.

(5) Finances. The governing body shall provide for the preparation of an annual budget and approve such budget. Copies of the current year's budget and expenditure records shall be maintained for examination and review by the department.

(a) The administrator and all persons authorized to receive and disburse operating funds shall be authorized by the governing body to do so.

(b) The program shall develop and implement a written schedule of client fees. The schedule shall identify all fees which are chargeable to clients and a copy of the schedule shall be provided to the client, or parent, or guardian, or responsible party upon request, during the admission process and subsequently upon request.

(c) A financial audit shall be completed annually by a certified public accountant or other qualified audit approved by the governing body.

(6) Client Records. A written record of each client assessed and each client admitted to the program must be maintained by the program.

(a) Contents. Each client record shall include all information necessary to monitor the client's condition and contain at least the following information:

1. Basic identifying information including name, address, telephone number, date of birth, sex, and race;

2. If applicable, the names, addresses, and telephone numbers of parents, or guardians, or responsible parties;

3. Persons to notify in case of an emergency if different from above;

4. The name of the client's attending physician, if any;

5. All records of screening and assessment, including a comprehensive psychosocial history;

6. If applicable, documentation of why the client was not admitted for treatment and suggested referrals given to client;

7. Written consent as required in rule .13(c)1.;

8. Documentation of orientation as required in rule .13(c)2.;

9. Rights of the client (State and Federal) including confidentiality and signed by the client;

10. Individualized treatment plan and treatment notes (including drug administration records if applicable);

11. Results of laboratory tests, as appropriate;

12. Discharge summary and aftercare plan;

13. Any other records relating to the client's treatment and stay in the program such as written grievances, reports about discipline to include any use of emergency safety interventions if an incident resulting in injury occurs while the patient is at the program location, observations, etc.

(b) Confidentiality and Retention of Client Records. Written policies and procedures shall be established and implemented for the maintenance and security of client records specifying who shall supervise the maintenance of such records, who shall have custody of such records, and to whom records may be released, how they may be released and for what purposes they may be released. The department shall have access to all client clinical records for the purpose of determining compliance with licensure requirements. Confidentiality, release, and retention of client records must comply with 42 CFR, Part 2 Confidentiality of Alcohol and Drug Abuse Patient Records.

(7) Personnel Records. A program shall maintain written records for each employee and the administrator. Each individual file shall include:

(a) Identifying information such as name, address, telephone number, emergency contact person(s);

(b) A ten year employment history or a complete employment history if the person has not worked ten years;

(c) Records of applicable licenses, health requirements, and educational qualifications as required by these rules;

(d) Date of employment;

(e) The person's job description or statements of the person's duties and responsibilities;

(f) Documentation of training and orientation required by these rules;

(g) Any records relevant to the employee's performance including at least annual performance evaluations; and

(h) The results of employment and criminal background checks conducted by the program prior to employment indicating that the employee has no history of violence or abuse which would pose a risk to clients receiving services through the treatment program.

(8) Emergency Services. During non-operating hours, the program must make provisions for 24 hour emergency services or a telephone "hot line" to assist a client in a crisis situation. This information must be provided to the client upon admission.

(9) HIV/AIDS. A licensed program shall provide HIV/AIDS education, risk assessment and the provision of HIV counseling and testing, either directly or by referral.

(10) Priority Access. Written policies and procedures must be developed for providing priority in access to services and admissions to programs for drug dependent pregnant females.

(11) Drug-free work place. Written policies and procedures shall be established and implemented to provide for a drug-free work place. Pre-employment and ongoing random urine drug screens shall be utilized for all program employees. Each sample collected shall be screened for opiates, methadone, amphetamines, cocaine, benzodiazepines, THC and other drugs either as indicated by the department or the employer.

(12) Referral to Other Programs. Each program shall have a formal plan of cooperation with other programs in the state for referral of clients to allow for continuity of care for drug dependent persons or for emergency hospitalization. The licensed programs must have identified resources that would be available to continue the drug dependent person's care and to have worked out referral/transfer arrangements where appropriate.

(13) Reporting. Written summary reports shall be made to the department, in a form acceptable to the department within 24 hours (with a detailed investigative report to follow in five work days if not provided initially) regarding serious occurrences involving clients that happened either at the facility or were connected with the care that the client received at the facility, such as accidents or injuries requiring medical treatment and/or hospitalization; death; emergency safety interventions resulting in any injury requiring medical treatment beyond first aid; or any incident which results in any federal, state, or private legal action by or against the facility which affects any child or the conduct of the facility. However, legal action involving the juvenile justice system is not required to be reported.

(14) Child Abuse Reports. Whenever the program has reason to believe that a client who is a minor in care has been subjected to child abuse it shall cause a report of such abuse to be made to the child welfare agency providing protective services as designated by the Department of Human Services (Division of Family and Children Services) or in the absence of such an agency to an appropriate police authority or district attorney in accordance with the requirements of O.C.G.A. Sec. 19-7-5. A copy of such report shall also be filed with the department.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.09
Authority: O.C.G.A. §§ 19-7-5, 26-5-5, 26-5-6.
History. Original Rule entitled "Administration" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013

Rule 111-8-19-.10. Staffing.

(1) The program shall have sufficient types and numbers of staff as required by these rules to provide the treatment and services offered to clients and outlined in its program description.

(2) Staff subject to professional practice acts must be in compliance with the state practice acts.

(3) Counseling services are provided by individuals qualified by education, training, and experience to provide substance abuse counseling and who are licensed/certified if required by state practice acts.

(4) The medical responsibility for each client will be vested in a licensed physician who oversees all medical services provided by the program. Physician assistants or nurse practitioners may be utilized to the extent allowed by state practice acts.

(5) Each program shall have available professional mental health consultation to review selected cases and to provide assistance to the staff in client management or for referral for psychiatric services.

(6) The clinical director must be either a doctor of medicine licensed to practice in this state, or a licensed practitioner who is licensed to provide treatment, therapeutic advice or counsel for the rehabilitation of drug dependent persons in compliance with state practice acts, or a certified addiction counselor.

(7) For any employee hired after the effective date of these rules, employment and criminal background checks shall be conducted prior to employment, and only persons with no history of violence or abuse which would pose a risk to the clients in treatment shall be employed by the program.

(8) Staff Training and Orientation. Prior to working with clients, all staff who provide treatment and services shall be oriented in accordance with these rules and shall thereafter receive additional training in accordance with these rules.

(a) Orientation shall include instruction in:

1. The program's written policies and procedures regarding its program purpose and description; client rights, responsibilities, and complaints; confidentiality; and other policies and procedures that are relevant to the employee's range of duties and responsibilities, including the use of universal precautions for infection control, use of behavior management and emergency safety interventions, and information about HIV/AIDS;

2. The employee's assigned duties and responsibilities; and

3. Reporting client progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services.

(b) Additional training consisting of a minimum of thirty (30) clock hours of training or instruction shall be provided annually for each staff member who provides treatment services to clients. Such training shall be in subjects that relate to the employee's assigned duties and responsibilities.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.10
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Staffing" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.11. Physical Plant and Safety.

(1) Required Approvals.

(a) A program shall be in compliance with all applicable local health, sanitation, building, and zoning requirements.

(b) A program shall be in compliance with all applicable laws and rules issued by the state fire Marshall, the proper local fire marshal or state inspector, and shall have a certificate of occupancy if required.

(2) All buildings and grounds shall be constructed and maintained in a safe manner and in accordance with these rules.

(3) A program shall have appropriate and sufficient space to meet the programmatic needs of its clients, and carry out the program's array of services. Such space shall include areas

conducive to privacy for counseling and group activities, reception/waiting areas, and bathrooms which assure privacy for collection of urine specimens.

(4) Sleeping Areas - Residential Programs.

(a) For residential programs initially licensed or expanded after the effective date of this rule, sleeping areas shall contain not less than 60 square feet of useable floor space per resident in multiple use bedroom and not less than 100 square feet of useable space in single bedrooms.

(b) Each resident shall be provided with his or her own personal space and furnishings for storage of clothes and personal belongings.

(c) Each resident shall be provided with his or her own personal bed and mattress. Clean sheets, pillows, and pillow cases, blankets or bed covering shall be provided and sheets and pillow cases shall be changed as needed, but at least weekly.

(d) Bedrooms shall be provided with outside ventilation by means of windows, air conditioners, or mechanical ventilation. All rooms that have windows that can be opened without special devices shall have insert window screens and the windows and screens must be in good repair.

(5) Lavatory and Bathing Facilities - Residential Programs.

(a) For residential programs initially licensed or expanded after the effective date of this rule, there shall be at least one lavatory (water basin and toilet) with hot and cold water for every six residents or fraction thereof. Lavatories that contain more than one toilet shall contain stalls for individual privacy. All lavatories shall be properly ventilated.

(b) For residential programs initially licensed or expanded after the effective date of this rule, there shall be at least one shower or bathtub with hot and cold water for every ten residents or fraction thereof. Bathtubs and shower stalls shall be equipped with non-slip surfaces.

(6) Dining Area - Residential Programs. There shall be a separate furnished dining area for serving meals that contains not less than ten square feet of useable floor space for each resident being served.

(7) Climate Control and Pest Control - Residential Programs. A program shall be maintained at a temperature range of sixty-five degrees Fahrenheit (72 degrees if serving pregnant women, infants or small children) to eighty-two degrees Fahrenheit, depending on the season of the year. An effective pest control system shall be implemented and documentation on file as to actions taken.

(8) Off-site Residences. Programs which provide off-site residences as a part of their programs must ensure that the residences also meet the above requirements.

(9) Premises. All grounds, space, and facilities, both those within the program and those regularly used by residents as an integral part of the program, shall be kept clean and free from hazards to health and safety and from litter.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.11
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Physical Plant and Safety" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.12. Food Service.

(1) A residential program which provides food service shall provide each resident with meals and snacks of food groups and serving sizes which meet the nutritional guidelines of the United States Department of Agriculture. Meals and snacks shall be varied daily. Modified diets based on medical or religious reasons shall be served as needed.

(2) If required by the local county board of health, a residential program shall obtain a valid food service permit from the local county board of health. All residential programs providing food services shall meet the following requirements:

(a) Food shall be stored, prepared, and maintained in a safe and sanitary manner commensurate with generally accepted and recognized food service standards.

(b) There shall be designated and separate space for food preparation and storage.

(c) All perishable and potentially hazardous foods shall be refrigerated at a temperature of forty-five degrees Fahrenheit unless frozen. Freezer temperatures shall be maintained at zero degrees Fahrenheit or below.

(d) Food shall be in sound condition, free from spoilage and contamination and shall be safe for human consumption when served to residents.

(e) Food service equipment and preparation areas shall be kept clean and free of accumulation of dust, dirt, food particles, and grease deposits.

(f) When non-disposable dishes, glasses, and flatware are used, they shall be properly cleaned by pre-rinsing and scraping, washing, sanitizing, and drying.

(3) Where a residential program provides food services through contract or arranges for food services, the residential program shall require that food served be safe for human consumption and that the meals/snacks provided meet the nutritional guidelines of the United States Department of Agriculture.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.12
Authority: O.C.G.A. §§ 26-5-5, 26-5-6, 26-5-8.

History. Original Rule entitled "Food Service" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.13. Client Referral, Intake, Assessment, and Admission.

(1) A program shall only accept referrals and shall only admit and retain clients whose known needs can be met by the program in accordance with its program purpose and description. Written policies and procedures for client referral, intake, assessment, and admission shall be established and implemented and shall include the following:

(a) Screening. All persons referred to the program or who present themselves for services shall be initially screened to determine if the prospective client appears to meet the program's admission criteria. Such screenings shall be done by a staff person who has been determined to be qualified by education, training, experience, and who are licensed/certified if required by state practice acts to perform such screenings. Screenings shall constitute an initial appraisal of the clients' dysfunctions and the types of services that appear needed. Persons whose needs cannot be met by the program shall not be admitted and should be referred to other programs that provide appropriate services. A record (log) will be kept of persons not admitted and reason(s) for not admitting. The program has the discretion to use information on clinical evaluations done within thirty days.

(b) Assessment. All clients admitted to the program shall be evaluated by a staff person who has been determined to be qualified by education, training, and experience and who are licensed/certified if required by state practice acts to perform or coordinate the provision of such assessments. Such evaluations shall include a comprehensive assessment of the client's physical, emotional, behavioral, social, recreational, and educational status and needs. The program has the discretion to use current clinical information concerning a transitioning client from another licensed program, licensed hospital, or a state or federal agency, if there has not been a discontinuance in treatment.

1. Physical Assessment. At the time of admission, a preliminary physical assessment shall be done, at a minimum, by a Registered Nurse or Licensed Practical Nurse under the supervision of a RN or physician and shall include documentation of vital signs, appropriate screening tests for STD and TB, urine drug screens, a determination of whether the client requires a physical or psychiatric examination by a physician according to established protocols, and laboratory tests as clinically indicated. Laboratory tests required upon admission for clients in each program modality, in addition to those tests required for all modalities, will be determined by the programs and documented in their policy and procedures as to the criteria used to determine and specify which minimum lab tests are to be done for each modality. Other lab tests may be required by the physician as clinically indicated. If an examination by a physician is indicated, arrangements shall be made for such an examination as appropriate. The assessment shall also

include circumstances leading to admission, mental status, support system, psychiatric and medical history, risk assessment for HIV, history of use of drugs, including the age of onset, duration, patterns, and consequences of use, family history of drug use, route of administration and previous treatment. If a client has been referred for treatment from another facility, the results of a physical examination and laboratory tests from the other facility may be documented and used to assess physical status, provided that such physical examination was done within six months of admission, and there has been no significant change in the physical status of the client. Further assessments or laboratory tests may be required depending upon the modality of treatment needed or the client's changing condition.

2. Psycho-social assessment. At the time of admission or as soon as clinically appropriate (but no longer than ten working days), a comprehensive psycho-social assessment shall be done and shall document personal and social history, including current relationships, educational status, living arrangements, social habits, employment status, legal status and related areas.

(c) Admission.

1. Consent. Except as otherwise authorized by law, no person shall be admitted for treatment without written authorization from the client and parent, guardian, or responsible party, if applicable. The following information must be explained by a trained staff person to the client and other consenters, and documented in the client's file.

   (i) The program's services and treatment;

   (ii) The specific condition that will be treated;

   (iii) The expected charges for services including any charges that might be billed separately;

   (iv) The Client's Rights and Responsibilities;

   (v) The rights of consenters to obtain information about the client's treatment, etc.; and

   (vi) The procedures for complaint and question resolution.

2. Orientation. The program shall provide orientation to clients admitted for treatment within 24 hours of admission or at such time that the client appears able to hear and respond to requests, but in no event later than 72 hours after admission. Orientation shall be done by a staff person who has

been determined to be qualified by education, training, and experience to perform the task. The following information must be explained to the client, and documented in the client's file.

(i) The expected benefits of the treatment that the client is expected to receive;

(ii) An explanation of individualized treatment planning;

(iii) The client's responsibilities for adhering to the treatment plan and the consequences of non-adherence;

(iv) The identification of the staff person that is expected to provide treatment or coordinate the treatment;

(v) Program rules including requirements for conduct and the consequences of infractions;

(vi) Client's Rights, Responsibilities, and Complaints;

(vii) The program's policies for use of behavior management and emergency safety interventions when necessary; and

(viii) Policies and procedures for visiting hours and communications with persons outside the program, if a residential program.

(2) Drug dependent pregnant females shall be given priority for admission and services when a program has a waiting list for admissions.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.13
Authority: O.C.G.A. §§ 26-5-2, 26-5-5, 26-5-6.
History. Original Rule entitled "Client Referral, Intake, Assessment, and Admission" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.14. Individual Treatment Planning.

A program must develop and implement a complete individualized treatment plan for each client. Such treatment plans shall be modified and updated as necessary, depending upon the clients' needs.

(a) Preliminary Treatment Plan. An initial treatment plan will be formulated at the time of admission after assessment (within a minimum of ten working days) and will include the initial treatment recommendation for the client. The initial treatment plan may be documented in the program notes.

(b) Complete Treatment Plan. The complete treatment plan must be comprehensive, formulated by a multi-disciplinary team with the input of the client, approved by the clinical director, completed within thirty days from admission, and shall contain sufficient information about the client's expected treatment including:

1. Descriptions of the client's problems and needs;

2. Measurable goals and desired outcomes that are to be attained by the client, which include both long term goals and short term objectives leading to these goals;

3. The interventions and services that the program will provide to help the client achieve the individual goals and desired outcomes;

4. The expected course of treatment; and

5. Identification of the staff person who will provide treatment or coordinate the treatment.

(c) Progress Notes. A program shall document the services received by the client and document chronologically observations of the client's clinical course of treatment which includes the client's response to treatment and progress towards achieving individual goals and desired outcomes. Progress notes shall be documented by the staff members assigned primary responsibility for the client's care, and shall be legible and recorded in the client's plan. Progress notes shall be recorded as applicable;

1. At the end of each shift in the client's medical record for residential detoxification programs;

2. Following any contact with a client undergoing ambulatory detoxification or narcotic treatment;

3. At least weekly for substance abuse treatment residences;

4. Daily for day treatment programs;

5. Whenever there are face-to-face contacts with the client for outpatient drug treatment programs;

6. Whenever the client is observed to engage in a behavior which may effect a change in the treatment plan; and

7. Immediately following the use of any emergency safety intervention with the client.

(d) Random urine drug screens are required for each client, the frequency of which is determined by the program in order to determine its effectiveness. Clinical directors electing to rely upon presumptive urinalysis results for client management must

demonstrate adequate access to definitive qualitative laboratory analysis for use when necessary.

(e) Plan Reviews. Plans shall be reviewed and updated, as needed, by the staff member who has primary responsibility for coordinating or providing for the care of the client. Reviews shall be done whenever necessary as indicated by the client's needs or at least every thirty (30) days for residential and sixty (60) days for outpatient.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.14
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Individual Treatment Planning" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.15. Medications.

If a program administers medications, written policies and procedures for prescription, administration and security of medications shall be established and implemented. Such policies and procedures shall include the following:

(a) Medications are prescribed by a physician, and/or other practitioners as allowed by state law, and the risks and benefits of the prescribed medication are explained to the client (and parent, guardian, or responsible party if applicable) by the physician or a staff person who has been delegated responsibility in writing by the physician to explain the risks and benefits. Documentation of such explanations of risks and benefits must be maintained by the program.

(b) The program may have written pre-medication screening protocols which are completed and approved by the physician. Such protocols shall include an assessment as required in rule .13(1)(b).

(c) Unless self-administered, all medications are administered by a physician, physician's assistant, or nurse.

(d) Any medications prescribed, administered or self-administered under supervision are documented on an individual medication administration record that is filed with the individual treatment plan, unless maintained as a clinical record at the client's bedside or in the medication room in a residential detoxification setting. The record must include:

1. Name of medication;

2. Date prescribed;

3. Dosage;

4. Frequency;

5. Route of administration;

6. Date and time administered; and

7. Documentation of staff administering medication or supervising self-administration.

(e) Adverse drug reaction and errors are reported to a physician immediately and corrective action is initiated. The adverse reaction or error is recorded in the drug administration record and the individual treatment plan, and all persons who are authorized to administer medication or supervise self-medication are alerted.

(f) All medications shall be stored under lock and key when not being administered or self-administered.

(g) Program staff shall adhere to all federal and state laws and rules regarding controlled substances.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.15
Authority: O.C.G.A. § 26-5-6
History. Original Rule entitled "Medications" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.16. Quality Assurance.

Written policies and procedures for an ongoing quality assurance process shall be established and implemented. Such process shall identify areas of treatment or treatment problems to be addressed; establish and monitor criteria by which the quality and appropriateness of the treatment are to be measured; analyze the outcomes; make recommendations for change, as needed; and monitor changes to ensure problem resolution. Responsibility for administering and coordinating the quality assurance process shall be delegated to a staff person who has been determined to be qualified by education, training, and experience to perform such tasks. If the program provides medical services, the medical director shall be actively involved in the process.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.16
Authority: O.C.G.A. §§ 26-5-5, 26-5-6**.**
History. Original Rule entitled "Quality Assurance" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.17. Discharge Summaries and Aftercare Plans.

A program must complete an individualized discharge summary for all clients discharged and also an aftercare plan for continuing services and support for those clients who complete their course of treatment.

(a) Discharge Summary. A discharge summary shall be completed within seven working days of discharge for clients who leave the program before completing treatment. A summary shall be completed by the person who has primary responsibility for coordinating or providing for the care of the client, and it shall include a final assessment of the client's status at the time of discharge, summary of progress towards treatment goals, and the reasons the client was discharged prior to completing treatment. For those who complete treatment, the discharge summary must be completed within ten working days and must include aftercare plans.

(b) Aftercare Plans. Aftercare plans for continuing services and support shall be developed and completed prior to discharge for clients who complete treatment. The plan shall be completed by the person who has primary responsibility for coordinating or providing for the care of the client, and it shall include a final assessment of the client's status at the time of discharge, summary of progress towards treatment goals, a description of what services and supports the client is expected to need following discharge, and a description of potential barriers to overcome to maintain a drug free life style. The client must participate in aftercare planning, and if applicable, parents, or guardians, or responsible persons must participate whenever feasible.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.17
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Discharge Summaries and Aftercare Plans" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.18. Residential Sub-acute Detoxification Programs.

Programs offering residential sub-acute detoxification programs must meet the rules listed in this subsection (.18), in addition to the general rules set forth.

(a) The program shall establish and implement written policies and procedures that address how the program manages the medical and detoxification services that it provides. The program shall operate 24 hours a day.

(b) Staffing. Treatment is provided by qualified medical staff and other professionals who are qualified by education, training, experience, and who are licensed/certified if required by state practice acts to perform detoxification services that meet the needs of clients.

1. Medical Staff. The medical staff is headed by a medical director who is licensed to practice medicine in Georgia, and all other medical staff are licensed to practice in Georgia. The medical director must approve all medical policies and procedures, including assessment tools, treatment protocols, and emergency procedures. Such policies and procedures shall include provisions for an effective infection control program.

2. Director of Nursing. A licensed registered nurse determined qualified by education, training, and experience to supervise nursing services for detoxification shall be designated as the Director of Nursing.

3. Medical Coverage.

   (i) Physician coverage shall be provided in accordance with the treatment protocol. At a minimum, there shall be on call physician coverage 24 hours a day, and a physician must be on site daily as medically indicated.

   (ii) Nursing coverage shall be provided in accordance with clients needs as determined by the number and condition of client population. At a minimum, there shall be one registered or licensed practical nurse awake and on duty on premises 24 hours per day to respond to client needs.

4. Other Medical Services.

   (i) Diagnostic Services. Clinical laboratory services and x-ray services shall be provided in accordance with the Department of Community Health's Rules for Licensure of Clinical Laboratories, Chapter 111-8-10, and Rules for X-Ray, Chapter 290-5-22.

   (ii) Emergency Medical Services. The program's medical policies and procedures include provisions for the delivery of emergency, medical services, which services are either provided directly or through an established procedure specifying how emergency services will be accessed.

   (iii) Pharmaceutical Services. Pharmaceutical services are offered through a licensed pharmacy service in the community or by the program's own licensed pharmacist.

(c) Treatment - Assessment. Admission Assessment of clients shall be performed by a physician, nurse practitioner, physician's assistant, or registered nurse. If an assessment is done by other than a physician, then the assessment must be communicated to physician by telephone prior to the client's admission. The assessment must include:

1. Drug history including past detoxification episodes, and current use of drugs and medications;

2. Causes that triggered the present need for services;

3. Descriptions of medical risks and any behavioral or emotional problems.

4. Taking and documentation of vital signs; and

5. Determination of whether or not a physical and/or psychiatric examination by a physician is needed immediately and arrangements for such examination, if the assessment was done by a registered nurse. If the assessment is done by a physician, nurse practitioner or physician's assistant, it will include a physical examination.

6. Laboratory tests will be ordered as indicated, but at a minimum will include: CBC, RPR, urinalysis (routine and microscopic). TB screening and urine drug screens.

(d) Treatment - Admission. Clients are admitted to treatment by physician's orders only following assessment and determination that the medical, emotional, and behavioral status of the client justifies admission. The initial detoxification care plan must be documented in the record and may be initiated by the order of the physician following admission.

(e) Treatment.

1. Within twenty-four hours of admission, or the next normal business day if admission occurred on a weekend or holiday, the client must be seen by a physician, nurse practitioner, or physician's assistant if the assessment required by rule .13(1)(b) and subparagraph (3) above was done by a registered nurse. If a physical examination is needed, such examination shall be done at that time.

2. Within 48 hours of admission, a complete Detoxification Care Plan shall be developed by a registered nurse, physician's assistant, or physician. If not done by a physician, the development of the plan shall be supervised and signed by a physician. Any changes to the plan must be documented in the plan and reviewed and signed by the physician. The plan shall address the nursing and medical procedures needed to stabilize the client and to manage the withdrawal.

3. In addition to medical management, the program shall provide the client substance abuse counseling and support by staff who are determined qualified by training, education, experience, and who are licensed/certified if required by state practice acts to provide such services. Such services shall be provided to clients as soon as it is determined that they can benefit from such services but no later than within three work days of admission.

4. A discharge summary and aftercare plan, if applicable, shall be completed in accordance with rule .17.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.18
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Residential Sub-acute Detoxification Programs" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.19. Ambulatory Detoxification Programs.

Programs offering outpatient ambulatory detoxification services must meet the rules listed in this subsection (.19) in addition to the general rules set forth.

(a) The program shall establish and implement written policies and procedures that address how the program manages the medical and detoxification services that it provides. The program shall be open and operate five days a week with on-call physician coverage as outlined below.

(b) Staffing. Treatment is provided by qualified medical staff and other professionals who are qualified by education, training, experience, and who are licensed/certified if required by state practice acts to perform detoxification services that meet the needs of clients.

1. Medical Staff. The medical staff is headed by a medical director who is licensed to practice medicine in Georgia, and all other medical staff are licensed to practice in Georgia. The medical director must approve all medical policies and procedures, including assessment tools, treatment protocols, and emergency procedures.

2. Medical Coverage. There shall be a physician, nurse practitioner, physician's assistant, registered nurse, or licensed practical nurse with at least two years of substance abuse experience under RN supervision on duty during all hours of operation to provide or supervise client treatment and assess individual clients as needed. Each physician employed by the program is determined qualified by training, education, and experience to manage detoxification treatment and assumes responsibility for the medical services provided by the staff.

3. On-Call Coverage. A staff physician shall provide 24-hour, on-call coverage when the program is closed or a physician is not present on the premises.

4. Other Medical Services.

   (i) Diagnostic Services. Clinical laboratory services and x-ray services shall be provided in accordance with the Department of Community Health's' Rules for Licensure of Clinical Laboratories, Chapter 111-8-10, and Rules for X-Ray, Chapter 290-5-22.

   (ii) Emergency Medical Services. The program's medical policies and procedures include arrangements for the delivery of emergency medical services.

   (iii) Pharmacy Services. Pharmaceutical services are provided through a licensed pharmacy in the community or the program's own licensed pharmacist.

(c) Treatment - Assessment. Admission Assessment of client shall be performed by a physician, nurse practitioner, physician's assistant or a registered nurse. If an assessment

is done by other than a physician, then the assessment must be communicated to a physician by telephone prior to the client's admission. The assessment must include:

1. Drug history including past detoxification episodes, and current use of drugs and medications;

2. Causes that triggered the present need for services;

3. Descriptions of medical risks and any behavioral or emotional problems;

4. Taking and documentation of vital signs;

5. Determination of whether or not a physical and/or psychiatric examination by a physician is needed immediately, and arrangements for such examinations, if indicated, if the assessment was done by a registered nurse; and

6. Determination that the prospective client appears to have the needed support and supervision from family members and others to benefit from ambulatory treatment.

7. Laboratory tests will be ordered as indicated, but at a minimum will include: CBC, RPR, urinalysis (routine and microscopic), TB screening and urine drug screens.

(d) Treatment - Admission. Clients are admitted to treatment by physicians' orders only following assessment and determination that the medical, emotional, and behavioral status of the client and his or her support systems are adequate to justify admission to an ambulatory program. Persons treated in ambulatory detoxification settings are without unusual or significant medical or behavioral problems that would pose a significant risk to the safe completion of an ambulatory detoxification program. The initial detoxification care plan must be documented in the record and may be initiated by the order of the physician following admission.

(e) Treatment.

1. Within twenty-four hours of admission, or the next normal business day if admission occurred on a weekend or holiday, the client must be seen by the physician, nurse practitioner, or physicians assistant if the assessment required by rule .13(1)(b) and subparagraph (3) above was done by a registered nurse. If a physical examination is needed, such examination shall be done at that time.

2. Within 48 hours of admission, a Detoxification Care Plan shall be developed by a registered nurse, physician's assistant, or the physician. If not done by a physician, the development of the plan shall be supervised and signed by a physician. Any changes to the plan must be documented in the plan and reviewed and signed by the physician. The plan shall address the nursing and medical procedures and monitoring activity needed to stabilize the client and to manage the withdrawal.

3. For the length of the detoxification care plan and while on medication, the client shall be required to visit the program at least once a business day for a check of vital signs and monitoring of medication by one of the medical staff.

4. In addition to medical management services, the program shall provide the client counseling and support by staff who are determined qualified by training, education, experience, and who are licensed/certified if required by state practice acts to provide such services. Such services shall be provided to clients as soon as it is determined that they can benefit from such services but no later than within three work days of admission.

5. A discharge summary and an aftercare plan, if applicable, shall be completed in accordance with rule .17.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.19
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Ambulatory Detoxification Programs" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.20. Residential Intensive Treatment Programs.

Such residences provide services for clients with significant substance abuse impairment, and who, typically, have not progressed in a less intensive setting, or lack supports and require a highly structured and specialized environment, or are transitioning from detoxification. In addition to the general rules set forth, programs offering residential intensive treatment programs shall meet the requirements of this subsection (.20).

(a) Client intake, assessment, and admission; individual treatment planning; and discharge and aftercare, if applicable, shall be done in accordance with rules .13, .14, and .17. Additional admission requirements, including laboratory tests, may be required by facility policy and/or determination of the medical/clinical director.

(b) A program shall provide a minimum of eight hours per day of various therapeutic services designed to enable the client to function without substance abuse. Such services shall be provided by persons who have been determined qualified by education, training, experience, and who are licensed/certified if required by state practice acts to render such services that meet the needs of clients.

(c) There shall be sufficient types and numbers of staff members on duty in the residence to provide for safe supervision of clients whenever clients are present.

(d) Provisions shall be made for mandatory education of children in care in accordance with O.C.G.A. Sections 20-2-690*et seq.* or its successor statute.

(e) A program shall have a written agreement with a physician for the provision of medical care.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.20
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Residential Intensive Treatment Programs" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.21. Residential Transitional Treatment Programs.

Such residences provide services on an intermediate basis for clients characterized as chronic substance abusers who are transitioning to the community or to other treatment modalities, and who, typically, lack a stable living situation and require variable levels of therapeutic services. Facilities that only provide housing for persons, such as half-way houses or temporary shelters, are not subject to licensure as residential transitional treatment programs, unless the residence offers treatment services or is a supportive service owned and/or controlled by a licensed program. In addition to the general rules set forth, programs offering residential transitional treatment programs shall meet the requirements of this subsection (.21).

(a) Client intake, assessment, and admission; individual treatment planning; and discharge and aftercare shall be done in accordance with rules .13, .14 and .17. Additional admissions requirements, including laboratory tests, may be required by facility policy and/or determination of the medical/clinical director. The program has the discretion to use physical and psycho-social assessment information from another licensed program, licensed hospital, or a state or federal agency, if the client is transitioning directly from another program.

(b) The program shall provide at least five or more hours per week of therapeutic services designed to enable the client to function without substance abuse. Such services shall be rendered by persons who have been determined qualified by training, education, experience, and who are licensed/certified if required by state practice acts to render such services.

(c) There shall be sufficient types and numbers of staff members on duty in the residence to provide for safe supervision of clients whenever clients are present.

(d) Provisions shall be made for mandatory education of children in care in accordance with O.C.G.A. Sections 20-2-690*et seq.* or its successor statute.

(e) A program shall have a written agreement with a physician for the provision of medical care.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.21
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Residential Transitional Treatment Programs" adopted. F. Sep. 9, 2013; eff. Sept.

29, 2013

Rule 111-8-19-.22. Specialized Day Treatment Programs.

Specialized day treatment programs emphasize continued abstinence, development of social support network and necessary lifestyle changes, educational skills, vocational skills, social and interpersonal skills, the understanding of addictive disease, and the continued commitment to a recovery program. The program provides structured treatment or therapeutic services, utilizing activity schedules as part of its operational method, i.e. plans or schedules of days or times of day for certain activities. The programs utilize methods, materials, settings, and outside resources that are appropriate to the development levels and ages of clients, and, age appropriate. These programs are provided over a period of several weeks or months and often follow detoxification or residential services. They may also utilize group and/or individual counseling and/or therapy. Such programs shall provide:

(a) Client intake, assessment, and admission; individual treatment planning; and discharge and aftercare shall be done in accordance with rules .13, .14, and .17. Additional admissions requirements, including laboratory tests, may be required by facility policy and/or determination of the medical/clinical director.

(b) Treatment must be provided by persons determined to be qualified by training, education, experience, and who are licensed/certified if required by state practice acts to render such services that meet the needs of the clients.

(c) Provisions shall be made for mandatory education of children in care in accordance with O.C.G.A. § 20-2-690*et seq.* or its successor statute.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.22
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Specialized Day Treatment Programs" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013

Rule 111-8-19-.23. Outpatient Drug Treatment Programs.

Outpatient drug treatment programs provide a variety of treatment and therapeutic services intended to enable clients to function drug free and to learn social and psychological skills. Typically, these include services such as psychosocial assessment; group, individual, and family counseling; supportive counseling; substance abuse education; and therapeutic recreational activities. Such services shall be provided in part outside normal business hours so that clients who work or go to school can attend. Such programs shall provide:

(a) Client intake, assessment, and admission; individual treatment planning; and discharge and aftercare shall be done in accordance with rules .13, .14, and .17.

(b) Treatment must be provided by persons determined to be qualified by training, education, experience, and who are licensed/certified if required by state practice acts to render such services that meet the needs of the clients.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.23
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Outpatient Drug Treatment Programs" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.24. Special Programs.

Structured programs that do not fit into existing program classifications but meet the requirements of these rules will be licensed as Special Programs. These programs may be part of other licensed programs or may be individually licensed.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.24
Authority: O.C.G.A. §§ 26-5-5, 26-5-6.
History. Original Rule entitled "Special Programs" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.25. Client's Rights, Responsibilities, and Complaints.

A program shall establish and implement written policies and procedures regarding the rights and responsibilities of clients, and the handling and resolution of complaints. At a minimum, the program must ensure that its clients enjoy the rights and responsibilities listed herein.

(a) Such policies and procedures shall include a written notice of rights and responsibilities which shall be provided to each client and parent, guardian, or responsible party, if applicable, when the client receives orientation. The required notice shall contain the following items:

1. Right to a humane treatment or habilitation environment that affords reasonable protection from harm, exploitation, and coercion;

2. Right to be free from physical and verbal abuse;

3. Right to be free from the use of physical restraints and seclusion unless it is determined that there are no less restrictive methods of controlling behavior to reasonably insure the safety of the client and other persons:

4. Right to be informed about plan of treatment and to participate in the planning, as able;

5. Right to be promptly and fully informed of any changes in the plan of treatment;

6. Right to accept or refuse treatment, unless it is determined through established authorized legal processes that the client is un-able to care for himself or is dangerous to himself;

7. Right to be fully informed of the charges for treatment;

8. Right to confidentiality of client records;

9. Right to have and retain personal property which does not jeopardize the safety of the client or other clients or staff and have such property treated with respect;

10. Right to converse privately, have convenient and reasonable access to the telephone and mails, and to see visitors, unless denial is necessary for treatment and the reasons are documented in the client's treatment plan;

11. Right to be informed of the program's complaint policy and procedures and the right to submit complaints without fear of discrimination or retaliation and to have them investigated by the program within a reasonable period of time;

12. Right to have access to their own client records and to obtain necessary copies when needed;

13. Right to receive a written notice of the address and telephone number of that state licensing authority, i.e. the department, which further explains the responsibilities of licensing the program and investigating client complaints which appear to violate licensing rules;

14. Right to obtain a copy of the program's most recent completed report of licensing inspection from the program upon written request. The program is not required to release a report until the program has had the opportunity to file a written plan of correction for the violations as provided for in these rules; and

(b) Such policies and procedures shall also include provisions for clients and others to present complaints, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.25
Authority: O.C.G.A. § 26-5-6.
History. Original Rule entitled "Client's Rights, Responsibilities, and Complaints" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.26. Behavior Management and Emergency Safety Interventions.

(1) Behavior Management.

(a) The program shall develop and implement policies and procedures on behavior management. Such policies and procedures shall set forth the types of clients served in accordance with its program purpose, the anticipated behavioral problems of the clients, and appropriate techniques of behavior management for dealing with such behaviors.

(b) Program staff shall be made aware of each client's known or apparent medical and psychological conditions and family history, as evidenced by written acknowledgement of such awareness, to ensure that the staff have adequate knowledge to deliver safe and healthy care to the client.

(c) Behavior management policies and procedures shall incorporate the following minimum requirements:

1. Behavior management principles and techniques shall be used in accordance with the individual treatment plan and written policies and procedures governing service expectations, treatment goals, safety, security, and these rules and regulations.

2. Behavior management shall be limited to the least restrictive appropriate method, as described in the client's treatment plan pursuant to Rule .14(a),(b)1. -5. and in accordance with the prohibitions as specified in these rules and regulations.

(b) Behavior management techniques shall be administered by trained staff and shall be appropriate for the client's age, intelligence, emotional makeup and past experience. The following forms of behavior management s hall not be used by program staff with client's receiving services through the program:

1. Assignment of excessive or unreasonable work tasks;

2. Denial of meals and hydration;

3. Denial of sleep;

4. Denial of shelter, clothing, or essential personal needs;

5. Denial of essential program services;

6. Verbal abuse, ridicule, or humiliation;

7. Manual holds, chemical restraints, or mechanical restraints not used appropriately as emergency safety interventions;

8. Denial of communication and visits unless restricted in accordance with Rule .13(2);

9. Corporal punishment;

10. Seclusion or confinement of a client in a room or area which may reasonably be expected to cause physical or emotional damage to the client; or not used appropriately as an emergency safety intervention; and

11. Seclusion or confinement of a client to a room or area for periods longer than those appropriate to the client's age, intelligence, emotional make up and previous experience, or confinement to a room or area without the supervision or monitoring necessary to ensure the client's safety and well-being.

(e) Clients shall not be permitted to participate in the behavior management of other clients or to discipline other clients, except as part of an organized therapeutic self-governing program in accordance with accepted standards of clinical practice that is conducted in accordance with written policy and is supervised directly by designated staff.

(f) Programs shall submit to the department electronically or by facsimile a report within 24 hours whenever the program becomes aware of an incident which results in any injury to a client requiring medical treatment beyond first aid that is received by a client as a result of or in connection with any behavior management.

(g) All forms of behavior management or emergency safety interventions used by staff shall also be documented in case records in order to ensure that such records reflect behavior management problems.

(h) The program shall take appropriate corrective action when the program staff become aware of or observe the use of prohibited forms of behavior management, as specified in sections .26(1)(d)1. through 10. Documentation of the incident and the corrective action taken by the program shall be maintained in the case records of the client.

(2) Emergency Safety Interventions.

(a) Emergency safety interventions may be used only by staff trained in the proper use of such interventions when it can be reasonably anticipated from a client's behavioral history, that a client may require the use of emergency safety interventions to keep either the client or others safe from immediate physical harm, and less restrictive means of dealing with the injurious behavior have not proven successful or may subject the client or others to greater risk of injury.

(b) Program staff working with such client shall be trained in emergency safety interventions utilizing a nationally recognized training program in emergency safety interventions which has been approved by the department.

(c) Emergency safety interventions shall not include the use of any restraint or manual hold that would potentially impair the client's ability to breathe or has been determine d to be inappropriate for use on a particular client due to a documented medical or psychological condition.

(d) The program shall have written policies and procedures for the use of emergency safety interventions, a copy of which shall be provided to and discussed with each client (as appropriate taking into account the client's age and intellectual development) and the client's parents and/or legal guardians prior to or at the time of admission. Emergency safety interventions policies and procedures shall include:

1. Provisions for the documentation of an assessment at admission and at each annual exam by the client's physician, a physician's assistant, or a registered nurse with advanced training working under the direction of a physician, or a public health clinic which states that there are no medical issues that would be incompatible with the appropriate use of emergency safety interventions on that client. Such assessment and documentation must be re-evaluated following any significant change in the client's medical condition; and

2. Provisions for the documentation of each use of an emergency safety intervention including:

   (i) Date and description of the precipitating incident;

   (ii) Description of the de-escalation techniques used prior to the emergency safety intervention, if applicable;

   (iii) Environmental considerations;

   (iv) Names of staff participating in the emergency safety intervention;

   (v) Any witnesses to the precipitating incident and subsequent intervention;

   (vi) Exact emergency safety intervention used;

   (vii) Documentation of the 15 minute interval visual monitoring of a client in seclusion;

   (viii) Beginning and ending time of the intervention;

(ix) Outcome of the intervention;

(x) Detailed description of any injury arising from the incident or intervention; and

(xi) Summary of any medical care provided.

3. Provisions for prohibiting manual hold use by any employee not trained in prevention and use of emergency safety interventions.

(e) Emergency safety interventions may be used to prevent runaways only when the client presents an imminent threat of physical harm to self or others, or as specified in the individual treatment plan.

(f) Program staff shall be aware of each client's medical and psychological conditions (e.g. obvious health issues, list of medications, history of physical abuse, etc.), as evidenced by written acknowledgement of such awareness, to ensure that the emergency safety intervention that is utilized does not pose any undue danger to the physical or mental health of the client.

(g) Clients shall not be allowed to participate in the emergency safety intervention of other clients.

(h) Immediately following the conclusion of the emergency safety intervention and hourly thereafter for a period of at least four hours where the client is with a staff member, the client's behavior will be assessed, monitored, and documented to ensure that the client does not appear to be exhibiting symptoms that would be associated with an injury.

(i) At a minimum, the emergency safety intervention program that is utilized shall include the following:

1. Techniques for de-escalating problem behavior including client and staff debriefings;

2. Appropriate use of emergency safety interventions;

3. Recognizing aggressive behavior that may be related to a medical condition;

4. Awareness of physiological impact of a restraint on the client;

5. Recognizing signs and symptoms of positional and compression asphyxia and restraint associated cardiac arrest;

6. Instructions on how to monitor the breathing, verbal responsiveness, and motor control of a client who is the subject of an emergency safety intervention;

7. Appropriate self-protection techniques;

8. Policies and procedures relating to using manual holds, including the prohibition of any technique that would potentially impair a client's ability to breathe;

9. Agency policies and reporting requirements;

10. Alternatives to restraint;

11. Avoiding power struggles;

12. Escape and evasion techniques;

13. Time limits for the use of restraint and seclusion;

14. Process for obtaining approval for continual restraints and seclusion;

15. Procedures to address problematic restraints;

16. Documentation;

17. Investigation of injuries and complaints;

18. Monitoring physical signs of distress and obtaining medical assistance; and

19. Legal issues.

(j) Emergency safety intervention training shall be in addition to the annual training required in Rule .10(8)(b) and shall be documented in the staff member's personnel record.

(j) All actions taken that involve utilizing an emergency safety intervention shall be recorded in the client's case record showing the cause for the emergency safety intervention, the emergency safety intervention used, and, if needed, approval by the clinical director, the staff member in charge of casework services, and the physician who has responsibility for the diagnosis and treatment of the client's behavior.

(l) Programs shall submit to the department electronically or by facsimile a report, in a format acceptable to the department, within 24 hours whenever the program becomes aware of an incident which results in injury to a client requiring medical

treatment beyond first aid that is received by a client as a result of or in connection with any emergency safety intervention.

1. For any program with a licensed capacity of 20 clients or more, any 30-day period in which three or more instances of emergency safety interventions of a specific client occurred and/or whenever the program has had a total of 10 emergency safety interventions for all clients in care within the 30-day period; and

2. For any program with a licensed capacity of less than 20 clients, any 30-day period in which three or more instances of emergency safety interventions of a specific client occurred and/or whenever the program has had a total of five instances for all clients in care within the 30-day period.

(m) Programs shall submit a written report to the program's clinical director on the use of any emergency safety intervention immediately after the conclusion of the intervention and, if the client is a child or has an assigned legal guardian, shall further notify the client's parents or legal guardians regarding the use of the intervention. A copy of such report shall be maintained in the client's file.

(n) At least once per quarter, the program, utilizing a master agency restraint log and the client's case record, shall review the use of all emergency safety interventions for each client and staff member, including the type of intervention used and the length of time of each use, to determine whether there was a clinical basis for the intervention, whether the use of the emergency safety intervention was warranted, whether any alternatives were considered or employed, the effectiveness of the intervention or alternative, and the need for additional training. Written documentation of all such reviews shall be maintained. Where the program identifies opportunities for improvement as a result of such reviews or otherwise, the program shall implement these changes through an effective quality improvement plan.

(o) No later than March 31, 2007 and ongoing thereafter, all program staff who may be involved in the use of emergency safety interventions, shall have evidence of having satisfactorily completed a nationally recognized training program for emergency safety interventions to protect clients and others from injury, which has been approved by the department and taught by an appropriately certified trainer in such program.

(p) Manual Holds.

1. Emergency safety interventions utilizing manual holds require at least one trained staff member to carry out the hold. Emergency safety interventions utilizing prone restraints require at least two trained staff members to carry out the hold.

2. Emergency safety interventions shall not include the use of any restraint or manual hold that would potentially impair the client's ability to breathe or has been determine d to be inappropriate for use on a particular client due to a documented medical or psychological condition.

3. When a manual hold is used upon any client whose primary mode of communication is sign language, the client shall be permitted to have his or her hands free from restraint for brief periods during the intervention, except when such freedom may result in physical harm to the client or others.

4. If the use of a manual hold exceeds 15 consecutive minutes, the clinical director or his or her designee, who possesses at least the qualifications of the clinical director and has been fully trained in the program's emergency safety intervention plan, shall be contacted by a two-way communications device or in person and determine that the continuation of the manual hold is appropriate under the circumstances. Documentation of any consultations and outcomes shall be maintained for each application of a manual hold that exceeds 15 minutes. Manual holds shall not be permitted to continue if the restraint is determined to pose an undue risk to the client's health given the client's physical or mental condition.

5. A manual hold may not continue for more than 30 minutes at any one time without the consultation as specified in subparagraph (4) of this subparagraph, and under no circumstances may a manual hold be used for more than one hour total within a 24-hour period.

6. If the use of a manual hold on a client reaches a total of one hour within a 24-hour period, the staff shall reconsider alternative treatment strategies, document same, and consider notifying the authorities or transporting the client to a hospital or mental health facility for evaluation.

7. The client's breathing, verbal responsiveness, and motor control shall be continuously monitored during any manual hold. Written summaries of the monitoring by a trained staff member not currently directly involved in the manual hold shall be recorded every 15 minutes during the duration of the restraint. If only one trained staff member is involved in the restraint and no other staff member is available, written summaries of the monitoring of the manual hold shall be recorded as soon as is practicable, but no later than one hour after the conclusion of the restraint.

(q) Seclusion.

1. If used, seclusion procedures in excess of thirty (30) minutes must be approved by the clinical director or designee. No client shall be placed in a seclusion room in excess of one (1) hour within any twenty-four (24) hour

period without obtaining authorization for continuing such seclusion from the client's physician, psychiatrist, or licensed psychologist and documenting such authorization in the client's record.

2. A seclusion room shall only be used if a client is in danger of harming himself or herself or others.

3. A client placed in a seclusion room shall be visually monitored at least every fifteen (15) minutes.

4. A room used for the purposes of seclusion must meet the following criteria:

   (i) The room shall be constructed and used in such ways that the risk of harm to the client is minimized;

   (ii) The room shall be equipped with a viewing window on the door so that staff can monitor the client;

   (iii) The room shall be lighted and well-ventilated;

   (iv) The room shall be a minimum fifty (50) square feet in area; and

   (v) The room must be free of any item that may be used by the client to cause physical harm to himself/herself or others.

5. No more than one client shall be placed in the seclusion room at a time.

6. A seclusion room monitoring log shall be maintained and used to record the following information:

   (i) Name of the secluded client;

   (ii) Reason for client's seclusion;

   (iii) Time of client's placement in the seclusion room;

   (iv) Name and signature of the staff member that conducted visual monitoring;

   (v) Signed observation notes; and

   (vi) Time of the client's removal from the seclusion room.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.26
Authority: O.C.G.A. §§ 26-5-14, 26-5-15, 26-5-16, 50-13-18.
History. Original Rule entitled "Behavior Management and Emergency Safety Interventions" adopted. F. Sep. 9,

2013; eff. Sept. 29, 2013.

Rule 111-8-19-.27. Enforcement and Penalties.

(1) When the department finds that any applicant for any license fails to fulfill the requirements of these rules, the department may, subject to notice and opportunity for a hearing, refuse to grant any license (denial); provided, however, that the department shall not be required to hold a hearing prior to taking such action.

(2) When the department finds that any licensed program violates any requirements of this chapter, the department may, subject to notice and opportunity for a hearing, suspend or revoke any license.

(a) The department may suspend any license for a definite period calculated by it as the period necessary for the facility to implement long-term corrective measures and for the facility to be deterred from lapsing into noncompliance in the future. As an alternative to suspending a license for a definite period, the department may suspend the license for an indefinite period in connection with the imposition of any condition or conditions reasonably calculated to elicit long-term compliance with licensing requirements which the program must meet and demonstrate before it may regain its license.

(b) The department may revoke any license, subject to notice and opportunity for hearing, when it determines that the facility is non-compliant with rules and regulations or sanctions previously imposed. If the sanction of license revocation is finally imposed, as defined by a final adverse finding, the department shall effectuate it by requiring the program to return its license to the department.

1. Notification of Action: The program shall notify clients and clients' representatives and family units of the department's actions to revoke the license or seek an emergency suspension of the program's license to operate.

2. The official notice of the revocation or emergency suspension action and any final resolution, together with the department's complaint intake phone number and website address, shall be provided to current and prospective clients and to their representatives and family units.

3. The program shall ensure the posting of the official notice at the program location in an area that is visible to the clients and to the clients' family units and representatives.

4. The program shall ensure that the official notice continues to be visible to the clients and to the clients' representatives and family units throughout the pendency of the revocation and emergency suspension actions, including any appeals.

5. The program shall have posted at the program location in an area that is readily visible to the clients and to the clients' representatives and family units any inspection reports that are prepared by the department during the pendency of any revocation or emergency suspension action.

6. It shall be a violation of these rules for the program to permit the removal or obliteration of any posted notices of revocation, emergency suspension action, resolution, or inspection survey during the pendency of any revocation or emergency suspension action.

7. The department may post an official notice of the revocation or emergency suspension action on its website or share the notice of the revocation or emergency suspension action and any information pertaining thereto with any other agencies that may have an interest in the welfare of the patients in care at the program.

8. If the sanction of license suspension is finally imposed, as defined by a final adverse findings, the department shall effectuate it by requiring the program to return its license to the department. Upon the expiration of any period of suspension, and upon a showing by the program that it has achieved compliance with licensing requirements, the department shall reissue the program a license. Where the license was suspended for an indefinite period in connection with conditions for the reissuance of a license, once the program can show that any and all conditions imposed by the department have been met, the department shall reissue the program a license.

(3) If the department identifies a violation of these rules, where an opportunity to correct is permissible, the department shall provide written notice specifying the rule(s) violated and setting a time, not to exceed ten (10) working days, within which a program may file an acceptable written plan of correction. If such plan of correction is determined not acceptable to the department because it does not adequately correct the identified violation, the department will advise the program that the plan of correction is not acceptable. The department may permit the program to submit a revised plan of correction.

(a) The program shall comply with an accepted plan of correction.

(b) Where the department determines that either the program has not filed an acceptable plan of correction or has not complied with the accepted plan of correction, the department may initiate an adverse action to enforce these rules.

(4) All actions to enforce the Rules and Regulations for Drug Abuse Treatment and Education Programs shall be administered in accordance with Chapter 13 of Title 50 of the Official Code of Georgia Annotated, the "Georgia Administrative Procedure Act," the Rules and Regulations for Enforcement of General Licensing and Enforcement

Requirements, Chapter 111-8-25, and O.C.G.A. § 26-5-1*et seq.* Any request for a hearing in response to any enforcement action undertaken pursuant to this chapter shall be in writing and must be submitted to the department no later than ten (10) calendar days from the date of receipt of any written notice of intent by the department to impose an enforcement action setting forth the proposed action or actions and the basis therefore. The department's notice of intent to impose an enforcement action shall be made within ninety days after an application is submitted or within 90 days of when the grounds for the actions are discovered.

(5) The department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared a public health emergency.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.27
Authority: O.C.G.A. §§ 26-5-6, 26-5-14 to 26-5-16, 31-2-8, 50-13-18.
History. Original Rule entitled "Enforcement and Penalties" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.28. Waivers and Variances.

The department may, in its discretion, grant waivers and variances of specific rules upon application or petition being filed on forms provided by the department. The department may establish conditions which must be met by the program in order to operate under the waiver or variance granted. Waivers and variances may be granted in accordance with the following considerations:

(a) Variance. A variance may be granted by the department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety and care of clients exist and will be met in lieu of the exact requirements of the rule or regulations in question.

(b) Waiver. The department may dispense entirely with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety and care of clients.

(c) Experimental Variance or Waiver. The department may grant waivers and variances to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant or petitioner that the intended protections afforded by the rule or regulation which is the subject of the request are met and that the innovative approach has the potential to improve service delivery.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.28
Authority: O.C.G.A. §§ 26-5-6, 31-2-7.

History. Original Rule entitled "Waivers and Variances" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-19-.29. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions thereof shall remain in full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-19-.29
Authority: O.C.G.A. § 26-5-6.
History. Original Rule entitled "Severability" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Subject 111-8-22. END STAGE RENAL DISEASE FACILITIES.

Rule 111-8-22-.01. Purposes of This Chapter.

These rules and regulations establish minimum standards for the operation of end state renal disease facilities in order to ensure the health, safety, and protection of the patients served, and establish procedures and requirements for the licensing of such facilities.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.01
Authority: O.C.G.A. §§ 31-2-4, 31-2-5, 31-2-7 and 31-44-3.
History. Original Rule entitled "Purposes of This Chapter" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.02. Definitions.

Unless another meaning is specifically indicated by context, these selected terms shall have the following definitions when used in these rules and regulations:

(a) **Applicant** means a person, business entity, corporation, partnership or association applying for a license to operate an end stage renal disease facility in Georgia;

(b) **Department** means the Department of Community Health of the state of Georgia;

(c) **Dialysis** means a process by which dissolved substances are removed from a patient's body by diffusion, osmosis, and convection (ultrafiltration) from one fluid compartment to another across a semi-permeable membrane;

(d) **Dialysis technician** means an individual who is not a registered nurse or physician and who provides dialysis care under the supervision of a registered nurse or physician;

(e) **End stage renal disease** means that stage of renal impairment that appears irreversible and permanent and that requires a regular course of dialysis or kidney transplantation to maintain life;

(f) **End stage renal disease facility** means a facility that provides dialysis treatment, home dialysis training, and support services, or any combination of such services, to individuals with end stage renal disease;

(g) **Equipment technician** means an individual who performs the required tasks for the maintenance, monitoring, and repair of dialysis, reuse processing, and water treatment systems and equipment at the facility;

(h) **Facility** means an end stage renal disease facility;

(i) **Healthcare personnel** means any person providing healthcare services directly to patients at the facility, including but not limited to the provision of medical or nursing care;

(j) **Initial license** means the first license issued by the Department for a particular end-stage renal disease facility, with subsequent licenses requiring review for renewal;

(k) **Nurse responsible for nursing services** means the Georgia licensed registered nurse who has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process or has 18 months of experience in nursing care of the patient on maintenance dialysis, or the nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process. Where the nurse responsible for nursing services is also in charge of self-care dialysis training, at least 3 months of the total required dialysis experience is in training patients in self-care;

(l) **Physician** means an individual who is licensed to practice medicine in Georgia under O.C.G.A. Chapter 43-34;

(m) **Preceptor** means an individual who provides direct supervision of the provision of patient care by trainees who are in the process of completing training as dialysis technicians, and who:

1. Is a licensed nurse or a dialysis technician with at least twelve months experience in hemodialysis, and

2. Has authorization from a supervising nurse or the medical director of the facility to be preceptor;

(n) **Reuse technician** means an individual who is not a registered nurse or licensed physician who performs the procedures necessary to clean and properly prepare kidney dialyzers for use for multiple treatments;

(o) **Special purpose facility** means an end stage renal dialysis facility providing dialysis services at special locations on a short-term basis to a group of dialysis patients who would otherwise be unable to obtain treatment in that special location; and

(p) **Temporary provisional license** means a license to provide end stage renal care for patients for a limited time period, not to exceed six months.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.02
Authority: O.C.G.A. § 31-44-1.
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.03. License Requirements and Exemptions.

(1) **License Requirements.** Unless specifically exempted under 111-8-22-.03(2), no person, business entity, association, partnership, or corporation shall operate an end stage renal disease facility in Georgia without having first obtained a license from the Department.

(a) A license issued by the Department is required prior to the initiation of dialysis or dialysis support services for patients.

(b) A facility is required to have a separate license for each physical address. Separate applications and licenses are required for facilities maintained separately, even if they are owned or operated by the same person(s), business, partnership, or corporation, and may be doing business under the same trade name.

(c) The license shall be effective for twelve (12) months following the date of issue; the temporary provisional license shall be effective for a maximum of six (6) months. If the facility applies for renewal as required by these regulations, the existing license shall remain in effect until the inspection for renewal is completed.

(d) The facility license is not transferable. A new license is required for any change in physical location, operational or trade name, or facility ownership. An application for a new license must be submitted at least 30 days prior to the change. The former license shall be considered revoked upon issuance of the new license, and shall be returned to the Department.

(e) The facility license shall be prominently displayed in a public area of the facility at all times of operation.

(f) If the facility anticipates that it will close or cease to operate, the governing body shall notify the Department and the patients at least thirty (30) days prior to the anticipated date of closure.

1. With the notification of intent to close, the facility shall submit a written plan for the orderly transfer of care of the facility's patients and their clinical records.

2. Upon closure, the facility shall return the existing license to the Department. The license shall be considered revoked, unless the facility has been placed on temporary inactive status as described in these rules.

(2) **Exempt Facilities.** The following facilities are not required to have a license:

(a) Any hospital permitted under O.C.G.A. 31-7 as a hospital that provides dialysis to individuals receiving services from the hospital;

(b) The office of a physician unless the office is used primarily as an end stage renal disease facility; and

(c) Federal or state agency facilities.

(d) Non-profit camps operating for eight (8) days or less which do not charge a fee to the campers or their families and which provide dialysis services through the use of staff who possess the same minimum qualifications as required of staff providing services under these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.03
Authority: O.C.G.A. § 31-44-5.
History. Original Rule entitled "License Requirements and Exemptions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.04. Application for a License and License Renewal.

(1) All applications for licenses shall be submitted on forms provided by the Department.

(2) No application shall be considered by the Department unless it is complete, and is accompanied by all required attachments and fee payments.

(3) The Department shall issue an annual license to an applicant if it is determined that the applicant and the facility meet the requirements of these rules.

(4) **Initial License.**

(a) **Application for Initial License.** The application for the initial license shall be submitted to the Department not later than thirty (30) days prior to the anticipated date of the opening and initiation of operations by the facility, shall be signed by

the executive officer of the facility's governing body, and shall be accompanied by:

1. The nonrefundable application fee;

2. The initial license fee as designated on the fee schedule;

3. A narrative description of the services to be offered at the facility, including the number of dialysis stations;

4. The name and contact information of the facility administrator as appointed by the facility's governing body;

5. Evidence that the facility has sufficient staff, qualified as required by these regulations, to meet the needs of patients, with a description of the organizational structure of the staffing; and

6. Proof of facility ownership:

   (i) If ownership is a corporation, the application shall be accompanied by a copy of the Certificate of Existence (Good Standing) from the Office of the Secretary of State of Georgia.

   (ii) If the facility is non-profit, the application shall be accompanied by legal proof of the organization and the names and addresses of all trustees.

   (iii) If ownership is neither a corporation nor a non-profit organization, the name and address of each person with ownership in the facility shall be submitted with the application.

(b) **Temporary Provisional License.** The Department may at its discretion issue a temporary provisional license to the facility. The temporary provisional license shall be effective for a period of no more than six (6) months.

1. A temporary provisional license shall be considered for only the following situations:

   (i) The facility has applied for an initial license or renewal of a license and cannot demonstrate full compliance with these rules, but has demonstrated satisfactory evidence that it is making progress toward meeting these rules and has submitted an acceptable plan of correction; or

   (ii) The facility has applied for a license in order to function as a special purpose facility, meeting the requirements of these rules, with

intended operation of no more than the six month period of effectiveness of the license.

2. A temporary provisional license may be issued by the Department only when the facility has demonstrated sufficient compliance with these rules that the health and safety of patients will not be endangered.

3. A 12-month license issued during the period of temporary provisional licensure shall not require an additional license fee.

(c) An end stage renal disease facility in operation at the time these rules initially become effective, and holding certification for participation in the federal Medicare program, shall be granted an initial license upon payment of the applicable license fee, without requiring inspection. This initial license shall be effective for a period of twelve (12) months, unless suspended or revoked as a result of an adverse action, and shall be subject to the renewal process.

(5) **Application for a New Annual License Due to Change in Facility Name, Facility Location, or Facility Ownership.**

(a) At least 30 days prior to the change in the facility's name, location, or ownership, a new application for license shall be submitted which shall contain the new name, location, proof of ownership, any changes in the official mailing address and contact telephone numbers, and a description of any organizational changes or changes in key personnel.

(b) The Department, at its discretion, may require an inspection of the facility prior to approval of the new license.

(c) The facility shall return to the Department the license issued under the prior name, location, or ownership, immediately upon the change of same, and it shall be considered revoked.

(6) **Renewal of License.** At least 30 days, but no more than 90 days, prior to the expiration of the license, the facility shall submit an application for license renewal on forms provided by the Department, with the applicable renewal fee.

(a) The Department shall conduct an inspection of the facility prior to renewal of the facility license, to ensure continued compliance with these rules and regulations.

(b) The facility shall be permitted to continue operation under the existing license until such time as the inspection has been completed and the renewal of the annual license is issued or denied.

(c) The renewed annual license shall have an effective date at the date of issue or at the expiration date of the previous license, whichever is later, and shall be effective for twelve (12) months from the effective date.

(7) **Denial of License Application or Renewal Application.** The Department may refuse to grant a license within the parameters described in "General Licensing and Enforcement Requirements", Chapter 111-8-25.

(a) The Department may refuse to grant an initial annual license without the requirement of holding a hearing prior to the action.

(b) Denial of an application for a new or renewal license from a facility shall be subject to notice and opportunity for a hearing.

(c) An application may be refused or denied if:

1. The facility has failed to demonstrate compliance with these rules and regulations;

2. The applicant has had a license denied, revoked, or suspended within one year of the date of a new application;

3. The applicant has transferred ownership of a facility within one year of the date of a new application in order to avert denial, suspension, or revocation of a permit; or

4. The applicant has knowingly made any verbal or written false statement of material fact in connection with the application for the license.

(8) **Request for Approval for Addition of Services.** A facility shall obtain written approval from the Department prior to any addition of services or increase in number of dialysis stations.

(a) At least thirty (30) days prior to the anticipated date of the addition of a new service or an increase in the number of dialysis stations, the facility shall submit a request for approval. The facility shall submit with the request:

1. A description of any modifications to the facility's physical plant to accommodate the change; and

2. Evidence that the facility has reviewed staffing availability and added staff positions if indicated to accommodate the change.

(b) The Department may at its discretion conduct an inspection of the facility prior to action on the request for change.

(c) The Department shall notify the facility of the approval of the request for change, or the reason for disapproval. If disapproved, the Department shall indicate the action or information required for approval of the change.

(9) **Notification of the Discontinuation of a Service.** At least thirty (30) days prior to the discontinuation of a facility service, the facility shall notify the Department of the planned discontinuation, and shall provide a description of impact of the change on the care of patients currently served. The facility shall also notify the patients of its planned discontinuation of a facility service.

(10) **Temporary Inactive Status.** If the facility is closing temporarily, and plans to reopen under the same ownership and name, the facility may request to have the license placed on temporary inactive status.

(a) Temporary inactive status shall be granted initially for a period of no more than ninety (90) days, and may be granted upon request for only one additional period of ninety (90) days at the discretion of the Department.

(b) When placed on temporary inactive status, the license shall be returned to the Department, and the facility shall not operate until the license has been reactivated.

(c) The facility shall request in writing that the permit be reactivated at least thirty (30) days prior to the desired date of re-opening. Prior to reactivation of the license, the facility shall be subject to inspection by the Department. If the license is not reactivated within six (6) months, the license shall be considered revoked.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.04
Authority: O.C.G.A. §§ 31-44-2, 31-44-6 and 31-44-11. .
History. Original Rule entitled "Application for a License and License Renewal" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.05. Facility Inspections.

(1) The facility shall be available during all hours of operation for observation and examination of the facility and the entirety of its administrative and service operations, by representatives of the Department. If dialyzers are reused for dialysis at the facility, the reprocessing of the dialyzers shall be subject to inspection.

(2) **Initial Inspections.**

(a) There shall be an initial inspection of a facility prior to the opening date in order to determine that the facility is in compliance with these rules. At the time of the

initial inspection the facility shall be ready to operate in compliance with these rules, and shall have available for review:

1. A copy of the Certificate of Occupancy as required by law;

2. Written operational policies and procedures for all services described in the application, and for all support and monitoring functions as required by these rules;

3. Documentation of any agreements with hospitals or other service providers;

4. Evidence of satisfactory water culture results and water chemical analysis; and

5. Documentation of qualifications of staff.

(b) During the period of temporary provisional license, and following the initiation of patient treatment services, the Department shall inspect the facility to determine eligibility for the annual license.

(3) **Periodic Inspections.** Prior to renewal of the license, and periodically as deemed necessary by the Department, the facility shall be subject to periodic inspections to determine that there is continued compliance with these rules.

(a) Upon receipt of a complaint alleging a rule violation by the facility, or if the Department has a reason to suspect there has been a rule violation, the facility shall be subject to inspection.

(b) If the facility is requesting addition of services or dialysis stations, the facility shall be subject to inspection.

(c) Periodic inspections shall be unannounced.

(4) **Plans of Correction.** If as a result of an inspection violations of these licensing rules are identified, the facility will be given a written report of the inspection which identifies the rules violated. The facility shall submit to the Department a written plan of correction in response to the report of inspection, which states what the facility will do, and when, to correct each of the violations identified. The plan of correction shall be submitted within ten calendar days of the facility's receipt of the written report of inspection.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.05
Authority: O.C.G.A. § 31-44-10.
History. Original Rule entitled "Facility Inspection" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.06. Facility Organization and Administration.

(1) **Governing Body.** The facility shall function under the control of an identifiable governing body, which has full legal authority for the governance and operation of the facility.

(a) The governing body shall specify in writing the operational objectives of the facility, including which services are to be offered.

(b) The governing body shall be responsible for the establishment, adoption, and annual review of administrative rules and regulations and facility policies and procedures, and for ensuring that they are in accordance with accepted standards of practice and safeguard the health and safety of patients.

(c) The governing body shall be responsible for ensuring that the facility's design and operation are in compliance with all relevant federal, state, and local legal requirements.

(d) The governing body shall adopt for the facility admission criteria that ensure equitable access to services for individuals needing care for end stage renal disease.

(e) The governing body shall designate sufficient staff and allocate sufficient staff time to implement the facility's quality management program, and shall provide for leadership support of the program.

(f) The governing body shall establish and implement written policies regarding the determination, selection, or privileging of medical staff for the facility.

(g) The governing body shall appoint a facility administrator to be responsible for the administrative management of the facility and the enforcement of adopted rules and regulations.

1. The governing body shall delineate the responsibilities of the facility administrator in writing and shall ensure that the administrator is sufficiently free of other duties to provide effective management of the facility.

2. The governing body of the facility shall notify the Department of a change in the administrator of the facility, and shall at that time provide the name and contact numbers of the new administrator.

(2) **Facility Administrator.**

(a) The facility administrator may serve on a full-time or part-time basis, but shall serve sufficient time to plan, organize, and direct the overall function of the facility, and to carry out those responsibilities as assigned by the governing body. The facility administrator shall meet one of the following qualifications:

1. Holds at least a baccalaureate degree and has at least one (1) year experience in an end stage renal disease facility; or

2. Meets the qualifications for a physician director or a nurse responsible for nursing services for an end stage renal disease facility as described in these rules; or

3. As of the first effective date of these rules, has been acting for at least two years as a facility administrator for an end stage renal disease facility which has been certified for a federal Medicare program.

(b) The facility administrator shall be responsible for:

1. Management of the facility's fiscal affairs, including maintenance of financial records and generating regular reports of expenses and revenues for review by the governing body;

2. Implementing the policies and procedures of the facility as approved by the governing body, and ensuring that all personnel at the facility are familiar with applicable policies as well as applicable state and federal regulations;

3. Coordinating the provision of services at the facility, including establishing clear lines of authority and accountability for those involved in patient care;

4. Ensuring that the facility employs sufficient qualified staff to provide patient care services, and adequately orients staff to their work responsibilities while meeting the following minimum staffing ratios:

   (i) There must be one (1) licensed and qualified nurse for every ten (10) patients receiving dialysis care and one qualified dialysis care giver for each four (4) patients present in the immediate clinical care area. At least one licensed and qualified registered nurse shall be available in the immediate clinical care area to provide nursing care whenever patients are being dialyzed.

   (ii) Trainees may not be counted in the staff:patient ratios.

5. Maintaining facility records, including a chronological record of patient care services provided, and submitting reports on facility functions and operations as required by the governing body or the Department.

(c) The facility administrator shall serve as the liaison between the governing body and the medical staff and other healthcare workers at the facility.

(d) The facility administrator shall designate in writing a qualified individual to act on his/her behalf in the event of his/her absence.

(e) The facility administrator shall be responsible for ensuring that the care of dialysis patients of the facility is coordinated appropriately when a patient is being transferred to a hospital or another dialysis provider or being received back by the facility.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.06
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Facility Organization and Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.07. Facility Communication Responsibilities.

(1) The facility shall develop, adopt, implement, and enforce policies and procedures to ensure that each patient is:

(a) Provided communication of information in a manner effective for the patient, which may include the services of an interpreter or written form, as appropriate;

(b) Fully advised of their medical condition in terms that they understand, or, if they are unable to understand, their representative is so advised;

(c) Informed of all treatment modalities and settings for the treatment of end stage renal disease, and of the criteria for suitability for each treatment modality and setting;

(d) Informed about, and given the opportunity to participate in, all decisions about care, including the right to refuse treatment and the medical consequences of refusal;

(e) Informed about all services provided by the facility, the qualifications and training of staff providing services, and the charges for services provided;

(f) Informed of the facility's reprocessing of dialyzers or bloodlines, if supplies are reused;

(g) Transferred or discharged only for medical reasons, for the welfare of the patient, other patients, or staff, or for on payment of fees, and given at least thirty (30) days advance notice of the transfer or discharge unless such delay presents significant risk to the patient or others, and that there is documentation of efforts to resolve issues leading to discharge when the discharge is against the patient's wishes;

(h) Provided information about, and allowed to formulate, advance directives and have them honored in accordance with current statutes; and

(i) Informed of the facility's internal mechanisms for receiving and responding to complaints from patients and others regarding services, and the mechanisms for filing a grievance or complaint against the facility through the licensing agency, without fear of denial of services or retaliation by the facility.

(2) The facility shall inform each patient upon admission of their responsibilities in the treatment process, and of the facility's rules regarding patient conduct.

(3) The facility shall report to the Department whenever any of the following incidents involving patients receiving dialysis services through the facility occurs:

(a) Any unanticipated patient death not related to the natural course of the illness or the patient's underlying condition occurring at the facility or as a direct result of treatment received in the facility;

(b) Any serious injury resulting from the malfunction or intentional or accidental misuse of patient care equipment;

(c) Exsanguination while at the facility;

(d) Any patient dialyzed with another patient's dialyzer where the facility reuses the hemodialyzers;

(e) Any deviation in fulfilling the patient prescription which results in a significant adverse patient outcome;

(f) Any sexual or physical assault of or by a patient which is alleged to have occurred in the facility.

(4) The facility shall make an initial report of the incident within twenty-four (24) hours or by the next business day from when the incident occurred, or from when the facility has reasonable cause to suspect a reportable incident. The initial report shall be received by the Department in confidence, and shall include at least:

(a) The name of the facility;

(b) The date of the incident and that date that the facility became aware that a possible reportable incident may have occurred;

(c) The medical record number(s) of any affected patient(s);

(d) The type of incident suspected, with a brief description of the incident; and

(e) Any immediate corrective action or preventative action taken by the facility to ensure against the replication of the incident prior to the completion of the facility investigation.

(5) The facility is required to conduct an investigation of any of the incidents listed above and to complete and retain on site a written report of the results of the investigation within forty-five (45) days of the discovery of the incident. The complete report of the investigation shall be available to the Department for inspection at the facility, and shall contain at least the following:

(a) An explanation of the circumstances surrounding the incident, including the results of a root cause analysis or other appropriate quality improvement process or tool;

(b) Any findings and conclusions associated with the review; and

(c) A summary of any actions taken to correct identified problems associated with the incident, and to reduce the potential for recurrence of the incident.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.07
Authority: O.C.G.A. §§ 31-44-3, 31-5-5, 31-7-131 and 31-7-133.
History. Original Rule entitled "Facility Communication Responsibilities" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.08. Continuous Quality Improvement.

(1) Through the facility administration, the medical director, and the medical and nursing staff, the facility shall develop and implement a facility-wide continuous quality improvement program, specific to the facility and designed to perform a systematic, ongoing, concurrent, and comprehensive review of the patient care provided, both in-facility and through the home dialysis program, if provided.

(2) All facility staff shall be involved in the continuous quality improvement program.

(3) Policies and procedures for the continuous quality improvement program shall include the use of a defined methodology for implementation. The methodology selected must include components for measuring the facility's performance, identifying opportunities for improvement through the use of such quality improvement tools as root cause analyses, setting priorities, and identifying expected outcomes. Reporting mechanisms shall be established, including at least a quarterly review of the continuous quality improvement activities.

(4) The continuous quality improvement program shall continuously monitor at a minimum:

(a) Morbidity and mortality;

(b) Hemodialyzer reuse, if applicable;

(c) Water quality;

(d) Preventable maintenance of facility equipment;

(e) Clinical outcomes, including but not limited to adequacy of dialysis and anemia management;

(f) Critical incidents;

(g) Patient complaints;

(h) Infection control; and

(i) Vascular access preservation and complications.

(5) The results of continuous quality improvement activities and monitoring shall be disseminated to the governing body, the medical director, the medical staff, and any service staff impacted by the results.

(6) The facility shall take and document remedial action to address service deficiencies identified through the continuous quality improvement program.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.08
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Continuous Quality Improvement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.09. Medical Staff and Medical Services.

(1) Medical Director. Any medical director beginning such a function for the first time in Georgia at any facility on or after July 1, 2002 shall be a licensed physician who is board-certified in nephrology. However, a physician who has completed a fellowship in nephrology after July 1, 2002 may direct a dialysis facility in a medically- underserved area for a maximum of two years provided that the physician obtains board certification as a nephrologist by the end of the two-year period. Any physician functioning as a facility medical director at the implementation date of these rules shall be board-eligible or board-certified in nephrology, internal medicine, or pediatrics, and shall have at least one year experience in the care of patients at an end stage renal disease facility.

(a) The medical director shall participate in the development of all patient care policies at the facility.

(b) The facility shall have mechanisms in place for communication of essential patient care issues and information to the medical director.

(c) The medical director shall be responsible for the daily clinical operations of the facility, and for the execution of patient care policies and procedures.

(d) The medical director shall be permitted to provide direct patient care services at the facility, in addition to the duties as the medical director.

(2) Medical Services. The medical director shall ensure that each patient at the facility receives medical care and supervision appropriate to the patient's dialysis needs.

(a) Each patient shall have an attending physician who is responsible on a continuing basis for the patient's medical care. Each patient's records shall clearly indicate the name and contact number for the patient's physician.

1. The facility shall require a history and physical examination of each patient following admission, prior to the development of the patient's care plan, and at least annually thereafter.

2. The facility shall require each patient to have a medical plan of care, prescribed by a physician, to include indicated dialysis or related treatments, dialysis orders, medications, diet, criteria for discharge and any other special services needed.

3. The facility shall require that the patient's physician participates in the development of the care plan for the patient, and shall assure that the plan for the patient's medical care is based on the assessment of the patient's individual needs.

4. The facility shall require and the medical director shall ensure that the patient's medical progress at the facility is monitored by a physician on-site at least monthly. The facility shall require that each patient have a scheduled opportunity to see a physician at least once per month. Medical patient monitoring and physician visits shall be documented by progress note entries in the patient's medical record.

5. The facility shall require and the medical director shall ensure that any adverse medical patient outcomes are communicated to the patient's physician, and that the facility takes appropriate corrective action.

(b) The medical director shall ensure that there is medical care available at all times for managing emergency situations, for both in-center and home dialysis patients. There shall be posted at each nursing/monitoring station a roster of physicians on-call for the provision of emergency care. The roster shall specify when each physician is available and how they can be reached.

(c) The facility shall ensure that each patient, or each patient's responsible party, is aware of how to access medical care in an emergency, as appropriate to the patient's age and abilities.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.09
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Medical Staff and Medical Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. May 9, 2017; eff. May 29, 2017.

Rule 111-8-22-.10. Staff Qualifications, Training, and Supervision and Staff Records.

(1) **Staff Orientation.**

(a) The facility shall provide a facility orientation program for all staff, approved by the medical director, to include at least:

1. A review of the services provided by the facility;
2. A review of facility policies and procedures, including general infection control procedures and use of universal precautions;
3. The facility's emergency procedures and disaster preparedness plans;
4. The facility's continuous quality improvement program; and
5. Documentation and records requirements.

(b) The facility shall document that each staff member has attended the orientation program.

(2) **Nursing Staff.**

(a) **Minimum Education and Experience Qualifications for Nursing Staff.**

1. Any registered nurse or licensed practical nurse providing services in the facility shall have and maintain a current Georgia license to practice nursing.
2. Registered nurses in charge of the training of patients in self-care, involving either home hemodialysis or peritoneal dialysis, shall have a minimum of three months of experience working with dialysis self-care patients.
3. Prior to providing dialysis care, all nursing staff shall demonstrate satisfactory completion of either the training program or educational

equivalency and the competency skills assessment checklist as required for dialysis technicians.

(b) **Supervision of Nursing Staff.**

1. **The nurse responsible for nursing services** shall ensure that the licensed practical nurses participating in the provision of appropriate nursing services are familiar with protocols established by the medical staff as necessary for patient care during dialysis treatment. At all times a registered nurse must be in the patient care area while patient care is being provided.

2. Any registered nurse or licensed practical nurse who is employed without previous experience in the dialysis process, and who has not yet successfully completed the skills competency checklist, shall be directly supervised when engaged in dialysis treatment activities with patients by a staff member who has demonstrated skills competency for dialysis treatment as required by these rules.

(c) **Training of Nursing Staff.**

1. When a facility hires a registered nurse who has not had previous dialysis experience, the facility shall conduct and document a training needs assessment to identify training needs specific to care for the dialysis patient, and shall document the provision of such training by an instructor meeting the qualifications for training dialysis technicians as indicated by the needs assessment, together with satisfactory completion of a skills competency checklist.

2. Licensed practical nurses providing dialysis care shall meet the same training and competency requirements, including the documentation of such training and competency, as required by these rules for dialysis technicians.

3. The facility shall require and maintain adequate documentation for all nursing staff of a minimum of twelve (12) clock hours per year of continuing education related to end stage renal disease treatment.

(d) **Competency Evaluation for Nurses.** The facility shall document for each licensed nurse the satisfactory completion of a skills competency checklist in dialysis treatment, signed by the registered nurse responsible for nursing services at the facility, or qualified instructor under these rules, prior to the unsupervised provision of hemodialysis or peritoneal dialysis treatment to patients and thereafter at least annually. The competency skills assessment shall reflect those patient care activities provided by the nurse, and shall include age-specific competencies when applicable.

(3) **Dialysis Technicians.**

(a) An individual may not function as or be represented to be a dialysis technician unless that individual has satisfied the training and competency requirements of these rules. The individual in the process of completing training as a dialysis technician shall be identified as a trainee when present in any patient area of the facility.

(b) **Minimum Qualifications for Dialysis Technicians.** Persons first employed by the facility as dialysis technicians after the effective date of these rules shall meet or exceed the following criteria:

1. A high school diploma or equivalent;

2. Documentation of the satisfactory completion of a training program with a curriculum equivalent to or exceeding the curriculum required by these rules for dialysis technicians; and

3. Documentation of the satisfactory completion within the past twelve months of a skills competency checklist equivalent to or exceeding the competencies required by these rules for dialysis technicians, administered at the current employment facility.

(c) **Required Training for Dialysis Technicians.**

1. A training program curriculum for dialysis technicians shall be approved by the medical director of the facility, and shall include minimally the following educational and clinical components, defined in written form with objectives for each component:

(i) Understanding of the individual with end stage renal disease, to include:

(I) Basic renal anatomy, physiology, and pathophysiology;

(II) The effect of renal failure on other body systems;

(III) Signs and symptoms of the uremic state;

(IV) Basic renal nutrition;

(V) Basic psychosocial aspects of end stage renal disease; and

(VI) Medications commonly administered to patients with end stage renal disease, and side effects, toxicity, and other common problems associated with medications;

(ii) Introduction to dialysis treatments and options including a history of dialysis and definitions and terminologies used;

(iii) Principles of hemodialysis to include at least:

(I) The use of osmosis and diffusion for blood cleaning;

(II) Access to the circulatory system; and

(III) Anticoagultion and the role of local anesthetics and normal saline;

(iv) Hemodialysis procedures to include at least:

(I) Using aseptic technique;

(II) Technical aspects of operation and monitoring of dialysis equipment, and of the initiation and termination of dialysis;

(III) Delivery of an adequate dialysis treatment and factors which may result in inadequate treatment;

(IV) Observation and reporting of patient reactions to treatment;

(V) Glucose monitoring, dialysis adequacy monitoring and hemoglobin/ hematocrit monitoring; and

(VI) Emergency procedures and responses such as cardiopulmonary resuscitation, air embolism management, management of hypo and hypertensive crises, response to line separation during hemodialysis, calling an ambulance, and handling patient death;

(v) Hemodialysis equipment to include at least:

(I) Theory and practice of conventional, high efficiency, and high flux dialysis;

(II) Dialysate composition, options, indications, complications, and safety;

(III) Safe equipment operation and monitoring; and

(IV) Equipment disinfection;

(vi) Water treatment to include:

(I) Standards for water treatment used for dialysis as described in the current American National Standard, Hemodialysis Systems, published by the Association for the Advancement of Medical Instrumentation (AAMI);

(II) Water treatment systems and devices;

(III) Monitoring of water; and

(IV) Risks to patients of unsafe water;

(vii) Reprocessing, if the facility practices dialyzer reuse, to include at least:

(I) Principles of reuse;

(II) Safety, quality control, universal precautions, and water treatment in reprocessing; and

(III) Standards for reprocessing of dialyzers for reuse, as described in the current American National Standard, Reuse of Hemodialyzers, published by the Association for the Advancement of Medical Instrumentation (AAMI);

(viii) Patient teaching, to include at least the role of the technician in supporting patient education goals;

(ix) Infection control during dialysis and in the dialysis environment, to include at least:

(I) Risks to patients of nosocomial infections, accidents, and errors in treatment;

(II) Sterile techniques and specimen handling;

(III) Basic bacteriology and epidemiology;

(IV) Risks to employees of blood and chemical exposure; and

(V) The importance of ongoing quality control activities in assuring safe dialysis treatments are provided to patients;

(x) The facility's grievance policies, and the handling of patient complaints.

2. If the dialysis technician is to participate in training or treatment with peritoneal dialysis patients, the following components must be included in the training curriculum in addition to those components listed above:

   (i) Principles of peritoneal dialysis;

   (ii) Sterile technique for peritoneal dialysis;

   (iii) Peritoneal dialysis delivery systems;

   (iv) Symptoms of peritonitis; and

   (v) Complications of peritoneal dialysis.

3. If the dialysis technician is to cannulate the access site, the training curriculum shall include, in addition to those components listed under 111-8-22-.10(3)(c)1. above, training in accessing the circulatory system, including at least:

   (i) The creation and development of a fistula, needle placement for access, and prevention of complications;

   (ii) The materials used and creation of grafts, needle placement for access in a graft, and prevention of complications; and

   (iii) Identification of signs and symptoms of complications when cannulating access.

4. The trainee shall independently complete a written examination at the completion of the training program, which shall encompass the content of the curriculum in subsection 1. of this section, and, as applicable, subsection 2. and/or 3. The trainee shall be required to obtain a passing score of 80% or greater on the written examination. Current certification as a dialysis technician by a nationally recognized certification organization or satisfactory evidence of having successfully passed a nationally standardized test of competency for dialysis care technicians approved by the Department may exempt an individual from the requirement of the training program and written examination, if permitted by facility policy.

5. The curriculum for the training program shall be:

(i) Reviewed at least annually by the medical director, and updated as needed by changes in the facility's equipment and/or procedures;

(ii) Administered under conditions that do not compromise the integrity of each individual assessment required for competency tests and the completion of skills checklists; and

(iii) Where the Department determines that the facility's training program does not appear to provide adequate evidence of training in accordance with these requirements as a result of the identification of rule violations associated with the quality of care being provided by dialysis technicians and/or the facility's performance falls below acceptable levels on at least three patient care quality indicators, such as mortality rate, hospitalization rate, catheter rates, fistula rates, hematocrit levels and urea reduction rates and the Department so notifies the facility, the facility will be required to utilize a nationally standardized competency test approved by the Department. The facility shall have one year from the date of the Department's notification to have all its dialysis care technicians providing care having passed an approved nationally standardized competency test for dialysis care technicians and must continue using the nationally standardized competency test for all new hires. No dialysis care technician hired after the facility has received notice of that nationally standardized competency test is being required by the Department shall be permitted to continue in employment at the facility for more than one (1) year without having satisfactorily completed a nationally standardized test of competency approved by the Department.

6. **Instructors.** Instructors for the training program for dialysis technicians shall have passed the training and clinic skills competency checklist for dialysis technicians. All instructors providing training for dialysis technicians two years from the effective date of these rules and thereafter, shall have passed a nationally recognized and standardized examination for the provision of dialysis care as approved by the Department.

(i) For the two years immediately following the adoption of these rules, a registered nurse or licensed practical nurse with at least twelve months of experience in hemodialysis, and at least three months experience in peritoneal dialysis, if applicable to the facility program, or an instructor qualified by education and training providing a dialysis technician training course through an accredited college or university may serve as an instructor of dialysis technicians.

(ii) **Adjunct Instructors.** With twelve (12) months experience in a dialysis setting, licensed dietitians, licensed social workers or qualified dialysis technicians providing training on water reuse or equipment maintenance may provide those components of the training program within their specific areas of expertise under the supervision of the instructor.

(d) **Clinical Supervision of Dialysis Technicians and Trainees.**

1. Trainees who are in the process of completing a dialysis technician training program shall provide patient care only as a part of the training program, and only under the immediate and direct monitoring of either:

   (i) A licensed nurse meeting the qualifications of this chapter, or

   (ii) An assigned preceptor, who is either a licensed practical nurse or a dialysis technician with at least one year of dialysis experience and a current satisfactory skills competency checklist as required of a dialysis technician on file at the facility.

2. The facility shall define by written policy the hours of directly monitored clinical patient care activities required for the completion of the training program for staff coming into the facility with credentials demonstrating appropriated competencies. At a minimum, facility policy must provide for 40 hours of monitored clinical patient care activities and completion of a skills checklist. For the first forty (40) hours of monitored patient care activities, this staff may not be counted in the staff:patient care ratio.

3. A licensed facility utilizing a temporary employment agency to provide patient care services must have a written agreement with the temporary agency that specifies that the staff the agency sends to provide patient care services to the facility must meet the staff qualification set forth in these rules. The facility will monitor contract performance to ensure that the agency staff providing patient care services in the facility are competent to perform the assigned patient care tasks and that the agency staff have been familiarized with the particular facility's environment and procedures for handling emergencies prior to caring for patients at the facility.

4. Dialysis technicians who have completed an acceptable training program and skills competency checklist shall be supervised by a registered nurse. A licensed registered nurse shall be immediately available in the dialysis area to monitor the care being provided by the dialysis technician to the patient.

(e) **Competency Evaluation for Dialysis Technicians.** In addition to the satisfactory completion of the required training program and written examination, the dialysis technician trainee, each dialysis technician newly employed, and each dialysis technician at least annually, shall be required to demonstrate satisfactory clinical patient care performance through a skills competency evaluation.

1. A licensed nurse who qualifies as an instructor in these rules shall administer to each trainee or technician an assessment of skills through a skills competency checklist which covers at least the following acts:

   (i) Assembling necessary supplies for hemodialysis;

   (ii) Preparing dialysate according to procedures and dialysis prescription;

   (iii) Assembling and preparing the dialysis extracorporeal circuit correctly;

   (iv) Securing the correct dialyzer for the specific patient;

   (v) Installing and rinsing the dialyzer and all necessary tubing;

   (vi) Testing monitors and alarms, conductivity, and (if applicable) presence and absence of residual sterilants;

   (vii) Setting monitors and alarms according to facility and manufacturer protocols;

   (viii) Obtaining predialysis vital signs, weight, and temperature according to facility protocol and informing the registered nurse of unusual findings;

   (ix) Inspecting access for patency and, after cannulation is performed and heparin administered, initiating dialysis according to the patient's prescription, observing universal precautions, and reporting unusual findings to a licensed nurse;

   (x) Adjusting blood flow rates according to established protocols and the patient's prescription;

   (xi) Calculating and setting the dialysis machine to allow fluid removal rates according to established protocols and the patient's prescription;

(xii) Monitoring the patient and equipment during treatment, responding appropriately to patient needs and machine alarms, and reporting unusual occurrences to a licensed nurse;

(xiii) Monitoring patient blood pressure and taking appropriate actions related to blood pressure according to facility protocol;

(xiv) Documenting findings and actions according to facility protocol;

(xv) Describing indicators and appropriate response to dialysis-related emergencies such as cardiac or respiratory arrest, needle displacement, or infiltration, clotting, blood leaks, or air emboli and to nonmedical emergencies such as power outages or equipment failure;

(xvi) Discontinuing dialysis and establishing hemostatis, to include at least:

(I) Inspecting, cleaning, and dressing the access site according to facility protocol; and

(II) Identifying and reporting unusual findings to a licensed nurse.

(xvii) Obtaining and recording post-dialysis vital signs, temperature, and weight and reporting unusual findings to a licensed nurse;

(xviii) Discarding supplies and sanitizing equipment and treatment chair according to facility protocol;

(xix) Communicating the patient's emotional, medical, psychological, and nutritional concerns to a licensed nurse;

(xx) Maintaining professional conduct, good communication skills, and attention to privacy and confidentiality during the care of the patient;

(xxi) For the dialysis technician trainee who will be assisting with training or treatment of peritoneal dialysis patients:

(I) Assisting patients in ordering supplies for dialysis;

(II) Making a dialysate exchange (draining and refilling the peritoneal space with dialysate) to include continuous ambulatory peritoneal dialysis exchange procedures and

initiation or discontinuation of continuous cycling peritoneal dialysis;

(III) Observing peritoneal effluent and identifying significant factors;

(IV) Collecting dialysate specimen;

(V) Performing a transfer tubing change; and

(VI) Setting up and operating continuous cycling peritoneal dialysis equipment.

(xxii) For the dialysis technician trainee who will be cannulating dialysis access, the performance of cannulation, to include:

(I) Inspecting the site for access;

(II) Preparing the skin;

(III) Using aseptic technique;

(IV) Placing and securing needles correctly;

(V) Establishing blood access;

(VI) Replacing needles; and

(VII) Recognizing problems and the need to call for assistance; and

(xxiii) For the licensed practical nurse functioning as a dialysis technician, the skills competency checklist shall include, in addition to the above, the protocols for administering medications and intravenous fluids, including but not limited to normal saline, heparin and subcutaneous lidocaine, during the dialysis treatment.

2. For any items failed during the administration of the skills competency checklist, the facility shall document additional training for the trainee or technician in the area(s) of failure, and the trainee or technician shall not be permitted to provide patient care without direct supervision until all checklist items have been demonstrated satisfactorily.

(f) **Verification and Demonstration of Completion of the Training Program and Competency Assessment for Dialysis Technicians.** When a trainee completes a dialysis technician training program at the facility, the facility shall issue and provide to the dialysis technician a document verifying completion of the training requirements under this chapter. This document may be accepted as proof of completion of training by another facility that later employs the dialysis technician, provided that the dialysis technician is able to satisfactorily complete a skills competency checklist administered by the new place of employment.

(g) **Dialysis Acts Permitted for Dialysis Technicians to Perform.** A dialysis technician who has successfully completed the training program outlined herein and the skills competency checklist may perform the following actions under the supervision of a licensed registered nurse:

1. Initiate routine dialysis treatments for those patients whom the technicians are not prohibited from dialyzing as outlined in section (h) below.

2. Administer normal saline via the extracorporeal circuit during the initiation and discontinuation of the dialysis treatment and during dialysis treatment according to specified written protocols established by the medical director. At the time that the technician administers normal saline during the course of the dialysis treatment, the technician shall immediately notify the nurse responsible for that patient.

3. Monitor patients during their dialysis treatment and make adjustments in rate of treatment in accordance with established protocols and instructions.

4. Discontinue routine dialysis treatment and establish hemostasis for those patients whom the technician is not prohibited from dialyzing as outlined in section (h) below.

(h) **Dialysis Acts Prohibited for the Dialysis Technician.** A dialysis technician who is not a licensed practical nurse shall not:

1. Initiate or discontinue hemodialysis via a central catheter, manipulate a central catheter, or change dressings for a central catheter;

2. Administer controlled substances or dangerous drugs to patients at any time, including those medication which may be required during routine dialysis treatment, except for normal saline as provided in paragraph (g)2. above.

3. Administer blood or blood products;

4. Perform non-access site arterial puncture;

5. Accept physician orders; or

6. Provide hemodialysis treatments to pediatric patients under fourteen (14) years of age or under 35 kilograms weight.

(4) **Reuse Technicians.**

(a) **Minimum Qualifications for Reuse Technicians.** Persons first hired after the effective date of these rules to process kidney dialyzers for reuse at the facility shall meet or exceed the following criteria:

1. A high school diploma or equivalency,

2. Documentation of the satisfactory completion of a training program with a curriculum equivalent to or exceeding the curriculum required by these rules for reuse technicians, and

3. Documentation of the satisfactory completion within the past twelve months of a skills competency checklist equivalent to or exceeding the competencies required by these rules for reuse technicians, administered at the facility where currently employed.

(b) **Required Training for Reuse Technicians.**

1. A training program curriculum for reuse technicians shall be approved by the medical director of the facility, and shall include minimally the following educational and technical components, defined in written form, with objectives for each component which comply with the American National Standard for Reuse of Hemodialyzers, published by the Association for the Advancement of Medical Instrumentation (AAMI) and herein incorporated by reference:

(i) The basic principles of hemodialysis, emphasizing the role of the dialyzer;

(ii) The rationale for and importance of the use of treated water in dialysis and dialyzer processing, including the risks of using untreated water;

(iii) The facility's protocols for the reprocessing dialyzers and the rationale for each step of the procedure;

(iv) The operation and maintenance of the equipment used by the facility in the reprocessing program;

(v) Infection control procedures; and the importance of infection control in the handling of dialyzers and reprocessing equipment and materials;

(vi) The risks of cross-contamination, and the methods to prevent it;

(vii) The disinfection procedures, including safe handling of disinfectants, cleaning spills and disposing of toxic substances, the importance of protective equipment and ventilation in the reprocessing area, and the procedures for testing for residual disinfectant in the dialyzer;

(viii) Documentation procedures and procedures for labeling dialyzers during and after reprocessing; and

(ix) Criterion for determining when a dialyzer should not be reused, and proper disposal of used dialyzers.

2. Instructor. An instructor for a reuse technician training program shall be a licensed nurse or trained reuse technician who has successfully completed the skills competency checklist for reuse technicians within the past year.

3. Prior to completion of the training program and satisfactory demonstration of competency, the reuse technician trainee or newly employed reuse technician shall not engage in any part of dialyzer reprocessing except as a part of the training program and under the direct supervision of an instructor as defined in 111-8-22-.10(4)(b)2.

(c) **Competency Evaluation for the Reuse Technician.** The reuse technician trainee, any newly employed reuse technician, and each reuse technician at least annually, shall be required to demonstrate satisfactory performance of reprocessing tasks through a skills competency evaluation administered by a qualified instructor as defined in 111-8-22-.10(4)(b)2.

1. The competency skills checklist for reuse technicians shall include at least the following:

(i) Performance of all steps of the facility's protocols for reprocessing dialyzers, including receiving and transporting, rinsing and cleaning, disinfecting, storage, and setup for reuse, and observance of required procedures to control risk of infection and crosscontamination.

(ii) Monitoring and documentation of air and water quality;

(iii) Monitoring and documentation of equipment function;

(iv) Handling of toxic substances and use of protective equipment and clothing, including management of spills;

(v) Labeling of dilaizyers; and

(vi) Documentation of reprocessing for each dialyzer, and completion of required logs and forms.

2. For any items failed during the administration of the skills competency checklist, the facility shall document additional training for the trainee or technician in the area(s) of failure, and the trainee or technician shall not be permitted to reprocess dialyzers without direct supervision until all checklist items have been demonstrated satisfactorily.

(d) **Verification and Documentation of Completion of the Training Program and Competency Evaluation for Reuse Technicians.** When a trainee completes a reuse technician training program at the facility, the facility medical director shall issue and provide to the reuse technician a document verifying completion of the training requirements under this chapter. This document may be accepted as documentation of completion of training by another facility that later employs the reuse technician, provided that the reuse technician is able to satisfactorily complete a skills competency checklist administered at the new place of employment.

(5) **Water Treatment System Technician.**

(a) **Minimum Qualifications for Water Treatment Systems Technicians.** Individuals first hired after the effective date of these rules who are assigned responsibility for the operation and monitoring of the water treatment system shall meet or exceed the following criteria:

1. A high school diploma or equivalency;

2. Documentation of completion of an on-site training program in the principles and fundamentals of water treatment and the operation and maintenance of the equipment currently used by the facility or a training program which covered the same material as provided in the on-site program prior to employment. An on-site training program, if provided, shall be approved by the medical director, and shall include the current standards and procedures for water treatment recommended by the Association for the Advancement of Medical Instrumentation (AAMI), under the title "Hemodialysis Systems", herein incorporated by reference.

3. Demonstration of an understanding of the risks of patients exposed to water which has not been treated to remove contaminants and impurities, and documentation of satisfactory completion of a skills competency checklist at least annually to include at least the following:

   (i) Basic operation and use of the facility's water treatment system, according to the manufacturer's protocols, at a minimum, from the water source through the water delivery system;

   (ii) Monitoring and testing for water quality and treatment system performance, and documentation of such monitoring, as required by facility protocol;

   (iii) Adherence to cleaning and disinfection schedules and procedures for the water treatment equipment;

   (iv) Calibration of measurement and monitoring instruments;

   (v) Troubleshooting for equipment malfunctions; and

   (vi) Procedures to be followed if abnormal findings are discovered during water quality monitoring.

(b) All water treatment technicians, regardless of the date of hire must successfully complete a skills competency checklist annually for all water treatment procedures which meets or exceeds the skills competency checklist for new trainees.

(6) **Equipment Technicians.** An individual first hired after the effective date of these rules who functions as an equipment technician shall have at least the following minimum qualifications:

(a) High school diploma or equivalency;

(b) Completion of a training program approved by the medical director of the facility, which includes at least an overview of mechanical and equipment systems at the facility, electrical safety (including lockout) and safety requirements of dialysate delivery systems, standards and protocols for monitoring water bacteriology, both in dialysate and water used for reprocessing;

(c) Prior to being assigned responsibility for performing any equipment-related maintenance and repairs, the facility must ensure that the technician has completed training in machine maintenance and repairs for the equipment used at the facility for dialysis, reprocessing, and water treatment for which the technician may be responsible for, as provided by the equipment manufacturer(s) or other qualified staff certified by the equipment manufacturer and must complete satisfactorily an

appropriate skills competency checklist administered by staff qualified to judge the required job competencies.

(d) All equipment technicians, whether hired before or after the effective date of these rules, must satisfactorily complete at least annually a skills competency checklist covering all assigned duties administered by staff qualified to judge the required job competencies.

(7) **Dietitian.** Any dietitian employed by the facility shall hold a current license in the state of Georgia to practice as a dietitian.

(8) **Social Worker.** The social worker employed by the facility shall hold a current license in the state of Georgia as either a Master's Social Worker or a Licensed Clinical Social Worker.

(9) **Continuing Education.** Facility staff providing patient care shall attend a minimum of twelve clock hours of continuing education activities related to end stage renal disease and treatment within twelve months of the effective date of these rules and annually thereafter. Continuing education activities may consist of, but are not limited to, seminars, lectures, and educational workshops or one-on-one training. Continuing education provided at the facility, including technician training programs, shall be accepted toward satisfaction of this requirement. The facility orientation program shall not be accepted for satisfaction of this requirement. Documentation of attendance at continuing education activities shall be kept in the personnel file for each staff member.

(10) **Staff Records.**

(a) The facility shall compile and maintain a personnel record for each staff member which include documentation of at least:

1. The staff member's employment history;

2. The staff member's job description;

3. The results of annual competency evaluations and job performance evaluations; and

4. Verification of the current status of any professional licenses or certifications, as applicable to the staff member's job functions.

(b) The facility shall maintain for each staff member a record of the evaluation(s) of the staff member's health status.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.10
Authority: O.C.G.A. §§ 31-44-3, 31-44-8 and 31-44-9.
History. Original Rule entitled "Quality Qualifications, Training and Supervision and Staff Records" adopted. F.

Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.11. Patient Care Services.

(1) Nursing Services.

(a) Nursing services shall be provided in accordance with current standards of practice as defined by Georgia law.

(b) The facility shall employ a full-time registered nurse to be the nurse responsible for nursing services, and to supervise the provision of patient care by licensed practical nurses and unlicensed personnel.

(c) A licensed registered nurse shall be present in the treatment area when patient treatments are in progress.

(d) The facility shall ensure the following patient care activities are assigned to and performed by appropriately licensed nurses:

1. Conducting nursing assessments on admission and when indicated by an observed or reported change in the patients' health status;

2. Provision of nursing input for the team review of a patient's progress;

3. Recommending to the team changes in treatment suggested by the patient's needs;

4. Administration of medications, including the introduction of intravenous saline;

5. Initiation and discontinuation of hemodialysis via a central catheter, and manipulation of a central catheter or change of dressing for a central catheter;

6. Administration of blood or blood products;

7. The facilitation of communication between the patient, the patient's family, and other members of the treatment team; and

8. Provision of oversight and supervision for dialysis technician trainees, dialysis technicians, and other unlicensed personnel involved in patient care activities, including the recording of treatment observations and interventions in progress notes, as qualified for such oversight and supervision by the rules contained in this chapter.

(e) Dialysis treatments for pediatric patients under fourteen years of age or under 35 kilograms in weight shall be performed by a licensed registered nurse with experience in pediatric dialysis.

(2) Nutrition Services. The facility shall provide nutrition services to the patients and the patients' families and caregivers, which are designed to maximize the patient's nutritional status. Services shall be provided by a qualified dietitian, as defined by these rules, and shall include at a minimum:

(a) Basic nutritional education must be initiated within two weeks of admission by the nursing or dietary staff. A comprehensive nutritional assessment report with recommendations for patient education will be completed within thirty days of admission and at least annually thereafter;

(b) Participation as a member of the interdisciplinary treatment team in the development of each patient's plan(s) of care and review of that plan;

(c) Availability of a qualified dietitian to provide counseling and assistance to patients during regular treatment times;

(d) Recommendations of therapeutic diets specific to each patient's needs, counseling and training for patients related to the dietary recommendations, and monitoring of nutritional status and adherence to dietary requirements by objective and subjective means, with timely intervention when changes are indicated; and

(e) Regular recording in the patient's medical record of the patient's nutritional status, monitoring data, and progress in meeting nutritional goals.

(3) Social Work Services. The facility shall provide social services which are directed toward supporting and maximizing the patient's social functioning and adjustment to management of end stage renal disease. Services shall be provided by a qualified social worker, as defined by these rules, and shall include at a minimum:

(a) Psychosocial evaluation of each patient, completed within thirty (30) days of admission and at least annually thereafter;

(b) Participation as a member of the interdisciplinary treatment team in the development of each patient's plan(s) of care and review of that plan;

(c) Recommendations regarding changes in treatment which may be indicated by the patient's psychosocial needs;

(d) The provision of case work and group work services to patients and their families in dealing with the problems and complications associated with end stage renal disease and dialysis;

(e) Identification of community service agencies and other support resources, and facilitation of patients' access to those resources;

(f) Provision of access to social work services during times of patient treatment; and

(g) Regular reporting of the patient's contact with the social worker in the patient's medical record.

(4) Laboratory Services. The facility shall provide or arrange for the laboratory services needed for safe and effective patient treatment.

(a) If the facility provides its own laboratory services:

1. The facility shall have current Georgia licensure and federal certification as required for the tests performed, or a waiver for the tests performed if licensure and certification are not required.

2. The facility performing waived tests shall have policies and procedures for obtaining samples, performing tests, and reporting results, which conform to current standards of practice and the manufacturer's specifications.

(b) If the facility receives services from an outside laboratory, such arrangements shall be made by written contract, which shall ensure that the laboratory meets all applicable state and federal licensing and certification requirements for the tests performed, and which ensures the provision of test results in a timely manner.

(5) Administration and Storage of Controlled Substances and Dangerous Drugs.

(a) Controlled substances and dangerous drugs shall be administered to patients only with an order from a licensed physician or from a physician's assistant or nurse practitioner as permitted by Georgia law.

(b) Controlled substances and dangerous drugs shall be administered to patients only by those persons authorized under Georgia law to administer medications. However, trained and competent dialysis technicians are permitted to administer saline via the extracorporeal circuit as provided under Section 111-8-22-.10(3)(g)2.

(c) Medications shall be prepared for administration in a work area that prevents contamination during preparation.

(d) Medications not given immediately shall be labeled with the patient's name, the name of the medication, and the dosage, and the date and time opened, and initialed by the person preparing the medication. All medications shall be administered by the individual who prepares them.

(e) The facility shall establish and implement procedures for limiting access to medications by unauthorized personnel.

(f) Medications requiring refrigeration shall be stored in refrigerators used only for that purpose and stored at appropriate temperatures.

(g) The facility shall regularly inventory controlled substances and dangerous drugs and medication supplies to ensure that outdated supplies are immediately disposed of in an appropriate manner, and that sufficient supplies of usable controlled substances and dangerous drugs are available to meet patient needs.

(h) Controlled substances shall be stored and dispensed in accordance with the provisions of the Georgia Pharmacy Practice Act and the Georgia Controlled Substance Act.

(6) Home Training Services for Hemodialysis or Peritoneal Dialysis.

(a) If the facility provides services for training and support of home dialysis, the facility shall meet the requirements for care plans for those patients, to include interdisciplinary conferences.

(b) In addition to other facility services and support requirements, the facility shall provide for home dialysis patients:

1. A written outline of the home dialysis training program, including didactic and practice components, including the performance of dialysis treatments by patients and/or their assisting partner and the requirements for facility surveillance of the patient's home adaptation and water quality, with the requirement that each patient (and their assisting partner, if applicable), satisfactorily complete the training program before beginning home dialysis;

2. Sufficient teaching materials available for patient use during and after home dialysis training;

3. A program for surveillance of the patient's home adaptation, to include an initial visit in the patient's home and subsequent supervisory visits by a licensed registered nurse, as indicated by the patient's medical status and training needs or at least annually, with documentation of all home visits in the patient's medical record;

4. A procedure for continuous re-evaluation of the suitability of home dialysis for the patient, to include evaluation of the adherence of the patient to physician's orders and policies and procedures of the facility, and the adequacy of the dialysis performed in the home;

5. Provision of supplies for the home sufficient to sustain dialysis treatment;

6. Routine transfer set changes, where applicable, for peritoneal dialysis patients at least every six (6) months and as needed;

7. Installation and maintenance of dialysis equipment in the home, including training for the patient in identifying equipment malfunctions and mechanisms for accessing equipment service; and

8. A system for routine monitoring, culturing, and disinfection of the water in the home of each hemodialysis patient, to ensure that the water quality meets the standards recommended by the Association for the Advancement of Medical Instrumentation (AAMI).

(c) The facility shall provide dialysis services at the facility or arrange for the provision of services at a site mutually agreeable to the facility and the patient for the home dialysis patient on those occasions when the home dialysis patient is unable to perform safe and adequate dialysis in the home.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.11
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Patient Care Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. May 9, 2017; eff. May 29, 2017.

Rule 111-8-22-.12. Patient Care Plans.

(1) The facility shall coordinate services for each patient through an interdisciplinary treatment team approach. An interdisciplinary treatment team shall be identified at the time of admission for each patient and shall consist of at least:

(a) The patient and any family member(s) or other(s) designated as a representative of the patient who wishes to participate and is invited by the patient to participate;

(b) Either the patient's attending physician or the medical director of the end stage renal disease facility;

(c) A qualified registered nurse, who is responsible for nursing services at the facility;

(d) A licensed social worker;

(e) A licensed dietitian; and

(f) A transplant surgeon or surgeon-designee.

(2) There shall be documentation of the participation of the patient (or their representative) in the development and review of the patient's plan of care, with consideration given to the

patient's preferences. If participation is declined, the declination shall be documented, and there shall be evidence that the content of the plan(s) or decisions were reviewed with the patient or their representative.

(3) The treatment team shall develop a written, individualized plan of care for each patient, designating a selected treatment modality and a selected setting for treatment.

(a) The care plan shall be developed within 30 days of admission to the facility.

(b) All suitable treatment modalities shall be considered by the treatment team, regardless of their availability at the current facility, and there shall be consideration of the patient's preferences as well as clinical and psychosocial needs.

(c) The care plan for patients deemed unsuitable for transplant shall indicate the specific rationale for the unsuitability.

(d) For patients for whom transplant referral has been selected, educational and rehabilitation needs shall be addressed as a part of the care plan.

(e) The care plan shall be reviewed and updated at least annually, or sooner if there has been a change in the selected treatment modality or setting.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.12
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Patient Care Plans" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. May 9, 2017; eff. May 29, 2017.

Rule 111-8-22-.13. Hemodialyzer Reuse.

(a) Facilities processing dialyzers for reuse shall adhere to the current American National Standard, Reuse of Hemodialyzers, published by the Association for the Advancement of Medical Instrumentation (AAMI), which are incorporated herein by reference.

(2) The facility practicing reuse shall provide each patient with information regarding the reuse practice at the facility and an opportunity to ask questions regarding the reprocessing of dialyzers, and shall obtain written informed consent from the patient, or the patient's representative, if applicable, for the use of a reprocessed dialyzer for the patient's hemodialysis.

(3) The facility shall develop and implement policies and procedures for dialyzer reprocessing which include but are not limited to criteria for determining the safe and useful life of a dialyzer, procedures for documenting the reprocessing history of each dialyzer, and procedures for documenting maintenance and monitoring of the functioning of the reprocessing equipment. If the facility uses an offsite

reprocessing service, the facility shall have policies and procedures regarding the coordination of this service with the handling of dialyzers within the facility, to ensure adequate documentation of the storage and transport of the dialyzers from the time they are re- moved from the dialysis machine to the time they are returned to the facility.

(4) The facility shall limit access to the reprocessing room to authorized personnel.

(5) The reprocessing room shall have a ventilation system, which is connected to an exhaust system vented to the outside, with a fan at the outside end to direct discharge of air outward. The exhaust outlet shall be arranged to minimize recirculation of the exhausted air into the building.

(6) The system providing water for reprocessing must meet all the requirements for pressure, flow rate, bacteriological and pyrogenic contamination, and other requirements for operating the reprocessing equipment under minimal and peak load conditions.

(7) If a facility utilizes an off-site reprocessing service, the facility shall be responsible and accountable for the safety and effectiveness of the reprocessing of the dialyzers. Such arrangements must be by written contract requiring that:

(a) The reprocessing services comply with the American National Standard, Reuse of Hemodialyzers, published by the Association for the Advancement of Medical Instrumentation (AAMI), in its current edition:

(b) The individuals performing the reprocessing meet training and competency standards equivalent to or exceeding those required for reuse technicians at the end stage renal disease facility;

(c) The service implements a continuous quality improvement program to monitor the effectiveness and safety of reprocessing procedures;

(d) There are provisions for transport of the dialyzers to and from the reprocessing site which are adequate to prevent contamination or deterioration; and

(e) The off-site reprocessing location shall be available during regular business hours for inspection of reprocessing procedures by representatives of the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.13
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Hemodialyzer Reuse" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.14. Medical Records.

(1) A current and complete medical record shall be maintained for each patient.

(2) The facility shall designate a supervisor for the medical records who shall be responsible for the organization, proper documentation, completion and preservation of the facility's medical records.

(3) The medical records shall be organized in a manner to facilitate the completion and retrieval of information.

(4) Patients' medical records for the most recent two years shall be kept on site. The remainder of the patient's medical record may be stored off-site if the record is readily available. Medical records shall be retained for at least five years following the date of death or discharge. For pediatric patients, the records shall be retained for three years after the patient reaches the age of majority, or at least five years, whichever is longer.

(5) Medical records shall be available for inspection only to members of the professional staff, the patient, representatives of the Department acting in an official capacity, or persons authorized in writing by the patient to have access to the medical record.

(a) The facility shall release copies of all or part of a patient's medical record to an authorized representative of the Department at no cost to the Department when the Department determines that said records are necessary in connection with the Department's licensing and certification responsibilities of a facility.

(b) The facility shall arrange for the prompt transfer of a courtesy copy of the following parts of the patient's medical record to the receiving facility: the patient's care plan, the last two weeks of run sheets and flow charts, a list of current medications, current treatment orders and the last three months of clinical laboratory test results to the receiving facility.

(c) The facility shall have a mechanism to release copies of all or part of a patient's medical records to the patient or to others with the written consent of the patient or the patient's legal guardian and to others where required by law. The facility may charge a reasonable fee for the copies so produced.

(d) The medical record for each patient shall contain at a minimum:

1. Patient identifying information (name, address, age, sex, marital status);

2. Dates of admission, transfer, and discharge, as applicable;

3. Names of referring and attending physicians;

4. Evaluation and assessment reports, including the history and physical examination administered prior to the initial treatment;

5. Reports from any special examinations and consultations, and laboratory and x-ray results;

6. Physician's orders;

7. Care plans;

8. Signed consent forms, as applicable;

9. Progress notes, including dialysis flow sheets; and

10. The discharge summary, including cause of death, if applicable.

(e) All entries in the medical records shall be permanent, accurate, dated with the actual date of entry, and signed by the individual making the entry. Late entries shall be labeled as late entries.

(f) Verbal or telephone orders, if allowed by facility policy, may only be entered by Georgia-licensed personnel, and must be authenticated by the ordering physician or individual taking responsibility for the order at the next patient visit or sooner as required by facility policy.

(g) All medical record entries shall be legible.

(h) Medical records shall be completed within forty-five (45) days after the patient's discharge.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.14
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Medical Records" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. May 9, 2017; eff. May 29, 2017.

Rule 111-8-22-.15. Environment of Care.

(1) **Safety.** The facility shall have sufficient staff, systems and equipment in place to provide a safe environment for patients, staff, and visitors, to include at least:

(a) A system for patients and staff to summon assistance, when needed, from treatment areas and bathrooms;

(b) An incident reporting and monitoring system that promptly identifies, investigates, and takes corrective action regarding all incidents that involve injury to patients or visitors, that involve damage to property, or which have the potential to cause such injury or damage if not corrected;

(c) Policies and procedures to prohibit and prevent verbal or physical abuse or neglect of patients while they are receiving services from the facility;

(d) A program which requires and documents the inspection, monitoring, and maintenance of biomedical equipment, electrical equipment, and any emergency power systems;

(e) An environment free of physical hazards such as broken or torn furniture, loose floors or wet flooring, or holes in walls, windows, or ceilings;

(f) Procedures, supplies, and equipment for the management of biomedical waste and the disposal of sharps in accordance with current accepted standards of practice;

(g) Adequate supplies of protective equipment for staff involved with patient care; and

(h) A working telephone on the premises accessible to the patients.

(2) **Cleanliness and Sanitation.** The facility premises and equipment shall be maintained in a clean and orderly condition. There must be evidence that the facility has systems that satisfactorily address at least the following:

(a) The description and performance of effective daily, interim, and terminal cleaning routines for all areas;

(b) Procedures, supplies, and facilities for the management of linens which include separate storage areas and separate transport containers for clean and dirty linens, separate storage areas for patient property if permitted by facility policy, and the requirement that no dirty linens or sanitation equipment shall be stored in a water treatment room or reuse room;

(c) Clean and orderly storage areas for supplies;

(d) Facilities and supplies for convenient and effective handwashing throughout the facility, including but not limited to:

1. For facilities newly constructed or undergoing major renovation after the effective date of these rules, at least one handwashing sink in the dialysis area for each eight dialysis stations;

2. If the facility conducts reuse hemodialysis, a separate handwashing sink in the reuse room;

3. If the facility provides on-site peritoneal dialysis, a handwashing sink in the room used for peritoneal dialysis which is separate from any facilities for disposal of effluent (peritoneal dialysis drainage); and

4. Hot and cold running water at each sink, with soap or sanitizing solution for washing hands, and clean disposable materials or air dryers for drying hands.

(e) Sufficient equipment and systems for prevention of infestation by insects, rodents, or other vermin or vectors;

(f) Systems for the storage and disposal of trash, garbage, and waste in a manner that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents; and

(g) Floor coverings that are intact, with no reservoirs or cracks in the surface where pathogens and standing water may accumulate.

(3) **Space and Equipment.** The facility shall provide adequate space and equipment to provide the scope of services offered, while ensuring the health and safety of patients and staff.

(a) For a facility constructed or undergoing renovation after the effective date of these rules, the facility shall have a minimum of 70 square feet of floor space at each treatment station, with the smallest dimension being 7 feet.

1. The 70 square feet may include counters, sinks, and aisles.

2. There shall be access to both sides of the patient bed/chair at each treatment station, with ease of passage for staff or a wheelchair.

(b) Public hallways, doorways, and elevators should be of sufficient size so as to accommodate passage of a wheelchair or ambulance gurney or stretcher.

(c) If the facility provides on-site peritoneal dialysis, there shall be a separate room for the peritoneal dialysis treatment.

(d) The facility shall have a private area for meetings with patients or family members, separate from the treatment areas.

(e) The facility shall have an examination room, equipped with a door that closes, an examining table, a readily accessible handwashing sink, and adequate floor space to accommodate the patient's treatment needs.

(f) If the facility offers services to patients with infectious diseases, the facility shall provide treatment for those patients in accordance with recommendations from the Centers for Disease Control. Some infectious diseases will require the use of isolation rooms and separate dialyzer equipment.

(g) There shall be sufficient office space for physicians, nurses, social services, administration, and dietetic and other ancillary services to work and meet, physically separated from the patient treatment area(s).

(h) The facility shall have at least one toilet facility with handwashing sink for patient use, which is accessible for a patient in a wheelchair.

(4) **Water Treatment System.**

(a) The facility shall operate a system for the analysis and treatment of water to ensure a continuous water supply sufficient in quantity and quality to conduct dialysis in accordance with accepted standards of practice.

1. Responsibility for the effective operation of the water treatment system shall be assigned to the medical director of the facility.

2. Policies and procedures shall be developed and implemented to govern all staff actions relative to water treatment; and

3. Systems for water treatment, water monitoring, water delivery, and water disposal shall adhere to the current standards for water treatment as described in the American National Standard,"Hemodialysis Systems", published by the Association for the Advancement of Medical Instrumentation (AAMI), herein incorporated by reference.

(b) The area used for water treatment shall be separate from the area(s) used for dialysis treatment, dialyzer reprocessing, or other activities and purposes at the facility. Mixing of dialysate may be performed in the area used or water treatment, if there is sufficient space for both functions.

(c) The facility's water treatment system shall be continuously monitored during patient treatment, and shall be equipped with a functional audible and visible alarm system to alert staff if there is a failure of the system.

(d) Staff assigned to the operation and monitoring of the water treatment system shall meet the training and competency qualifications for water treatment technicians required under this chapter.

(e) Staff shall maintain a written log of the operation of the water treatment system throughout each treatment day. Entries into the log shall be current and legible, and shall indicate that each component of the system is operating within required parameters or shall describe actions taken when operation is outside required parameters.

(f) Monthly testing of product water from selected sample sites within the system shall be conducted to assess compliance with AAMI water quality standards. In

addition, a sample of product water shall be submitted for chemical analysis every six months, or sooner if there have been changes to the system or if the monthly results indicate there may have been a significant change in quality. Reports of all water testing shall be reviewed and signed by the medical director.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.15
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Environment of Care" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.16. Infection Control.

(1) The facility shall have an infection control committee composed of at least the facility administrator, a physician, and a registered nurse. The infection control committee shall develop and implement policies and procedures for preventing and controlling hepatitis and other infections at the facility, including but not limited to:

(a) Operational procedures for the prevention of the spread of infectious diseases, including identification of job classifications or work areas or tasks requiring the use of protective barriers and other universal precautions as recommended by the Centers for Disease Control;

(b) Procedures for facility-wide surveillance and reporting of infections, to include mechanisms for tracking infection rates and suspected pyrogenic reactions;

(c) Procedures for the safe handling of waste and contaminants, including the safe disposal of sharps;

(d) Specific procedures for the sterilization and disinfection of equipment, including dialysis machines;

(e) Procedures for maintaining a safe and clean physical environment;

(f) Procedures for the prevention of contamination by blood and other body fluids of facility areas outside the dialysis and dialyzer reprocessing areas;

(g) Procedures for prevention of cross-contamination in storage and treatment areas and in the dialyzer reprocessing area, if applicable;

(h) Procedures for providing dialysis for patients testing positive for hepatitis B surface antigen or other bloodborne infectious diseases as outlined by the CDC in its current guidelines for infection control in dialysis centers, including reservation or special disinfection of dialysis equipment;

(i) Procedures for providing dialysis for patients with active pulmonary tuberculosis or other active airborne infectious disease;

(j) Procedures for the protection of patient clothing, blankets, or other personal articles during the time when blood lines are opened or needles inserted or withdrawn; and

(k) Procedures for the investigation of infections.

(2) Reports of infections such as bacterimia, septicemia, hepatitis, any wound that may allow for cross-contamination of patients and any suspected pyrogenic reactions and other communicable diseases of patients shall be made to the infection control committee through established mechanisms, and noted in patient files. Reports maintained by the infection control committee shall include documentation of efforts to determine the origin of the infection, and, where the dialysis procedure or environment was found to be related to the transmission of the infection, shall include documentation of the actions taken to prevent recurrence.

(3) Facility policies and procedures shall require that all employees be tested upon employment and that attending physicians and physician extenders, be tested at the time privileges are granted for hepatitis B virus and tuberculosis infection and any other infectious diseases which the Centers for Disease Control have deemed to be endemic to the area served. The facility policy and procedures shall also require all employees, attending physicians and physician extenders to be tested for the diseases listed herein at least annually and when the health and safety of the patients require it. The facility shall have a mechanism for monitoring the health status of employees and referring for health evaluations and treatments as necessary to ensure the safety of patients.

(4) Dialysis patients shall be tested initially and at least annually for the presence of Hepatitis B surface antigen, and for tuberculosis and any other infectious diseases which the Centers for Disease Control have deemed to be endemic to the area served, to determine the need for special treatment precautions and surveillance of the infection. Results of the screenings, as well as any refusals to submit to such testing signed by the patient, shall be included in the patient's medical record.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.16
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Infection Control" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.17. Emergency and Disaster Preparedness.

(1) The facility shall establish and implement procedures that describe staff and patient actions in medical and non-medical emergencies, including at least fire, equipment

failure, power outages, medical emergencies, unscheduled facility closing, and natural disasters which are likely to threaten the health and safety of patients or staff.

(2) The facility shall provide training for staff and patients in where to go, what to do, and whom to contact if a medical or non-medical emergency occurs. Patient training in the handling of emergencies shall be documented in the patient's medical record and review with the patient at least annually.

(3) The facility plan shall include method of access to community emergency services. Contact numbers for emergency needs, shall be conspicuously posted near a telephone readily available to the clinical treatment area.

(4) The facility shall have and maintain appropriate equipment and supplies, in ready-to-operate condition, for managing medical emergencies, in a location accessible by all healthcare personnel. By October 1, 2002, all licensed facilities shall have an automatic external defibrillator. Emergency trays or carts shall include at least:

(a) Emergency drugs and supplies for administering treatment;

(b) Oxygen or compressed air for respiratory support;

(c) Equipment for mechanical assistance with ventilation; and

(d) Oral airway access-devices and suctioning equipment.

(5) The facility shall establish and implement a plan for management of staff and patients in the event of a fire and provide for patient education on emergency evacuation.

(a) Evacuation routes shall be posted in all treatment areas, and patients shall be informed of these routes.

(b) The facility shall conduct and document regular fire and/or disaster drills for all shifts of service provision. Fire and/or disaster drills shall be conducted at least every six months.

(c) The facility shall have and maintain operable fire extinguishers adequate for the space and conditions.

(d) All facility staff shall be trained in the operation of emergency equipment, as appropriate to their qualifications and licensure.

(e) All staff shall be knowledgeable of emergency procedures and their role in the event of an emergency or disaster situation.

(f) All personnel at the facility who provide direct healthcare services for patients must maintain current certification in Basic Cardiopulmonary Life Support

(BCLS) and the use of the automatic external defibrillator when the facility acquires one.

(g) The facility shall prepare a plan for procedures in the event of a natural or other disaster which may affect the facility's ability to provide patient treatment.

1. The disaster preparedness plan shall include at a minimum plans for the following emergency situations:

   (i) Local or widespread weather emergencies or natural disasters, such as tornadoes, hurricanes, earthquakes, ice or snow storms, or floods;

   (ii) Unanticipated interruption of service of utilities, including water, gas, or electricity, either within the facility or within a local or widespread area;

   (iii) Loss of heat or air conditioning;

   (iv) Fire, explosion, or other physical damage to the facility.

2. The facility shall have a written agreement with at least one other licensed facility that can provide dialysis services, to assure that the facility's patients will be treated in the event that an emergency situation at the facility renders it unable to provide scheduled dialysis services.

3. The facility shall have an emergency lighting system sufficient to allow for safe discontinuation of treatments and evacuation of the facility in the event of power failure.

4. The facility's disaster preparedness plan shall be made available to the Department for inspection upon request.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.17
Authority: O.C.G.A. § 31-44-3.
History. Original Rule entitled "Emergency and Disaster Preparedness" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.18. Requests for Waiver or Variance.

(1) A facility may request a waiver or variance of a specific rule by application on forms provided by the Department.

(2) The Department may grant or deny the request for waiver or variance at its discretion. If the waiver or variance is granted, the Department may establish conditions, which must

be met by the facility in order to operate under the waiver or variance. Waivers or variances may be granted with consideration of the following:

(a) **Variance.** A variance may be granted by the Department upon a showing by the applicant that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application would cause undue hardship. The applicant must also show that adequate standards exist for affording protection for the health, safety, and care of patients, and these existing standards would be met in lieu of the exact requirements of the rule or regulation.

(b) **Waiver.** The Department may dispense altogether with the enforcement of a rule or regulation by granting a waiver, upon a showing by the applicant that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, and care of the patients.

(3) **Experimental Waiver or Variance.** The Department may grant a waiver or variance to allow experimentation and demonstration of new and innovative approaches to delivery of services, upon a showing by the applicant that the intended protections afforded by the rule or regulation in question are met and that the innovative approach has the potential to improve service delivery.

(4) Waivers and variances granted by the Department shall be for a time certain, as determined by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.18
Authority: O.C.G.A. § 31-2-47.
History. Original Rule entitled "Requests for Waiver or Variance" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.19. Enforcement of Rules and Regulations.

(1) An end stage renal disease facility that fails to comply with these rules and regulations shall be subject to sanctions and/or license revocation as provided by law.

(2) The Department may take actions to enforce these rules and regulations as prescribed in the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25, pursuant to O.C.G.A. § 31-2-8, and/or by appointment of a temporary manager as described in these rules.

(3) **Voluntary Appointment of a Temporary Manager.** A person holding a controlling interest in an end stage renal disease facility may, at any time, request the Department to assume the management of the facility through the appointment of a temporary manager.

(a) If the Department considers the appointment appropriate for the protection of the health and safety of patients, the Department may enter into an agreement

providing for the appointment of the temporary manager to manage the facility under conditions agreed upon by both parties.

1. The agreement shall specify all terms and conditions of the temporary manager's appointment and authority.

2. The agreement shall preserve all rights granted by law to patients of the facility.

(b) The primary duty of the temporary manager shall be to ensure that adequate and safe services are provided to patients until temporary management ceases.

(c) The appointment shall terminate at the time specified by the agreement.

(4) **Involuntary Appointment of a Temporary Manager.** The Department may request that the state Attorney General bring an action for the appointment of a temporary manager to manage the facility, if:

(a) The facility is operating without a license;

(b) The Department has denied, suspended, or revoked the facility's license but the facility continues to operate;

(c) License denial, suspension, or revocation proceedings against the facility are pending and the Department determines that there exists an imminent or reasonable foreseeable threat to the health and safety of a patient of the facility;

(d) The Department determines that an emergency exists that presents an immediate threat to the health and safety of a patient of the facility; or

(e) The facility is closing and arrangements for the care of patients by other licensed facilities have not been made before closure.

(5) A temporary manager appointed under either voluntary or involuntary condition shall be entitled to a reasonable fee as determined by the court. The fee shall be paid by the facility.

(6) A temporary manager appointed voluntarily may petition the court to order the release of any payment owed to him/her for care and services provided to patients at the facility if the payment has been withheld before or during the period of appointment, including any Medicaid, Medicare, or insurance payment, or payment from another third party.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.19
Authority: O.C.G.A. §§ 31-2-8 and 31-44-13*et seq*.
History. Original Rule entitled "Enforcement of Rules and Regulations" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-22-.20. Severability of These Rules.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court or competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rule or portions of rules shall remain in full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.20
Authority: O.C.G.A. §§ 31-2-4, 31-2-7 and 31-44-1*et seq.*
History. Original Rule entitled "Severability of These Rules" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-25. GENERAL LICENSING AND ENFORCEMENT REQUIREMENTS.

Rule 111-8-25-.01. Legal Authority, Title and Purpose.

These rules shall be known as the Rules and Regulations for Enforcement of General Licensing and Enforcement Requirements. The purposes of these rules are to provide for general licensing and enforcement actions requirements by the department with respect to violations of licensing requirements by certain applicants or licensees operating facilities subject to regulation by the department as set forth under Chapters 7, 13, 22, 23 and 44 of Title 31, Chapter 5 of Title 26, paragraph (8) of subsection (d) of Code § 31-2-4 and Article 7 of Chapter 5 of Title 49; to provide for licensing, payment of licensing activities fees, inspections, investigations and examinations of such facilities; compliance with plans of correction; and to provide that certain facilities give notice of violations giving rise to the receipt of notice of the imposition of any sanction under federal or state laws or regulations. These rules are adopted and published pursuant to the Official Code of Georgia Annotated (O.C.G.A.) §§ 31-2-4, 31-2-9, 31-2-11 and 31-7-2.2.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.01
Authority: O.C.G.A. Secs. 31-2-4, 31-2-9, 31-2-11, 31-7-2.2.
History. Original Rule entitled "Legal Authority" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.
Repealed: New Rule entitled "Legal Authority, Title and Purpose" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-25-.02. Definitions.

(1) "Administrative action" means the initiation of a contested case as defined in the Georgia Administrative Procedures Act (APA), O.C.G.A. § 50-13-2(2).

(2) "Alter ego" means a person who acts pursuant to the control or influence of another while purporting to act independently.

(3) "Commissioner" means the Commissioner of the Department of Community Health.

(4) "Department" means the Department of Community Health, its agents and employees.

(5) "Document" means any book, record, paper, or other information related to initial and continued licensing.

(6) "Facility" means any agency, institution, entity or person subject to regulation by the department under Chapters 7, 13, 22, 23, 44 of Title 31, paragraph (8) of subsection (d) of Code § 31-2-4, Chapter 5 of Title 26, and Article 7 of Chapter 6 of Title 49 of the Official Code of Georgia Annotated.

(7) "Final Adverse Finding" means

(a) the issuance of a ruling by the Commissioner on any appeal from a decision of a hearing officer or hearing examiner pursuant to a contested case involving the imposition of a sanction;

(b) when a decision of the hearing officers or hearing examiner becomes final by operation of law because no appeal is made to the Commissioner;

(c) where the parties to a contested case dispose of the case by settlement; or

(d) where a facility does not contest within the allotted time period a sanction imposed by the department.

(8) "Formal Order" means any ruling following an administrative or judicial hearing or an emergency directive issued by the Commissioner as authorized by law related to the initial or continued licensing of a facility which requires the facility to take or refrain from taking specified action. Formal orders include, but are not limited necessarily to final administrative hearing decisions and settlement agreements between the department and facilities. Additionally, formal orders, as defined herein, may include any orders issued by the Commissioner as authorized by law, such as but not limited to O.C.G.A. § 31-7-2.2 or as authorized by similar statues enacted after the effective date of these rules.

(9) "Inspection" means any examination by the department or its representatives of a facility, including but not necessarily limited to the premises, and staff, persons in care, and documents pertinent to initial and continued licensing so that the department may determine whether a facility is operating in compliance with licensing requirements. The term "inspection" includes any survey, monitoring visit, or other inquiry conducted for the purpose of making a compliance determination with respect to licensing requirements.

(10) "Investigation" means any examination, conducted in response to an allegation or allegations of noncompliance, by the department or its representative of a facility, including but not necessarily limited to the premises, and staff, persons in care, and documents pertinent to initial and continued licensing so that the department may determine whether a facility has violated any licensing requirement.

(11) "License" means the official authorization granted by the department pursuant to any of the provisions of law cited in Rule 111-8-25-.01 to operate a facility physically located in Georgia. The term "license" includes any permit, registration, commission, or similar designation reflecting such authorization.

(12) "Licensee" means any person holding a license.

(13) "Licensing requirements" means any provisions of law, rule, regulation, or formal order of the department which apply to facilities with respect to initial or continued authority to operate.

(14) "Long-term care facility" means a licensed adult day center, assisted living community, home health agency, hospice, intermediate care home, nursing home, personal care home or private home care provider.

(15) "Management or Control", for the purpose of imposing the sanction pursuant to Rule 111-8-25-.04(1)(c) or 111-8-25-.04(2)(b), means the exercise of or authority to exercise direction, administration, or oversight over a facility's operations by certain persons which include owners, directors, or administrators.

(16) "Memory Care Certificate" means a certificate issued by the department to a licensed assisted living community or personal care home to authorize the operation of a memory care center.

(17) "Person" means any individual, agent, representative, governing authority, firm, organization, partnership, agency, association, corporation, facility, or other entity.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.02
Authority: O.C.G.A. §§. 31-2-9, 31-7-2.1, 31-7-2.2, 31-7-3.2, 31-7-12.4.
History. Original Rule entitled "Title and Purposes" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.
Repealed: New Rule entitled "Definitions" adopted. F. July 14, 2010; eff. August 3, 2010.
Amended: F. Apr. 16, 2021; eff. May 6, 2021.

Rule 111-8-25-.03. General Licensing Requirements and Fee Schedules.

(1) No facility shall offer or provide services which are required to be licensed under rules enforced by the department without a current license issued by the department.

(2) No license shall be issued by the department unless the facility is in compliance with applicable rules set forth in these rules, specific rules applicable to the particular facility type and all licensure activity fees due the department have been paid.

(3) Fees will be assessed to facilities and applicants for licensure for the following licensure activities: processing applications for a new license or a change in ownership, initial license fees, annual licensure activity fees to maintain current license, follow-up visits to

periodic inspections, training materials, returned check and mail processing charges and civil monetary penalties.

(4) Application for License. An application for a license to provide regulated services shall be submitted on forms made available by the department in a format acceptable to the department. No application shall be acted upon by the department until the application is determined complete by the department with all required attachments and applicable fees submitted.

(5) Where the department denies an initial license for non-payment of fees or any other reason, such action may be taken by the department prior to an administrative hearing on the denial being held. The applicant whose license has been denied may obtain an administrative hearing, subsequent to the decision to deny the license, as authorized under Georgia law.

(6) Ongoing Licensure Activity Fees. All licenses issued by the department require payment of ongoing licensure activity fees as calculated by the department each state fiscal year, including the state fiscal year that these rules take effect. For annual licenses, such licensure activity fees will be due on the anniversary date of the issuance of the previous year's license. For continuing licenses, such ongoing licensing activity fees will be due October 31st of each state fiscal year. The annual fees shall include the base licensure activity fee and any additional fees incurred during the previous year. Such fees are due and payable to the department within thirty (30) days of receipt of the licensure activity fee invoice. Fees will be calculated by the department in a manner so as to help defray the direct and indirect costs incurred by the department in providing such licensure activities for all programs, but in no event shall exceed such costs.

(7) Effective January 31, 2011, the department may revoke any license if the facility has failed to pay the annually recurring licensure activity fees within sixty (60) days of receipt of a written invoice from the department. The revocation action is subject to written notice of the proposed revocation and a right to receive an administrative hearing on the amount past due and owing prior to the revocation action becoming final.

(8) Schedule of Fees. Fees collected by the department are not refundable, except in extraordinary circumstances as determined by the department in its sole discretion. The decision of the department as to whether to refund a payment is final and may not be appealed. Payment of fees must be in a form of payment accepted by the department. Some forms of electronic payment may result in an additional convenience charge being added to the licensing fee that is due. Any convenience charge for which the user is responsible must be disclosed to the potential user before completion of the transaction. No cash payments are accepted by the Department. The following schedule of fees applies for the listed licensure activities:

Licensure Activity	Fee	Fee Frequency

Application Processing Fee, Change in Ownership, Change in Service Level (requiring on site visit), Name Change - Any Program	$300	Upon submission
Initial Provisional or Regular License (Same as annual licensure activity fee for each program type)	Varies by program	Submitted with application processing fee
Involuntary Application Processing Fee subsequent to unlicensed complaint investigation	$550	
Follow-up Visit to Periodic Inspection - Any Program	$250	License renewal date
Licenses and Certificates		
Adult Day Centers **	$250 (social) $350 (medical)	Annually
Ambulatory Surgical Treatment Centers **	$750	Annually
Assisted Living Communities ** (see Personal Care Homes)		
Birthing Centers **	$250	Annually
Clinical Laboratories **	$500	Annually
Community Living Arrangements **	$350	Annually
Drug Abuse Treatment Programs **	$500	Annually
End Stage Renal Disease Centers **		Annually
1-12 stations	$600	Annually
13-24 stations	$1,000	Annually
25 or more	$1,100	Annually
Stand Alone ESRD Facilities Offering Peritoneal Dialysis Only	$800	Annually
Eye Banks	$250	Annually
HMOs (if subject to licensure)	$2,000	Annually
Home Health Agencies **	$1,000	Annually
Hospices **	$1,000	Annually
Hospitals **		Annually
CAHS < 25 beds	$250	Annually
25 =< 50 beds	$750	Annually
>50 beds	$1,500	Annually
Imaging Centers (rules to be developed) **	$3,000	Annually

Infirmaries	$250	Annually
Intermediate Care Facilities/MR (private) **	$250	Annually
Memory Care Certificate **	$200	Annually
Narcotic Treatment Programs **	$1,500	Annually
Nursing Homes **		Annually
1 =< 99	$500	Annually
>99	$750	Annually
Personal Care Homes **		Annually
< 25 beds	$350	Annually
25 =< 50 beds	$750	Annually
>50 beds	$1,500	Annually
Private Home Care Providers **		Annually
For each service offered: Companion Sitter, Personal Care and/or Nursing Maximum of $750	$250 (per service)	Annually
Traumatic Brain Injury Facilities	$250	Annually
X-Ray Facilities (per machine)	$300	Annually
Miscellaneous Fees		
Civil monetary penalties as finally determined		Case-by-case basis
Late Fee: Sixty (60) days past due	$150	Per instance
Lists of Facilities by license type (electronic only)	$25	Per request
Replacement of Lost Permit	$50	Per request
Returned check charge - as assessed by bank	<$50	Per instance
Special handling charges when required (special courier/mailing costs)	Cost	Per instance
Training materials - cost to reproduce for participant	$.25 per page, $5 per disc	Per participant
** Eligible for a 25% discount if currently accredited by a nationally recognized accreditation organization approved by the department as having standards comparable to specific state licensure requirements, and complete copy of current decision is submitted to the department at the time of renewal or is already on file with the department.		

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.03
Authority: O.C.G.A. §§ 31-2-4, 31-2-7, 31-2-8, 31-7-3.
History. Original Rule entitled "Definitions" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.
Repealed: New Rule entitled "General Licensing Requirements and Fee Schedules" adopted. F. July 14, 2010; eff. August 3, 2010.
Amended: F. Aug. 22, 2012; eff. Sept. 11, 2012.

Amended: F. Apr. 16, 2021; eff. May 6, 2021.

Rule 111-8-25-.04. Enforcement.

The department shall have the authority to impose any one or more of the sanctions enumerated in paragraphs (1), (2) and (3) of Rule 111-8-25-.05 upon a finding that an applicant or licensee has:

(a) Knowingly made any verbal or written false statement of material fact either in connection with the application for a license; or on documents submitted to the department as part of any inspection or investigation; or in the falsification or alteration of facility records made or maintained by the facility;

(b) Failed or refused, without legal cause, to provide the department with access to the premises subject to regulation or information pertinent to the initial and continued licensing of the facility.

(c) Failed to comply with the licensing requirements of this state; or

(d) Failed to comply with the provisions of O.C.G.A. § 31-2-11 or with the provisions of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.04
Authority: O.C.G.A. Sec. 31-2-11.
History. Original Rule entitled "Enforcement" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Rule 111-8-25-.05. Sanctions.

(1) **Sanctions against Licensees.** When the department finds that any licensee has violated any provision of Rule 111-8-25-.04, Enforcement, the department, subject to notice and opportunity for a hearing, may impose any one or more of the sanctions in subparagraphs (a) through (f) below.

(a) **Administer a Public Reprimand.** If the sanction of public reprimand is finally imposed, as defined by a final adverse finding, the public reprimand shall consist of a notice prepared by the department that the facility has been reprimanded; such notice shall include a written report of the department's findings along with the facility's response and corrective action plan.

1. **Location of Notice.** The facility shall post the public reprimand in places readily accessible and continuously visible to persons in care and their representatives. Additionally, if the facility maintains a website, it shall post a web link in a prominent location on the main page of the website that provides access to a copy of the public reprimand.

2. **Timing of Notice.** The facility shall post the public reprimand on the day the public reprimand is received by the facility and such reprimand shall remain posted for a period of ninety (90) days.

3. **Notice for Service Inquiries.** During any period that the reprimand is required to be posted, the facility shall advise persons seeking services and representatives of persons seeking services of the reprimand. In response to a notice by the department of the imposition of a public reprimand, a facility may request that the department not require the facility to advise persons seeking services and representatives of persons seeking services of the reprimand if such requirement would compromise its ability to provide services, and is not feasible given the facility's range of services and the ways its services are provided. Such request must be made within ten (10) calendar days from receipt of the notice from the department. The department upon such a convincing showing, as well as a showing that the correction of the violation has been achieved and will be sustained by the facility, may elect not to enforce this requirement. If the department elects to enforce the requirement and the facility appeals the imposition of the sanction, the issue of this requirement may become an issue for consideration by the hearing examiner at any hearing held on the sanction, unless waived by the facility.

(b) **Suspend any License.** The department may suspend for a definite period or for an indefinite period in connection with any condition which may be attached to the restoration of said license.

1. The department may impose the sanction of suspension for a definite period calculated by it as the period necessary for the facility to implement long-term corrective measures and for the facility to be deterred from lapsing into noncompliance in the future. As an alternative to suspending a license for a definite period, the department may suspend the license for an indefinite period in connection with the imposition of any condition or conditions reasonably calculated to elicit long-term compliance with licensing requirements which the facility must meet and demonstrate before it may regain its license.

2. If the sanction of license suspension is finally imposed, as defined by a final adverse finding, the department shall effectuate it by requiring the facility to return its license to the department. Upon the expiration of any period of suspension, and upon a showing by the facility that it has achieved compliance with licensing requirements, the department shall reissue the facility a license. Where the license was suspended for an indefinite period in connection with conditions for the re-issuance of a license, once the

facility can show that any and all conditions imposed by the department have been met, the department shall reissue the facility a license.

(c) **Prohibit Persons in Management or Control.** The department may prohibit a licensee from allowing a person who previously was involved in the management or control of any facility which has had its license revoked or application denied within the past twelve (12) months to be involved in the management or control of such facility. Any such person found by the department to have acted diligently and in good faith to ensure correction of violations in a facility which has had its license revoked or denied, however, shall not be subject to this prohibition if that person became involved in the management or control of the facility after the facility was notified by the department of violations of licensing requirements giving rise to a revocation or denial action. This subparagraph shall not be construed to require the department to obtain any information that is not readily available to it regarding any person's involvement with a facility. For the purpose of this Rule, the twelve (12) month period will begin to run from the date of any final adverse finding or the date that any stay of enforcement ceased, whichever first occurs.

(d) **Revoke any License.** The department may revoke any license. If the sanction of license revocation is finally imposed, as defined by a final adverse finding, the department shall effectuate it by requiring the facility to return its license to the department.

(e) **Impose a Civil Penalty Fine.** The department may impose a civil penalty fine of up to $2,000 per day for each violation of a law, rule, regulation, or formal order related to the initial or continued licensing of a facility; provided, however, that no such fines shall exceed $40,000 for violations found during the same inspection. If a violation is found on two (2) consecutive inspections, there shall exist a rebuttable presumption that the violation continued throughout the period of time between each inspection.

1. **Categories of Violations.** Violations shall be assigned a category based upon the following criteria:

   (i) **Category I** ($1,201-$2,000 per violation per day): A violation or combination of violations of licensing requirements which has caused death or serious physical or emotional harm to a person or persons in care or poses an imminent and serious threat or hazard to the physical or emotional health and safety of one or more persons in care;

   (ii) **Category II** ($601-$1,200 per violation per day): A violation or combination of violations of licensing requirements which has direct adverse effect on the physical or emotional health and safety of a person or persons in care; and

(iii) **Category III** ($100-$600 per violation per day): A violation or combination of violations of licensing requirements which indirectly or over a period of time has or is likely to have an adverse effect on the physical or emotional health and safety of a person or persons in care, or a violation or violations of administrative, reporting, or notice requirements.

2. **Fine Amounts.** The specific amount of the fine for each violation in each category shall be determined based upon whether and when the particular or similar rule, law, or order, or the act, omission, incident, circumstance, or conduct giving rise to the violation of the same regulatory requirement, or one substantially similar thereto, has been cited by the department previously. In no case, however, shall a facility be sanctioned for a violation characterized as a subsequent or repeat violation unless the time frame identified in the acceptable plan of correction has passed and the facility nonetheless has failed to attain or maintain correction.

   (i) **Initial Violation.** If the same or a substantially similar violation has not been cited previously by the department within the past twenty-four (24) months against the facility, it shall be considered to be an initial violation. The fine amount for initial violations shall be the bottom figure in the appropriate category.

   (ii) **Subsequent Violation.** If the present violation or a substantially similar violation had been found and cited by the department as the result of the last inspection of the facility, or as the result of any one other inspection during the previous twenty-four (24) months, the violations shall be considered to be a subsequent violation. The fine amount for subsequent violations shall be in the range between the top and bottom figures of the appropriate category and other factors, such as the existence of mitigating or aggravating circumstances, shall be considered in determining the fine amount within the range.

   (iii) **Repeat Violation.** If the present violation or a substantially similar violation also had been found and cited any two (2) other times during the past twenty-four (24) months, it shall be considered to be a repeat violation. The fine amount for repeat violations shall be the top figure in the category.

3. **Limitation of Fines.** A single act, omission, incident, circumstance, or conduct shall not give rise to the imposition of more than one fine even though such act, omission, incident, circumstance, or conduct may have violated more than one licensing requirement. In such a case, the fine shall be based upon the highest category in which any one violation resulting

from the same act, omission, incident, circumstance, or conduct falls. Correction by the facility of cited violations tolls the continuation of the assessment of the daily fine, provided, however, that the department shall confirm that such cited violations were corrected.

4. **Financial Hardships.** In response to a notice by the department of the imposition a fine, a facility may request that the department reduce the fine amount if the fine would cause significant financial hardship that would compromise its ability to provide care or services in compliance with licensing requirements. The department, in its discretion, upon such a convincing showing as well as a showing that correction of the violation has been achieved and will be sustained by the facility, may reduce the amount of the fine. If the department proceeds with the imposition of the fine as proposed, the issue of significant financial hardship may become an issue for consideration by the hearing examiner at any hearing held on the sanction, unless waived by the facility.

5. **Mandatory Fines.** The Department shall impose a mandatory fine of no less than $5,000.00 for a violation of a law, rule, regulation, or formal order related to the initial or ongoing licensing of a long-term care facility which has caused the death of or serious physical harm to a resident in such facility. For purposes of this subparagraph, the term 'serious physical harm' means an injury which causes any significant impairment of the physical condition of the resident as determined by qualified medical personnel which may be proven by testimony or by submission of the medical record. Any mandatory fine imposed by the Department may not be reduced on the basis of financial hardship.

6. **Federal Preemption.** No fine, whether discretionary or mandatory, may be imposed against any nursing facility, nursing home, or intermediate care facility which is subject to intermediate sanctions under the provisions of 42 U.S.C. § 1396 r(h)(2)(A), as amended, whether or not those sanctions actually are imposed.

(f) **Limit or Restrict any License.** The department may limit or restrict any license as the department deems necessary for the protection of the public (a provisional or temporary time-limited license granted by the department shall not be considered to be a limited or restricted license).

1. Limitation or restriction of a license may occur to:

   (i) prohibit the provision of a particular service or services when a facility is unable or unwilling to render or perform the service or services in compliance with licensing requirements;

(ii) restrict the authorized number of persons cared for by a facility when the facility is unable or unwilling to render care in compliance with licensing requirements; and/or

(iii) prohibit a facility from caring for persons with specific types or degrees of needs that the facility is not capable of meeting in compliance with licensing requirements.

2. If the sanction of license limitation or restriction is finally imposed, as defined by a final adverse finding, the department shall effectuate it by sending the facility a restricted or limited license. Upon receipt of the restricted or limited license, the facility shall return to the department its original license. Upon expiration of the restriction or limitation period, and upon proof by the facility that it has taken effective corrective action and has sustained that action during the period of the sanction, the department shall fully restore the facility's license. The department shall take any steps it deems necessary to verify compliance prior to the expiration of the sanction period so that a compliant facility is restored its license without delay.

(2) **Sanctions against Applicants.** When the department finds that any applicant for a license has violated any provision of Rule 111-8-25-.04, Enforcement, the department, subject to notice and opportunity for a hearing, may impose any one or more of the following sanctions in subparagraphs (a) through (c) below.

(a) **Refuse to Grant License.** The department may refuse to grant (deny) a license; provided, however, that the department may refuse to grant an initial license without holding a hearing prior to taking such action.

1. The department may deny an application for a license where the facility has failed to demonstrate compliance with licensing requirements. Additionally, the department may deny an application for a license where the applicant or alter ego of the applicant has had a license denied, revoked, or suspended within one year of the date of an application, or where the applicant has surrendered the license or transferred ownership or governing authority of a facility within one year of the date of a new application when such surrender or transfer was made in order to avert denial, revocation, or suspension of a license or payment of fines. For the purpose of determining the one-year denial period, the period shall begin to run from the date of the final adverse finding, or the date any stay of enforcement ceased, whichever first occurs. In further determining whether to grant or deny a license, the department may consider the applicant's overall record of compliance with licensing requirements.

(b) **Prohibit Persons in Management or Control.** The department may prohibit an applicant from allowing a person who previously was involved in the management or control of any facility which has had its license revoked or application denied within the past twelve (12) months to be involved in the management or control of such facility. Any such person found by the department to have acted diligently and in good faith to ensure correction of violations in a facility which has had its license revoked or denied, however, shall not be subject to this prohibition if that person became involved in the management or control of the facility after the facility was notified by the department of violations of licensing requirements giving rise to denial action. This subparagraph shall not be construed to require the department to obtain any information that is not readily available to it regarding any person's involvement with a facility. For the purpose of this rule, the twelve (12) month period will begin to run from the date of any final adverse finding or the date that any stay of enforcement ceased, whichever first occurs.

(c) **Limit or Restrict any License.** The department may limit or restrict any license as it deems necessary for the protection of the public (a provisional or temporary time-limited license granted by the department shall not be considered to be a limited or restricted license).

1. Limitations or restrictions of a license may include any or all of the following as determined necessary by the department:

   (i) prohibiting the provision of a particular service or services when a facility is unable or unwilling to render or perform the service or services in compliance with licensing requirements;

   (ii) restricting the authorized number of persons cared for by a facility when the facility is unable or unwilling to render care in compliance with licensing requirements; and

   (iii) prohibiting a facility from caring for persons with specific types or degrees of needs that the facility is not capable of meeting in compliance with licensing requirements.

2. The department may restrict a license where any applicant or alter ego of the applicant has had a license denied, revoked, or suspended within one (1) year of the date of an application, or where the applicant has surrendered the license or transferred ownership of governing authority of a facility within one (1) year of the date of a new application when such surrender or transfer was made in order to avert denial, revocation, suspension of a license, or payment of fines. For the purpose of determining the one (1) year denial period, the period shall begin to run from the date of the final adverse finding or the date any stay of enforcement ceased, whichever occurs first.

3. If the sanction of license limitation or restriction is finally imposed, as defined by a final adverse finding, the department shall effectuate it by sending the facility a restricted or limited license. Upon receipt of the restricted or limited license, the facility shall return to the department its original license if one was granted. Upon expiration of the restriction or limitation period, and upon proof by the facility that it has taken effective corrective action and has sustained that action during the period of the sanction, the department may issue the facility a license. The department shall take any steps it deems necessary to verify compliance prior to the expiration of the sanction period so that a compliant facility may be issued a license without delay.

(3) **Extraordinary Sanctions Where Imminent and Substantial Danger.** Where the Commissioner of the department determines that the patients or residents in the care of an institution, community living arrangement or drug abuse treatment program subject to licensure are subject to an imminent and substantial danger, the Commissioner may order any of the extraordinary sanctions listed in subsections (b), (c), (d) and (e), of this rule, 111-8-25-.05(3), to take effect immediately unless otherwise specified in the order, without notice and opportunity for hearing prior to the order taking effect.

(a) **Content of the Order.** The order shall contain the following:

1. the scope of the order;

2. reasons for the issuance of the order;

3. effective date of the order if other than the date the order is issued;

4. person to whom questions concerning the order are to be addressed; and

5. notice of the right to obtain after the issuance of the order, a preliminary hearing and an administrative hearing regarding the emergency order as a contested case.

(b) **Emergency Relocation.** The Commissioner may order emergency relocation of the patients or residents of any institution, community living arrangement or drug abuse treatment program subject to licensure to the nearest appropriate institution, community living arrangement or drug abuse treatment program. Prior to issuing an emergency order, the Commissioner may consult with persons knowledgeable in the field of medical care and a representative of the facility to determine if there is a potential for greater adverse effects on patient or resident care as a result of the proposed issuance of an emergency order. The Commissioner shall provide for notice to the patient or resident, his or her next of kin or guardian and his or her physician of the emergency relocation and the reasons therefore; relocation to the nearest appropriate institution, community living arrangement or drug abuse

treatment and education program and other protection designed to ensure the welfare and, when possible, the desires of the patient or resident.

1. When provided with the notice of the execution of the emergency relocation order, the institution, community living arrangement or drug abuse treatment program shall make patient/resident information available to the department in usable formats.

2. The institution, community living arrangement or drug abuse treatment program that is the subject of the emergency relocation order shall not impede in any way the Department's communications with the patients/residents, next of kin or guardians of the patients/residents and attending physicians.

3. The institution, community living arrangement or drug abuse treatment program shall continue to provide care and services to the patients/residents and shall prepare records required by the receiving facility which are necessary to facilitate continuity of patient/resident care for the patients/residents to be relocated.

4. The institution, community living arrangement or drug abuse treatment program shall make any personal property, such as but not limited to patient/resident funds, available to the receiving facility at the time of transfer.

(c) **Emergency Placement of Monitor.** The Commissioner may order the emergency placement of a monitor in an institution community living arrangement or drug abuse treatment program subject to licensure when conditions at the facility require immediate oversight for the safety of the patients or residents.

1. **Conditions.** The placement of a monitor may be required when one or more of the following circumstances are present:

   (i) the institution, community living arrangement or drug abuse treatment program is operating without a permit or license;

   (ii) the department has denied the application for a permit or a license or has initiated an action to revoke the existing permit or license of the institution, community living arrangement or drug abuse treatment program;

   (iii) the institution, community living arrangement or drug abuse treatment program is closing or plans to close and adequate arrangement for the relocation of the patients or residents have not been made at thirty (30) days before the date of closure; or

(iv) the health, safety, security, rights or welfare of the patients or residents cannot be adequately assured by the institution, community living arrangement or drug abuse treatment program. For example, the department is informed that essential service vendors (electricity, gas, water, food or pharmacy) have not been paid and anticipate discontinuing service and the institution, community living arrangement or drug abuse treatment program does not have a signed contract with another vendor establishing that there will be no disruption in service.

2. **Role of Monitor.** The monitor may be placed in the institution, community living arrangement or drug abuse treatment program for no more than ten (10) days during which time the monitor shall observe conditions and compliance with remedial action recommended by the department. The monitor shall not assume any administrative responsibility for the institution, community living arrangement or drug abuse treatment program, nor shall the monitor be liable for any of the actions of the institution, community living arrangement or drug abuse treatment program.

3. **Cost of Monitor.** The institution, community living arrangement or drug abuse treatment program shall pay the costs associated with the placement of the monitor unless the Commissioner's order placing the monitor is determined to be invalid in a contested case proceeding under the Georgia Administrative Procedure Act, Chapter 13 of Title 50.

(d) **Emergency Prohibition of Admissions.** The Commissioner may order the emergency prohibition of admissions to an institution, community living arrangement or drug abuse treatment program when such facility has failed to correct a violation of departmental permit rules within a reasonable period of time, as specified in the department's corrective order, and the violation could either jeopardize the health and safety of the residents/patients if allowed to remain uncorrected or is a repeat violation over a twelve (12) month period, which is intentional or due to gross negligence.

(e) **Emergency Suspension of Admissions.** The Commissioner may order admissions to an institution, community living or drug abuse treatment program, may be suspended until the department has determined that the violation has been corrected or until the department has determined that the facility has undertaken the action necessary to effect correction of the violation.

(f) **Preliminary Hearing.** The institution, community living arrangement or drug abuse treatment program affected by the Commissioner's emergency order, may request that the department hold a preliminary hearing within the department on

the validity of the order and the need for its continuation. Such hearing shall occur within ten (10) days following the request.

1. A request for a preliminary hearing shall be made in writing to the representative of the department designated in the emergency order. Unless a request is made to appear in person, the preliminary hearing shall consist of an administrative review of the record, written evidence submitted by the institution affected, and a preliminary written argument in support of its contentions.

2. If a request is made to appear in person at the preliminary hearing, the following information shall be included in the request, or provided prior to the hearing:

   (i) the name and address of person or persons, if any, who will be representing the institution in the preliminary hearing;

   (ii) the names and titles of all other persons who will attend the preliminary hearing; and

   (iii) any additional evidence the institution wishes to submit for consideration at the hearing.

3. Upon receipt of a request for a preliminary hearing, the department shall set and give notice of the date, time, and location of the preliminary hearing. The preliminary hearing shall be held within ten (10) calendar days of receipt of the request.

4. If a personal appearance is requested, the preliminary hearing shall consist of a review of the evidence in the record; any additional evidence introduced at the hearing; and any arguments made. A sound recording shall be made of the hearing.

5. Within seven (7) calendar days of the close of the preliminary hearing, the department shall render a written decision. The decision shall be divided as follows:

   (i) description of additional evidence submitted by the affected institution;

   (ii) summary of the arguments and/or brief submitted by the institution in support of its contention that the emergency order is invalid;

   (iii) a statement as to whether the emergency order issued by the department is found valid and the reasons therefore; and

(iv) notice of the affected institution's right to obtain an administrative hearing regarding the Commissioner's emergency order pursuant to O.C.G.A. § 50-13-13, if the emergency order is found valid as a result of the department's preliminary hearing.

6. Pending final appeal of the validity of any emergency order issued as provided herein through the administrative hearing process, such emergency order shall remain in full effect until vacated or rescinded by the Commissioner.

(g) **Cumulative Remedy.** The department is not limited to a single emergency action under these rules, nor is the department precluded from other actions permitted by other law or regulations during the time an emergency order is in force.

(4) **Standards for Taking Sanctions.** In taking any of the actions pursuant to subparagraphs (1), (2) or (3) of this rule, the department shall consider the seriousness of the violation or violations, including the circumstances, extent, and gravity of the prohibited act or acts or failure to act, and the hazard or potential hazard created to the physical or emotional health and safety of the public.

(5) **Non-Compliance with Sanctions.** Failure on the part of any facility to abide by any sanction, including payment of a fine, which is finally imposed against it, shall constitute grounds for the imposition of additional sanctions, including revocation.

(6) **Settlements.** With regard to any contested case instituted by the department pursuant to this Chapter or other provisions of law or regulation which may now or hereafter authorize remedial or disciplinary grounds and action, the department may, in its discretion, dispose of the action so instituted by settlement. In such cases, the department, the facility, and those persons deemed by the department to be successors in interest to any settlement agreement, shall be bound by the terms specified therein. Violation thereof by any applicant or licensee, their agents, employees, or others acting on their behalf, shall constitute grounds for the imposition of any sanctions enumerated in this Chapter, including revocation.

(7) **Sanctions for Nursing Facilities.** With respect to any facility classified as a nursing facility, nursing home, or intermediate care home, the department may not take an action to fine or restrict the license of any such facility based on the same act, occurrence, or omission for which: the facility has received an intermediate sanction under the provisions of 42 U.S.C. § 1396 r(h)(2)(A), as amended, or 42 U.S.C. § 1395 i - 3(h)(2)(B); or such facility has been served formal notice of intent to take such a sanction which the Division of Medical Assistance, based on administrative review, or any other appropriate body, based on administrative or judicial review, determines not to impose, provided however, that nothing in this subparagraph shall prohibit the department from using the provisions authorized by law in paragraph (5) above.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.05
Authority: O.C.G.A. §§. 31-2-8, 31-7-2.2, 31-7-4.
History. Original Rule entitled "Sanctions" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.
Repealed: New Rule entitled "Sanctions" adopted. F. July 14, 2010; eff. August 3, 2010.
Amended: F. Apr. 16, 2021; eff. May 6, 2021.

Rule 111-8-25-.06. Investigations, Inspections and Plans of Correction.

(1) **Authority to Investigate.** The department shall have the authority to make public or private investigations inside or outside this state. Such investigations may be initiated at any time, in the discretion of the department, and may continue during the pendency of any action initiated by the department pursuant to Rule 111-8-25-.05 of this Chapter.

(2) **Consent to Entry and Access.** An application for a license or the issuance of the same by the department constitutes consent by the applicant or licensee and the owner of the premises for the department's representatives, after displaying identification to any facility staff, to enter the facility for the purpose of conducting an investigation or an inspection.

(a) Department representatives shall be allowed reasonable and meaningful access to the facility's premises, and information pertinent to licensure including staff and persons in care. The department shall have the authority to require the production of any documents related to the initial and continued licensing of any facility.

(3) **Cooperation with Inspection.** Facility staff shall cooperate with any inspection or investigation conducted by the department and shall provide, without unreasonable delay, any documents which the department is entitled hereunder.

(4) **Assessment of Expenses.** Pursuant to the inspection, investigation, and enforcement powers given to the department by O.C.G.A. § 31-2-11 and other applicable laws, and the provisions of this Chapter, the department may assess against a facility reasonable and necessary expenses incurred by the department pursuant to any administrative or legal actions required by the failure of a facility to fully comply with licensing requirements. Such expenses may be assessed only pursuant to the initiation of sanction actions under this Chapter and may only be collected if such actions result in final adverse findings. A facility shall be notified of the department's action to assess expenses when the department sends a facility a notice of the sanction. If the sanction is appealed, the assessment may become an issue for consideration by the hearing examiner at any hearing held on the sanction.

(a) **Reasonable and Necessary Expenses.** Reasonable and necessary expenses, as used in this subparagraph, shall include, but not necessarily be limited to: hourly compensation of department representatives, commuting expenses (including mileage at the current state reimbursement rate), and lodging and meal expenses (at the rate approved for reimbursement by the state) associated with overnight out-of-town travel; and other similar costs. Assessments shall not include

attorney's fees and expenses of litigation, shall not exceed actual expenses, and shall be made only if inspections, investigations, or enforcement actions result in final adverse findings.

(b) **Payment of Assessed Expenses.** Expenses assessed against a facility shall be paid within thirty (30) days of receipt of a statement of expenses. In response to an assessment, a facility may request that the department reduce the assessment or agree to a payment plan if full payment within thirty (30) days would cause significant financial hardship that would compromise its ability to provide care or services in compliance with licensing requirements. The issue of significant financial hardship caused by the assessment may become an issue for consideration by the hearing examiner at any hearing held on the sanction.

(5) **Outcome of Investigation Available.** When an investigation is initiated due to an allegation of noncompliance by any person acting on his or her own or another's behalf, the outcome of the investigation shall be provided by the department to that person and to the facility upon request after the investigation is completed; provided however, that the names and identifying information regarding the complainants are classified as confidential. Nothing in this rule shall be construed to require the department to release the name or identifying information regarding a complainant without first obtaining proper authorization from such complainant. Nor shall this rule be construed to require the department to release any other confidential or privileged information without first obtaining proper authorization.

(6) **Compliance with Plan of Correction**. If violations of any licensing rules are identified, the facility will be given a written report of the violation that identifies the rule violated. The facility shall submit a written plan of correction in response to the report of violation, which stats what the facility will do, and when, to correct each of the violations identified. The facility may offer an explanation or dispute the findings of violations in the written plan of correction, so long as an acceptable plan of correction is submitted within ten (10) days of the facility's receipt of the written report of inspection. If the initial plan of correction is unacceptable to the department, the facility will be provided with at least one (1) opportunity to revise the unacceptable plan of correction. The facility shall comply with the plan of correction accepted by the department.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.06
Authority: O.C.G.A. Secs. 31-2-11, 31-5-5, 31-7-2.2, 31-7-4.
History. Original Rule entitled "Investigations and Inspections" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.
Repealed: New Rule entitled "Investigations, Inspections and Plans of Correction" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-25-.07. Immunity.

For any action taken or any proceeding held under this Chapter or under color of law, except for gross negligence or willful or wanton misconduct, the department, when acting in its official

capacity, shall be immune from liability and suit to the same extent that any judge of any court of general jurisdiction in this state would be immune.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.07
Authority: O.C.G.A. Sec. 31-2-11.
History. Original Rule entitled "Immunity" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Rule 111-8-25-.08. Exemptions.

In an administrative or legal proceeding under this Chapter, a person claiming an exemption or an exception granted by law, rule, regulation, or formal order has the burden of proving this exemption or exception.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.08
Authority: O.C.G.A. Sec. 31-2-11.
History. Original Rule entitled "Exemptions" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Rule 111-8-25-.09. Applicability of Administrative Procedures Act.

This Chapter and all sanction actions resulting from its provisions shall be administered in accordance with Chapter 13 of Title 50 of the Official Code of Georgia Annotated, the Georgia Administrative Procedure Act. Any request for hearing in response to any sanction action undertaken pursuant to this Chapter shall be in writing and shall be submitted to the department no later than 10 calendar days from the date of receipt of any notice of intent by the department to impose a sanction setting forth the proposed sanction or sanctions and the basis therefore.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.09
Authority: O.C.G.A. Secs. 31-2-11, 50-13-18.
History. Original Rule entitled "Applicability of Administrative Procedures Act" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Rule 111-8-25-.10. Notice of Violations.

(1) Where a nursing home or intermediate care home is required by the provisions of O.C.G.A. § 31-7-3.2 to give notice of violations giving rise to the imposition of any sanction, the notice shall contain the information required by that code section and shall conform to the following requirements:

   (a) **Size and Format of Notice.** The facility may post the Report of Licensure Inspection and Medicare/Medicaid Statement of Deficiencies, along with the notices by the department, the department's Division of Medical Assistance and/or the Center for Medicare and Medicaid Services of intent to impose any sanction. These may be posted in their original forms as the notice required by O.C.G.A. § 31-7-3.2(a)and(b). If the facility chooses to post the notice of the agency taking

the action and the Report of Licensure Inspection and Statement of Deficiencies, there shall be a conspicuous heading clearly visible from at least twenty feet away, calling the attention of the observer to them. As an alternative, the facility may post its own notice which accurately and thoroughly reflects the violations found which give rise to the sanctions imposed or proposed and which describes each sanction or notice of sanction issued by any of the above-described agencies. Any such notice shall be at least 11 1/2 inches by 17 1/2 inches in size. Words and letters shall be in bold print and shall be at least one centimeter in size;

(b) **Location of Notice.** The facility shall post the notice in a place readily accessible and continuously visible to persons in care and their representatives;

(c) **Timing of Notice.** The facility shall post the notices within fourteen days after it receives notification of the imposition of a sanction for a violation which requires the notice. The notices shall remain in place until the department has determined that cited violations no longer exist, at which time the notice may be removed; and

(d) **Mailing of Notices.** Where any person has made a written request for a copy of the notice or notices, the facility shall mail the same to the requester within 5 business days of receipt of the request when such request is accompanied by a postage paid self addressed envelope.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.10
Authority: O.C.G.A. Secs. 31-2-11, 31-7-2.1, 31-7-3.2.
History. Original Rule entitled "Notice of Violations" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Rule 111-8-25-.11. Applicability of Other Laws.

The provisions of this Chapter shall be supplemental to and shall not operate to prohibit the department from acting pursuant to those provisions of law which may now or hereafter authorize remedial or disciplinary grounds and action for the department. In cases where those other provisions of law so authorize other disciplinary grounds and actions, but this Chapter limits such grounds or actions, those other provisions shall apply.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.11
Authority: O.C.G.A. Sec. 31-2-11.
History. Original Rule entitled "Applicability of Other Laws" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Rule 111-8-25-.12. Inspection Warrants.

In addition to the enforcement actions authorized by this Chapter with respect to refusal to provide the department with access to a facility, the department may make application to a court of competent jurisdiction for an inspection warrant if its representatives are denied meaningful access to the premises, staff, persons in care, and documents or other information of a licensed

facility or of a facility which the department believes is required to have a license but which does not have one. Upon the grant of such a warrant, the department may gain entry and meaningful access to such facility, its staff, and persons in care therein, facility documents, and other information deemed pertinent by the department to making a compliance determination, unless the warrant specifically limits the entry or access allowed to department representatives. This rule shall not be construed to require the department to seek entry and be denied the same before it may apply for an inspection warrant.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.12
Authority: O.C.G.A. Secs. 31-2-11, 31-5-20*et seq.*
History. Original Rule entitled "Inspection Warrants" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Rule 111-8-25-.13. Injunctive Relief.

The department may, without regard to the availability of other remedies, including the remedies set forth in this Chapter, seek an injunction against the continued operation of a facility without a license. The department likewise may seek injunctive relief against the continued operation of a facility in violation of licensing requirements.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.13
Authority: O.C.G.A. Secs. 31-2-11, 31-5-9.
History. Original Rule entitled "Injunctive Relief" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Rule 111-8-25-.14. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions thereof shall remain in full force and effect as if such rule or portions thereof so determined, declared or adjudicated invalid or unconstitutional were not originally part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-25-.14
Authority: O.C.G.A. Sec. 31-2-11.
History. Original Rule entitled "Severability" adopted. F. Mar. 17, 2010; eff. Apr. 6, 2010.

Subject 111-8-28. EYE BANKS.

Rule 111-8-28-.01. Definitions.

Unless a different meaning is required by the context, the following terms as used in these regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Eye bank" means a facility which is maintained and operated for the extraction, removal, care, storage, preservation, and/or use of human eyes or parts thereof for purposes of sight preservation or restoration, medical education, instruction pertaining to sight preservation or restoration, or research.

(b) "Person" or "persons" means any individual, firm, partnership, corporation, trustee, association, or combination thereof.

(c) "Department" means the Georgia Department of Community Health.

(d) "Medical Director" means a physician who has specialized in the field of ophthalmology, is certified by the American Board of Ophthalmology and is responsible for the medical supervision of the eye bank.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.01
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.02. Application.

Any person or persons desiring to establish an eye bank shall apply in writing to the Department for a permit. The application shall include the following information:

(a) Name of hospital or medical school;

(b) Name and qualifications of medical director of the proposed eye bank;

(c) Name of the eye bank facility;

(d) Address of the eye bank;

(e) Brief description of equipment and facilities;

(f) Concise description of scope of service to be offered;

(g) Proof of tax-exempt and non-profit status.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.02
Authority: O.C.G.A. §§ 31-2-4 and 31-23-1*et seq.*
History. Original Rule entitled "Application" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.03. Approval.

(1) Upon compliance with all of the requirements for establishing an eye bank the governing authority for establishing said eye bank shall be issued a permit by the Department.

(2) It shall be unlawful to establish and operate an eye bank without a permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.03
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Approval" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.04. Inspection.

Inspections of facilities, equipment and operational procedures of the eye bank shall be made by the Department. If the eye bank is found to be deficient in any point in these rules and regulations, notice of these deficiencies will be given to the eye bank. Correction of such deficiencies must be accomplished for continuation of licensure.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.04
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Inspection" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.05. National Standards.

In addition to the requirements of these regulations, the eye bank shall meet the current medical standards approved by the Eye Bank Association of America.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.05
Authority: O.C.G.A. §§ 31-2-4 and 31-23-1*et seq.*
History. Original Rule entitled "National Standards" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.06. Administration.

(1) The eye bank shall be under the control of a hospital or medical school's governing authority. This control may be shared through contractual agreement with other charitable institutions.

(2) The eye bank shall have a medical director.

(3) The eye bank may receive gifts, donations and bequests for purposes stated under the law.

(4) The eye bank shall be non-profit.

(5) The eye bank shall offer, on an as-needed basis, an appropriate course in eye extractions for embalmers.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.06
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.07. Records.

(1) All records of the eye bank shall be confidential and shall be made available only to duly authorized persons.

(2) The following records shall be kept by each eye bank:

(a) donor record; the signed and witnessed duplicate donor card of every intended donor as well as the consent form for every eye received in the eye bank must be kept on file. The consent form shall be witnessed by two (2) persons of legal majority.

(b) history record; this shall be a record of the enucleation, identification and condition of the eye or eyes. It shall include a full medical history, the cause of death, time of death, recorded time of enucleation, and when available, gross and slit lamp examination of the enucleated eye.

(3) These records shall be retained for a minimum of six (6) years.

(4) If the eye bank ceases operation, provision must be made for the retention of records in a manner acceptable to the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.07
Authority: O.C.G.A. §§ 31-2-4 and 31-23-1*et seq.*
History. Original Rule entitled "Records" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.08. Consent Requirements in Coroner or Medical Examiner Cases.

(1) In any case in which a donor is having an autopsy performed, the following consent requirements shall be met prior to enucleation:

(a) A decedent who may provide a suitable eye for the transplant is under the jurisdiction of a coroner or medical examiner and an autopsy is required in accordance with O.C.G.A. § 45-16-20*et seq.*; or the physician has been requested, as provided by law, to perform an autopsy on a decedent who may provide a suitable eye for the transplant:

(b) The express written consent to the removal of the eye is given by the next of kin of the decedent; and

(c) The removal of the eye will not interfere with the subsequent course of an investigation or autopsy.

(2) For corneal excision the following consent requirements shall be met:

(a) The decedent from whom the tissue is to be taken is under the jurisdiction of a coroner or medical examiner pursuant to O.C.G.A. § 45-16-25;

(b) No objection by the decedent during his lifetime or after his death, by the appropriate person listed in paragraph (d) of this subsection is known to the coroner, medical examiner, or authorized official acting for the coroner at the time the tissue is removed;

(c) The person designated by the eye bank to remove the tissue is a person authorized to do so under O.C.G.A. § 31-23-5.

(d) Objection to the removal of corneal tissue may be made known to the coroner, medical examiner, hospital, funeral director, or authorized official acting for the coroner by the decedent during his lifetime or by the following persons after the decedent's death:

1. The decedent's spouse;

2. f no spouse survives him, any of the decedent's adult children;

3. If no adult children or spouse survive him, either of the decedent's parents;

4. If no parents, adult children, or spouse survive him, any of the decedent's brothers or sisters; or

5. If none of the foregoing survive him, the decedent's next of kin.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.08
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Consent Requirements in Coroner or Medical Examiner Cases" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.09. Consent Requirements in Non-Coroner or Non-Medical Examiner Cases.

Standard hospital and/or eye bank consent requirements shall be met.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.09
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-7-1 *et seq.* and 31-23-1.
History. Original Rule entitled "Consent Requirements in Non-Coroner or Non-Medical Examiner Cases" adopted.

F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.10. Persons Authorized to Extract Eyes.

Eye banks may authorize the following persons to perform eye extractions:

(a) Any physician;

(b) any embalmer licensed by the state of Georgia who has completed a course in eye extraction approved by the Department;

(c) any technician trained by and authorized by the eye bank to perform extractions.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.10
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Person Authorized to Extract Eyes" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.11. Medical and Surgical Procedures.

Procedures involved in the enucleation, transportation, and storage of eye tissue shall comply with the eye bank's policies for such procedures. These procedures shall conform to the current prevailing medical standards.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.11
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Medical and Surgical Procedures" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.12. Shipment.

(1) Shipping of eyes shall be the fastest and most convenient transportation methods.

(2) Eyes used for transplanting purposes shall be shipped in sturdy, insulated shipping containers that will maintain a maximum temperature of 4°C. for at least 36 hours.

(3) A shipping carton, for the transportation of eyes, shall be supplied to the participating physicians by the Eye Bank and shall contain for each donated eye:

   (a) a sterile storage chamber with cotton balls.

   (b) history record card;

   (c) printed instructions for removal of eyes.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.12
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Shipment" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.13. Publicity.

All publicity, with the objective of informing and educating the general public to take an active part in the eye donor program, all fund raising activities, and the solicitation of donor eye pledges, must be done by the most dignified means. Such activities shall conform to prevailing medical ethics and at a minimum provide that:

(a) Eye tissue shall neither be bought nor sold.

(b) Eye tissue shall be distributed without discrimination based on race, creed, color, or national origin.

(c) Eye tissue shall be distributed only to qualified opthalmologists on a first come, first served basis, except in an emergency.

(d) The wishes of the immediate family shall be respected in carrying out the donor's eye pledge.

(e) The names of donor and recipient shall not be disclosed without written consent.

(f) Eye pledges shall be solicited in a dignified manner.

(g) Fund raising shall be ethically conducted.

(h) Eye banks shall not compete with one another.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.13
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Publicity" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.14. Penalty.

(1) It shall be unlawful:

(a) for any person to sell either his eyes or any parts thereof or the eyes or any parts thereof of another person or to receive any remuneration for the giving of a human eye or any part thereof;

(b) for the person or persons operating and maintaining any eye bank to sell any donated eye or donated part thereof or knowingly to extract, remove, or take

possession of any human eye or part thereof for which any person received compensation or remuneration;

(c) for any person or persons to establish or operate any eye bank without approval of the Department or otherwise not in accordance with this chapter.

(2) Any person who violates any provision of O.C.G.A. § 31-23-9 shall be guilty of a misdemeanor.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.14
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-9.
History. Original Rule entitled "Penalty" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.15. Waivers, Variances, Exemptions.

(1) The Department upon petition may grant variances or waivers of specific rules and regulations as provided for in O.C.G.A. § 31-2-7, when it has been shown that the rule or regulation is not applicable or to allow experimentation and demonstration of new and innovative approaches to delivery of services.

(2) The Department may exempt classes of facilities from regulation as provided for in O.C.G.A. § 31-2-7, when regulation would not permit the purpose intended or the class of facilities is subject to similar requirements under other rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.15
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-23-1 *et seq.*
History. Original Rule entitled "Waivers, Variances, Exemptions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-28-.16. Enforcement.

The administration and enforcement of these rules and regulations shall be as prescribed in O.C.G.A. § 31-2-8 and as prescribed by the Georgia Administrative Procedure Act, O.C.G.A. § 50-13-1*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-28-.16
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-23-1 *et seq.* and 50-13-1 *et seq.*
History. Original Rule entitled "Enforcement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-29. RULES AND REGULATIONS FOR HEALTH MAINTENANCE ORGANIZATIONS.

Rule 111-8-29-.01. Introduction and Purpose.

(1) The Department of Community Health is authorized by the Georgia Health Maintenance Organization Act of 1979, Ga. Laws of 1979, p. 1148, et seq., (Ga. Insurance Code Chapter 56-36) to promulgate rules and regulations necessary to establish and control the standards of health care which any Health Maintenance Organization (HMO)created under that Act shall be required to maintain. Before the Insurance Commissioner may issue a Certificate of Authority to operate an HMO, the Commissioner of the Department of Community Health must certify to the Insurance Commissioner that the standards of health care are met by the applicant HMO.

(2) The purpose of these rules and regulations is to establish the standards of health care which will be required by the Department of Community Health of HMOs. Minimum parameters of operation for the clinical staff and management of HMOs and components thereof will also be set. In recognition that HMOs are intended to be a cost effective alternative for the delivery of health care services, the Department is supportive of efforts to assure their availability to all citizens. It is the intent of the Department to assist the growth and development of HMO programs in Georgia and to aid in providing technical assistance needed for their efficient and effective utilization.

(3) HMOs are subject to review by the Office of Health Planning, pursuant to the Georgia Certificate of Need Law and 1122 of the Social Security amendment (where applicable). Evidence of completion of this review shall be Submitted to the Department of Community Health as a documentation requirement during the Certificate of Authority process.

(4) Copies of these rules and regulations shall be available within the HMO, and employees shall be fully informed and instructed with reference to their requirements.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.01
Authority: Ga. L. 1964, pp. 499, 507, 523; Ga. L. 1979, p. 1148 *et seq.*; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Introduction and Purpose" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.02. Definitions.

Unless a different meaning is required or given in the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:

(a) "Basic Health Care Services" means healthcare services which an enrolled population might reasonably require in order to be maintained in good health, including as a minimum but not restricted to, preventive care, emergency care, inpatient hospital and physician care, and outpatient medical services;

(b) "Commissioner" means the Commissioner of the Georgia Department of Community Health or his designee;

(c) "Complaint" means a written expression of concern by an enrollee or provider regarding the provision of health care services by the HMO or a condition in the operation of an HMO which affects an enrollee or provider to such an extent as to be viewed by such as deserving of formal redress;

(d) "Department" means the Georgia Department of Community Health (DCH);

(e) "Enrollee" means an individual person who is enrolled in a health benefits plan;

(f) "Governing Body" means the person or persons, natural or corporate, in which the ultimate responsibility, authority and accountability for the conduct of the HMO is vested;

(g) "Health Benefits Plan" means any arrangement whereby any person undertakes to provide, arrange for, pay for, or reimburse any part of the cost of any health care services and at least part of such arrangement consists of arranging for or the provision of health care services, as distinguished from an arrangement which provides only for indemnification against the cost of such services, on a prepaid basis through insurance or otherwise;

(h) "Health Care Services" means any services included in the furnishing to any individual of medical or dental care, or hospitalization or incident to the furnishing of such care or hospitalization, as well as the furnishing to any person of any and all other services for the purpose of preventing, alleviating, curing, or healing human illness or injury;

(i) "Health Education" means the provision of health information and the use of educational techniques to modify an individual's or family's knowledge and/or behavior to achieve and maintain optimum physical and mental health and to prevent illness, injury, chronicity, or unnecessary disability;

(j) "Health Maintenance Organization" or "HMO" means any legal entity subject to the provisions of the Georgia Health Maintenance Organization Act;

(k) "Health Professional" means those professionals engaged in the delivery of health services who are currently licensed to practice in the State of Georgia, or provide services authorized under an institutional license, or are certified, or practice under authority consistent with Georgia laws;

(l) "In-Area" means the geographical area defined by the health maintenance organization as its service area in which it provides health services to its enrollees directly through its own resources or through arrangements with other providers in the area;

(m) "Insurance Commissioner" means the Insurance Commissioner of the State of Georgia or his designee;

(n) "Medical Audit" means the retrospective examination and evaluation of the documentation of clinical application of medical knowledge as revealed inpatient health records for the purposes of education, accountability, and quality assurance;

(o) "Out-of-Area" means that area outside of the geographical area defined by the health maintenance organization as its service area;

(p) "Physician" means an individual who is currently licensed to practice medicine, surgery, or osteopathy in the State of Georgia, under the Georgia Medical Practice Act, Chapter 84-9, Georgia Laws Ann.;

(q) "Primary Care Physician" means the physician responsible for the management of medical care and coordination of health care services of an enrollee;

(r) "Provider" means any physician, hospital, or other person or facility which is licensed or otherwise authorized in this State to furnish health care services;

(s) "Peer Review" means professional evaluation by currently licensed professional persons in the same category as those being reviewed, of the performance of individuals in the medical and related health care fields for the purpose of achieving and maintaining high standards of care and professional practice;

(t) "Person" means any individual, institution, partnership, association, corporation, the State, or any municipalities or subdivision thereof, or any other entity whether organized for profit or not;

(u) "Quality Assurance Program" means the planned systematic medical and/or management actions which assure consistent rendering of high quality health care services through the use of monitoring and evaluation techniques;

(v) "Service Area" means the defined geographical area (i.e., boundaries of political subdivisions, census tracts, Area Planning and Development Commissions or Health System's Agencies, etc.) in which HMO services are available and readily accessible to enrollees;

(w) "Subscriber" means an enrollee who has entered into a contractual relationship for the provision of/or arrangement of health care services from an HMO for himself and/or his dependents;

(x) "Supplemental Health Services" means those health services offered in addition to "Basic Health Care Services."

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.02
Authority: Ga. L. 1964, pp. 499, 507, 523; Ga. L. 1979, p. 1148 *et seq.*; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Definitions" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.03. Basic Health Care Services.

An HMO shall provide or arrange for the provision of basic health care services to its enrollees as needed and without limitations as to time, cost, type of service, or waiting period, e.g.

maternity benefits, except as otherwise provided for in these rules and regulations. Provided, however, that such persons or institutions shall not be required to provide or receive services which conflict with their religious belief or moral objection. Exemptions claimed under this provision must be fully disclosed in the health benefits plan. Upon the determination of necessity, the HMO shall be responsible for medically necessary emergency care 24-hours per day, seven days per week, during the time of an existing contract. The HMO is responsible to provide or arrange for the provision of nonemergency care during reasonable and customary working hours and days. An HMO must provide the basic health care services listed herein and may not provide less service, nor may the HMO withhold a basic health care service because of an enrollee's known or unknown health condition. An HMO may provide one or more health benefits plans which exceed the basic health care services by including one or more supplemental health services. The basic health care services are:

(a) Preventive Care Services (including family planning services and services for the detection of asymptomatic diseases). The following services will be provided on a periodic basis, as specified in the plan:

1. The full range of family planning services;

2. Services for infertility;

3. Preventive eye/ear examinations by a physician, optometrist, or other qualified health professional to determine the need for correction, for children through age seventeen (17). The cost of corrective appliances and/or artificial aids shall not be included as a basic service unless otherwise specified in the health benefits plan;

4. Pediatric and adult immunizations in accordance with the Immunization Program of the Georgia Department of Public Health;

5. Periodic health examinations with appropriate protocols for specific age and sex groups, which may include pelvic and breast examinations and pap smears for women and other special diagnostic and screening procedures for enrollees considered to be at risk for specific disease states (e.g., obesity, hypertension, diabetes, glaucoma, cardiovascular disorders, lung diseases, cancer, sickle cell disease, etc.);

6. Well-child care services aimed at preventing problems and promoting the well-being of the child according to an established schedule of examinations and services planned for early detection and treatment of disorders for the promotion of healthy growth and development (e.g., health assessments, nutrition counseling, immunizations, screening, health education, etc.); and

7. Health education activities (including nutritional education and counseling). Health education activities shall state in writing the targeted population, purposes and techniques to be utilized in the program and the evaluation of results.

(b) Emergency Care.

1. Medically necessary emergency care service is medical care rendered by affiliated or non-affiliated providers, whether in or out of the service area, under unforeseen conditions requiring services necessary for the repair of accidental injury, relief of acute pain and/or infection, protection of the person's health, or the amelioration of illness which, if not immediately diagnosed and treated, would result in physical or mental impairment or loss of life. Outpatient and inpatient in-area medically necessary emergency health services shall be available 24-hours a day, seven days a week. Emergency health services shall include in-area ambulance services to the nearest facility designated by the HMO plan. The HMO shall have a plan for coverage of out-of-area emergencies; the plan shall cover ambulance service. An HMO associated physician or other delegated health professional shall authorize the use of nonemergency ambulance services.

2. Medically necessary emergency services shall include psychiatric emergency care provided in an emergency room. Such care shall not be considered among the limited short-term outpatient mental health visits.

3. Emergency care related to alcohol use and abuse shall include:

   (i) immediate medical evaluation and care;

   (ii) medical management of intoxicated persons until they are no longer incapacitated by the effects of alcohol; and/or

   (iii) initiation of other appropriate health services needed for continuity of care.

4. Emergency care related to drug abuse and addiction shall include treatment for overdose and adverse reactions to psychotropic substances such as barbiturates, amphetamines, hallucinogens (including marijuana), tranquilizers and narcotics.

(c) Outpatient Medical Services and Inpatient Hospital Services.

1. Outpatient medical services shall include diagnostic or treatment services or both for patients who are ambulatory and may be provided in a non-hospital-based health care facility or in a hospital.

2. Inpatient hospital services shall include, but not be limited to room (private, if determined medically necessary by the physician) and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, intensive care unit and services, x-ray, laboratory and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, physical therapy, respiratory therapy, radiation therapy, administration of whole blood and blood products (or components) and derivatives, other diagnostic therapeutic and rehabilitative services as needed, and coordinated discharge planning including the planning of

such continuing care as may be necessary both medically and as a means of preventing possible early rehospitalization.

3. Outpatient medical services and inpatient hospital services shall include appropriate short-term rehabilitative services. The HMO must clearly define and make known its policy to enrollees.

4. Prenatal, intrapartum and postnatal maternity care shall be covered. This shall include complications of pregnancy of the mother and care with respect to the newborn child from the moment of birth; and necessary care and treatment of illness, injury, and congenital defects of the infant.

5. Medically necessary plastic surgery shall be provided as needed for the purpose of improving function by anatomic alterations. The HMO has flexibility to determine a policy for elective plastic surgery and must clearly define and make known its policy to enrollees.

6. Prescribed drug(s) and/or injection(s) may be provided to an enrollee at the time of outpatient care as a basic healthcare service. The HMO must clearly define and make known its policy to enrollees.

7. Experimental procedures or biomedical clinical research investigations undertaken by the HMO or by health professionals associated with the HMO which involve HMO enrollees must comply with all current Federal and State regulations, especially with regard to informed patient consent, peer review, and the rights of human subjects.

8. The HMO shall provide outpatient evaluative and crisis intervention mental health services. These basic mental health services may be provided through lesser or longer time periods if enrollees are equitably assured the equivalency of twenty full 50-55 minute session visits per enrollee per year. Modifications of the standard therapeutic full session shall be fully and fairly disclosed to enrollees of the HMO.

9. Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs includes detoxification on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to treatment for other medical conditions.

10. Alcohol and drug referral services may be for either medical or for nonmedical ancillary services. Medical services shall be a part of basic health services; nonmedical ancillary services need not be a part of basic health services.

11. Diagnostic laboratory and diagnostic and therapeutic radiology services shall include, but are not to be limited to clinical and anatomic pathology, and diagnostic radiology, including special procedures, therapeutic radiology, nuclear medicine, electrocardiography, electroencephalography, and other generally

accepted diagnostic and therapeutic technology. Laboratory and diagnostic radiology services necessary for the care and management of a condition of an enrollee shall be readily accessible.

12. Home health services are services which are provided at an enrollee's home by health care personnel, as prescribed or directed by the primary care physician. Home health services may include such rehabilitative therapy as medical social services and home health aide services. Homemaker services are not a required basic health service.

(d) Physician Care. Physician services (including consultant and referral services by a physician) shall be provided by or at the direction of a currently licensed physician.

1. Consultant services are defined as those services requiring the skills of a physician or other licensed health professional who by training and experience has acquired or demonstrated proficiency in specialized clinical areas. Coordination of patient care shall continue to be the responsibility of the primary care physician associated with the HMO.

2. Referral services are defined as those health and medical services provided directly to an enrollee by another health professional or health agency. Referrals shall be authorized and coordinated through the enrollee's primary care physician.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.03
Authority: Ga. L. 1964, pp. 499, 507, 523; Ga. L. 1979, p. 1148 *et seq.*; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Basic Health Care Services" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.04. Supplemental Health Services.

(1) An HMO may provide or arrange for the provision of supplemental health services for which the enrollee has contracted and for which the required health manpower is available.

(2) An HMO must define the level and scope of each supplemental benefit to be offered, i.e., covered days of care, number of visits, or other specific units of service to be offered. Health service facilities, type of health professionals and range of specific services, and the capabilities made available under each benefit, shall be fully disclosed to enrollees and kept current and updated.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.04
Authority: Ga. L. 1964, pp. 499, 507, 523; Ga. L. 1979, p. 1148 *et seq.*; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Supplemental Health Services" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.05. Health Services Information System.

(1) The HMO and/or its providers shall establish and maintain an organized health services information system for the collection, processing, maintenance, storage and retrieval of information concerning health services received by HMO enrollees.

(2) An individual record shall be maintained within the system for each enrollee to include the following minimum data:

(a) Identification - name; address; identifying number; enrollment date; age and birthdate; sex; marital status; occupation; and telephone number;

(b) An initial health evaluation including a chronological record of past medical history, drug use profile, personal and social history, family history and results of physical examinations, including laboratory and x-ray reports;

(c) A health care plan which identifies enrollee problem(s) and need(s) and the service(s) that will be provided for the enrollee's health maintenance, including revisions as indicated;

(d) The chief complaint and purpose of each visit; clinical diagnosis or impression; studies ordered; treatment given; disposition, recommendations, and instruction to patient; and a progress note for each follow-up visit;

(e) Copies of all consultation and/or referral requests and responses from other health care providers within and without of the organization, which shall be entered into the health record within 14 calendar days following the completion of services by the provider; and

(f) Other records, such as laboratory, x-ray and other test reports, vision/hearing records, immunization records, prenatal/postnatal records, copies of discharge summaries from inpatient health facilities, etc.

(3) The system shall be kept current and available to staff or agencies authorized to use the system.

(4) Health services information shall be retained for a period of six years after the last patient encounter for adults, and for six years after a minor reaches the age of majority. This information may be retained as originals, microfilms, or other usable forms and shall afford a basis for complete audit of professional information. If the HMO dissolves or changes ownership, the plan for retention shall be placed into effect and the Department shall be advised of the disposition and/or location of said records.

(5) Sufficient space and equipment for record processing, storage and retrieval shall be provided.

(6) Policies and procedures shall be written and implemented to assure organization and continuous maintenance of the health services information system.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.05
Authority: Ga. L. 1964, pp. 499, 507, 523; Ga. L. 1979, p. 1148 *et seq.*; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Health Services Information System" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.06. Confidentiality of Medical Information.

Any data or information pertaining to the diagnosis, treatment, or health of any enrollee obtained from such person or from any provider by any HMO shall be held in confidence and shall not be disclosed to any person except to the extent that it may be necessary to carry out the purposes of these regulations; or upon the express consent of the enrollee; or pursuant to statute or court order for the production of evidence or the discovery thereof or in the event of claim or litigation between such person and the HMO wherein such data or information is pertinent. An HMO shall be entitled to claim any statutory privileges against such disclosure which the provider who furnished such information to the HMO is entitled to claim.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.06
Authority: Ga. L. 1979, pp. 1148, 1171, 1172; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Confidentiality of Medical Information" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.07. Quality Assurance.

(1) Program Planning and Evaluation. The HMO shall have a formal organized plan for an ongoing quality assurance program. The purpose of the quality assurance plan is to assure that the quality of health care services is continually monitored, reviewed and evaluated for appropriate resource utilization, cost containment, and improvement of healthcare delivery. The written plan shall be approved by the governing body and implemented under the direction of the medical director of the HMO or the medical group. At a minimum, the plan shall include:

(a) The role and responsibilities of the medical director;

(b) An organizational structure created for the purpose of monitoring, reviewing, and evaluating the quality of health care services provided and appropriate resource utilization and cost containment;

(c) Mechanisms to collect data; identify problem areas and make recommendations for changes or improvements; develop plans for correction of identified problems; and follow-up;

(d) Arrangements for routine reporting of results of quality assurance program activities to the governing body and administration;

(e) Provision for maintenance of minutes and records of quality assurance program activities; and

(f) A peer review process which will evaluate and document the internal quality assurance program and the professional standards and practices of the providers, and services provided.

(2) Accessibility and Availability of Services.

(a) Basic health care services and supplemental health services for which enrollees have contracted shall be accessible (capable of being reached) to each enrollee and shall be readily available (present or ready for immediate use), within the defined service area of the HMO.

(b) An HMO shall provide or arrange for regular and reasonable hours during which an enrollee may receive services. An orderly system for scheduling services to enrollees is required and shall take into account the immediacy of the need for service.

(c) The HMO shall have a physician available or arrange for physician services to be available at all times to provide diagnostic and treatment services. The HMO shall assure that every enrollee seen for a medical complaint is evaluated by a physician or other qualified health professional pursuant to Georgia law. Each enrollee shall have the opportunity to select his primary care physician from among those available at the HMO.

(d) Medically necessary emergency services shall be available and accessible within the service area 24-hours a day, seven days a week.

(e) The ratio of enrollees to staff, including health professionals, administrative and other supporting staff, directly or through referrals, shall be such as to reasonably assume that all services offered by the HMO will be accessible without delays detrimental to the health of the enrollees. The HMO shall demonstrate an adequate ratio of primary care physicians to enrollees.

(f) The HMO shall provide for the availability and accessibility to services of medical specialists as determined to be medically necessary for the enrollee.

(g) Each HMO shall have a procedure for monitoring and evaluating availability and accessibility of its services, including a system for addressing problems that develop.

(3) Continuity of Care.

(a) Each provider shall establish and maintain an individual health record on each enrollee served, which shall contain information relating to the health care of that enrollee. These records shall be available to accommodate the flow of pertinent information to and from primary care physicians, as needed to assure continuity of care.

(b) The HMO shall offer counseling in dealing with the physical, emotional, and economic impact of illness and disability through services such as pre- and post-hospitalization planning, referral to services provided through community health, social and welfare agencies for family counseling, home health services, mental health services, health education, etc.

(4) Personnel.

(a) All HMO personnel and providers of services shall be currently licensed to perform the services they provide, when such services require licensure or registration under applicable State laws.

(b) The HMO shall assure that there is a sufficient number of health professionals to meet the needs of its enrollees. The specialty mix of licensed physicians shall be consistent with the projected health needs of the enrolled population. Emphasis shall be placed on having an adequate number of primary health care physicians.

(c) The HMO shall arrange for programs of continuing education for its staff and providers, either internally or by external organizations or agencies, to maintain and update skills and to assure quality of health care services.

(d) The HMO shall maintain an individual personnel folder on each employee and/or provider. This file shall include all personal information concerning the employee and/or provider, including applications and qualifications for employment. The employee's and/or provider's current license or registration number shall be included, if applicable.

(5) Facilities and Equipment.

(a) All facilities and equipment used for and in the delivery of services which are required to be licensed and/or certified by law, shall be so licensed and/or certified. This includes but is not necessarily limited to hospitals, nursing and intermediate care homes, clinical laboratories, pharmacies, psychiatric hospitals, and state- operated facilities.

(b) Providers shall have a functional, sanitary, and comfortable environment for patients, personnel, and the public. At all times the privacy and dignity of patients will be upheld.

(c) There shall be an adequate amount of space for services provided and disabilities treated, including waiting and reception areas, staff space, examining rooms, treatment areas, and storage.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.07
Authority: Ga. L. 1964, pp. 499, 507, 523; Ga. L. 1979, p. 1148 *et seq.*; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Quality Assurance" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.08. Policies and Procedures of the HMO.

The HMO shall have written policies and procedures governing the provision of services which are based on the stated objectives of the HMO. Policies and procedures shall be approved by the governing body and reviewed and updated at least annually. All policies/procedures shall be available for review by staff, enrollees, and providers. Policies and procedures shall include the following subjects:

(a) Administrative Policies:

1. Advisory Panels. Enrollees shall be afforded an opportunity to participate in health care matters of policy and operation through the establishment of advisory panels, by the use of advisory referenda on major policy decision, or through the use of other mechanisms;

2. Complaint System. The HMO shall establish and maintain a complaint system approved by the Insurance Commissioner after consultation with the Commissioner;

3. Annual Report. The HMO shall annually, on/or before the first day of March, file with the Insurance Commissioner's Office an annual statement as of December 31st of the preceding year which has been certified by at least two principal officers of said HMO. This report shall include summary information and statistics relating to the quality of health care, cost of operations, the pattern of utilization of services, availability and accessibility to services, use of the complaint system, and such other matters as may be required by the Commissioner;

4. Separation of Medical Decisions. The HMO plan shall be able to demonstrate through its quality assurance program and utilization review process that medical decisions are not hindered by fiscal and administrative management;

5. Service Area. The HMO shall maintain a current, explicit, definition of its service area and a statement of any restrictions or limitations on out-of-area health care.

(b) Policies Related to Professional Services:

1. Physician Services. The enrollee shall have a choice of any of the primary care physicians under contract to the HMO subject to availability;

2. Other Services. A system shall be established for referral, consultant, and other services not directly provided by the HMO to ensure continuity and availability of care;

3. Inpatient Admission and Discharge Policies. The HMO shall have policies and procedures for inpatient health facility utilization and utilization review.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.08
Authority: Ga. L. 1964, pp. 499, 507, 523; Ga. L. 1979, pp. 1148, 1153, 1157, 1159, 1160, 1161; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Policies and Procedures of the HMO" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.09. Statistical Information.

(1) The HMO shall develop, compile, evaluate, and report statistics to the Department as requested relating to the cost of its operations, the pattern of utilization of its services, and the availability and accessibility of its services. The HMO shall provide the Department with full access to all operational and statistical data to enable the Department to verify the HMO's compliance.

(2) The annual statistical report shall contain the following information and shall be made on forms to be provided by the Commissioner. (Federally qualified HMO's may substitute for this annual statistical report, a copy of their four (4) most recent quarterly reports under the National Data Reporting Requirements).

(a) Enrollee statistics:

1. Number of employer contracts and total number of enrollees served by the contracts;

2. Number of subscriber contracts and total number of enrollees served by the contracts;

3. Number of enrollees at the beginning of the reporting year, and number of enrollees at the end of the reporting year, additions during the reporting year, losses during the reporting year;

4. Number of Medicaid and Medicare enrollees.

(b) Provider contracts:

1. Number by type of provider (i.e. physician, dentist, hospital, etc.);

2. Additions during the year;

3. Number of terminations during the year.

(c) Utilization, availability, accessibility, and cost data on the following:

1. Inpatient services;

2. Ambulatory care;

3. Preventive health care services.

(d) Other relevant information as determined by the Commissioner.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.09
Authority: Ga. L. 1964, pp. 499, 507, 523; Ga. L. 1979, pp. 1153, 1159, 1160, 1161; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Statistical Information" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.10. Examinations.

(1) The HMO shall be available at all reasonable and/or scheduled operating hours for observation and examination by properly identified representatives of the Department. These examinations shall pertain to all matters relating to the quality of healthcare services of the HMO and all providers with whom such HMO has contracts, agreements, or other arrangements pursuant to its health benefits plan, as often as the Commissioner shall deem it necessary for the protection of the interests of the people of the State, but not less than once every five years. Such examinations may include any accounts, records, documents and files in the possession or control of the HMO, its officers, employees, representatives and providers, which relate to the subject of the examination. An HMO shall be entitled to claim any statutory privileges against such disclosure which the provider who furnished such information to the HMO is entitled to claim.

(2) The administrator or his representative shall accompany the Department representative on all tours of inspection and shall sign the completed checklist.

(3) Each HMO shall be periodically inspected to determine whether it is continuing to meet these requirements or is making satisfactory progress on approved plans of correction.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.10
Authority: Ga. L. 1964, pp. 499, 505, 507, 523; Ga. L. 1979, pp. 1148, 1164, 1165; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Examinations" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.11. Regulatory Process.

Upon certification to the Insurance Commissioner's Office that the HMO does not meet the requirements of Section 56-3603(1) (b) of the HMO Act of Georgia; or the HMO is unable to fulfill its obligations to furnish health care services as required under its health benefits plan(s); or the HMO has violated any provision of the rules and regulations of the Department, the HMO shall be subject to the regulatory process as prescribed by the HMO Act of Georgia.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.11
Authority: Ga. L. 1979, pp. 1148, 1166, 1167, 1168; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Regulatory Process" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.12. Enforcement.

(1) Informal Procedure. If the Commissioner shall for any reason have cause to believe that any violation of these rules and regulations or of the Georgia Laws governing HMO's has occurred or is threatened, the Commissioner may give notice to the HMO and to its representatives, or to other persons who appear to be involved in the suspected violation, to arrange a conference with the alleged violators or their authorized representatives for the purpose of ascertaining the facts relating to each suspected violation. In the event it appears that any violation has occurred or is threatened, the conferees may determine an adequate and effective means of correcting or preventing such violation. The proceedings under this subsection may be conducted in the manner deemed appropriate by the Commissioner under the particular circumstances.

(2) Formal Regulatory Process. In the event the Department does not choose to use the informal procedure set out above, or if an HMO does not correct or prevent the alleged violations as required by the Commissioner when the Department finds an HMO does not meet the requirements of these regulations or an HMO is unable to fulfill its obligations to furnish health care services as required under its health benefits plan, the Department shall so certify to the Insurance Commissioner for enforcement proceeding by that Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.12
Authority: Ga. L. 1979, pp. 1170, 1171; O.C.G.A. § 33-21-1 *et seq*.
History. Original Rule entitled "Enforcement" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.13. Applicability of Regulations.

These regulations are applicable only to HMO's and the services provided therein, and do not modify or revoke any of the provisions of other published rules of DCH.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.13
Authority: Ga. L. 1964, p. 499 *et seq*; Ga. L. 1979, p. 1148 *et seq*.; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Applicability of Regulations" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-29-.14. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions thereof shall remain of full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Board of Community Health to establish rules and regulations that are constitutional and enforceable so as to safeguard the health and well-being of the people of the State.

Cite as Ga. Comp. R. & Regs. R. 111-8-29-.14
Authority: Ga. L. 1979, p. 1172; O.C.G.A. § 33-21-1*et seq*.
History. Original Rule entitled "Severability" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Subject 111-8-31. HOME HEALTH AGENCIES.

Rule 111-8-31-.01. Purpose.

Under the authority of O.C.G.A. § 31-7-150, the Department of Community Health is authorized and required to establish the licensing procedures and standards of operation for home health agencies operating in this State. These rules and regulations are provided for this purpose.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.01
Authority: O.C.G.A. § 31-7-150*et seq.*
History. Original Rule entitled "Purpose" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.02. Applications and Licenses.

Each person, private or public organization, political subdivision, or other governmental agency desiring to operate a home health agency, as defined herein, must first apply for and obtain a license using the forms furnished by the Department of Community Health. A license is not assignable or transferable and is subject to suspension or revocation at any time for failure to comply with these rules and regulations.

(a) Applications.

1. The governing body of the home health agency shall submit to the Department an application for a license of each agency and/or subunit. Such application(s) shall be signed by the executive officer of the governing body.

2. The application for a license shall be filed at least thirty (30) days prior to the anticipated date of opening and commencement of operation of a new home health agency.

3. Corporations shall submit a copy of their charter and the name and address of all owners with five percent or more of the stock and shall identify each corporate officer.

4. An application for a change in service(s) or service area(s) which is subject to review under O.C.G.A. § 31-6-1*et seq.* and applicable rules shall be accompanied by a letter of approval from the Office of Health Planning within the Division of Healthcare Facility Regulation, Department of Community Health.

(b) Licenses.

1. To be eligible for a license, the home health agency must be in satisfactory compliance with these rules and regulations and other applicable Federal, State and local laws.

2. The license shall be returned to the Department when the home health agency ceases to operate, or is leased, or is moved to another location, or the ownership changes, or the license is suspended or revoked.

3. Any person or agency wishing to appeal the denial, suspension or revocation of a license is entitled to request a hearing under the provisions of the "Georgia Administrative Procedure Act."

4. Licenses will be renewed on an annual basis.

5. The license shall be prominently and appropriately displayed.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.02
Authority: O.C.G.A. §§ 31-6-1*et seq.*, 31-7-150 *et seq.* and 50-13-13 *et seq.*
History. Original Rule entitled "Applications and Licenses" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.03. Certificate of Need Review.

Home health agencies which are required by state laws to obtain a certificate of need shall submit evidence that such requirements have been met when applying for a license.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.03
Authority: O.C.G.A. §§ 31-6-1*et seq.* and 31-7-155.
History. Original Rule entitled "Certificate of Need Review" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.04. Exemptions.

These rules and regulations shall not apply to services which are provided under the following conditions:

(a) Persons who provide personal or paraprofessional health services, either with or without compensation when there is no claim that the service is provided as a part of a licensed home health agency;

(b) Persons who provide professional services for which they are duly licensed under

Georgia laws, when there is no claim that the service is provided as a part of a licensed home health agency;

(c) Services provided under the provisions of any other license issued by the State of

Georgia when there is no claim that the service is provided as a part of a licensed or certified home health agency;

(d) Any home health agency certified in a federal program for reimbursement of Medicare or Medicaid services shall be exempt from an additional on-site licensure inspection upon presentation of evidence of such certification.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.04
Authority: O.C.G.A. §§ 31-2-7 and 31-7-150*et seq.*
History. Original Rule entitled "Exemptions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.05. Inspections.

For the purpose of insuring compliance with these rules and regulations, each home health agency shall be subjected to periodic inspections by an authorized representative of the Department. Such inspections shall take place during reasonable hours and, if possible, during scheduled operating hours. The administrator or his representative shall accompany the Department representative on tours of inspection and shall sign the completed checklist.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.05
Authority: O.C.G.A. § 31-7-150*et seq.*
History. Original Rule entitled "Inspections" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.06. Definitions.

Unless a different meaning is required or given in the context, the following terms as used in these rules and regulations shall have the meaning respectively ascribed to them:

(a) "Administrator" means the full-time person by whatever title used, to whom the governing body has delegated the responsibility for day-to-day administration of the home health agency, including the implementation of the rules and policies adopted by the governing body, and who:

1. is a licensed physician; or
2. is a registered nurse; or
3. has training and experience in health service administration and at least one (1) year of supervisory or administrative experience in home health care or related health programs.

(b) "Board" means the Board of Community Health.

(c) "Branch Office" means a location or site identified in the application or endorsement thereto from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the requirements of these rules and regulations.

(d) "By-Laws" means a set of rules adopted by a home health agency for governing the agency's operation.

(e) "Certificate of Need" shall have that meaning as defined in O.C.G.A. § 31-6-1*et seq.* and applicable rules.

(f) "Clinical Note" means a dated and signed written notation by the providing member of the health team of a contact with a patient containing a description of signs and symptoms, treatment and drug given, the patient's reaction, and any changes in physical or emotional condition.

(g) "Department" means the Georgia Department of Community Health.

(h) "Governing Body" means the person or persons, natural or corporate, in which the ultimate responsibility, authority and accountability for the conduct of the home health agency is vested.

(i) "Health Professionals" means those professionals engaged in the delivery of health services Who are currently licensed to practice in the State of Georgia, or are certified, or practice under authority consistent with Georgia laws.

(j) "Home Health Agency" means: a public, non-profit, or proprietary organization; whether owned or operated by one or more persons or legal entities, which is engaged in providing home health services.

(k) "Home Health Services" means those items and services provided to an individual, according to a written plan of treatment signed by the patient's physician, by a home health agency or others under arrangement with the home health agency on a visit or

hourly basis, in a place of temporary or permanent residence used as the individual's home as follows:

1. part-time or intermittent skilled nursing care as ordered by a physician and provided by or under the supervision of a registered nurse and at least one other service listed below;

2. physical, occupational, or speech therapy;

3. medical social services;

4. home health aide services.

(l) "License" means a license issued by the Department.

(m) "Licensee" means the individual, corporation, or public entity with whom rests the ultimate responsibility for maintaining approved standards for the home health agency.

(n) "Licensed Practical Nurse or LPN" means an individual who is currently licensed as a licensed practical nurse in Georgia.

(o) "Occupational Therapist" means a qualified individual who:

1. Is currently licensed as an occupational therapist in Georgia; and

2. Meets the federal conditions for participation.

(p) "Occupational Therapy Assistant" means a qualified individual who:

1. Is currently licensed as an occupational therapy assistant in Georgia and assists in the practice of occupational therapy under the supervision and direction of a Georgia licensed occupational therapist; and

2. Meets the federal conditions for participation.

(q) "Parent Home Health Agency" means the agency that develops and maintains administrative controls of subunits or branch offices.

(r) "Physical Therapist" means a qualified individual who:

1. Is currently licensed as a physical therapist in Georgia; and

2. Meets the federal conditions for participation.

(s) "Physical Therapy Assistant" means a qualified individual who:

1. Is currently licensed as a physical therapy assistant in Georgia and assists in the practice of physical therapy under the supervision and direction of a Georgia licensed physical therapist; and

2. Meets the federal conditions for participation.

(t) "Physician" means an individual who is currently licensed or authorized to practice medicine and surgery in Georgia.

(u) "Plan of Treatment" means an individual plan written, signed, and reviewed at least every sixty days by the patient's physician prescribing items and services for the patient's condition.

(v) "Primary Home Health Agency" means the agency (parent or subunit) that is responsible for the service rendered to patients and for implementation of the plan of treatment.

(w) "Progress Note" means a dated and signed written notation by the providing member of the health team, summarizing facts about care and the patient's response during a given period of time.

(x) "Registered Nurse or RN" means an individual who is currently licensed as a registered professional nurse in Georgia.

(y) "Service Area" means the geographical area in which a home health agency provides services, as defined by the State Health Planning and Development unit of the Department.

(z) "Social Work Assistant" means an individual who meets the federal conditions of participation and applicable Georgia laws.

(aa) "Social Worker" means an individual who meets the federal conditions of participation and applicable Georgia laws.

(bb) "Speech Pathologist" and/or "Audiologist" means a qualified individual who:

1. Is currently licensed as a speech pathologist and/or audiologist in Georgia; and

2. Meets the federal conditions of participation.

(cc) "Subunit" means a semiautonomous organization, which serves patients in a geographic area different from that of the parent agency. The subunit by virtue of the distance between it and the parent agency is judged incapable of sharing administration, supervision, and services on a daily basis with the parent agency, and must, therefore, independently meet the licensing requirements for a home health agency, and shall be separately licensed.

(dd) "Supervision" means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.06

Rule 111-8-31-.07. Administrative Standards.

(1) Organizations, Services, Administration. Organizations, services provided, administrative control, and lines of authority for the delegation of responsibility down to the patient care level shall be clearly set forth in written policies and procedures. Administrative and supervisory functions shall not be delegated to another agency or organization. Services not provided directly shall be monitored and controlled by the primary agency, including services provided through subunits of the parent agency. If an agency has subunits, appropriate administrative records shall be maintained for each subunit.

(2) Governing Body. There shall be a governing body which assumes full legal authority and responsibility for the operation of each home health agency. The governing body shall appoint a qualified administrator, arrange for professional advice, adopt and periodically review written bylaws and oversee the management and fiscal affairs of the agency. The name and address of each officer, directors, and owner shall be disclosed to the Department. If the agency is a corporation, all ownership interests of five (5) percent or more (direct or indirect) shall also be disclosed.

(3) Group of Professional Personnel.

(a) A group of professional personnel, which shall include at least one physician and one registered nurse, with appropriate representation from other professional disciplines, shall establish and annually review the policies of each home health agency governing scope of services offered, admission and discharge policies, medical supervision and plans of treatment, emergency care, clinical records, personnel qualifications, and program evaluation. There must be at least one member of the group who is neither an owner nor an employee of the agency.

(b) The group of professional personnel shall meet at least once per quarter unless circumstances require more often to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in its community information program. The minutes shall be documented by dated minutes.

(4) Administrator. The administrator (who may also be the supervising physician or registered nurse), is responsible for organizing and directing the agency's ongoing functions; maintaining ongoing liaison among the governing body, the group of professional personnel, and the staff; employing qualified personnel and ensuring

adequate staff education and evaluations; ensuring the accuracy of public information, materials and activities; and implementing an effective budgeting and accounting system. A qualified person shall be authorized in writing to act in the absence of the administrator.

(5) Supervising Physician or Registered Nurse. Skilled nursing and other therapeutic services provided shall be under the supervision and direction of a physician or a registered nurse. This person or similarly qualified alternate shall be available at all times during operating hours and: participate in all activities relevant to the professional services provided, including the developing of qualifications and assignments of personnel.

(6) Personnel Policies. Personnel practices shall be supported by appropriate, written personnel policies. Individual personnel records shall include job descriptions, qualifications, licenses, performance evaluations, and health examinations, and shall be kept current. If personnel under hourly or per visit contracts are utilized by the home health agency, there shall be a written contract between such personnel and the agency clearly designating:

(a) that patients are accepted for care only by the primary home health agency;

(b) the services to be provided;

(c) the necessity to conform to all applicable agency policies including personnel qualifications;

(d) the responsibility for participating in developing plans of treatment;

(e) the manner in which services will be controlled, coordinated, and evaluated by the primary agency;

(f) the procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation; and

(g) the procedure for determining charges and reimbursement.

(7) Planning and Budget. A home health agency, under the direction of the governing body, shall prepare an overall plan and budget which provides for an annual operating budget. If capital expenditures are anticipated, a three-year capital expenditure plan shall be provided and updated annually. The overall plan, budget and capital expenditure plan shall be reviewed and updated at least annually.

(8) Evaluation.

(a) A home health agency shall have written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), home health agency staff, and consumers; or by professional people outside the agency working in conjunction

with consumers. The evaluation shall consist of an overall policy and administrative review and a clinical record review. The evaluation shall assess the extent to which the agency's program is appropriate, adequate, effective and efficient. Results of the evaluation shall be reported to the governing body and maintained separately as administrative records. Mechanisms shall be established in writing for the collection of pertinent data to assist in this evaluation. This data to be considered may include but is not limited to:

1. number of patients receiving each service offered;
2. number of patient visits;
3. reasons for discharge;
4. breakdown by diagnosis;
5. sources of referral;
6. number of patients not accepted with reasons; and
7. total staff days for each service offered.

(b) At least quarterly, appropriate health professionals representing at least the scope of the program, shall review a sample of both active and closed clinical records to assure that established policies are followed in providing services (direct services as well as services under arrangement). Evidence of this review shall be documented by dated minutes.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.07
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-150 *et seq.*
History. Original Rule entitled "Administrative Standards" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.08. Scope of Services.

A home health agency shall provide part-time or intermittent skilled nursing services and at least one other therapeutic service, e.g., physical, speech, or occupational therapy; medical social services; or home health aide services. Services shall be made available on a visiting basis, in a place of residence, as a patient's home.

(a) Nursing Services. A home health agency shall provide skilled nursing service by or under the supervision of a registered nurse and in accordance with the plan of treatment.

1. Duties of the Registered Nurse (RN). A registered nurse shall make the initial evaluation visit, regularly reevaluate the patient's nursing needs, initiate the plan of

treatment and necessary revisions, provide those services requiring substantial specialized nursing skill, initiate appropriate preventive and rehabilitative nursing procedures, prepare clinical and progress notes, coordinate services inform the physician and other personnel of changes in the patient's condition and needs, counsel the patient and family in meeting nursing and related needs, participate in inservice programs, and supervise and teach other personnel.

2. Duties of the Licensed Practical Nurse (LPN). The licensed practical nurse shall provide services in accordance with agency policies, prepare clinical and progress notes, assist the physician and/or registered nurse in performing specialized procedures, prepare equipment and materials for treatments observing aseptic technique as required and assist the patient in learning appropriate self-care techniques.

(b) Therapy Services. All therapy services offered by the home health agency directly or under arrangement shall be given by a qualified therapist in accordance with the plan of treatment. The qualified therapist shall assist the physician in evaluating level of function, help develop the plan of treatment (revising as necessary), prepare clinical and progress notes, advise and consult with the family and other agency personnel, and participate in inservice programs. Therapy services include, but are not limited to:

1. Physical Therapy;

2. Occupational Therapy;

3. Speech Therapy;

4. Audiology.

(c) Medical Social Services. Medical social services, when provided, shall be given by a qualified social worker in accordance with the plan of treatment. The social worker shall assist the physician and other team members in understanding the significant social and emotional factors related to the health problems, participate in the development of the plan of treatment, prepare clinical and progress notes, work with the family, utilize appropriate community resources, participate in discharge planning and inservice programs, and act as a consultant to other agency personnel.

(d) Home Health Aide Services.

1. Home health aides shall be selected on the basis of such factors as a sympathetic attitude toward the care of the sick; ability to read, write, and carry out directions; and maturity and ability to deal effectively with the demands of the job. Aides shall be carefully trained in at least the following areas: methods of assisting patients to achieve maximum self-reliance, principles of nutrition and meal preparation, the aging process and emotional problems of illness, procedures for maintaining a clean, healthful, and pleasant environment, recognizing changes in a patient's

condition that should be reported, work of the agency and the health team; ethics, confidentiality, and recordkeeping. Aides shall be closely supervised to assure their competence in providing care.

2. A home health aide shall be assigned to a particular patient by a registered nurse. Written instructions for patient care shall be prepared by a registered nurse or therapist as appropriate. Home health aide duties shall be limited to the performance of simple procedures such as an extension of therapy services, personal care, ambulation and exercise, household services essential to health care at home, assistance with medications that are ordinarily self-administered, reporting changes in the patient's condition and needs, and completing appropriate records.

3. A registered nurse, or other appropriate professional staff member, if other services are provided, shall make a supervisory visit to the patient's residence at least every two weeks, either when the aide is present to observe and assist, or when an aide is absent, to assess relationships and determine whether goals are being met. A record of the supervisory visit shall be dated and documented by a clinical note in the patient clinical record.

(e) Coordination of Patient Services. All personnel providing services shall maintain a liaison with the home health agency to assure that their efforts effectively complement one another and sup- port the objectives outlined in the plan of treatment. The clinical record shall contain dated minutes of case conferences verifying that effective interchange, reporting, and coordinated patient evaluation does occur. A written summary report of clinical and progress notes for each patient shall be sent to the attending physician at least every sixty (60) days and upon discharge. A copy of these reports shall become a permanent part of the patient's clinical record.

(f) Services Under Arrangements. All services provided under arrangements shall be subject to a written contract. Contracts for home health services shall conform with the specific requirements of Rule 111-8-31.07(6)(a)through(g).

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.08
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-150 *et seq.*
History. Original Rule entitled "Scope of Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.09. Standards for Patient Care.

Patients shall be accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Patients shall not be denied services because of their age, sex, race, religion, or national origin. Care shall follow a written plan of treatment established and periodically reviewed by a physician, and shall continue under the supervision of a physician.

(a) Plan of Treatment. An individual plan of treatment shall be developed for each patient in consultation with agency staff, and shall cover all pertinent diagnosis, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, safety measures to protect against injury, instructions for timely discharge or referral, and other appropriate items. If a physician refers a patient under a plan of treatment which cannot be completed until after an evaluation visit, the physician shall be consulted to approve additions or modifications to the original plan. Orders for therapy services shall specify the procedures and modalities to be used, and the amount, frequency, and duration.

(b) Periodic Review of Plan of Treatment. The total plan of treatment shall be reviewed by the attending physician and home health agency personnel as often as the severity of the patient's condition requires, but at least once every sixty (60) days. Date of the review and approval of the plan shall be documented by the physician's signature. Agency professional staff shall promptly alert the physician to any changes that suggest a need to alter the plan of treatment.

(c) Conformance with Physician's Orders. Drugs and treatment shall be administered by agency staff only as ordered by the physician. The nurse or therapist shall immediately record and sign oral orders and forward the written order within five (5) business days to the physician for countersignature. Documentation of the physician's countersignature must appear in the patient's medical record within thirty (30) days of the verbal order. Professional agency staff shall check all medicines a patient may be taking to identify possible ineffective drug therapy or adverse reactions, significant side effects, drug allergies, and contraindicated medication, and shall promptly report any problems to the physician.

(d) Clinical Records.

1. A clinical record shall be established and maintained on each patient in accordance with accepted professional standards and shall contain:

   (i) pertinent past and current findings;

   (ii) plan of treatment;

   (iii) appropriate identifying information;

   (iv) name of physician;

   (v) drug, dietary, treatment and activity orders;

   (vi) signed and dated clinical and progress notes (clinical notes are written the day service is rendered by the providing member of the health team and incorporated no less often than weekly);

(vii) copies of case conferences;

(viii) copies of summary reports sent to the physician; and

(ix) a discharge summary.

2. If a patient transfers to another home health agency or a health facility, a copy of the record or abstract shall be furnished to accompany the patient.

3. Sufficient space and equipment for record processing, storage and retrieval shall be provided.

4. Policies and procedures shall be written and implemented to assure organization and continuous maintenance of the clinical records system.

(e) Retention of Records. Clinical records shall be retained for a period of six years after the last patient encounter for adults, and for six years after a minor reaches the age of majority. These records may be retained as originals, microfilms, or other usable forms and shall afford a basis for complete audit of professional information. If the home health agency dissolves or changes ownership, a plan for record retention shall be developed and placed into effect. The Department shall be advised of the disposition and/or location of said records.

(f) Protection of Records. Clinical record information shall be safeguarded against loss or unauthorized use. Written procedures shall govern the use and removal of records and conditions for release of information. A patient's written consent is required for release of information not authorized by law.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.09
Authority: O.C.G.A. § 31-7-150*et seq.*
History. Original Rule entitled "Standards for Patient Care" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.10. Penalties.

Any person who operates a home health agency without first obtaining a license pursuant to the provisions of the Georgia Home Health Agency Act shall be deemed guilty of a misdemeanor, and upon conviction shall be fined not to exceed $500.00 or imprisoned for a period not to exceed six months or both.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.10
Authority: O.C.G.A. § 31-7-158.
History. Original Rule entitled "Penalties" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.11. Fees.

Each application for initial and annual renewal licenses shall be accompanied by a fee as prescribed by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.11
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-150 *et seq.*
History. Original Rule entitled "Fees" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.12. Enforcement.

The administration and enforcement of these rules and regulations shall be as prescribed in the "Georgia Administrative Procedure Act," O.C.G.A. § 50-13-1*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.12
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 50-13-1 *et seq.*
History. Original Rule entitled "Enforcement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.13. Applicability of Regulations.

These regulations are applicable only to home health agencies as defined herein and the services they provide, and do not modify or revoke any of the provisions of other published rules of the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.13
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-150 *et seq.*
History. Original Rule entitled "Applicability of Regulations" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-31-.14. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions thereof shall remain of full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Board of Community Health to establish rules and regulations that are constitutional and enforceable so as to safeguard the health and well being of the people of the State.

Cite as Ga. Comp. R. & Regs. R. 111-8-31-.14
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-150 *et seq.*
History. Original Rule entitled "Severability" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-37. RULE AND REGULATIONS FOR HOSPICES.

Rule 111-8-37-.01. Title and Purpose.

These rules shall be known as the Rules and Regulations for Hospices. The purpose of these rules is to provide for the inspection and issuance of licenses for hospices and to establish minimum requirements for facilities operating under hospice licenses.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.01
Authority: O.C.G.A. § 31-7-170*et seq.*
History. Original Rule entitled "Title and Purpose" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.02. Authority.

The legal authority for this Chapter is O.C.G.A § 31-7-170*et seq.*, the "Georgia Hospice Law" and O.C.G.A. § 31-2-4*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.02
Authority: O.CG.A. §§ 31-2-4 and 31-7-170*et seq.*
History. Original Rule entitled "Authority" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.03. Definitions.

(1) Unless the context otherwise requires, these identified terms mean the following when used in these rules:

(a) "Administrator" means the person, by whatever title used, to whom the governing body has delegated the responsibility for the day-to-day administration of the hospice, including the implementation of the policies and procedures adopted by the governing body.

(b) "Advanced and progressive disease" means a serious life-threatening medical condition which is irreversible and which will continue indefinitely, where there is no reasonable hope of recovery, but where the patient's medical prognosis is one in which there is a life expectancy of up to two years. The term does not include terminally ill patients as defined in paragraph (ee) of this rule.

(c) "Attending physician" means the physician identified by the hospice patient or the patient's representative as having primary responsibility for the hospice patient's medical care and who is licensed to practice medicine in this state.

(d) "Bereavement services" means the supportive services provided to the family unit to assist it in coping with the patient's death, including follow-up assessment and assistance through the first year after death.

(e) "Clergy" means an individual representative of a specific spiritual belief who has documentation of ordination or commission by a recognized faith group and who has completed at least one unit of clinical pastoral education from a nationally recognized provider.

(f) "Counseling" means those techniques used to help persons learn how to solve problems and make decisions related to personal growth, vocation, family, social, and other interpersonal concerns.

(g) "Department" means the Georgia Department of Community Health.

(h) "Dietitian" means a specialist in the study of nutrition who is licensed as required by O.C.G.A. § 43-11A-1*et seq.*, the "Dietetics Practice Act."

(i) "Family unit" means the terminally ill person or person with an advanced and progressive disease and his or her family, which may include spouse, children, siblings, parents, and other relatives with significant personal ties to the patient.

(j) "Governing body" means the board of directors, trustees, partnership, corporation, association, or person or group of persons who maintain and control the operation of the hospice and who are legally responsible for its operation.

(k) "Home care" means hospice care primarily delivered in the residence of the hospice patient, whether that place is the patient's permanent or temporary residence. A hospice patient who considers his or her residence to be a licensed assisted living community, licensed nursing home, licensed intermediate care home, licensed personal care home, or residential hospice setting is considered to be receiving home care while a resident of that facility.

(l) "Hospice" means a public agency or private organization or unit of either providing to persons terminally ill and to their families, regardless of ability to pay, a centrally administered and autonomous continuum of palliative and supportive care, directed and coordinated by the hospice care team primarily in the patient's home but also on an outpatient and short-term inpatient basis and which is classified as a hospice by the Department. In addition, such public agency or private organization or unit of either may also provide palliative care to persons with advanced and progressive diseases and to their families, directed and coordinated by the hospice care team.

(m) "Hospice care" means both regularly scheduled care and care available on a 24 hour on-call basis, consisting of medical, nursing, social, spiritual, volunteer, and bereavement services substantially all of which are provided to the patient and to the patient's family regardless of ability to pay under a written care plan established and periodically reviewed by the patient's attending physician, by the medical director of the hospice program, and by the hospice care team.

(n) "Hospice care team" means an interdisciplinary working unit composed of members of the various helping professions (who may donate their professional services), including but not limited to: a physician licensed or authorized to practice in this state, a registered professional nurse, a social worker, a member of the clergy or other counselors, and volunteers who provide hospice care.

(o) "Inpatient care" means short-term, 24-hour medically supervised care for the purpose of adjusting and monitoring the terminally ill patient's medications for pain control or managing acute or chronic symptoms that cannot be managed in another setting. Inpatient care is provided within the confines of a licensed hospital, a licensed skilled nursing facility, or a licensed inpatient hospice facility.

(p) "Inpatient hospice facility" means a facility that is licensed to provide acute inpatient care for hospice patients in beds that are not included in the certified bed capacity of another licensed facility.

(q) "License" means a license issued by the Department to the governing body to operate a hospice.

(r) "Medical director" means a physician licensed in this state who is a member of the hospice care team and is responsible for the direction and quality of the medical component of the care rendered by the hospice to patients.

(s) "Palliative care" means those interventions by the hospice care team which are intended to achieve relief from, reduction of, or elimination of pain and of other physical, emotional, social, or spiritual symptoms of distress to achieve the best quality of life for the patients and their families.

(t) "Patient" means a terminally ill individual receiving the hospice continuum of services, regardless of ability to pay and also means an individual with an advanced and progressive disease.

(u) "Patient representative" means an individual who, under applicable laws, has the authority to act on behalf of the patient where the patient is incapable of making decisions related to health care.

(v) "Personal care services" means assistance with activities of daily living, personal care, ambulation and exercise; provision of household services essential to health care at home; assistance with self-administration of medication; and preparation of meals.

(w) "Physician" means an individual who is licensed to practice medicine in this state by the Georgia Composite Medical Board.

(x) "Primary caregiver" means a person or entity designated in writing by the patient or the patient's representative who agrees to give and/or arrange for continuing support and care and who may advocate on behalf of the patient.

(y) "Professional counselor" means a person licensed or certified as a professional counselor or associate professional counselor as required by O.C.G.A. § 43-10A-1*et seq.*, the "Professional Counselors, Social Workers, and Marriage and Family Therapists Licensing Law."

(z) "Registered nurse" means an individual who is currently licensed to practice nursing under the provisions of Article 1 of Chapter 26 of Title 43 of the Official Code of Georgia Annotated.

(aa) "Residential hospice facility" means a small home-like residential facility or unit that is a part of a licensed hospice program, designed, staffed, and organized to provide non-acute hospice care, 24-hours per day, seven days per week, under the supervision of the hospice physician and hospice registered nurses to terminally ill hospice patients and their family units.

(bb) "Respite care" means short-term inpatient or residential care provided for the patient to provide relief for that patient's family unit from the stress of providing care.

(cc) "Restraint" means any manual, physical, or mechanical method, device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort); or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(dd) "Social worker" means an individual who is qualified by education, training, and experience and licensed as required by law to perform social work for hospice patients and their family units.

(ee) "Terminally ill" means that the individual is experiencing an illness for which therapeutic intervention directed toward cure of the disease is no longer appropriate, and the patient's medical prognosis is one in which there is a life expectancy of six months or less.

(ff) "Volunteer" means a lay or professional person who provides, without compensation, support and assistance to the patient and the patient's family under

the supervision of a member of the hospice staff unit in accordance with the plan of care developed by the hospice care team.

(2) As used in these rules and regulations, the singular indicates the plural and the plural the singular when consistent with the intent of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.03
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Definitions" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.04. Licensure Procedures.

(1) Operating, establishing or maintaining a hospice in the State of Georgia without first obtaining a valid license from the Department is prohibited.

(2) Use of the term "hospice" to imply or indicate that a person or entity is providing hospice services to patients and their families unless the person or entity holds a valid license to provide hospice care is prohibited.

(3) A governing body desiring to operate a hospice must file with the Department an initial application on forms prescribed and made available by the Department. The application must be complete, accurate, and signed by the hospice administrator or the executive officer of the hospice's governing body and must include:

(a) The applicant's name, address, phone number, and business e-mail address for receiving inspection reports and communications concerning the license from the Department.

(b) **Proof of ownership.** In the case of corporations, partnerships, and other entities authorized by law, the applicant must provide a copy of its certificate of incorporation or other acceptable proof of its legal existence and authority to transact business within the state;

(c) A list of counties proposed to be served by the hospice; and

(d) A list of the locations of any additional hospice care facilities operated by the hospice on separate premises, as applicable, and the number of beds at such facilities.

(4) Knowingly supplying materially false, incomplete, or misleading information is grounds for denial or revocation of a license.

(5) Following evidence of substantial compliance with these rules and regulations and any provisions of law as applicable to the construction and operation of the hospice, the

Department may issue a license to provide hospice services primarily to terminally ill patients in their own homes.

(6) An initial license may be issued for a period of six months to allow a new hospice to demonstrate its ability to comply with these rules and regulations. After becoming fully operational and demonstrating substantial compliance with the rules and regulations, the hospice shall become eligible for a regular license.

(7) Inpatient and residential services and palliative care services are not eligible to be licensed separately from hospice home care services.

(8) The license must be displayed in a prominent place in the hospice's administrative offices.

(9) Licenses are not transferable from one governing body to another or from one hospice location to another.

(10) Each planned change of ownership or lease or change of location must be disclosed to the Department at least 30 days prior to such change by submitting an application and the required fees from the proposed new owners or lessees for a new license.

(11) Changes in the hospice that require the submission of a new application and the issuance of a new license include a change in name, the addition of another service location, a change in the number of licensed beds if residential services are provided or a change in the scope of services provided. The new application that reflects the proposed change must be filed at least 30 days prior to the proposed change. Hospices licensed before the effective date of these rules desiring to change their scope of service solely to include palliative care to patients with advanced and progressive diseases who are not terminally ill, will not be required to pay an application change processing fee to add palliative care if the Department receives the palliative care change request within 180 days of these rules taking effect.

(12) A license is no longer valid and must be returned to the Department when the hospice ceases to operate, changes locations, is issued a new license or the license is suspended or revoked. The facility must notify referring individuals and entities of the closure and patients' families regarding the location of medical records.

(13) **Temporary Inactive Status.** If the hospice is closing for a period of less than 12 months, and plans to reopen under the same ownership, governing body, and name, the hospice may request to have the license placed on temporary inactive status. The hospice must submit its request in writing and provide a written plan for notifying referring individuals and entities of the closure and patients' families regarding the location of medical records.

(a) When placed on temporary inactive status, the license must be returned to the Department within 10 days of closure and the hospice must not operate until the license has been reactivated.

(b) The hospice must request in writing that the permit be reactivated at least 30 days prior to the desired date of reopening. Prior to reactivation of the license, the hospice may be subject to inspection by the Department. If the license is not reactivated within 12 months, the license is void.

(14) **Multiple Hospice Locations.** Separate applications and licenses are required for hospices operated at separate locations; however, the Department has the option of approving a single license for multiple hospice locations based on evidence that the hospice meets all of the following requirements:

(a) All locations are owned and operated by the same governing body and conduct business under the same set of by-laws and the same trade name;

(b) Each location is responsible to the same governing body and central administration managed together under the same set of policies and procedures;

(c) The governing body and central administration demonstrate the capacity to adequately manage all locations and ensure the quality of care at all locations as evidenced by a prior history of satisfactory compliance with hospice regulations and appropriate staffing;

(d) Supervision and oversight at additional locations is sufficient to ensure that hospice care and services meet the needs of patients and the patients' family units;

(e) The medical director assumes responsibility for the medical component of the hospice's patient care at all locations;

(f) Additional locations provide the same full range of services and the same level and quality of care including timely responses, that is provided by the primary location;

(g) Each patient is assigned to a specific hospice care team responsible for ongoing assessment, planning, monitoring, coordination, and provision of care, which has ready access to the patient's clinical record;

(h) All hospice patients' clinical records that are requested by the Department at the time of inspection must be available at the hospice's primary location; and

(i) All locations maintain the same Medicare provider number, as applicable.

(15) **Hospice Care Facilities.** Hospices desiring to provide facilities for residential and/or acute inpatient hospice services as a part of the licensed hospice must submit an application to the Department requesting a change in service level. The Department will not approve the change in service level that includes residential and/or inpatient hospice services, unless the hospice:

(a) Is licensed and in substantial compliance with these rules and regulations that apply to home care hospice services;

(b) Submits a copy of the certificate of occupancy issued by local building officials for the facility or unit;

(c) submits evidence of compliance with the applicable provisions of the *Life Safety Code®*, as enforced by the state fire marshal*;*

(d) Provides evidence to the Department of compliance or ability to comply with all the applicable requirements of paragraph (14) of this rule relating to multiple hospice locations; and

(e) Demonstrates substantial compliance with all the applicable requirements of Rule 111-8-37-.24, Hospice Care Facilities, as evidenced by an on-site inspection by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.04
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Licensure Procedures" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.05. Inspections and Investigations.

(1) The hospice staff, any facilities where hospice care is being delivered, and the hospice patients must be accessible during all hours of operation to properly identified representatives of the Department for inspections and investigations relating to the hospice's license.

(2) The Department will periodically inspect each hospice to ensure that the licensee is providing quality care to its patients; provided, however, that a hospice is exempt from routine periodicon-site licensure inspection if it is certified as a hospice in accordance with federal regulations. Where the Department receives or becomes aware of a complaint alleging that the hospice is not acting in compliance with the requirements of these rules, the Department may conduct an inspection at any time to determine whether the licensed hospice is in compliance with these rules.

(3) For the purposes of any inspection, investigation, or survey conducted by the Department, the hospice must provide to properly identified representatives of the Department meaningful access to all books, records, papers, or other information related to the initial or continued licensing of the hospice.

(4) The hospice must submit to the Department, in a format acceptable to the Department, a written plan of correction in response to any inspection report of violations identified by the Department. The plan of correction must specify what the hospice will do by a date

certain to correct each of the violations identified. The plan of correction must be submitted within 10 days of the hospice's receipt of the inspection report of violations. A plan of correction must be determined to be acceptable by the Department. Hospices may be allowed an additional 48 hours to revise any plan of correction deemed unacceptable by the Department. Failure to submit an acceptable plan of correction may result in the Department commencing enforcement procedures. The hospice must correct all violations cited.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.05
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Inspections and Investigations" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.06. Reports to the Department.

(1) **Patient Incidents Requiring Report.** The hospice must report to the Department, on forms made available by the Department, within 24 hours or the next business day, whenever any of the following incidents involving patients occurs or the hospice has reasonable cause to believe that an incident involving a patient has occurred:

(a) Any death of a hospice patient not related to the natural course of the patient's terminal illness or advanced and progressive disease, or any identified underlying condition;

(b) Any rape, assault, or any abuse, neglect or exploitation of a patient; and

(c) Any time a patient, who is admitted to a residential or inpatient hospice facility cannot be located, where there are circumstances that place the health, safety, or welfare of the patient or others at risk and the patient has been missing for more than eight hours.

(2) Where the hospice staff has reasonable cause to believe that a disabled adult or elder person has been the victim of abuse, other than by accidental means, or has been neglected or exploited, the hospice must report such information to an adult protection agency providing protective services as designated by the Department and to an appropriate law enforcement agency or prosecuting attorney.

(3) The hospice, through its peer review committee, must submit the reports of patient incidents listed in subparagraph (1)(a) through (c) of this rule. The Department will receive and retain such peer review reports concerning the listed incidents in confidence.

(4) Reports of patient incidents made through the peer review process must include:

(a) The name of the hospice, the name of the administrator or site manager, and a contact telephone number for information related to the report;

(b) The date of the incident and the date the hospice became aware of the incident;

(c) The type of incident, with a brief description of the incident; and

(d) Any immediate corrective or preventative action taken by the hospice to ensure against the replication of the incident.

(5) The hospice must conduct an internal investigation of any of the patient incidents listed in subparagraph (1)(a) through (c) and must complete and retain on-site a written report of the results of the investigation within 45 days of the discovery of the incident. The complete report must be made available to the Department for inspection at the hospice office and contain at least:

(a) An explanation of the circumstances surrounding the incident, including the results of a root cause analysis or any other detailed system analysis;

(b) Any findings or conclusions associated with the review; and

(c) A summary of any actions taken to correct identified problems associated with the incident and to prevent recurrence of the incident, and also any changes in procedures or practices resulting from the investigation.

(6) The hospice must report to the Department any pending involuntary discharge of a hospice patient initiated by the hospice. The report must be made no later than the time of notification to the patient of the pending discharge.

(7) **Other Events Requiring Report.**

(a) The hospice must report in an acceptable format to the Department whenever any of the following events involving hospice operations occur or when the hospice becomes aware that any such events are likely to occur, to the extent that such events are expected to cause or cause a significant disruption of care for hospice patients:

1. An external disaster or other community emergency situation; or

2. An interruption of services vital to the continued safe operation of a hospice facility, such as telephone, electricity, gas, or water services.

(b) The hospice must make a report of the event within twenty-four hours or by the next regular business day from when the reportable event occurred or from when the hospice has reasonable cause to anticipate that the event is likely to occur. The report must include:

1. The name of the hospice, the name of the hospice administrator or site manager, and a contact telephone number for information related to the report;

2. The date of the event, or the anticipated date of the event, and the anticipated duration, if known;

3. The anticipated effect on care and services for hospice patients; and

4. Any immediate plans the hospice has made regarding patient management during the event.

(c) Within 45 days of the discovery of the event, the hospice must complete an internal evaluation of the hospice's response to the event where opportunities for improvement related to the hospice's disaster preparedness plan were identified. The hospice must make changes to the disaster preparedness plan as appropriate. The complete report must be available to the Department for inspection at the hospice office.

(8) While self-reported incidents made through the hospice's peer review process are received by the Department in confidence and not considered open records, where the Department's internal review determines that a rule violation related to any self-reported incident or event has occurred, the Department shall initiate a separate complaint investigation of the incident. The complaint investigation report and the report of any rule violation compiled by the Department arising either from the initial report received from the hospice or an independent source shall be subject to disclosure in accordance with applicable laws.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.06
Authority: O.C.G.A. §§ 31-7-130*et seq.*, 31-7-170 *et seq.*
History. Original Rule entitled "Reports to the Department" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.07. Governing Body.

(1) The hospice must have an established and functioning governing body that is responsible for the conduct of the hospice and that provides for effective hospice governance, management, and budget planning.

(2) The governing body must appoint an administrator and delegate to the administrator the authority to operate the hospice in accordance with these rules and management policies established and approved by the governing body.

(3) The governing body must appoint a medical director and delegate to the medical director the authority to establish and approve, in accordance with current accepted standards of care, all patient care policies related to medical care.

(4) The governing body must ensure that no member of the governing body, administration, staff associated or affiliated with the hospice, or family member of staff causes, encourages or coerces any patient or family member of a patient to:

(a) name any person associated or affiliated with the hospice as a beneficiary under a will, trust, or life insurance policy;

(b) take out or otherwise secures a life insurance policy on any patient; or

(c) give or loan anything of value to a member of the governing body, administration, staff associated or affiliated with the hospice or family member of staff.

(5) The governing body must be responsible for determining, implementing, and monitoring the overall operation of the hospice, including the quality of care and services, management, and budget planning. The governing body must:

(a) Be responsible for ensuring the hospice functions within the limits of its current license granted by the Department;

(b) Ensure that the hospice provides coordinated care that includes at a minimum medical, nursing, social, spiritual, volunteer, and bereavement services that meet the needs of the patients;

(c) Ensure that the hospice is staffed and equipped adequately to provide the services it offers to patients, whether the services are provided directly by the hospice or under contract;

(d) Develop and make available to patients and their families, a description of services offered by the hospice, including patient eligibility for the various services and whether the hospice provides palliative care to patients who have not been determined to be terminally ill but have been diagnosed with an advanced and progressive disease;

(e) Ensure the development and implementation of effective policies and procedures that address the management, operation, and evaluation of the hospice, including all patient care services and those services provided by independent contractors;

(f) Ensure there is an individual authorized in writing to act for the administrator during any period the administrator is absent;

(g) Appoint an individual to assume overall responsibility for a quality assurance, utilization, and peer review program for monitoring and evaluating the quality and level of patient care in the hospice on an ongoing basis;

(h) Ensure that hospice advertisements are factual and do not contain any element that might be considered coercive or misleading;

(i) Ensure that hospice care to patients who have been determined to be terminally ill is provided regardless of the patient or the family unit's ability to pay; and

(j) Ensure that there are policies and procedures in place that specify the manner in which transitions across care sites and providers (e.g. hospital to home hospice) will be handled to ensure that communications are effective to address continuity of care issues for the patient.

(6) The governing body shall comply with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12, as applicable.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.07
Authority: O.C.G.A. §§ 31-7-170 et seq., 31-7-350 et seq.
History. Original Rule entitled "Governing Body" adopted. F. May 26, 2015; eff. June 15, 2015.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.

Rule 111-8-37-.08. Administrator.

(1) Each hospice must have a qualified administrator, designated by the governing body, who must be responsible for the ongoing and day-to-day operation of the hospice.

(2) The hospice administrator must be either a Georgia-licensed health care professional, who has at least one year of supervisory or management experience in a hospice setting or an individual with education, training and experience in health services administration and at least two years of supervisory or management experience in a hospice setting. The term, licensed health care professional, includes the following who hold Georgia licenses: physicians, nurse practitioners, physicians' assistants, registered professional nurses, clinical social workers, physical therapists and psychologists, but does not include practical nurses.

(3) The hospice administrator must ensure that the hospice:

(a) Implements policies and procedures for the provision of hospice care and palliative care to persons with advanced and progressive diseases, if it offers such services, which have been developed with interdisciplinary participation from the hospice care team;

(b) Employs qualified staff, including physicians, practitioners, nurses, social workers, clergy, volunteers, or other persons providing services at the hospice;

(c) Has implemented policies and procedures related to the management, operation, and evaluation of the overall performance of the hospice;

(d) Has a qualified director of nursing services along with sufficient qualified staff to meet the needs of patients admitted for hospice care and palliative care, if offered to persons with advanced and progressive diseases but who have not been determined to be terminally ill, and as outlined in the patients' plans of care;

(e) Provides an orientation, training, and supervision program for every employee and volunteer that addresses hospice care and palliative care for persons with advanced and progressive diseases, when offered, and the performance of the specific job to which the employee or volunteer is assigned;

(f) Ensures that the staff members complete their annual training and education program; and

(g) Ensures that there are effective mechanisms to facilitate communication among the hospice staff, hospice care team, and patients, their family units, and their legal guardians, if any.

(4) The hospice administrator shall comply with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12, as applicable.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.08
Authority: O.C.G.A. §§ 31-7-170 et seq., 31-7-350 et seq.
History. Original Rule entitled "Administrator" adopted. F. May 26, 2015; eff. June 15, 2015.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.

Rule 111-8-37-.09. Quality Management.

(1) The hospice must appoint an interdisciplinary quality management committee that reflects the hospice's scope of services. The committee must develop and implement a comprehensive, effective and ongoing quality management, utilization, and peer review program that evaluates, maintains and improves the quality of patient care provided, including the appropriateness of the level of service received by patients, and submits required patient incident reports to the Department.

(2) The quality management, utilization, and peer review program must establish and use written criteria as the basis to evaluate the provision of patient care. The written criteria must be based on accepted standards of care and must include, at a minimum, systematic reviews of:

(a) Appropriateness of admissions, continued stay, and discharge;

(b) Appropriateness of professional services and level of care provided;

(c) Effectiveness of pain control and symptom relief;

(d) Patient injuries, such as those related to falls, accidents, and restraint use;

(e) Errors in medication administration, procedures, or practices that compromise patient safety;

(f) Infection control practices and surveillance data;

(g) Patient and family complaints and on-call logs;

(h) Inpatient hospitalizations;

(i) Staff adherence to the patients' plans of care; and

(j) Appropriateness of treatment.

(3) Findings of the quality management utilization, and peer review program must be utilized to correct identified problems, revise hospice policies, and improve the care of patients.

(4) There must be an ongoing evaluation of the quality management, utilization, and peer review committee to determine its effectiveness, with the results of the evaluation presented at least annually for review and appropriate action to the medical staff and the governing body.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.09
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Quality Management" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.10. Patient and Family Rights.

(1) The hospice must ensure that patients and their families receive hospice care and palliative care for persons with advanced and progressive diseases, when offered, in a manner that respects and protects their dignity and ensures all patients' rights to:

(a) Participate in the hospice voluntarily and sever the relationship with the hospice at any time;

(b) Receive only the care and services to which the patient and/or the patient's family have consented;

(c) Receive care in a setting and manner that preserves the patient's dignity, privacy, and safety to the maximum extent possible;

(d) Receive hospice care in a manner that neither physically nor emotionally abuses the patient, nor neglects the patient's needs;

(e) Receive care free from unnecessary use of restraints;

(f) Receive education in the availability and use of the hospice's grievance process for all patients;

(g) Communicate grievances, concerns or complaints to the hospice for prompt resolution;

(h) Refuse any specific treatment from the hospice without severing the relationship with the hospice;

(i) Choose their own private attending physician, so long as the physician agrees to abide by the policies and procedures of the hospice;

(j) Exercise the religious beliefs and generally recognized customs of their choice, not in conflict with health and safety standards, during the course of their hospice treatment and exclude religion from their treatment if they so choose;

(k) Have their family unit, legal guardian, if any, and their patient representative present any time during an inpatient stay, unless the presence of the family unit, legal guardian, if any, or patient representative poses a risk to the patient or others;

(l) Participate in the development of the patient's plan of care and any changes to that plan;

(m) Have maintained as confidential any medical or personal information about the patient;

(n) Continue hospice care and not be discharged from the hospice during periods of coordinated or approved appropriate hospital admissions;

(o) Be provided with a description of the hospice care provided and levels of care to which the patient is entitled depending upon whether the patient is terminally ill or suffering from an advanced and progressive disease, and any charges associated with such services;

(p) Review, upon request, copies of any inspection report completed by the Department within the two years preceding the request;

(q) Make self-determinations concerning medical care, which encompass the right to make choices regarding life-sustaining treatment, including resuscitative services;

(r) Continue to receive appropriate hospice care when terminally ill without regard for the ability to pay for such care; and

(s) Have communication of information provided in a method that is effective for the patient. If the hospice cannot provide communications in a method that is effective for the patient, attempts to provide such shall be documented in the patient's medical record.

(2) The hospice must provide to the patient, the patient's representative, and/or the patient's legal guardian oral and written explanations of the rights of the patient and the patient's family unit while receiving hospice care for the terminally ill and palliative care for persons with advanced and progressive diseases. The explanation of rights must be provided at the time of admission into the hospice.

(3) At the time of admission, the hospice must provide to the patient, the patient's representative, and the patient's legal guardian the contact information, including the website address of the Department, for reporting complaints about hospice care to the Department.

(4) The hospice shall post the following information in a public area at the facility:

(a) A copy of the patient rights as outlined in Rule 111-8-37-.10(1) in a public area at the facility; and

(b) Contact information, including the website address of the Department, for reporting complaints about hospice care to the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.10
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Patient and Family Rights" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.11. Disaster Preparedness.

(1) Every hospice must have a current disaster preparedness plan that addresses potential situations where services to patients may be disrupted and outlines appropriate courses of action in the event a local or widespread disaster occurs including communications with patients and their families and emergency management agencies.

(2) The disaster preparedness plan must include at a minimum plan for the following emergency situations:

(a) Local and widespread severe weather emergencies or natural disasters, such as floods, ice or snowstorms, tornados, hurricanes, and earthquakes;

(b) Interruption of service of utilities, including water, gas, or electricity, either within the facility or patients' homes or within a local or widespread area; and

(c) Coordination of continued care in the event of an emergency evacuation of the area.

(3) If the hospice offers residential and/or inpatient services, in addition to the procedures specified in paragraph (2) of this rule, the plan must also include:

(a) Fire safety and evacuation procedures and procedures for the provision of emergency power, heat, air conditioning, food, and water; and

(b) Plans for the emergency transport or relocation of all or a portion of the hospice patients, should it be necessary, in vehicles appropriate to the patients' conditions when possible, including written agreements with any facilities which have agreed to receive the hospice's patients in such situations, and notification of the patients' representatives.

(4) The hospice must have plans to ensure sufficient staffing and supplies to maintain safe patient care during the emergency situation.

(5) The plan must be reviewed and revised annually, as appropriate, including any related written agreements.

(6) Disaster preparedness plans for hospice care facilities must be rehearsed at least annually. Rehearsals must be documented to include staff and patient participants, a summary of any problems identified, and the effectiveness of the rehearsal. In the event an actual disaster occurs in any given year, the hospice may substitute the actual disaster's response in place of that year's rehearsal.

(7) Hospices must include emergency management agencies in the development and maintenance of their disaster preparedness plans and also provide copies of such plans to those agencies as requested.

(8) The Department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared that a state of emergency or disaster exists as a result of a public health emergency.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.11
Authority: O.C.G.A. §§ 31-7-170 et seq., 50-13-4.
History. Original Rule entitled "Disaster Preparedness" adopted. F. May 26, 2015; eff. June 15, 2015.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.

Rule 111-8-37-.12. Infection Control.

The hospice must have an effective infection control program designed to reduce the transmission of infections in patients, health care workers, caregivers, families, visitors and volunteers.

(a) The hospice must develop an infection control surveillance plan that is tailored to meet the needs of the hospice and the hospice patients and includes both outcome and process surveillance.

(b) The hospice must develop and implement effective policies and procedures that address infection control issues in all components of the hospice. These policies and procedures shall be based on accepted standards of infection control, approved by the administrator and the medical director, and shall address at least the following:

1. Hand hygiene;
2. Wound care;
3. Urinary tract care;
4. Respiratory therapy;
5. Enteral therapy;
6. Infusion therapy;
7. Cleaning, disinfecting, and sterilizing patient care equipment;
8. Isolation precautions;
9. Handling, transport, and disposal of medical waste and laboratory specimens;
10. Requirements for initial and annual health screenings for staff, including tuberculosis surveillance and required immunizations;
11. Use of personal protective equipment and exposure reporting/follow-up;
12. Work restrictions for staff with potentially infectious diseases;
13. Evaluation of the patient and the home environment related to infection control risks;
14. Outbreak investigation procedures;
15. Dietary practices in hospice care facilities; and
16. Reporting of communicable diseases, as required by law.

(c) The infection control program must be evaluated at least annually to ensure effectiveness of the program related to the prevention of the transmission of infections to patients, health care workers, caregivers, families, visitors and volunteers.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.12
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Infection Control" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.13. Human Resources.

(1) All persons providing services for a hospice must be qualified by education, training, and experience to carry out all duties and responsibilities assigned to them.

(2) All persons providing services for a hospice must receive an orientation to the hospice to include, but not be limited to:

(a) Hospice concepts and philosophy;

(b) Patient rights including abuse reporting requirements; and

(c) Hospice policies and procedures, including, but not limited to, disaster preparedness, fire safety and emergency evacuations, and reporting abuse and neglect.

(3) Where a patient does not have a do-not-resuscitate order, the hospice must ensure that all persons providing hands-on care directly to that patient on behalf of the licensed hospice have current certification in basic cardiac life support (BCLS) or cardiopulmonary resuscitation.

(4) The hospice must have an effective annual training and education program for all staff and volunteers who provide hands-on care to patients that addresses at a minimum:

(a) Emerging trends in infection control;

(b) Recognizing abuse and neglect and reporting requirements;

(c) Patient rights; and

(d) Palliative care.

(5) The administrator and each staff member and volunteer who has direct contact with patients or their family units must receive an initial and annual health screening evaluation, performed by a licensed health care professional in accordance with accepted standards of practice, sufficient in scope to ensure that the staff and volunteers screened are free of communicable and health diseases that pose potential risks to patients, their family units, and other staff and volunteers.

(6) Human resource files must be maintained for the following individuals delivering any services associated with the written plan of care: each staff member, independent contractor, and volunteer. The files must contain the person's application, employment

history, emergency contact information, evidence of qualifications, job description, evidence of initial and annual health screening, yearly skills competency assessments, evidence of verified licensure or certification, and criminal record check as appropriate, and evidence of orientation, education, and training. These files must be available for inspection by the appropriate enforcement authorities on the premises.

(7) Where the hospice contracts with a staffing agency to provide any services specified in a plan of care, the written contract must require the contracting agency to verify licensing credentials, where applicable, of contract workers to ensure that such workers meet the same qualifications and licensure requirements as specified for hospice employees providing such services directly. The hospice must retain a copy of the contract.

(8) The hospice must comply with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12, with respect to direct access employees and maintain documentation of a satisfactory fingerprint criminal record check determination in the individual's personnel file.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.13
Authority: O.C.G.A. §§ 31-7-170 et seq., 31-7-350 et seq.
History. Original Rule entitled "Human Resources" adopted. F. May 26, 2015; eff. June 15, 2015.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.

Rule 111-8-37-.14. Admissions, Discharges, and Transfers.

(1) **Admissions.** The hospice must not admit any patients unless the hospice believes that it is capable of meeting the care needs of the patients. The hospice must have written criteria that address the eligibility for admission into home hospice care, residential, or inpatient hospice care and palliative care for persons with advanced and progressive diseases, if such palliative care is offered.

(2) **Terminally Ill Patient Admissions for Home Care**. The hospice program offered to terminally ill patients in their homes must admit only patients that meet the following minimum criteria:

(a) The patient has a referral from a physician who has personally evaluated the patient and diagnosed the patient as terminally ill, where the medical prognosis is less than six months of life if the terminal illness takes its normal course, and in need of hospice care;

(b) The patient has received from the hospice an initial assessment, performed by an appropriate representative of the hospice care team, that reflects a reasonable expectation that the patient's medical, nursing, and psychological needs can be met adequately by the hospice and further reflects that the patient has a need for and can benefit from hospice care;

(c) The patient has been given a description of the scope of services and has personally or through an authorized patient representative given informed consent in writing to receive hospice care;

(d) The patient has been certified in writing by the hospice to have an anticipated life expectancy of six months or less if the terminal illness takes its normal course;

(e) The patient lives within the hospices service area; and

(f) The patient has identified a primary caregiver. In the absence of a primary caregiver, the hospice must develop a detailed plan for meeting the daily care and safety needs of the patient.

(g) The hospice must ensure the development of an initial plan of care, within 24 hours of admission to the hospice, based on the initial assessment and with appropriate input from a physician or registered nurse to meet the immediate needs of the patient.

(h) The hospice must ensure that no terminally ill patient is excluded from participation in or denied benefits of any hospice care because of an inability to pay for such hospice care.

(3) **Inpatient Hospice Admissions.** Hospices must admit to acute inpatient hospice care only those terminally ill patients who meet the following criteria:

(a) The patient has an order from a physician to be transferred to inpatient status and requires any of the following:

1. Nursing care supervised by a registered nurse that cannot feasibly be provided in another hospice setting;

2. Procedures that are necessary for pain control or acute or chronic symptom management;

3. Medication adjustment, observation, or other stabilizing treatment; or

4. Psycho-social monitoring; or

(b) Respite care.

(4) **Residential Hospice Admissions.** In addition to the home care admissions, hospices that elect to offer residential services must admit to a residential facility only those terminally ill patients who do not require acute management of symptoms or stabilization in an inpatient care setting and who meet the following criteria:

(a) The patient lacks a sufficient number of capable and willing caregivers; or

(b) The patient's care needs are too complex and difficult for non-medical caregivers to perform confidently; or

(c) The patient's primary home is not suitable or available and/or the home cannot be adapted to meet the patient's needs; or

(d) The patient has no other home available or desires not to live at home.

(5) **Palliative Care Admission Requirements**. Hospices that elect to provide palliative care to persons with advanced and progressive diseases in any setting, other than an inpatient or residential hospice, must admit only those persons who meet the following criteria:

(a) have an order from a physician indicating the patient has an advanced and progressive disease;

(b) request the intervention of a hospice care team to alleviate suffering and achieve relief from physical, emotional or spiritual symptoms of distress to achieve the best quality of life for the person and his or her family; and

(c) have stated needs that the hospice believes it has the capability to meet.

(6) **Discharge Requirements.**

(a) Once a hospice admits a patient who is terminally ill for hospice care, the hospice at its discretion must not discharge the patient unless either the patient freely and voluntary requests the discharge or the hospice determines that an involuntary discharge is necessary in accordance with these rules.

(b) No hospice is permitted to require or demand that a terminally ill patient request voluntary discharge from the hospice or require or demand a hospice patient to execute a request for voluntary discharge from the hospice as a condition for admission or continued care.

(c) In situations where the hospice identifies issues where the safety of the terminally ill patient, the patient's family unit, or a hospice staff member or volunteer is compromised, the hospice must make every effort to resolve the issues before considering the option of involuntary discharge.

1. All such efforts for resolution by the hospice must be documented in the patient's record.

2. If involuntary discharge is the elected option, the hospice must give no less than 14 days' notice of discharge to the terminally ill patient and the patient's representative, except in cases of imminent danger or immediate peril to the terminally ill patient, other terminally ill patients, or staff.

3. The hospice must notify the Department of the pending involuntary discharge of a terminally ill patient at the time of patient notification.

(d) No terminally ill patient receiving hospice care may be discharged due to inability to pay for the hospice services.

(e) No hospice is permitted to discontinue hospice care for a terminally ill patient, nor discharge or transfer the patient, during a period of coordinated or approved appropriate hospital admission for the treatment of conditions related to the patient's terminal illness or any other condition.

(f) Hospices must assist in coordinating continued care should any hospice patient be transferred or discharged from the hospice.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.14
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Admissions, Discharges, and Transfers" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.15. Assessment and Plan of Care.

(1) The hospice must designate a hospice care team for each patient admitted by the hospice. The hospice care team must be composed of individuals who provide or supervise the care and services offered by the hospice.

(2) The hospice care team must include at least the following individuals:

(a) A physician;

(b) A registered nurse;

(c) A social worker;

(d) A member of the clergy or other counselors; and

(e) Volunteers.

(3) The appropriate members of the hospice care team must provide a comprehensive assessment, as dictated by the identified needs of the patient, no later than five days after admission that includes at least medical, nursing, psychosocial, and spiritual evaluations of the patient, as well as the capability of the family unit in meeting the care needs of the patient and the need for bereavement services.

(a) The assessment must be designed to trigger identification of any referral needed by the patient for additional services, including at a minimum:

1. Professional counseling;

2. Spiritual counseling by a member of the clergy or other counselor;

3. Bereavement services;

4. Dietitian services; and

5. Other therapeutic services, as needed.

(b) If additional services are identified for a terminally ill patient, the hospice must ensure that those services are provided by qualified individuals who must be added to the patient's hospice care team. Such qualified individuals include, but are not limited to:

1. Other appropriately licensed counselors, as applicable to the patient's needs; and

2. Volunteers who provide services for the patient.

(4) Based on the results of the assessment of the patient, the hospice care team must:

(a) Establish the plan of care; and

(b) Provide and supervise hospice care and services in accordance with accepted standards of care and the plan of care.

(5) The hospice care team must establish and maintain a written plan of care for each patient prior to providing care.

(a) The plan of care must be developed with the input of the patient, the patient's family unit if designated by the patient, the patient's caregivers where the patient resides in a licensed facility, and the patient's representative, if any.

(b) The plan of care must detail the scope and frequency of services to be provided to meet the needs of the patient and the patient's family unit.

(c) The hospice care team must meet as a group to review each terminally ill patient's plan of care. The plan of care must be reviewed and updated as the patient's condition changes and as additional service needs are identified. The plan of care for terminally ill patients must be reviewed and updated at intervals of no more than 15 days. All reviews and updates shall be documented in the patient's medical record. Plans of care for patients receiving palliative care who have not been

determined to be terminally ill will be reviewed and updated as the patient's condition changes or the patient requests additional services.

(d) Documentation of plan of care review for the terminally ill patient must include a record of those participating and must also include evidence of the attending physician's opportunity to review and approve of any revised plans of care. In the absence of the attending physician's written approval of the revised plan of care, the revised plan of care must have the written approval of the medical director.

(6) The hospice care team must ensure that the patient receives treatment free from restraints, unless use of such restraints has been determined by a physician to be necessary for a temporary period to protect the patient from injury.

(a) Prior to using any restraint with a patient, the hospice care team must attempt less restrictive measures to accomplish the patient's treatment while affording the patient the maximum amount of personal freedom possible. The hospice must document the attempts at use of such less restrictive measures in the patient's medical record.

(b) If it is determined that restraints are necessary to prevent patient injury:

1. The hospice must obtain and document consent, specific to the type of restraint proposed, from the patient and/or the patient's representative for use of the restraint and such consent shall be obtained prior to the use of the restraint;

2. There must be a physician's order for the restraint, specifying the type of restraint to be used and the circumstances under which the restraint is to be applied, which is subject to the following conditions:

(a) The physicians order must be time limited; and

(ii) The order for the restraint must be re-evaluated prior to subsequent orders for the restraint;

3. The plan of care for the patient must include the plan and standard of care for use of the restraint, including the type and frequency of monitoring of the patient when the restraint is used. The plan must include maximum duration for each restraint application, with mandatory release at least every two hours, and a requirement that time, date, and duration of each restraint application are recorded and documented;

4. The plan of care must include procedures to ensure that the patient's comfort and safety needs are addressed during any period of restraint use;

5. The hospice must ensure safe and proper application and monitoring of the use of the restraint by adequately training staff and evaluating competency of each staff member treating patients in the use of the restraint and by directly observing staff performance with patients; and

6. The hospice staff must provide training to other patient caregivers in safe and proper use and monitoring of the restraint. Such training must be documented in the patient's medical record.

(c) A positioning or securing device utilized during medical treatment procedures to temporarily maintain the patient's position or immobilize the patient will not be considered a restraint, provided such necessity is documented in the patient's plan of care and the physician orders it. Such devices must only be applied by trained nursing or medical personnel and the plan of care must require monitoring sufficient to ensure the patient's safety.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.15
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Assessment and Plan of Care" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.16. Home Care.

(1) The hospice must provide home care services to patients primarily in the patients' home. At least 51 percent of the total of all hospice care days, delivered by the hospice in the fiscal year to terminally ill patients must be delivered in the homes of the terminally ill patients.

(2) During home care visits, the hospice employee must provide continuing education for the patient and the patient's primary caregiver regarding the progression of the patient's illness and the patient's care needs.

(3) If, during the home care visit, there are observed or communicated significant changes in the patient's condition or needs, or if the hospice employee or volunteer observes that the patient's primary caregiver cannot provide the continuing support and care the patient requires, such findings must be communicated to the patient's hospice care team in a sufficiently timely manner to ensure that the patient's care and safety needs are addressed.

(4) When hospice services are provided to a patient who is a resident of a licensed nursing home, licensed intermediate care home, licensed personal care home or licensed assisted living community, or another licensed hospice operating an inpatient unit, there must be written communication evidencing an understanding between the hospice and the licensed facility that makes clear that the hospice takes full responsibility for professional management of the patient's hospice care and that the licensed nursing home, licensed

intermediate care home, licensed personal care home or licensed assisted living community takes responsibility for the other services the patient needs or receives that the licensed facility is authorized to provide.

(a) The written communication must clearly specify the patient-care activities and responsibilities that will be performed by the hospice employees and volunteers and those patient care tasks that will be performed by employees of the facility where the hospice patient resides. Hospice employees and volunteers must provide those services for which they are assigned responsibility in the hospice's plan of care for the patient.

(b) The written communication must specify an individual from the hospice and an individual from the facility where the patient resides who shall be responsible for communication between services providers regarding each patient's treatment and condition and for addressing any care issues. Such communication must be ongoing throughout the period of hospice service provision and must be documented in the patient's hospice medical record.

(c) The hospice must provide a copy of any self-determination documentation to the licensed nursing home, licensed intermediate care home, licensed personal care home or licensed assisted living community where the patient resides and must communicate with the facility as to the procedure for the appropriate implementation of any advance directive or physician's order for life sustaining treatment.

(5) If the hospice does not offer inpatient services directly, the hospice must have a contractual agreement with a licensed hospital, a licensed skilled nursing facility, or a licensed inpatient hospice for the provision of short-term, acute inpatient care and respite care for hospice patients.

(6) The hospice must arrange for transport services when necessary to transport hospice patients to and from inpatient hospice care.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.16
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Home Care" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.17. Medical Services.

(1) Medical services must be under the direction of the medical director. In addition to palliation and management of the terminal illness and related conditions, physicians of the hospice, including the physician members of the hospice care team, must also address the basic medical needs of the patients to the extent that such needs are not met by each patient's attending physician or other physician of the patient's choice.

(2) **Medical Director.** The medical director for the hospice must be a physician licensed to practice in this state and must have at least one year of documented experience on a hospice care team or in another setting managing the care of terminally ill patients. The medical director must:

(a) Be either an employee of the hospice or work under a written agreement with the hospice;

(b) Have admission privileges at one or more hospitals commonly serving patients in the hospice's geographical area;

(c) Be responsible for the direction and quality of the medical component of the care provided to patients by the hospice care team, including designating a licensed physician, employed by the hospice or working under a written agreement, to act on his or her behalf in the medical director's absence;

(d) Participate in the interdisciplinary plan of care reviews, patient case review conferences, comprehensive patient assessment and reassessment, and the quality improvement and utilization reviews;

(e) Review the clinical material of the patient's attending physician that documents basic disease process, prescribed medicines, assessment of patient's health at time of entry and the drug regimen;

(f) Ensure that each terminally ill patient receives a face-to-face assessment, by either the medical director or the terminally ill patient's attending physician, or is measured by a generally accepted life-expectancy predictability scale for continued admission eligibility at least every six months, as documented by a written certification from the medical director or the terminally ill patient's attending physician that includes:

1. The statement that the terminally ill patient's medical prognosis is for a life expectancy of six months or less if the terminal illness runs its natural course;

2. The specific current clinical finding and other documentation supporting a life expectancy of six months or less if the illness takes its natural course for the terminally ill patient; and

3. The signature of the physician.

(g) Communicate with each patient's attending physician and act as a consultant to attending physicians and other members of the hospice care team;

(h) Help to develop and review policies and procedures for delivering care and services to the patients and their family units;

(i) Serve on appropriate committees and report regularly to the hospice administrator regarding the quality and appropriateness of medical care;

(j) Ensure written protocols for symptom control and medication management are available; and

(k) Assist the administrator in developing, documenting and implementing a policy for discharge of patients from hospice care.

(3) In addition to the hospice medical director, the hospice may appoint additional hospice physicians who shall assist the medical director in the performance of his or her duties, as prescribed by the hospice.

(4) The medical director must assist the administrator in developing, documenting, and implementing effective policies and procedures for the delivery of physicians' services, for orientation of new hospice physicians, and for continuing training and support of hospice physicians. These policies and procedures must:

(a) Ensure that a hospice physician is on-call 24 hours a day, seven days a week; and

(b) Provide for the review and evaluation of clinical practices within home care, residential, and inpatient hospices in coordination with the quality management, utilization, and peer review committee.

(5) Verbal orders for medications and controlled substances shall only be given to appropriately licensed staff members, acting within the scope of their licenses, and must be immediately recorded, signed, and dated by the licensed staff member receiving such order.

(a) The individual receiving the order shall immediately repeat the order and the prescribing physician must verify that the repeated order is correct. The individual receiving the order must document in the patient's medical record that the order was "repeated and verified."

(b) The hospice must provide a written copy of the order to the prescribing physician within 24 hours of such order or by the end of the next business day.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.17
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Medical Services" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.18. Nursing Services.

(1) The hospice shall have a system to make available nursing services 24-hours a day, seven days a week to meet the needs of the patients.

(a) A registered nurse must be available at all times to provide or supervise the provision of nursing care.

(b) On-site nursing services must be made available within one hour of notification where the terminally ill patient and the patient with an advanced and progressive disease who has contracted for nursing services experiences a symptom-management crisis situation.

(c) The hospice must maintain an on-call log for all calls received after normal business hours, the records of which shall be kept for a period of two years.

(2) The hospice must designate a director of nursing who must be a Georgia-licensed registered nurse and who must be responsible for implementing a system for delivery, supervision, and evaluation of nursing and personal care services.

(a) The director of nursing must establish and implement effective policies and procedures for nursing and personal care services based on generally accepted standards of nursing practice.

(b) The director of nursing must ensure that nursing personnel are oriented to nursing policies and procedures and are qualified and competent for their assigned duties.

(c) The director of nursing must ensure the types and numbers of nursing personnel necessary to provide appropriate nursing care for each patient in the hospice.

(d) The director of nursing must ensure patient assignments are made that reflect a consideration of patient needs as well as nursing staff qualifications and competencies.

(3) Nursing staff must administer medications and other treatments in accordance with the physicians' orders, generally accepted standards of practice, and any federal and state laws pertaining to medication administration.

(4) When a patient who is terminally ill or whose death is anticipated and who is receiving hospice care from a licensed hospice dies, a physician assistant, a nurse practitioner, or a registered professional nurse licensed in this state and employed by the hospice at the time of the apparent death of such person, may make the determination and pronouncement of the patient's death in the absence of an attending physician. Such determination or pronouncement shall be made in writing on a form approved by the Department.

(5) **Personal Care Services.** Personal care services must be available and provided in all components of the hospice to meet the needs of patients. The hospice may utilize licensed nurses or qualified personal care aides for the provision of personal care services.

(a) Personal care aides considered qualified by training and experience to provide services to patients include:

1. Georgia Certified Nursing Aides with current certification as such; or

2. Individuals who have completed and can provide validation or documentation of completion of a home health aide training and competency evaluation program conducted in a Medicare-certified home health agency; or

3. Individuals who have successfully completed a personal care aide-training program, provided by the hospice under the direction of a registered nurse, which meets the following requirements:

   (i) The personal care aide-training program must be conducted through classroom and supervised practical training totaling at least 75 hours;

   (ii) At least 16 of the 75 hours of training shall be devoted to supervised practical training;

   (iii) The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training;

   (iv) Supervised practical training must be provided either in a laboratory setting or in one of the components of the hospice in which the trainee demonstrates knowledge while performing tasks on an individual or patient under the direct supervision of a registered nurse or licensed practical nurse; and

   (v) The personal care aide-training program must address each of the following subject areas:

      (I) Communications skills;

      (II) Observation, reporting, and documentation of patient status and the care or service furnished;

      (III) Reading and recording temperature, pulse, and respiration;

      (IV) Basic infection control procedures;

      (V) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor;

      (VI) Maintenance of a clean, safe, and healthy environment;

(VII) Recognizing emergencies and knowledge of emergency procedures;

(VIII) The physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, the patient's privacy, and the patient's property;

(IX) Appropriate and safe techniques in personal hygiene and grooming that include:

I. Bed bath;

II. Sponge, tub, or shower bath;

III. Shampooing in the sink, tub, or bed;

IV. Nail and skin care;

V. Oral hygiene; and

VI. Toileting and elimination;

(X) Safe transfer techniques and ambulation;

(XI) Normal range of motion and positioning;

(XII) Adequate nutrition and fluid intake, including preparing and assisting with eating;

(XIII) Any other task that the hospice may choose to have the personal care aide perform, as authorized by law; and

(XIV) Patient rights, including effectuating advance directives and abuse reporting requirements.

(b) Prior to providing care independently to patients, a registered nurse must observe personal care aides actually delivering care to patients and complete an initial competency evaluation for all personal care tasks assigned to the aide.

(c) Personal care aides must receive at least 12 hours of continuing education annually regarding applicable aspects of hospice care and services.

(d) A registered nurse must prepare for each personal care aide written instructions for patient care that are consistent with the interdisciplinary plan of care and must make and document supervisory visits to the terminally ill patient's residence or living facility at least every two weeks to assess the performance of the personal care aide services.

(e) At least annually, there must be written evidence for each personal care aide that reflects that the personal care aide's performance of required job tasks was directly observed by a registered nurse and such performance was determined to be competent for all job tasks required to be performed.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.18
Authority: O.C.G.A. §§ 31-2-4, 31-7-170*et seq.*
History. Original Rule entitled "Nursing Services" adopted. F. May 26, 2015; eff. June 15, 2015.
Amended: F. Mar. 19, 2018; eff. Apr. 8, 2018.

Rule 111-8-37-.19. Other Services.

Hospices must make supportive services available to both the patient and the patient's family unit, including, but not limited to, bereavement services provided both prior to and after the patient's death, as well as spiritual counseling and any other counseling services identified in the interdisciplinary plan of care for the patient and the patient's family unit.

(a) **Bereavement Services.** Hospices must have an organized program for the provision of bereavement services under the supervision of a licensed professional counselor or licensed social worker or other professional determined, in compliance with applicable laws, to be qualified by training and education to provide the required supportive services. Bereavement services must be a part of the interdisciplinary plan of care and shall address the needs of the patient and the patient's family unit, the services to be provided, and the frequency of services. Bereavement services, including educational and spiritual materials and individual and group support services, must be available to the terminally ill patient's family unit for a period of at least one year following the terminally ill patient's death. Hospices must maintain documentation of all bereavement services.

(b) **Spiritual Counseling.** Hospices must make available spiritual counseling and must notify patients and patients' family units as to the availability of clergy. In the delivery of spiritual counseling services, hospices must not impose any value or belief system on the patient or the patient's family unit.

(c) **Other Counseling.** Additional counseling for the patient or the patient's family unit may be provided by other qualified members of the hospice care team as well as by other qualified professionals in accordance with state practice acts. Such counseling includes, but is not limited to, access to a licensed clinical social worker or professional counselor for the provision of counseling to the patient or the patient's family unit or primary

caregiver on a short-term basis to resolve assessed clear or direct impediments to the treatment of the patient's medical condition.

(d) **Physical Therapy, Occupational Therapy, and Speech Language Pathology Services.** Physical therapy services, occupational therapy services, and speech language pathology services must be available to the patient and, when provided, offered by qualified personnel, in accordance with state practice acts, in a manner consistent with accepted standards of practice.

(e) **Dietary and Nutritional Services.** Dietary and nutritional services, as required, must be available to all patients in all components of hospice care and provided or supervised by a licensed dietitian. Hospices must develop, document, and implement effective written policies and procedures for dietary and nutritional services.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.19
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Other Services" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.20. Volunteer Services.

(1) The hospice must establish a program that utilizes volunteers to provide services to terminally ill patients and family units in accordance with patients' plans of care and/or to provide administrative support services for the hospice.

(2) The hospice must designate a coordinator of volunteer services who assists the administrator in developing, documenting, and implementing a volunteer services program.

(3) The hospice volunteer coordinator must establish and implement effective written policies and procedures relating to volunteer services. These policies and procedures must address at a minimum:

(a) Recruitment and retention;

(b) Screening;

(c) Orientation;

(d) Scope of function;

(e) Supervision;

(f) Basic infection control;

(g) Ongoing training and support; and

(h) Documentation of volunteer activities; and

(i) Patient rights and reporting abuse and other serious incidents.

(4) Volunteer services must be provided without compensation.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.20
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Volunteer Services" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.21. Pharmaceutical Services.

(1) The hospice must provide for the procurement, storage, administration, and destruction of drugs and biologicals utilized for hospice care in accordance with accepted professional principles and in compliance with all applicable state and federal laws.

(2) The hospice must:

(a) Ensure medication and pharmacy procedures are approved by a licensed pharmacist who is either employed directly or has a formal arrangement with the hospice;

(b) Ensure the availability of a licensed pharmacist on a 24-hour per day basis to advise the hospice staff regarding medication issues and to dispense medications;

(c) Ensure that any emergency drug kit placed in the hospice is in accordance with all applicable laws and rules and regulations:

(d) Ensure that drugs and biologicals are labeled in accordance with current accepted standards of practice;

(e) Ensure effective procedures for control and accountability of all drugs and biologicals throughout the hospice, including records of receipt, disposition, destruction, and reconciliation of all controlled substances and dangerous drugs; and

(f) Ensure that only licensed nurses or physicians, acting within the scope of their licenses, administer medications on behalf of the hospice, except for liquid morphine administered in accordance with O.C.G.A. § 31-7-12.2(g)(7)(G).

(3) In the event of special circumstances under which the hospice is unavailable to administer liquid morphine to a hospice patient residing in an assisted living community, the hospice may train a certified medication aide at the community to administer the medication, subject to the following requirements:

(a) The patient is under a physician's written order that contains specific instructions for indication, dosage, frequency and route of administration;

(b) The initial dose is administered by a licensed hospice health care professional;

(c) The hospice provides adequate training to ensure that the medication aide who will be administering the liquid morphine can do so safely and properly;

(d) The morphine administration training is repeated at least on an annual basis to ensure continuing competency; and

(e) The hospice maintains documentation of compliance with these requirements.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.21
Authority: O.C.G.A. §§ 31-7-170 et seq., 31-7-12.2(g)(7)(G).
History. Original Rule entitled "Pharmaceutical Services" adopted. F. May 26, 2015; eff. June 15, 2015.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.

Rule 111-8-37-.22. Medical Supplies.

The hospice must make available sufficient medical supplies and equipment for the palliative care and management of the illness or conditions directly attributable to the terminal diagnosis of terminally ill patients.

(a) If the hospice directly provides medical supplies and equipment, the hospice must:

1. Develop and implement effective policies and procedures to maintain the supplies and equipment in good working order per the manufacturers' recommendations;

2. Ensure the safe handling and storage of supplies and equipment to ensure function and cleanliness;

3. Instruct the caregiver on the use and maintenance of the equipment; and

4. Replace supplies and equipment as essential for the care of terminally ill patients.

(b) If the hospice contracts for medical supplies and equipment services, the hospice must ensure that contract agreements include requirements consistent with subparagraph (a) of this rule and must ensure that contractors adhere to such agreements.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.22
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Medical Supplies" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.23. Medical Records.

(1) In accordance with accepted standards of practice, the hospice must establish and maintain a medical record for every patient admitted for care and services. The medical record must be complete, promptly and accurately documented, readily accessible, and systematically organized to facilitate retrieval and to support the provision of patient care.

(2) Entries must be made for all services provided and must be signed and dated on the day of delivery by the individual providing the services for inclusion in the patient's medical record within seven days. The record must include all services whether furnished directly or under arrangements made by the hospice.

(3) Each patient's medical record must contain:

(a) Identification data;

(b) The initial and subsequent assessments;

(c) Pertinent medical and psychosocial history;

(d) Consent and authorization forms;

(e) The interdisciplinary plan of care;

(f) The name of the patient's attending physician; and

(g) Complete documentation of all services and events, including evaluations, treatments, progress notes, transfers, discharges, etc.

(4) The hospice must have the patient's medical record readily accessible and must safeguard the medical record against loss, destruction, and unauthorized use.

(5) Medical records must be preserved as original records, microfilms, or other usable forms and must be such as to afford a basis for complete audit of professional information. Hospices must retain all medical records at least until the sixth anniversary of the patient's death or discharge, and as otherwise required by law. If the patient is a minor, medical records must be retained for at least five years past the age of majority or, in the event the minor patient dies, for at least five years past the year in which the patient would have reached the age of majority. In the event the hospice ceases operation, the hospice must provide prior notice to the local community, referring providers and the Department of the location of the medical records and how such records may be retrieved.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.23
Authority: O.C.G.A. §§ 31-7-170*et seq.*
History. Original Rule entitled "Medical Records" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.24. Hospice Care Facilities.

(1) Hospices providing home care services may establish, as optional services, small home-like residential facilities or units, in order to provide 24-hour non-acute palliative hospice care, and/or inpatient units, in order to provide short-term, 24-hour acute hospice care to terminally ill hospice patients. Residential hospices built, or undergoing major renovations after the effective date of these rules must meet the Facility Guidelines Institute, Guidelines for Design and Construction of Residential Health, Care, and Support Facilities, including the provisions specifically applicable to hospices.

(2) The environment of the hospice care facility must be designed, equipped, and maintained in accordance with applicable life safety code requirements to provide for the comfort, privacy, and safety of no more than 25 patients and family members in any one self-contained, home-like unit. A hospice may operate multiple self-contained, home-like units of no more than 25 beds each, either at the same location or separate locations, provided that each unit is fully staffed to meet the needs of the hospice patients in that unit, the locations are within 35 miles of the principal location and the governing body does not have a history of poor compliance with licensure requirements. Hospice care facilities, whether residential, inpatient, or residential and inpatient facilities, must provide:

(a) An emergency power source capable of providing electrical service for communication systems, alarm systems, egress lighting, and patient care areas;

(b) Décor and room configuration that is home-like in design and function;

(c) Space accommodations, other than patient rooms, for private patient/family visiting and grieving;

(d) Accommodations for at least one family member to remain with the patient throughout the night;

(e) Separate restrooms for staff and public use;

(f) A program to inspect, monitor and maintain biomedical, electrical equipment in proper and safe working order;

(g) Procedures that prevent infestations of insects, rodents, or other vermin or vectors;

(h) Security procedures sufficient for the protection of patients;

(i) Procedures for the safe management of medical gases;

(j) Procedures for infection control, including isolation of patients, in accordance with accepted standards;

(k) An environment that is clean, in good repair, and designed and equipped to minimize the spread of infection;

(l) Adequate lighting, ventilation, and control of temperature and air humidity; and

(m) An alternative power source to support the needs of the patients.

(3) Patient rooms and bathrooms must be designed and equipped to allow for easy access to the patient and for the comfort and safety of patients.

(4) Each residential and/or inpatient hospice care facility must provide rooms that:

(a) Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multi-patient room;

(b) Are private rooms, unless consent for a roommate is obtained and then only if the following requirements are met:

1. The hospice must provide an alternative temporary accommodation for a patient whose roommate is in a crisis situation;

2. In no case shall more than two patients share a room;

(c) Are equipped with a bathroom with an adequate supply of hot water and with automatically regulated temperature control of the hot water;

(d) Are at or above grade level and have a window to the outside;

(e) Contain a suitable bed and mattress for each patient, suitable furniture that allows family to remain in the room overnight, chairs for seating, and closets or furniture for storage of personal belongings;

(f) Are equipped with a system for patients to summon for assistance when needed;

(g) Are equipped with a telephone in each room or telephones located in private areas convenient to bedrooms; and

(h) Have an adequate amount of clean bed linens, towels, and washcloths.

(5) In addition to complying with all other requirements of these rules and regulations, each facility that is newly constructed or expands its existing facility after the date these rules and regulations take effect shall also provide a tub or shower in each patient room.

(6) In addition to the hospice's applicable home-care policies and procedures, hospice care facilities must develop and implement additional policies and procedures for post-mortem care and for pronouncement of deaths, in accordance with applicable law.

(7) Hospice care facilities must have policies regarding smoking which apply to employees, volunteers, patients, and visitors.

(8) Hospice care facilities must ensure adequate staff are on duty at all times in order to meet the needs of patients, in accordance with patients' plans of care and in accordance with accepted standards of nursing and hospice care. Residential and/or inpatient hospice care facilities must provide:

(a) At least two staff members on duty 24 hours per day, seven days per week, with additional staff as needed to meet the needs of patients; and

(b) A registered nurse must direct and supervise all patient care in accordance with the needs of patients and the individual plans of care.

1. Residential hospice care facilities may utilize licensed practical nurses for patient care provided that a registered nurse supervises the care and is available on call at all times.

2. Inpatient hospice care facilities must have a registered nurse present during each shift who provides direct patient care.

(9) Meals must be provided in accordance with established dietary practice and the dietary needs and wishes of patients. The hospice must:

(a) Serve three meals a day with not more than 14 hours between a substantial evening meal and breakfast, unless medically contraindicated;

(b) Have a system for providing meals for patients outside the normal meal service hours, when requested;

(c) Have snacks available between meals and at night, as appropriate to each patient's needs and medical condition;

(d) Purchase, store, prepare, and serve food in a manner that prevents food borne illness;

(e) Ensure patient diets follow the orders of physicians;

(f) Ensure that a qualified staff member plans and supervises meals to ensure meals meet patient's nutritional needs and to ensure meals follow recommended dietary allowances and menu plans; and

(g) Ensure the services of a licensed dietitian to review meal plans and to consult in practical freedom of choice diets to ensure that patients' favorite foods are included in their diets whenever possible.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.24
Authority: O.C.G.A. §§ 31-7-170*et seq.*

History. Original Rule entitled "Hospice Care Facilities" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.25. Waivers and Variances.

(1) A hospice may request a waiver or variance of a specific rule by application on forms provided by the Department.

(2) The Department may grant or deny the request for waiver or variance at its discretion. If the waiver or variance is granted, the Department may establish conditions that must be met by the hospice in order to operate under the waiver or variance. Waivers or variances may be granted with consideration of the following:

(a) **Variance.** A variance may be granted by the Department, at its discretion, upon a showing by the applicant that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application would cause undue hardship. The applicant must also show that adequate standards exist for affording protection for the health, safety, and care of patients, and these existing standards would be met in lieu of the exact requirements of the rule or regulation.

(b) **Waiver.** The Department may, at its discretion, dispense altogether with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, and care of the patients.

(c) **Experimental Waiver or Variance.** The Department may grant a waiver or variance, at its discretion, to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant that the intended protections afforded by the rule or regulation in question are met and that the innovative approach has the potential to improve service delivery.

(3) Waivers and variances granted by the Department must be for a time certain, as determined by the Department.

(4) The hospice may request a final review of the initial waiver or variance decision made by program staff to the chief of the Division of Healthcare Facility Regulation by filing a written request for review of the initial decision and providing any additional information which supports the request for review. The chief of the Division will issue a final decision on behalf of the Department.

(5) Where the Department has denied the application for a waiver or variance in writing, the Department will not consider a subsequent application for the same waiver or variance from the same hospice unless the applicant includes new evidence of a substantial change in the circumstances which formed the basis for the initial request.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.25
Authority: O.C.G.A. §§ 31-2-4 7 and 31-7-170 *et seq.*
History. Original Rule entitled "Waivers and Variances" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.26. Enforcement.

A hospice that fails to comply with licensing requirements as contained in the Rules and Regulations for Hospices, Chapter 111-8-37 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25, is subject to civil and administrative actions brought by the Department to enforce licensing requirements as provided by applicable laws and rules. Such actions will be initiated in compliance with the Georgia Administrative Procedures Act, O.C.G.A. §§ 50-13-1*et seq.*, 31-2-8 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

However, the Department may suspend any requirements of these rules and the enforcement of any rules when the Governor of the State of Georgia has declared a public health emergency.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.26
Authority: O.C.G.A. §§ 31-2-8, 31-7-170*et seq.* and 50-13-1 *et seq.*
History. Original Rule entitled "Enforcement" adopted. F. May 26, 2015; eff. June 15, 2015.

Rule 111-8-37-.27. Severability.

In the event that any rule, sentence, clause, or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portion thereof. The remaining rules or portions of rules shall remain in full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-37-.27
Authority: O.C.G.A. §§ 31-2-4 and 31-7-170*et seq.*
History. Original Rule entitled "Severability" adopted. F. May 26, 2015; eff. June 15, 2015.

Subject 111-8-40. RULES AND REGULATIONS FOR HOSPITALS.

Rule 111-8-40-.01. Title and Purpose.

These rules shall be known as the Rules and Regulations for Hospitals. The purpose of these rules is to provide for the inspection and issuance of permits for hospitals and to establish minimum requirements for facilities operating under a hospital permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.01
Authority: O.C.G.A. §§ 31-2-4, 31-2-5, 31-7-2.1 and 31-7-3.

History. Original Rule entitled "Title and Purpose" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.02. Definitions.

Unless a context otherwise requires, these identified terms mean the following when used in these rules:

(a) *Board certified* means current certification of a licensed physician by a specialty board recognized by the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) or other nationally recognized specialty's certifying board.

(b) *Board eligible* means a licensed physician who meets the criteria for examination for the designated specialty as published by that nationally recognized specialty's certifying board.

(c) *Bylaws* means a set of laws or rules formally adopted internally by the facility, organization, or specified group of persons to govern internal functions or practices within that group, facility, or organization.

(d) *Department* means the Department of Community Health of the State of Georgia.

(e) *Governing body* means the hospital authority, board of trustees or directors, partnership, corporation, entity, person, or group of persons who maintain and control the hospital.

(f) *Hospital* means any building, facility, or place in which are provided two (2) or more beads and other facilities and services that are used for persons received for examination, diagnosis, treatment, surgery, or maternity care for periods continuing for twenty-four (24) hours or longer and which is classified by the department as a hospital.

(g) *Inpatient* means a person admitted to a hospital for an intended length of stay of twenty-four (24) hours or longer.

(h) *Rural Free Standing Emergency Department* means any hospital that downgrades its existing scope of services to meet all of the following conditions:

(i) is currently licensed by the Department as a hospital or was previously licensed by the Department as a hospital and such license expired within the previous 12 months;

(ii) is located in a rural county as defined by O.C.G.A. § 31-6-2(32);

(iii) is located no more than 35 miles from a licensed general hospital;

(iv) is open 7 days a week, 24 hours a day;

(v) provides non-elective emergency treatment and procedures for periods continuing less than 24 hours;

(vi) may provide elective, out-patient surgical treatment and procedures for periods continuing less than 24 hours;

(vii) may provide basic obstetrics and gynecology treatment and procedures for periods continuing less than 24 hours; and

(viii) is classified by the department, as provided for in this chapter, as a Rural Free Standing Emergency Department.

Rural Free Standing Emergency Departments may provide elective endoscopy or other elective treatment and procedures which are not performed in an operating room environment.

(i) *Medical record* means the written or electronic collection of diagnostic and/or treatment information and data pertaining to the patient, including but not limited to identifying information and, as applicable, medical orders, assessment findings, diagnostic test results, progress notes, x-rays films, monitoring data, and details of treatment.

(j) *Medical staff* means the body of licensed physicians, dentists, and/or podiatrists, appointed or approved by the governing body, to which the governing body has assigned responsibility and accountability for the patient care provided at the hospital.

(k) *Organized service(s)* means any inpatient or outpatient service offered by the hospital which functions as an administrative or operational unit under the governing body of the hospital.

(l) *Outpatient* means a person who presents to a hospital for diagnostic or treatment services and who is not admitted to the hospital as an inpatient by a member of the medical staff.

(m) *Patient* means any person presenting at a hospital for the purpose of evaluation, diagnosis, monitoring, or treatment of a medical condition, mental condition, disease, or injury.

(n) *Peer review* means the procedure by which professional health care providers evaluate the quality and efficiency of services ordered or performed by other professional health care providers in the hospital for the purposes of fostering safe and adequate treatment of the patients and compliance with standards set by an association of health care providers and with the laws, rules, and regulations applicable to hospitals.

(o) *Permit* means the authorization granted by the Department to a hospital governing body to operate the hospital's authorized services.

(p) *Physical restraint* means any manual method or physical or mechanical device used with a patient such that the patient's freedom of movement or access to his/her own body is restricted.

(q) *Physician* means any person who is licensed to practice medicine in this state by the Georgia Composite State Board of Medical Examiners.

(r) *Practitioner* means any individual engaged in the practice of the profession for which they are licensed, certified, or otherwise qualified or authorized to practice.

(s) *Professional staff* means a person or persons licensed by the state of Georgia to practice a specified health profession and employed by or contracting with the hospital for the practice of that profession.

(t) *Rules and regulations* means the set of rules formally adopted internally by a specified hospital body to provide guidance for internal functions or practices.

(u) *Seclusion* means the confinement of a person to a room or an area where the person is prevented from leaving.

(v) *Surveillance* means the systematic method of collecting, consolidating, and analyzing data concerning the distribution and determinants of a given disease or medical event, followed by the dissemination of that information to those who can improve the outcomes.

(w) The singular indicates the plural, the plural indicates the singular, and the masculine the feminine, when consistent with the intent of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.02
Authority: O.C.G.A. §§ 31-7-1, 31-7-2.1, 31-7-15 and 31-7-131.
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Apr. 29, 2014; eff. May 19, 2014.

Rule 111-8-40-.03. Hospital Permit Requirement.

No person, corporation, association, or other entity shall establish, operate, or maintain a hospital in Georgia without a permit or provisional permit.

(a) A permit is required for each hospital. Multi-building hospitals may request a single permit to include all buildings provided that the hospital buildings are in close proximity to each other, the facilities serve patients in the same geographical area, and the facilities are operated under the same ownership, control, and bylaws.

1. Services offered in separate buildings or on separate premises, which do not by themselves meet the definition of a hospital, including, but not limited to, satellite

urgent care centers, outpatient or mammography clinics, or hospital-owned physicians' offices, shall be considered organized services of the hospital for the purposes of these rules.

2. Only those services operated by the hospital under the permit as approved by the Department shall be presented to the public as a service of the hospital.

(b) A permit, either continuing or provisional, is required prior to the admission of any patients or initiation of any patient care services in the hospital. A provisional permit may be issued for a limited time to a newly established hospital to allow the hospital to demonstrate that its operational procedures equal standards specified by the rules.

(c) The permit shall designate the classification of the hospital as determined by the Department following evaluation of the hospital's services and in accordance with the Certificate of Need.

1. The classification shall be one of the following:

(i) Classification as a general hospital means a facility meets the definition of a hospital and provides continuous care for a variety of patients who have a variety of medical conditions. A critical access hospital shall fall under the general hospital classification;

(ii) Classification as a specialized hospital means a facility that meets the definition of a hospital and provides care to a specialized or specified group of patients and/or patients who have specified conditions. The type of specialization shall be designated on the hospital permit; or

(iii) Classification as a Rural Free Standing Emergency Department.

2. If changes occur in the organized services offered by the hospital, including the addition of any services requiring CON review or off-campus service locations, the hospital's administrator or governing body shall submit to the Department a new description of services at least thirty (30) days prior to the change. Change in the classification of the hospital shall require application for a new permit.

(d) To be eligible for a permit the hospital shall be in substantial compliance with these rules and regulations and any provisions of law as applicable to the construction and operation of the hospital. In its discretion, the Department may issue a provisional permit for a limited time to a new or existing hospital to allow the hospital a reasonable length of time to come into compliance with these rules provided the Department has received an acceptable plan of correction.

(e) The permit issued to the hospital shall be prominently displayed in a public area of the hospital at all times.

(f) A permit is not transferable from one governing body to another nor from one hospital location to another.

(g) If the hospital anticipates that it will close or cease to operate, the governing body shall notify the Department at least thirty (30) days prior to the anticipated closure.

1. Prior to hospital closure, the hospital shall inform the Department of the planned storage location for patients' medical records, medical staff information, and other critical information after closure. The hospital shall publish in a widely circulated newspaper(s) in the hospital's service area a notice indicating where medical records and other critical information can be retrieved and shall notify the Department of Transportation of the anticipated date of closure for removal of the hospital locator signs. Following closure, the Department shall be notified of any change in location of the patients' medical records, medical staff information, and other critical information from the published location.

2. When the hospital ceases to operate, the permit shall be returned to the Department within ten (10) days of closure. The permit shall be considered revoked, unless placed on inactive status as described in these rules.

3. If the hospital is closing for a period of less than twelve (12) months, and plans to reopen under the same ownership, name, classification, and bed capacity, the hospital may request to have the permit placed on temporary inactive status.

(i) When placed on temporary inactive status, the permit shall be returned to the Department within ten (10) days of closure and the hospital shall not operate until the permit has been reactivated. The hospital shall notify the Department of Transportation of the intended closure.

(ii) The hospital shall request in writing that the permit be reactivated at least thirty (30) days prior to the desired date of reopening. Prior to reactivation of the permit, the hospital may be subject to inspection by the Department. If the permit is not reactivated within twelve (12) months, the permit shall be considered revoked.

(h) A new permit may be obtained by application to the Department and is required if the hospital is moved to another location, has a change in operational or trade name, has a change in ownership or classification, or has a change in the authorized bed capacity. The former permit shall be considered revoked upon the issue of a new permit and the former permit shall be returned to the Department.

(i) A permit shall remain in effect unless suspended or revoked or otherwise rescinded or removed as provided in these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.03
Authority: O.C.G.A. §§ 31-7-1, 31-7-2, 31-7-2.1 and 31-7-3.
History. Original Rule entitled "Hospital Permit Requirement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Amended: F. Apr. 29, 2014; eff. May 19, 2014.

Rule 111-8-40-.04. Facilities Exempt from These Rules.

The following classes of hospitals are exempt from these rules:

(1) **Federally owned and/or operated hospitals.** Hospitals owned or operated by the federal government are exempt from these rules and the requirement for a Georgia hospital permit; and

(2) **Residential Mental Health Facilities for Children and Youth.** A sub-classification of specialized hospitals which are licensed to provide twenty-four (24) hour care and have as their primary function the diagnosing and treating patients to age twenty-one (21) with psychiatric disorders are exempt from these rules in lieu of meeting the specific regulations under Chapter 111-8-68.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.04
Authority: O.C.G.A. §§ 31-2-7, 31-7-2 and 31-7-5.
History. Original Rule entitled "Facilities Exempt from These Rules" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.05. Application for a Permit.

An application for a permit to operate a hospital shall be submitted on forms provided by the Department. The application submitted to the Department shall be an original document. No application shall be considered by the Department unless it is complete and accompanied by all required attachments.

(a) **Application for Initial Permit.** The application for an initial permit shall be submitted to the Department not later than thirty (30) days prior to the anticipated date of the opening and initiation of operations by the hospital. The application shall be signed by the hospital administrator or the executive officer of the hospital's governing body and shall include:

1. A listing of the services provided:

2. Proof of hospital ownership. In the case of corporations, partnerships, and other entities authorized by law, the applicant shall provide a copy of its certificate of incorporation, or other acceptable proof of its legal existence together with the names and addresses of all persons owning five (5) percent or more;

3. A list of the locations of any services offered by the hospital on separate premises; and

4. A copy of the Certificate of Need (CON) from the Department.

(b) **Application Due to a Change in Name, Location, or Bed Capacity of a Hospital.**

The application for a new permit due to a change in name, location, or authorized bed capacity of a hospital shall be submitted at least thirty (30) days prior to the proposed effective date of the change.

(c) **Application Due to a Change in Classification of the Hospital.** The application for a new permit due to a change in the classification for the hospital shall be submitted at least thirty (30) days prior to the proposed effective date of the change. The application shall be signed by the hospital administrator or the executive officer of the governing body and shall include:

1. A listing of the service(s) to be provided; and

2. A copy of the required Certificate of Need (CON) from the Department, if applicable.

(d) **Application Due to a Change in Ownership.** The application for a new permit due to a change in ownership shall be submitted at least thirty (30) days prior to the change whenever possible. Proof of ownership documents, as required with the application for the initial permit and any other approvals required by state law, shall be submitted upon the completion of the transaction changing ownership.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.05
Authority: O.C.G.A. § 31-7-3.
History. Original Rule entitled "Application for a Permit" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.06. Permit Denial and Sanctions.

The Department may refuse to grant an initial permit, revoke a current permit, or impose other sanctions as described herein and in the rules for the "General Licensing and Enforcement Requirements," Chapter 111-8-25.

(a) **Denial of an Application for a Permit.** The Department may refuse to grant an initial permit or provisional permit without the requirement of holding a hearing prior to the action. Denial of an application for a change to a permit from an existing facility shall be subject to notice and opportunity for a hearing following the denial. An application may be refused or denied if:

1. The hospital has failed to demonstrate compliance with these rules and regulations;

2. The applicant or alter ego of the applicant has had a permit denied, revoked, or suspended within one (1) year of the date of a new application;

3. The applicant has transferred ownership or governing authority of a hospital within one (1) year of the date of the new application when such transfer was made in order to avert denial, suspension, or revocation of a permit; or

4. The applicant has knowingly made any verbal or written false statement(s) of material fact in connection with the application for the permit or on documents submitted to the Department as part of any inspection or investigation or in the falsification or alteration of facility records made or maintained by the hospital.

(b) **Sanction of a Permit.**

1. The Department may take an action to sanction the hospital permit holder, subject to notice and opportunity for a hearing, where the Department finds that the hospital has:

   (i) Knowingly made any verbal or written false statement of material fact either in connection with the application for the permit or on documents submitted to the Department as part of any inspection or investigation or in the falsification or alteration of hospital records made or maintained by the hospital;

   (ii) Failed or refused, without legal cause, to provide the Department with access to the premises subject to regulation or information pertinent to the initial and continued licensing of the hospital;

   (iii) Failed to comply with the licensing requirements of this state; or

   (iv) Failed to comply with the provisions of O.C.G.A. § 31-2-8 or Rules for General Licensing and Enforcement Requirements, Chapter 111-8-25.

2. Such sanctions may include any one or more of the following:

   (i) Administration of a public reprimand;

   (ii) Suspension of the permit;

   (iii) Prohibition of persons in management or control;

   (iv) Imposition of civil penalties as provided by law; and

   (v) Revocation of the permit.

(c) If the sanction hearing process results in revocation of the permit, the permit shall be returned to the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.06
Authority: O.C.G.A. §§ 31-2-8 and 31-7-1*et seq.*, and the Rules for General Licensing and Enforcement

Requirements, Chapter 111-8-25.
History. Original Rule entitled "Permit Denial and Sanctions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.07. Hospital Inspections and Required Reports to the Department.

(1) **Inspections by the Department.** The hospital shall be available during all hours of operation for observation and examination by properly identified representatives of the Department.

(a) **Initial Inspection.** There shall be an initial inspection of a hospital prior to the opening date in order to determine that the hospital is in substantial compliance with these rules. Prior to this initial inspection, the hospital shall submit to the Department:

1. A copy of the certificate of occupancy;

2. Verification of building safety and fire safety from local and state authorities; and

3. Evidence of appropriate approvals by the state architect.

(b) **Periodic Inspections.** The hospital shall be subject to periodic inspections to determine that there is continued compliance with these rules, as deemed necessary by the Department.

(c) **Random Inspections.** The hospital may be subject to additional or more frequent inspections by the Department where the Department receives a complaint alleging a ruleviolation by the hospital or the Department has reason to believe that the hospital is in violation of these rules.

(d) **Plans of Correction.** If violations of these licensing rules are identified, the hospital will be given a written report of the violation that identifies the rules violated. The hospital shall submit to the Department a written plan of correction in response to the report of violation, which states what the hospital will do, and when, to correct each of the violations identified. The hospital may offer an explanation or dispute the findings or violations in the written plan of correction, so long as an acceptable plan of correction is submitted within ten (10) days of the hospital's receipt of the written report of inspection. If the initial plan of correction is unacceptable to the department, the hospital will be provided with at least one (1) opportunity to revise the unacceptable plan of correction. The hospital shall comply with its plan of correction.

(e) **Accreditation in Place of Periodic Inspection.** The Department may accept the accreditation of a hospital by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the American Osteopathy Association

(AOA), or other approved accrediting body, in accordance with specific standards determined by the Department to be substantially equivalent to state standards, as representation that the hospital is or remains in compliance with these rules.

1. Hospitals accredited by an approved accrediting body shall present to the Department a copy of the full certification or accreditation report each time there is an inspection by the accreditation body and a copy of any reports related to the hospital's accreditation status within thirty (30) days of receipt of the final report of the inspection.

2. Hospitals accredited by an approved accrediting body are excused from periodic inspections. However, these hospitals may be subjected to random inspections by the Department for continuation of the permit when:

   (i) A validation study of the accreditation process is necessary;

   (ii) There has been a complaint alleging a rule violation which the Department determines requires investigation;

   (iii) The Department has reason to believe that there is a patient incident or situation in the hospital that presents a possible threat to the health or safety of patients; or

   (iv) There are additions to the services previously offered by the hospital which the Department determines requires an on-site visit.

(2) **Required Reports to the Department.**

(a) **Patient Incidents Requiring Report.**

1. The hospital's duly constituted peer review committee(s) shall report to the Department, as required below, whenever any of the following incidents involving hospital patients occursor the hospital has reasonable cause to believe that a reportable incident involving a hospital patient has occurred:

   (i) Any unanticipated patient death not related to the natural course of the patient's illness or underlying condition;

   (ii) Any rape which occurs in a hospital;

   (iii) Any surgery on the wrong patient or the wrong body part of the patient; and

   (iv) Effective three (3) months after the Department provides written notification to all hospitals the hospital's duly constituted peer review committee(s) shall also report to the Department, whenever

any of the following incidents involving hospital patients occurs or the hospital has reasonable cause to believe that a reportable incident involving a hospital patient has occurred:

(I) Any patient injury which is unrelated to the patient's illness or underlying condition and results in a permanent loss of limb or function;

(II) Second or third degree burns involving twenty (20) percent or more of the body surface of an adult patientor fifteen (15) percent or more of the body surface of a child which burns were acquired by the patient in the hospital;

(III) Serious injury to a patient resulting from the malfunction or intentional or accidental misuse of patient care equipment;

(IV) Discharge of an infant to the wrong family;

(V) Any time an inpatient, or a patient under observation status, cannot be located, where there are circumstances that place the health, safety, or welfare of the patient or others at risk and the patient has been missing for more than eight (8) hours;and

(VI) Any assault on a patient, which results in an injury that requires treatment.

2. The hospital's peer review committee(s) shall make the self-report of the incident within twenty-four (24) hours or by the next regular business day from when the hospital has reasonable cause to believe an incident has occurred. Theself-report shall be received by the Department in confidence and shall include at least:

(i) The name of the hospital;

(ii) The date of the incident and the date the hospital became aware that a reportable incident may have occurred;

(iii) The medical record number of any affected patient(s);

(iv) The type of reportable incident suspected, with a brief description of the incident; and

(v) Any immediate corrective or preventative action taken by the hospital to ensure against the replication of the incident prior to the completion of the hospital's investigation.

3. The hospital's peer review committee(s) shall conduct an investigation of any of the incidents listed above and complete and retain on site a written report of the results of the investigation within forty-five (45) days of the discovery of the incident. The complete report of the investigation shall be available to the Department for inspection at the facility and shall contain at least:

   (i) An explanation of the circumstances surrounding the incident, including the results of a root cause analysisor other systematic analysis;

   (ii) Any findings or conclusions associated with the review; and

   (iii) A summary of any actions taken to correct identified problems associated with the incident and to prevent recurrence of the incident and also any changes in procedures or practices resulting from the internal evaluation using the hospital's peer review and quality management processes.

4. The Department shall hold the self-report made through the hospital's peer review committee(s) concerning a reportable patient incident in confidence as a peer review document or report and not release the self-report to the public. However, where the Department determines that a rule violation related to the reported patient incident has occurred, the Department will initiate a separate complaint investigation of the incident. The Department's complaint investigation and the Department's report of any rule violation(s) arising either from the initial self-report received from the hospital or an independent source shall be public records.

(b) **Other Events/Incidents Requiring Report.**

1. The hospital shall report to the Department whenever any of the following events involving hospital operations occurs or when the hospital becomes aware it is likely to occur, to the extent that the event is expected to cause or causes a significant disruption of patient care:

   (i) A labor strike, walk-out, or sick-out;

   (ii) An external disaster or other community emergency situation; and

(iii) Aninterruption of services vital to the continued safe operation of the facility, such as telephone, electricity, gas, or water services.

2. The hospital shall make a report of the event within twenty-four (24) hours or by the next regular business day from when the reportable event occurred or from when the hospital has reasonable cause to anticipate that the event is likely to occur. The report shall include:

   (i) The name of the hospital;

   (ii) The date of the event, or the anticipated date of the event, and the anticipated duration, if known;

   (iii) The anticipated effect on patient care services, including any need for relocation of patients; and

   (iv) Any immediate plans the hospital had made regarding patient management during the event.

3. Within forty-five (45) days following the discovery of the event, the hospital shall complete an internal evaluation of the hospital's response to the event where opportunities for improvement relating to the emergency disaster preparedness plan were identified. The hospital shall make changes in the emergency disaster preparedness plan as appropriate. The complete report of the evaluation shall be available to the Department for inspection at the facility.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.07
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-2.1, 31-7-15, 31-7-133, 31-7-140 and 50-18-72.
History. Original Rule entitled "Hospital Inspections and Required Reports to the Department" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.08. Hospital Ownership.

There shall be full disclosure of hospital ownership to the Department at the time of the initial application and when requested. In the case of corporations and partnerships, the names of all corporate officers, partners, and all others owning five (5) percent or more of corporate stock or ownership shall be made known to the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.08
Authority: O.C.G.A. § 31-7-3.
History. Original Rule entitled "Hospital Ownership" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.09. Governing Body and Hospital Administration.

The hospital shall have an established and functioning governing body that is responsible for the conduct of the hospital as an institution and that provides for effective hospital governance, management, and budget planning.

(a) The governing body shall be organized under bylaws and shall be responsible for ensuring the hospital functions within the classification for which it is permitted by the Department.

(b) The governing body shall appoint members of the medical staff within a reasonable period of time after considering the recommendations of the medical staff, if any, and shall ensure the following:

1. That every inpatient is under the care of a qualified member of the medical staff;

2. That the medical staff is organized and operates under medical staff bylaws and medical staff rules and regulations, which shall become effective when approved by the governing body; and

3. That the medical staff is responsible to the governing body for the quality of all medical care provided to patients in the hospital and for the ethical and professional practices of its members while exercising their hospital privileges.

(c) If the hospital does not provide emergency services as an organized service, the governing body shall ensure that the hospital has written policies and procedures approved by the medical staff for the appraisal of emergencies, the initial treatment of emergencies, and the referral for emergency patients as appropriate.

(d) The governing body shall identify an administrator or chief executive officer who is responsible for the overall management of the hospital. The administrator or chief executive officer shall:

1. Ensure that there are effective mechanisms in the hospital's organization to facilitate communication between the governing body, the medical staff, the nursing staff, and other departments of the hospital;

2. Ensure that patients receive the same quality of care throughout the hospital; and

3. Be responsible for reporting to the appropriate licensing board any member of the medical staff whose privileges at the hospital have been denied, restricted, or revoked, or who has resigned from practice at the hospital, to the extent required by state law.

(e) The hospital shall advise the Department immediately and in writing of a change in the designation of the administrator or chief executive officer.

(f) The governing body shall ensure that the hospital is staffed and equipped adequately to provide the services it offers to patients, whether the services are provided within the facility or under contract. All organized services providing patient care shall be under the supervision of qualified practitioners.

(g) The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to the hospital.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.09
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Governing Body and Hospital Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.10. Hospital-Patient Communications.

The hospital shall develop, implement, and enforce policies and procedures to ensure that each patient is:

(a) Informed about the hospital's grievance process, including whom to contact to file a grievance or complaint with the hospital and that individual's telephone number, and the name, address, and telephone number of the state regulatory agency;

(b) Provided an opportunity to give informed consent, or have the patient's legally authorized representative give informed consent, as required by state law, with documentation of provision of such opportunity in the patient's medical record;

(c) Afforded the right to refuse medical and surgical treatment to the extent permitted by law;

(d) Have advance directives honored in accordance with the law and afforded the opportunity to issue advance directives if admitted on inpatient status;

(e) Provided, upon request, a written summary of hospital charge rates, per service, sufficient and timely enough to allow the patient to compare charges and make cost-effective decisions in the purchase of hospital services;

(f) Provided an itemized statement of all charges for which the patient or third-party payer is being billed; and

(g) Provided communication of information in a method that is effective for the recipient, whether the recipient is the patient or the patient's designated representative. If the hospital cannot provide communications in a method that is effective for the recipient, attempts to provide such shall be documented in the patient's medical record.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.10
Authority: O.C.G.A. §§ 10-1-393, 31-7-2.1, 31-7-11, 31-9-2, 31-9-7, 31-11-82, 31-32-1*et seq.*, 31-33-2, 31-33-3.

History. Original Rule entitled "Hospital-Patient Communications" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.11. Medical Staff.

Each hospital shall have an organized medical staff that operates under bylaws adopted by the medical staff and approved by the governing body. The bylaws may provide for the exercise of the medical staff's authority through committees.

(a) **Organization of the Medical Staff.** The medical staff shall be organized and may operate through defined committees as appropriate.

1. Any physician, podiatrist, or dentist providing patient care, whether directly or by contract with the hospital, shall obtain clinical privileges through the hospital's medical staff credentialing process.

2. The medical staff shall be responsible for the examination of credentials of any candidate for medical staff membership and for any other individuals seeking clinical privileges and for the recommendations to the governing body concerning appointment of such candidates. Minimum requirements for medical staff appointments and clinical privileges shall include:

   (i) Valid and current Georgia license to practice the respective profession;

   (ii) Confirmed educational qualifications for the position of appointment;

   (iii) References for practice and performance background;

   (iv) Current health and mental status sufficient to perform medical and professional duties;

   (v) Current Drug Enforcement Agency registration; if applicable;

   (vi) Evidence of inquiry through relevant practitioner databases, such as databases maintained by licensing boards and the National Practitioner Data Bank; and

   (vii) Congruity of the qualifications and/or training requirements with the privilege requested.

3. The medical staff shall evaluate at least biennially the credentials and professional performance of any individual granted clinical privileges for consideration for reappointment.

4. The medical staff shall establish a system for the approval of temporary or emergency staff privileges when needed.

(b) **Medical Staff Accountability.** The medical staff shall be accountable to the governing body for the quality of medical care provided to all patients.

1. The medical staff shall require that all individuals granted clinical privileges comply with generally accepted standards of practice.

2. The medical staff shall implement measures, including peer review, to monitor the on-going performance of the delivery of patient care by those granted clinical privileges, including monitoring of compliance with the medical staff bylaws, rules and regulations, and hospital policies and procedures.

3. The medical staff shall establish effective systems of accountability for any hospital services ordered by physicians and other practitioners.

4. The medical staff shall review and, when appropriate, recommend to the governing body denial, limitation, suspension, or revocation of the privileges of any practitioner who does not practice in compliance with the scope of privileges, the medical staff bylaws, rules and regulations, generally accepted standards of practice, or hospital policies and procedures.

(c) **Medical Staff Bylaws and Rules and Regulations.** The medical staff of the hospital shall adopt and enforce bylaws and rules and regulations which provide for the self-governance of medical staff activities and accountability to the governing body for the quality of care provided to all patients. The bylaws and rules and regulations shall become effective when approved by the governing body and shall include at a minimum:

1. A mechanism for participation of medical staff in policy decisions related to patient care in all areas of the hospital;

2. A plan for administrative organization of the medical staff and committees thereof, which clearly delineates lines of authority, delegation, and responsibility for various tasks and functions;

3. Description of the qualifications and performance to be met by a candidate in order for the medical staff to recommend appointment or reappointment by the governing body;

4. Criteria and procedures for recommending the privileges to be granted to individual physicians, dentists, or podiatrists;

5. A requirement that members of the medical staff comply with ethical and professional standards;

6. Requirements for regular health screenings for all active members of the medical staff that are developed in consultation with hospital administration, occupational health, and infection control/ safety staff. The health screenings shall be sufficient to identify conditions which may place patients or other personnel at risk for

infection, injury, or improper care. There shall be a mechanism for the reporting of the screening results to the hospital, either through the medical staff or otherwise;

7. A mechanism for ensuring physician response to inpatient emergencies twenty-four (24) hours per day;

8. A mechanism for physician coverage of the emergency department and designation of who is qualified to conduct an emergency medical screening examination where emergency services are provided;

9. A requirement that referral for consultations will be provided to patients when a patient's physical or mental condition exceeds the clinical expertise of the attending member of the medical staff;

10. The requirements for the patient's history and physical examination, which must be performed either within twenty-four (24) hours after admission or within the thirty (30) days prior to admission and updated upon admission. See Rule 111-8-40-.28(a)(2) for history and physical requirements when surgery is being performed;

11. Establishment of procedures for the choice and control of all drugs in the hospital;

12. The requirements for the completion of medical records;

13. The requirements for verbal/telephone orders, to include which Georgia-licensed or Georgia-certified personnel or other qualified individuals may receive verbal/telephone orders, and the acceptable timeline for authentication of the orders, not to exceed the timeline requirements of these rules;

14. A mechanism for peer review of the quality of patient care, which includes, but is not limited to, the investigation of reportable patient incidents involving patient care as described in Rule 111-8-40-.07(2)(a); and

15. A procedure for review and/or update of the bylaws and rules and regulations as necessary, but at least once every three (3) years.

(d) **Other Medical Staff Policies.** If not addressed through the medical staff bylaws or rules and regulations, the medical staff shall develop and implement policies to address, at a minimum:

1. Criteria for when an autopsy shall be sought and a requirement that the attending physician be notified when an autopsy is performed; and

2. A requirement that every member of the medical staff provide appropriate medical care for each of their patients until the patient is stable for discharge or until care of

the patient has been transferred to another member of the medical staff or to another facility.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.11
Authority: O.C.G.A. §§ 31-7-2.1 and 31-7-15.
History. Original Rule entitled "Medical Staff" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.12. Human Resources Management.

The hospital shall select and organize sufficient qualified and competent personnel to meet patients' needs and in a manner appropriate to the scope and complexity of the services offered.

(a) The hospital shall establish and implement human resources policies and procedures to include at least:

1. Procedures for selecting qualified personnel;
2. A system for documenting the current licensure and/or certification status for those personnel whose positions or functions require such licensure or certification;
3. A system for assessing competency of all personnel providing health care services, on a time schedule defined by hospital policy; and
4. Policies and procedures regarding the hospital-approved method for identification of personnel to patients, other staff, and visitors.

(b) **Written Job Descriptions.** The hospital shall have a written description of responsibilities and job duties, with qualification requirements, for each position or job title at the hospital.

(c) **Health Screenings.** The hospital shall have in place a mechanism and requirement for initial, regular, and targeted health screenings of personnel who are employed or under contract with the hospital or providing patient care services within the hospital setting. The screening shall be sufficient in scope to identify conditions that may place patients or other personnel at risk for infection, injury, or improper care. The health-screening program shall be developed in consultation with hospital administration, medical staff, occupational health, and infection control/safety staff.

(d) **Personnel Training Programs.** The hospital shall have and implement a planned program of training for personnel to include at least:

1. Hospital policies and procedures;
2. Fire safety, hazardous materials handling and disposal, and disaster preparedness;

3. Policies and procedures for maintaining patients' medical records;

4. The infection control program and procedures; and

5. The updating of job-specific skills or knowledge.

(e) Personnel records shall be maintained for each employee of the hospital and shall contain, at a minimum:

1. The employment application or resume;

2. Dates of hire and position changes since hiring;

3. The job or position description(s) for the employee;

4. All evaluations of performance or competencies for the employee since the date of hire or at least the last five (5) years;

5. Credible evidence of current registration, licensure, or certification as required for that position by state law;

6. Evidence of completion of in-service training as required by hospital policy; and

7. Evidence of completion of any requirements of the occupational health program at the hospital.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.12
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Human Resources Management" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.13. Quality Management.

The governing body shall establish and approve a plan for a hospital-wide quality management program, which includes the use of peer review committees. The purpose of the quality management program is to measure, evaluate, and improve the provision of patient care.

(a) The scope and organization of the quality management program shall be defined and shall include all patient services and clinical support services, contracted services, and patient care services provided by the medical staff.

(b) The hospital's quality management program shall be designed to systematically collect and assess performance data, prioritize data, and take appropriate action on important processes or outcomes related to patient care, including but not limited to:

1. Operative procedures and other invasive and non-invasive procedures that place patients at risk;

2. Nosocomial infection rates;

3. Patient mortality;

4. Medication use;

5. Patient injuries, such as, but not limited to, those related to falls and restraint use;

6. Errors in procedures or practices which could compromise patient safety ("near-miss" events);

7. Discrepancies or patterns of discrepancies between preoperative and postoperative diagnosis, including those identified during the pathologic review of specimens removed during surgical or invasive procedures;

8. Significant adverse drug reactions (as identified by the hospital);

9. Adverse events or patterns of adverse events during anesthesia;

10. Equipment malfunctions, for equipment used for patient care; and

11. Reportable patient incidents as required under Rule 111-8-40-.07.

(c) The quality management program shall utilize a defined methodology for implementation, including at least mechanisms and methodology for:

1. Performance measurement including consideration of scope of services;

2. Monitoring, evaluating, and assessing accountability;

3. Setting priorities;

4. Root cause analyses, as appropriate, of problems identified;

5. Process improvement;

6. Identification of expected outcomes;

7. Reporting mechanisms; and

8. Authority for problem resolution.

(d) Results or findings from quality management activities shall be disseminated to the governing body, the medical staff, and any services impacted by the results.

(e) The hospital shall take and document action to address opportunities for improvement identified through the quality management program.

(f) There shall be an on-going evaluation of the quality management program to determine its effectiveness, which shall be presented at least annually for review and appropriate action to the medical staff and governing body.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.13
Authority: O.C.G.A. §§ 31-7-2.1 and 31-7-15.
History. Original Rule entitled "Quality Management" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.14. Physical Environment.

The hospital shall be equipped and maintained to provide a clean and safe environment for patients, employees, and visitors.

(a) **Safety.** The hospital shall develop and implement an effective hospital-wide safety program that includes the following components:

1. A fire safety program including compliance with the applicable provisions of the *Life Safety Code* (NFPA 101), as enforced by the state fire marshal;

2. An incident monitoring system that promptly identifies, investigates, and takes effective action regarding all incidents that involve injury to patients, employees, or visitors or that involve significant damage to property;

3. A program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators;

4. A program for the monitoring and maintenance of electrical safety;

5. Security procedures for controlling access to sensitive areas, as defined by the hospital, for patients, employees, and visitors;

6. Procedures for the safe management of medical gases;

7. A system for patients or staff to summon assistance, when needed, from patient rooms, bathrooms, and treatment areas;

8. Policies regarding smoking which apply to employees, patients, and visitors; and

9. Procedures for storage and disposal of biohazardous medical waste in accordance with applicable laws.

(b) **Cleanliness and Sanitation.** The hospital shall maintain an environment that is clean and in good repair, through a program that establishes and maintains:

1. Standardized daily, interim, and terminal cleaning routines for all areas;

2. Facilities for convenient and effective hand washing throughout the hospital;

3. Systems for management of linens, including collection, sorting, transport, and washing of soiled linens, and storage and distribution of clean linens;

   (i) Collection and sorting procedures shall be designed to prevent contamination of the environment and personnel. Collection procedures shall include bagging of soiled linen at site of use. Sorting and rinsing of soiled linens shall not take place in patient care areas;

   (ii) Clean and soiled linens shall be transported in separate containers or carts;

   (iii) The laundering process for soiled linens shall be sufficient to remove organic soil and render the linen incapable of causing human illness; and

   (iv) Any soiled linen processing area shall be separate from the area used for clean linen storage, from patient care areas, and from areas where clean or sterilized supplies and equipment are stored;

4. Standards regarding the use of hospital disinfectants;

5. Systems for the storage and disposal of garbage, trash, and waste in a manner that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents; and

6. Procedures for the prevention of infestation by insects, rodents, or other vermin or vectors.

(c) **Light, Temperature, and Ventilation.** The hospital shall provide adequate lighting, ventilation, and control of temperature and air humidity for optimal patient care and safety of the hospital's patients and staff and shall monitor and maintain such systems to function at least minimally to the design standards current at the time of approved facility construction or renovation.

(d) **Space.** The hospital shall provide sufficient space and equipment for the scope and complexity of services offered.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.14
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Physical Environment" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.15. Disaster Preparedness.

The hospital shall prepare for potential emergency situations that may affect patient care by the development of an effective disaster preparedness plan that identifies emergency situations and outlines an appropriate course of action. The plan must be reviewed and revised annually, as appropriate, including any related written agreements.

(a) The disaster preparedness plan shall include at a minimum plans for the following emergency situations:

1. Local and widespread weather emergencies or natural disasters, such as tornadoes, hurricanes, earthquakes, ice or snowstorms, or floods;
2. Manmade disasters such as acts of terrorism and hazardous materials spills;
3. Unanticipated interruption of service of utilities, including water, gas, or electricity, either within the facility or within a local or widespread area;
4. Loss of heat or air conditioning;
5. Fire, explosion, or other physical damage to the hospital; and
6. Pandemics or other situations where the community's need for services exceeds the availability of beds and services regularly offered by the hospital.

(b) There shall be plans to ensure sufficient staffing and supplies to maintain safe patient care during the emergency situation.

(c) There shall be plans for the emergency transport or relocation of all or a portion of the hospital patients, should it be necessary, in vehicles appropriate to the patient's condition(s) when possible, including written agreements with any facilities which have agreed to receive the hospital's patients in these situations.

(d) The hospital shall document participation of all areas of the hospital in quarterly fire drills.

(e) In addition to fire drills, the hospital shall have its staff rehearse portions of the disaster preparedness plan, with a minimum of two (2) rehearsals each calendar year either in response to an emergency or through planned drills, with coordination of the drills with the local Emergency Management Agency (EMA) whenever possible.

(f) The plan shall include the notification to the Department of the emergency situation as required by these rules.

(g) The hospital shall provide a copy of the internal disaster preparedness plan to the local Emergency Management Agency (EMA) and shall include the local EMA in development of the hospital's plan for the management of external disasters.

(h) The hospital's disaster preparedness plan shall be made available to the Department for inspection upon request.

(i) The Department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared a public health emergency.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.15
Authority: O.C.G.A. §§ 31-7-2.1, 31-7-3 and 31-12-2.1.
History. Original Rule entitled "Disaster Preparedness" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.16. Infection Control.

The hospital shall have an effective infection control system to reduce the risks of nosocomial infections in patients, health care workers, volunteers, and visitors.

(a) The hospital shall designate qualified infection control staff to coordinate the infection control program.

(b) The administrative and medical staff of the hospital, as well as staff from appropriate organized services, shall participate in the infection control program.

(c) The infection control program shall function from a well-designed surveillance plan that is based on accepted epidemiological principles, is tailored to meet the needs of the hospital, and includes both outcome and process surveillance methodologies.

(d) The surveillance plan shall require collection of sufficient baseline data on the incidence of nosocomial infections in order that outbreaks can be identified.

(e) The infection control methodologies for effective investigation and control of outbreaks, once identified, shall include at least:

1. The availability of microbiology laboratory capacity to detect and investigate outbreaks;

2. A system for obtaining appropriate clinical specimens for culture;

3. Access to necessary information in order to investigate infectious outbreaks; and

4. Administrative, physician, and nursing support to direct hospital changes to achieve immediate control of outbreaks and for implementation of corrective actions.

(f) The program shall specify policies and procedures for infection control that apply to all areas of the hospital, and these shall include at least the following:

1. The approved hospital isolation system;

2. The approved procedures for handling and disposing of hazardous waste products;

3. The standards for approved cleaning, disinfection, and sterilization of all areas of the hospital;

4. The standards for hand washing and hand antisepsis; and

5. A communicable disease health-screening plan for the hospital that includes required communicable disease activities, immunizations, exposure evaluations, tuberculosis surveillance, and work restrictions. There shall be evidence that the plan was developed in consultation with hospital administration, medical staff, and safety staff.

(g) The infection control program shall have an organized and effective on-going education plan for hospital health care workers and volunteers that includes at least:

1. An orientation plan;

2. A plan for on-going training on isolation precautions, aseptic practices, and prevention of blood and body fluid exposure; and

3. Provision of specially designed training programs that result from outcome and process surveillance data.

(h) The hospital shall designate which departments are responsible for the reporting of communicable diseases as required by law.

(i) The infection control program shall be evaluated at least annually to determine the effectiveness of the program at lowering the risks and improving the trends of nosocomial infections in patients, health care workers, and volunteers. Changes in the infection control program shall reflect consideration of the results of the evaluations.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.16
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Infection Control" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.17. Sterile Processing Services.

Each hospital shall designate a sterile processing service area designated for the decontamination, cleaning, sterilizing of reusable equipment, instruments, and supplies.

(a) With the collaboration of the infection control program, the staff providing sterile processing services shall develop and implement standardized policies and procedures that conform to generally accepted standards of practice for:

1. Decontamination and cleaning of instruments and other items and description of reprocessing protocols for contaminated patient equipment;

2. Disinfecting and/or sterilizing equipment and other items;

3. Monitoring of the systems used for sterilization;

4. Procedures for ensuring the sterility of packaged instruments and supplies;

5. Recall of items; and

6. Mechanisms for protection of workers from exposure to blood and other potentially infectious materials and environmental hazards.

(b) The sterile processing service shall be staffed by qualified personnel.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.17
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Sterile Processing Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.18. Medical Records.

(1) **Management of Patients' Medical Records.** The hospital shall have an efficient and organized medical records service that establishes the policies and procedures for the maintenance of the medical records for all patients and that is administratively responsible for the management of those records.

(a) The medical records service shall maintain a list of accepted abbreviations, symbols, and medical terminology to be utilized by persons making entries into patients' medical records.

(b) The medical records service shall utilize systems to verify the author(s) of entries in the patients' medical records. Delegation of use of computer codes, signature stamps, or other authentication systems, to persons other than the author of the entry, is prohibited.

(c) The hospital shall utilize systems defined by hospital policies and procedures to ensure that patients' medical records are kept confidential. Medical records shall be accessible only to hospital and medical staff involved in treating the patient and to other individuals as permitted by federal and state laws. The Department, in exercising its licensing authority, shall have the right to review and copy any patients' medical records.

(d) At any time during or after their course of treatment, patients shall be provided with copies of their medical records upon their written requests or the written requests of their authorized representatives in accordance with state law. Copies shall be provided within a reasonable time period not to exceed thirty (30) days after the request, unless the patient agrees to a lengthier delivery time. Copies of records shall be provided to patients for a reasonable fee in accordance with applicable laws.

(e) Copies of the patient's medical records shall be released to persons other than the patient or the patient's legally authorized representative either at the written request of the patient or as otherwise allowed by law. If the individual designated to receive a copy of the record is a health care provider, the copy of the record shall be released by the hospital in a timely manner so as not to interfere with the continuation of the patient's treatment.

(f) Patients' medical records shall be coded and indexed in a manner that allows for timely retrieval by diagnosis or procedure when necessary.

(g) The hospital shall utilize an effective process to ensure that patients' medical records are completed within thirty (30) days after the patients are discharged from the hospital. Records of other parts of patients' records that are not within the control of the hospital or its medical staff shall be added to the patients' records as soon as they become available to the hospital.

(h) The hospital shall retain all patients' medical records at least until the fifth anniversary of the patients' discharges. If the patient is a minor, the records must be retained for at least five (5) years past the age of majority. Records may be preserved in the hospital's format of choice, including but not limited to paper or electronic format, so long as the records are readable and capable of being reproduced in paper format upon request.

(i) Medical records shall be secured in such a manner as to provide protection from damage or unauthorized access.

(2) **Entries in the Medical Record.** All entries in the patient's medical records shall be accurate and legible and shall contain sufficient information to support the diagnosis and to describe the treatment provided and the patient's progress and response to medications and treatments. Inpatient records shall also contain sufficient information to justify admission and continued hospitalization.

(a) The date of the entry and the signature of the person making the entry, shall accompany all entries in the patient's medical record. Late entries shall be labeled as late entries.

(b) The hospital, through its medical staff policies, shall appropriately limit the use of verbal/telephone orders. Verbal/telephone orders shall be used only in situations

where immediate written or electronic communication is not feasible and the patient's condition is determined to warrant immediate action for the benefit of the patient. Verbal/telephone orders shall be received by an appropriately license or otherwise qualified individual as determined by the medical staff in accordance with state law.

(c) The individual receiving the verbal/telephone order shall immediately enter the order into the medical record, sign and date the order, with the time noted, and, where applicable, enter the dose to be administered.

(d) The individual receiving the order shall immediately repeat the order and the prescribing physician or other authorized practitioner shall verify that the repeated order is correct. The individual receiving the order shall document, in the patient's medical record, that the order was "repeated and verified."

(e) The verbal/telephone order shall be authenticated by the physician or other authorized practitioner giving the order, or by a physician or other authorized practitioner taking responsibility for the order, in accordance with hospital and medical staff policies.

1. Where the procedures outlined in subparagraph (2)(d) of this rule are followed, the hospital shall require authentication of all verbal/telephone orders no later than thirty (30) days after the patient's discharge.

2. As an alternative to meeting the requirements set forth in subparagraph (2)(d) of this rule, the hospital shall require that verbal/ telephone orders be authenticated within forty-eight (48) hours, except where the patient is discharged within forty-eight (48) hours of the time the verbal/telephone order was given, in which case authentication shall occur within thirty (30) days after the patient's discharge.

(f) The hospital's quality improvement plan shall include monitoring of the appropriate use of verbal/telephone orders in accordance with these rules and hospital policy and taking appropriate corrective action as necessary.

(3) **Minimum Requirements for Patients' Medical Records.** Upon completion, medical records for inpatients and outpatients shall contain, at minimum, the documents as specified below. Records for patients at the hospital for other specialized services, such as emergency services or surgical services, shall contain such additional documentation as required for those services.

(a) **Inpatient Records.** Medical records for inpatients shall contain at least the following:

1. A unique identifying number and a patient identification form, which includes the following when available: name, address, date of birth, sex, and person to be notified in an emergency;

2. The date and time of the patient's admission;

3. The admitting diagnosis and clinical symptoms;

4. The name of the attending physician;

5. Any patient allergies;

6. Documentation regarding advanced directives;

7. The report from the history and physical examination;

8. The report of the nursing assessment performed after admission;

9. Laboratory, radiological, electrocardiogram, and other diagnostic assessment data or reports as indicated;

10. Reports from any consultations;

11. The patient's plan of care;

12. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders;

13. Progress notes from staff members involved in the patient's care, which describe the patient's response to medications, treatment, procedures, anesthesia, and surgeries;

14. Data, or summary data where appropriate, from routine or special monitoring;

15. Medication, anesthesia, surgical, and treatment records;

16. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required by law;

17. Date and time of discharge;

18. Description of condition, final diagnosis, and disposition on discharge or transfer;

19. Discharge summary with a summary of the hospitalization and results of treatment; and

20. If applicable, the report of autopsy results.

(b) **Outpatient Records.** Medical reports for outpatients shall contain at least the following:

1. A unique identifying number and a patient identification form, which includes the following if available: name, address, date of birth, sex, and person to be notified in an emergency;

2. Diagnosis of the patient's condition;

3. The name of the physician ordering treatment or procedures;

4. Patient allergies;

5. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders as applicable;

6. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required by law;

7. Reports from any diagnostic testing; and

8. Sufficient information to justify any treatment or procedure provided, report of outcomes of treatment or procedures, and, as appropriate, progress notes and the disposition of the patient after treatment.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.18
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Medical Records" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.19. Patient Assessment and Treatment.

All patient care services provided by the hospital shall be under the direction of a member of the medical staff or a licensed physician, dentist, osteopath, or podiatrist who has been granted hospital privileges.

(a) **Patient Assessment/Screening on Admission.** The hospital shall provide each inpatient with an appropriate assessment of the patient's condition and needs at the time of admission. Such assessments shall be provided by personnel authorized by hospital policy

or the medical staff bylaws and/or rules and regulations and shall be designed to trigger referral for further assessment needs.

1. A history and physical examination shall be completed within the first twenty-four (24) hours after admission. A history and physical examination completed by either the patient's physician or the appropriate practitioner operating under the direction of the physician as authorized by law no more than thirty (30) days prior to the admission may be accepted but must be updated to reflect the patient's condition at the time of admission. Where the patient is admitted solely for oromaxillofacial surgery, such history and physical may be completed by the oromaxillofacial surgeon.

2. A basic nursing assessment to include at least evaluation of physical and psychological status sufficient to develop an initial plan of care shall be completed within the first twelve (12) hours after admission. Within twenty-four (24) hours after admission, a comprehensive nursing assessment will be completed to include at least:

   (i) Screening and referral for further assessment of patient needs related to social, nutritional, and functional status; and

   (ii) Screening of educational and potential post-hospitalization needs.

3. Inquiry as to the status of any advance directives for the patient shall be made at the time of admission.

   (i) If a patient has an advance directive in place that the patient wishes to invoke, but the written directive is not available at the time of admission, there shall be a mechanism in place to trigger a recheck by hospital personnel for the document within a reasonable period of time.

   (ii) If the patient does not have an advance directive in place, admissions procedures shall require that designated hospital personnel will offer information regarding advance directives according to hospital policy and timelines.

(b) **Patient's Plan of Care.**

1. On admission, the plan of care shall be initiated by the designated hospital staff for each patient to meet the needs identified by the initial assessments. The initial plan of care shall be placed in the patient's record within twelve (12) hours of admission.

2. As the patient's treatment progresses, the plan of care shall be updated to reflect any changes necessary to address new or changing needs.

(c) **Reassessments of the Patient's Condition.** Reassessment of the patient's condition shall be performed periodically at appropriate intervals and defined in hospital policy. In addition, reassessments shall occur at least as follows:

1. During and following an invasive procedure;
2. Following a change in the patient's condition or leve l of care;
3. During and following the administration of blood and blood products;
4. Following any adverse drug reaction or allergic reaction; and
5. During and following any use of physical restraints or seclusion.

(d) **Other Treatment Requirements.**

1. All patients shall be given the opportunity to participate, or have a designated representative participate, in decisions regarding their care.
2. Patients shall be provided treatment free from physical restraints or involuntary seclusion, unless utilized solely for protection during brief transport to a specified destination or authorized by a physician's order, for a limited period of time, to protect the patient or others from injury. Policies and procedures shall be in place to require that a patient's physical comfort and safety needs are addressed during any period of required physical restraint or confinement. A positioning or securing device used to maintain the position, limit mobility, or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint.
3. Patients shall receive care in a manner free from all forms of abuse or neglect.
4. Patients shall receive treatment in an environment that respects their personal privacy, both of their physical person and their treatment information.
5. The hospital shall establish and enforce policies and procedures that require that all personnel providing direct care to the patient identify themselves to the patient by name and title or function.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.19
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Patient Assessment and Treatment" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.20. Discharge Planning and Transfers for Inpatients.

The hospital shall utilize an effective and on-going discharge planning process that identifies post-hospital needs of inpatients and arranges for appropriate resource referral and follow-up care.

(a) On admission, the nursing assessment shall identify patients who are likely to suffer adverse consequences upon discharge in the absence of adequate discharge planning.

(b) For those patients identified as needing a discharge plan, designated qualified staff shall complete an evaluation of post-hospital needs and shall develop a plan for meeting those needs. The discharge plan shall be revised as needed with changes in the patient's condition.

(c) The hospital shall provide education to patients, and their family members or interested persons as necessary or as requested by the patient, to prepare them for the patient's post-hospital care.

(d) The hospital shall arrange for the initial implementation of any discharge plan, including, as applicable, any transfer or referral of the patient to appropriate facilities, agencies, or outpatient services for follow-up or ancillary care. The hospital shall be responsible for the transfer of any necessary medical information to other facilities for the purpose of post-hospital care.

(e) The hospital shall regularly reassess the discharge planning process to ensure that it is responsive to patients' discharge needs.

(f) The hospital shall adopt and enforce a policy requiring annually during influenza season (inclusive of at least October 1st through March 1st) and prior to discharge, any inpatient 65 years of age or older shall be offered vaccinations for the influenza virus and pneumococcal disease unless contraindicated and contingent on availability.

1. The hospital policy may authorize such vaccinations to be administered per hospital medical staff approved standing order and protocol following an assessment for contraindications.

2. The hospital policy must also require the inpatient's medical record, where such vaccination is administered, to contain an assessment for contraindications, the date of such administration and patient response.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.20
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Discharge Planning and Transfers for Inpatients" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.21. Nursing Services.

The hospital shall have an organized nursing service that provides twenty-four (24) hour nursing care to meet the needs of patients. Critical access hospitals are exempted from providing on-site twenty-four (24) hour nursing care when there are no hospitalized patients.

(a) **Organization of Nursing Services.** The hospital's nursing services shall be directed by a licensed registered nurse who shall be responsible for implementing a system for supervision and evaluation of nursing clinical activities.

1. The chief nurse executive shall establish and implement policies and procedures for nursing services based on generally accepted standards of practice including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

2. The chief nurse executive shall be responsible for ensuring that nursing personnel are oriented to nursing policies and procedures.

3. Nursing services shall have and follow a written plan for organization, administrative authority, delineation of responsibilities for patient care, and staff qualifications and competencies.

   (i) The nursing service plan shall include the types and numbers of nursing personnel necessary to provide appropriate nursing care for each patient in the hospital.

   (ii) Specialty areas shall specify nursing requirements for their areas that also define any special nursing competency requirements, staffing patterns based on patient acuity, and the required ratio of nurses to technical staff.

   (iii) A system of patient assignment shall be defined which reflects a consideration of patient needs and nursing staff qualifications and competencies.

(b) **Delivery of Nursing Services.** Nursing services must be delivered in accordance with patients' needs and generally accepted standards of practice.

1. A license registered nurse must be on duty at all times to provide or supervise the provision of care. Critical access hospitals are permitted some flexibility in meeting this requirement as set forth in Rule 111-8-40-.38.

2. Within the first twelve (12) hours after admission, a basic nursing assessment shall be completed for each patient and a plan of care initiated.

3. The patient's condition shall be monitored by nursing staff on a schedule appropriate to the patient's needs.

4. Nursing staff shall be responsible for updating the patient's plan of care based on any changes in the patient's condition.

5. Nursing staff administering drugs and biologicals shall act in accordance with the orders from the medical staff responsible for the patient's care, generally accepted standards of practice, and any federal and state laws pertaining to medication administration.

6. Nursing staff shall report medication administration errors and adverse drug reactions in accordance with established hospital policies.

7. Blood transfusions and other blood products shall be administered by licensed nursing staff or other qualified practitioners as authorized by law in accordance with established hospital policies, which shall include, at a minimum, the following:

   (i) Obtaining and documenting appropriate patient consent to treatment and procedures, as required;

   (ii) Responding to and reporting of transfusion reactions;

   (iii) Monitoring patients appropriately; and

   (iv) Designating personnel qualified to perform these procedures.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.21
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Nursing Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.22. Pharmaceutical Services.

The hospital shall provide or have access to effective pharmaceutical services to meet the needs of its patients in accordance with generally accepted standards of practice and applicable laws and regulations.

(a) **Pharmacy Director.** All pharmaceutical services in the hospital shall be under the direction of a pharmacist licensed in Georgia. The responsibilities of the director of pharmaceutical services shall include:

   1. Developing, supervising, and coordinating all activities of the pharmaceutical service to be in compliance with state rules and regulations for hospital pharmacies including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program; and

   2. Developing and implementing an effective system that does the following:

(i) Minimizes drug errors and identifies potential drug interactions and adverse drug reactions;

(ii) Controls the availability and storage of drugs throughout the hospital;

(iii) Distributes and administers the drugs in compliance with generally accepted standards of practice;

(iv) Tracks the receipt and disposition of all scheduled drugs;

(v) Staffs pharmaceutical services to provide sufficient qualified personnel to respond to the pharmaceutical needs of the patient population being served, including twenty-four (24) hours per day, seven (7) days per week emergency coverage;

(vi) Labels and dispenses drugs, including a requirement that only licensed pharmacists or properly supervised licensed pharmacy interns are permitted to compound, label, and dispense drugs or biologicals;

(vii) Manages drug recalls;

(viii) Addresses the removal of drugs when a pharmacist is not available;

(ix) Compiles and reports data related to drug ordering; dispensing and administration errors, and possible adverse drug reaction to the hospital's quality management program; and

(x) Reviews all activities and functions of the hospital's pharmaceutical services.

(b) **Management of Drugs.** The pharmacist shall be responsible for the management of drugs within the hospital.

1. The hospital's pharmaceutical services shall access, compile, and make available to medical and professional staff information relating to drug or food interactions, drug therapy, side effects, toxicology, dosage indicators, and routes of administration.

2. Loss and theft of controlled substances shall be reported to the pharmacy director, to the hospital administration, and to others as required by applicable laws and regulations.

3. All drugs and pharmaceuticals shall be stored in an area or on a cart which shall be locked when unattended to prevent access by unauthorized individuals.

4. Outdated, mislabeled, or otherwise unusable drugs and pharmaceuticals shall not be available for patient use.

5. Certain drugs and pharmaceuticals not specifically prescribed as to limitation of time or number of doses shall be automatically discontinued after a specified time pursuant to guidelines developed by the medical staff in conjunction with the pharmacy director.

6. Drug administration errors, adverse drug reactions, and drug incompatibilities shall be immediately reported in a timely manner to the attending physician and the pharmacist.

7. Drugs brought into the hospital by a patient may be administered to the patient only if the medications can be accurately identified, properly stored and secured, and ordered by the attending physician for the patient's hospitalization. If the drugs cannot be administered to the patient, the drugs shall be returned to an adult member of the patient's immediate family or returned to the patient upon discharge unless otherwise prohibited by law.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.22
Authority: O.C.G.A. §§ 16-4-77, 16-13-20*et seq.* and 31-7-2.1.
History. Original Rule entitled "Pharmaceutical Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.23. Food and Dietary Services.

The hospital shall have an organized food and dietary service that is directed and staffed by an adequate number of qualified personnel to meet the nutritional needs of hospital patients. All hospital food service areas and operations shall comply with current federal and state laws and rules concerning food service.

(a) **Organization of Food and Dietary Services.**

1. **Food Service Manager.** The hospital shall have a manager of food and dietary services who has training and experience in management of a food service system in a health care setting and receives on-going training. The responsibilities of the manager shall include:

   (i) Overall coordination and integration of the therapeutic and administrative aspects of the service;

   (ii) Development and implementation of policies and procedures concerning the scope and conduct of dietary services, including food preparation and delivery systems;

(iii) Orientation and training programs for dietary service personnel and other hospital personnel involved in food delivery on all applicable dietary services policies and procedures, including personal hygiene, safety, infection control requirements, and proper methods of waste disposal;

(iv) The implementation of a system to ensure that prescribed diets are delivered to the correct inpatients;

(v) Maintenance of a staff of sufficient numbers of administrative and technical personnel competent in their assigned duties to carry out the dietary service program;

(vi) Procurement of food, paper, chemical, and other supplies sufficient to meet the anticipated food service needs of the hospital; and

(vii) Implementation of procedures to rotate all food items to ensure use in a timely manner.

2. **Dietitian.** Clinical supervision of the hospital's dietary service shall be provided by a dietitian on a full-time, part-time, or consultant basis, as determined by the needs of the hospital. If supervision by the dietitian is provided by a contractual arrangement or on a consultation basis, such services shall occur at least once per month for not less than eight hours. The dietitian shall be responsible for:

(i) Evaluation of inpatients' nutritional status and needs. If the admission screening identifies that an inpatient may be nutritionally at risk, the follow-up evaluation by the dietitian must be performed within twenty-four (24) hours of determination of the need for evaluation of the patient;

(ii) Review and approval of all menus, including menus for therapeutic or prescribed diets;

(iii) Participation in the development, revision, and review of policies and procedures for dietary services;

(iv) Guidance to the manager of dietary services and to the staff of the service on methods for maintaining nutritionally balanced meals that meet the needs of each patient and in maintaining sanitary dietary practices; and

(v) Appropriate documentation in the inpatients' medical records of any evaluation of nutritional status or needs.

(b) **Physical Environment Requirements for Food Service Areas.** The hospital shall provide adequate space, equipment, and supplies for efficient, safe, and sanitary receiving, storage, refrigeration, preparation, and service of food. The physical

environments for food service activities must meet the requirements of state regulations for food service.

(c) **Delivery of Dietary Services.** Dietary services shall be delivered in accordance with the nutritional needs of the hospital's patients.

1. There shall be a mechanism in place for the evaluation of nutritional needs for inpatients identified during admission as needing further assessment. The mechanism shall require that such evaluations be completed promptly, with modifications to patients' diets, if any, recorded in the patients' medical records within twenty-four (24) hours of notification of the need for the evaluation.

2. A current therapeutic diet manual, approved by the dietitian and medical staff, shall be readily available to all medical, nursing, and dietary service personnel.

3. Therapeutic diets shall be prescribed by the member of the medical staff responsible for the care of the inpatient.

4. A written order for the modified diet prescription as recorded in the inpatient's medical record shall be readily available to dietary service personnel throughout the duration of the order.

5. When clinically indicated, the dietary staff shall provide education for inpatients regarding their diets and nutritional needs. This training shall be documented in the inpatients' medical records.

6. Unless medically contraindicated, at least three (3) meals a day shall be provided for inpatients, with no more than fifteen (15) hours elapsing between dinner and breakfast.

7. There shall be a system for providing means for inpatients outside the normal meal service hours, when necessary.

8. A system for meal requisition shall be in place and shall require a notation regarding the inpatients' food allergies, if any.

9. Snacks shall be available between meals and at night, as appropriate to each patient's needs and medical condition.

10. The dietary service shall follow policies and procedures approved by the medical staff for the management of possible food and drug interactions.

11. Pertinent observations and information related to special diets, the inpatients' food habits, and response to dietetic treatment or diet modifications shall be recorded in the inpatients' medical records.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.23
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Food and Dietary Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.24. Imaging and Therapeutic Radiology Services.

(1) **Imaging Services.** The hospital shall maintain or arrange for effective imaging services to meet the needs of patients. The radiological imaging services shall be provided by the hospital in accordance with the rules under Chapter 290-5-22 Rules and Regulations for X-rays, where applicable.

(a) **Organization and Staffing for Imaging Services**. The hospital shall have an organizational plan for imaging services that identifies the scope of the services provided and the qualifications of the individuals necessary for the performance of various aspects of imaging services and delineates the lines of authority and accountability.

1. There shall be a qualified director of imaging services who is a member of the medical staff and a licensed doctor of medicine or osteopathy with knowledge andexperience in imaging services to supervise the provision of imaging services on a full-time or part-time basis.

2. The director shall be responsible for all clinical aspects of the organization and delivery of imaging services, including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

3. Basicradiological imaging services shall be available at all times, or there shall be an on-call procedure to provide access to qualified x-ray personnel within thirty (30) minutes.

4. The hospital shall have qualified staff performing imaging services.

(b) **Orders of Imaging Procedures.** No imaging procedures shall be performed without an order or referral from a licensed doctor of medicine or osteopathy, chiropractor, dentist, podiatrist, physician assistant or nurse with advanced training where such order is in conformity with an approved job description or nurse protocol, and as authorized under state law for such licensed healthcare professionals.

(c) Verbal/telephone orders for imaging services shall be given only to health care professionals licensed or certified by state law or authorized by medical staff rules and regulations and other hospital policy to receive those orders, in accordance with these rules, and shall be entered into the patient's medical record by those licensed, certified, or authorized health care professionals.

(2) **Reports of Imaging Interpretations.** Interpretation of imaging test results or procedures shall be made only by those medical staff designated as qualified to interpret those tests or procedures. Interpretations must be signed and dated by the medical staff providing the interpretation.

(a) Reports of all imaginginterpretations and consultations shall be included in the patient's medical record.

(b) The hospital shall have an effective procedure for notifying in a timely manner the patient's physician and responsible nursing staff of critical interpretations identified through imaging tests.

(c) Films, scans, and other images shall be retained by the hospital for at least five years after the date of the procedureunless the release of the original images is required for the care of the patient. When original images are released, documentation of the disposition of the original images shall be retained for the applicable five-year period. If the patient is a minor, the records shall be retained for at least five years past the age of majority.

(3) **Therapeutic Radiology Services.** Radiation oncology services, if provided, must be directed by a physician with training and experience in therapeutic radiology. The service must have a medical oncologist and hematologist available for consultation.

(a) Therapeutic radiology procedures shall be ordered by a licensed doctor of medicine or osteopathy and administered by persons trained and qualified for those procedures and as required under current state law and regulations.

(b) Reports of all imaging interpretations, consultations, and therapies shall be included in the patient's medical record.

(c) Radiation Safety. If the hospital is providing diagnostic or therapeutic radiological services, hospital policies and procedures shall be implemented to ensure that patients and hospital staff are not exposed to unnecessary or unsafe levels of radiation. All imaging staff and therapeutic radiology staff shall be trained in these policies and procedures.

(d) Medical Emergencies. The hospital shall have written protocols for managing medical emergencies in the imaging area and therapeutic radiology area.

(e) Infectious Disease. The hospital shall have written protocols for managing patients with infectious diseases and critical care patients in the imaging area, or wherever imaging services are provided, and in the therapeutic radiology area.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.24
Authority: O.C.G.A. §§ 31-7-2.1 and 31-13-1*et seq.*
History. Original Rule entitled "Imaging and Therapeutic Radiology Services" adopted. F. Feb. 20, 2013; eff. Mar.

12, 2013.

Rule 111-8-40-.25. Laboratory Services.

The hospital shall maintain or arrange for clinical laboratory services to meet the needs of hospital patients.

(a) **Organization and Staffing for Clinical Laboratory Services.** The administration, performance, and operation of all laboratories used by the hospital, as well as any laboratory functions performed by the hospital, shall conform to the Rules and Regulations for Licensure of Clinical Laboratories, Chapter 111-8-10.

1. The hospital shall have an organizational plan for laboratory services that identifies the scope of the services provided and the qualifications of the individuals necessary for the performance of various aspects of clinical laboratory services and delineates the lines of authority and accountability.

2. There shall be a qualified director of clinical laboratory services who is a member of the medical staff and meets the requirements for a director set forth in the Rules and Regulations for Clinical Laboratories, Chapter 111-8-10.

3. The director shall be responsible for the administration of clinical laboratory services, including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

(b) The hospital shall have emergency laboratory services available at all times.

(c) The hospital shall provide for medical staff a written description of all laboratory services available.

(d) Reports of laboratory procedures and results shall be included in the patient's medical record.

(e) The hospital shall have an effective procedure for notifying in a timely manner the patient's physician and responsible nursing staff of critical values from laboratory tests.

(f) The hospital shall require that the laboratory report any epidemiologically significant pathogens to the hospital's infection control program.

(g) **Tissue Pathology.** Hospitals which provide surgery services shall have or arrange for tissue pathology services through a licensed or certified clinical laboratory which has a system for:

1. Designation of those tissue specimens which require examination and for procedures for maintaining a tissue file; and

2. Directing pathology reports to the patient's medical record and for reporting unusual or abnormal results to the attending physician in a timely manner.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.25
Authority: O.C.G.A. Ch. 31-22, Sec. 31-7-2.1.
History. Original Rule entitled "Laboratory Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.26. Respiratory/Pulmonary Services.

The hospital shall provide or arrange for effective services to meet the respiratory/ pulmonary needs of patients and shall define in writing the scope and complexity of the respiratory/pulmonary services offered by the facility.

(a) **Organization and Staffing of Respiratory/Pulmonary Services.**

1. The hospital shall have an organizational plan for respiratory/ pulmonary services that clearly defines the necessary staff for the services and the lines of authority and accountability.

2. **Director.** There shall be a qualified director of respiratory/pulmonary services who is a member of the medical staff and a licensed doctor of medicine or osteopathy with knowledge, experience, and capability to supervise the services on a full-time or part-time basis including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

   (i) The director shall be responsible for all clinical aspects of the organization and delivery of clinical respiratory care services, including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

   (ii) The director shall be responsible for the development, implementation, and periodic review of policies, procedures, and protocols for respiratory/pulmonary care, which shall reflect the scope of services offered, including at least:

      (I) Routine inspection, cleaning, and maintenance procedures for respiratory equipment, as well as protocols for their assembly and operation;

      (II) Adverse reaction protocols;

      (III) Safety practices and interventions;

      (IV) Staff participation in emergency situations at the facility;

(V) Infection control procedures;

(VI) Procedures for handling, storage, and dispensing of therapeutic gases;

(VII) Procedures for obtaining blood samples and analysis of samples, as applicable;

(VIII) Procedures for testing of pulmonary function, as applicable;

(IX) Procedures for therapeutic percussion and vibration and for broncho-pulmonary drainage, as applicable;

(X) Procedures for mechanical ventilation and oxygenation support and for administration of aerosol, humidification, and therapeutic gases, as applicable;

(XI) Policies for administration of medications;

(XII) A system for the reissuing and discontinuing of respiratory therapy orders; and

(XIII) Procedures for verbal/telephone orders taken by state-certified respiratory care professionals.

3. There shall be a sufficient number of qualified competent professionals and support personnel to respond to and meet the respiratory/ pulmonary care needs of the patients.

(b) **Delivery of Respiratory/Pulmonary Services.** Respiratory/ Pulmonary services shall be delivered in accordance with the needs of the patients.

1. Respiratory services shall be provided only in response to medical orders. Medical orders for services shall include the modality to be used, the type, frequency, and duration of treatment, and the type and dose of medications, including dilution ratios. Verbal/telephone orders for respiratory service shall be dated, timed, and given only to appropriately licensed or otherwise qualified individuals as determined by the medical staff in accordance with state law and these rules and shall be entered into the patient's medical record by those appropriately licensed or otherwise qualified individuals.

2. The hospital shall provide equipment and supplies sufficient to support the scope of the respiratory services offered.

3. All respiratory care services provided shall be documented in the patient's medical record, including the type of therapy, date and time of administration, effects of therapy, and any adverse reactions.

4. If blood gases or other clinical laboratory tests are performed by respiratory care staff, those staff shall have demonstrated competency in the administration of the tests as point-of-care technicians.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.26
Authority: O.C.G.A. Ch. 31-22, Sec. 31-7-2.1.
History. Original Rule entitled "Respiratory/Pulmonary Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.27. Organ, Tissue, and Eye Procurement and Transplantation.

The hospital shall participate, as appropriate, in the procurement of anatomical gifts.

(a) **Receipt of Donations.** The hospital shall receive donations of organs or tissues for the purposes of medical and dental education, research, advancement of medical or dental science, therapy, or transplantation only in accordance with the provisions of the "Georgia Anatomical Gift Act," O.C.G.A. Section 44-5-140, and the applicable rules of Chapter 111-8-5.

(b) **Voluntary Expression of Intent to Donate.** The hospital shall establish and implement policies and procedures for documenting requests by patients regarding their intentions for disposition of their bodies or organs and for seeing that these expressed intentions are honored upon death when possible.

(c) **Hospital Requests for Anatomical Gifts.** The hospital shall establish and implement policies and procedures for requesting anatomical gifts on or before the occurrence of death in the absence of a patient's expressed intentions.

1. Policies and procedures shall provide for a written agreement(s) with an organ bank or storage facility with the provisions specified in Rules for Anatomical Gifts, Chapter 111-8-5-.07, and provisions for the training of staff authorized to request the gifts, when applicable.

2. Where the hospital does not have the Organ Procurement Organization handle requests for anatomical gifts, the hospital shall designate staff authorized to make requests for anatomical gifts, and such staff shall be appropriately trained in the following areas:

   (i) Psychological and emotional considerations when dealing with bereaved families;

(ii) Social, cultural, ethical, and religious factors affecting attitudes toward donations;

(iii) General medical concepts and issues in organ, tissue, and eye donations;

(iv) Procedures for declaring death and collecting and preserving organs, tissues, and/or other body parts and for how these procedures are to be explained to decedents' families;

(v) Procedures for notifying and involving banks or storage facilities; and

(vi) procedures for recording the outcomes of requests.

3. If the hospital engages in harvesting tissue and/or transplanting organs and tissues from living donors, the hospital shall develop a living donor organ/transplants policy that addresses the issues related to such donations.

(d) **Physicians Participating in the Removing or Transplanting of Organs or Tissues.** Where the medical staff participates in organ recovery, the hospital shall designate which medical staff members may not participate in the procedures for removing and transplanting of organs and body parts in accordance with the Rules for Anatomical Gifts, Chapter 111-8-5-.08.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.27
Authority: O.C.G.A. §§ 31-7-2.1 and 44-5-140.
History. Original Rule entitled "Organ, Tissue, and Eye Procurement and Transplantation" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.28. Surgical Services.

If the hospital provides surgical services, the services shall be provided in a manner which protects the health and safety of the patients and follows current accepted standards of medical and surgical practice. Personnel, equipment, policies and procedures, and the number of operating rooms shall be appropriate for the scope of services offered.

(a) **Organization of Surgical Services.** The hospital shall have an organizational plan which defines lines of authority, responsibility, and accountability within all operating room areas where surgical procedures are performed.

1. There shall be a current roster of surgical privileges granted each medical staff member available to nursing and scheduling staff in the surgical services area(s).

2. The hospital shall have bylaws, rules, or policies and procedures developed by the medical staff which require that within twenty-four (24) hours prior to surgery either a history and physical examination or an update of a previous history and physical is completed for every surgical patient. Where an update is used, the previous history and physical examination must not have occurred more than thirty (30) days prior to surgery.

3. Roles, responsibilities, and qualifications for any non-physician first and second assistants participating in surgery shall be defined by the hospital medical staff, including any limitations to their roles in patient care.

4. **Chief(s) of Surgery.** Physician member(s) of the medical staff, who have been appropriately trained in the provision of surgical services, shall be designated by the medical staff to direct the hospital's surgical services, and shall be responsible for all clinical aspects of organization and delivery of the particular surgical services including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

   (i) The chief(s) of surgery shall be responsible for implementation of hospital policy related to medical staff utilizing the surgical suite.

   (ii) In conjunction with the hospital's medical staff, the chief(s) of surgery shall implement procedures requiring an operative report for each surgery performed.

      (I) The operative report shall describe techniques, findings, complications, tissues removed or altered, and the general condition of the patient during and following surgery.

      (II) The full operative report shall be written or dictated immediately after surgery and signed or authenticated by the surgeon. Where the full operative report is not available to be placed immediately in the record, an operative/progress note by the surgeon must be entered into the medical record immediately.

5. **Nurse Manager.** A licensed registered nurse, who has been appropriately trained in the provision of surgical nursing services, shall manage the surgical suite(s) and shall be responsible for:

   (i) Ensuring that a sufficient number of nursing personnel are on duty in the surgical suite to meet the needs and safety of the patients;

   (ii) Ensuring that surgical technicians perform scrub functions only under the supervision of a licensed registered nurse who is immediately available to respond to emergencies;

(iii) Delineating the duties of scrub personnel and circulating registered nurses in the surgical suite;

(iv) Providing for orientation and on-going education and training of surgical personnel providing services within the surgical suite, to include at least equipment usage and inspections, infection control and safety in the surgical area, cardiopulmonary resuscitation, patient rights, and informed consent;

(v) Ensuring that patients are monitored and provided with nursing care from the time they enter the surgical suite to the time they exit the area;

(vi) Developing criteria for the use of equipment and supplies brought into the surgical suite from other areas; and

(vii) Ensuring that the operating room register is current and complete.

(b) **Infection Control in the Surgical Suite.** The hospital shall develop and implement infection control procedures specific to the surgical services areas, which include at least requirements for:

1. Surgical attire;
2. Surgical scrub procedures;
3. Housekeeping functions;
4. Cleaning, disinfecting, and sanitizing the area;
5. Appropriate maintenance of the heating, ventilation, and air conditioning systems for the surgical suite;
6. Packaging, sterilizing, and storage of equipment and supplies;
7. Waste disposal;
8. Traffic control patterns, including who may enter the operating room areas and under what circumstances; and
9. A surgical site surveillance system appropriate to the population served.

(c) **Minimum Equipment for the Surgical Suite.** The following emergency equipment shall be available and functional for the operating room(s) and for the post-anesthesia area, as appropriate:

1. A call system;

2. Cardiac monitors;
3. Resuscitation equipment;
4. A defibrillator;
5. Aspiration/suction equipment;
6. A traecheostomy kit;
7. A pulse oximeter; and
8. A end-tidal carbon dioxide monitor.

(d) **Post-Anesthesia Care Unit.**

1. The post-anesthesia care unit shall be located in an area of the hospital in close proximity to but physically separated from the operating room.
2. Policies and procedures for the post-anesthesia care unit shall include at a minimum the criteria for admission to and discharge from the unit.
3. If patients are not transferred to the post-anesthesia care unit following surgery, provisions shall be made for monitoring the patient until it is determined that the patient is stable.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.28
Authority: O.C.G.A. §§ 31-7-2.1 and 31-9-6.1.
History. Original Rule entitled "Surgical Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.29. Anesthesia Services.

Any hospital offering surgical or obstetrical services shall have an organized anesthesia service which shall be responsible for all anesthesia delivered at the hospital. The anesthesia services will be provided in a manner which protects the health and safety of patients in accordance with generally accepted standards of practice.

(a) **Organization of Anesthesia Services.**

1. Anesthesia services shall be directed by a qualified physician member of the medical staff who is responsible for organizing the delivery of anesthesia services provided by the hospital in accordance with generally accepted standards of practice.

2. The anesthesia director shall be responsible for monitoring the quality and appropriateness of anesthesia services and for ensuring that identified problems are addressed through the quality management program.

3. The anesthesia director shall be responsible for establishing an orientation and continuing education program for anesthesia services staff that include, at a minimum, instruction in safety precautions, emergency patient management, equipment use and inspections, and infection control procedures in the surgical suite.

(b) **Anesthesia Service Delivery.**

1. Anesthesia shall be administered only by qualified members of the medical staff or qualified individuals who have been granted clinical privileges to administer anesthesia in accordance with these rules and as permitted by state laws and regulations. Persons qualified to administer anesthesia may include:

   (i) Anesthesiologists;

   (ii) Physicians;

   (iii) Dentists or oral surgeons possessing an active permit for administration of general anesthesia as issued by the State of Georgia;

   (iv) Certified registered nurse anesthetists administering such anesthesia under the direction and responsibility of duly licensed physicians who are members of the medical staff; and

   (v) Physician's assistants licensed by the State of Georgia with approved job descriptions as anesthesia assistants functioning under the direct supervision of anesthesiologists who are members of the medical staff and as otherwise authorized by applicable laws and regulations.

2. A pre-anesthesia patient evaluation shall be completed for each patient by a person qualified and granted privileges to administer anesthesia within a reasonable period of time preceding the surgery. The patient evaluation shall be updated immediately prior to induction. The pre-anesthesia evaluation must include review of heart and lung function, diagnostic data (laboratory, x-ray, etc., as applicable), medical and anesthesia history, notation of anesthesia risk, any potential anesthesia problems identified, and notation of patient's condition immediately prior to induction.

3. Checks of all anesthesia equipment shall be performed and documented immediately prior to each anesthesia administration.

4. A person qualified and granted privileges to administer anesthesia shall be continuously present throughout the administration of all general anesthesia or major regional anesthesia and monitored anesthesia care.

5. During the administration of anesthesia, patients shall be monitored as appropriate for the nature of the anesthesia. Such monitoring shall include as appropriate:

   (i) Heart and breath sounds, using a precordial or esophageal stethoscope;

   (ii) Oxygenation levels;

   (iii) Ventilation;

   (iv) Circulatory function;

   (v) The qualitative content of expired gases, if the patient has an endotracheal tube; and

   (vi) The patient's temperature.

6. The intraoperative anesthesia record shall document all pertinent actions and events that occur during the induction, maintenance, and emergence from anesthesia.

7. The person qualified and granted privileges to administer anesthesia shall remain immediately available until the patient has been determined to be stable and is ready for discharge or transfer from the post-anesthesia care unit.

8. A person qualified and granted privileges to administer anesthesia shall complete the post-anesthesia evaluation for each patient receiving anesthesia, and it shall be included in the patient's medical record.

   (i) The evaluation shall note at a minimum the presence or absence of anesthesia-related abnormalities or complications, the patient's level of consciousness and cardiopulmonary status, and any follow-up care needed.

   (ii) For outpatients, the post-anesthesia evaluation shall be performed prior to hospital discharge to check for anesthesia recovery in accordance with procedures and timelines established by the hospital's medical staff.

(c) **Anesthesia Safety Precautions.** Safety precautions related to the administration of anesthesia shall be clearly identified in written policies and procedures which are enforced and shall include at a minimum:

1. Routine maintenance and inspection of anesthesia equipment, recorded in a service record for each machine;

2. Emergency preparedness plans;

3. Life safety measures, including alarm systems for ventilators capable of detecting disconnection of any components, monitoring for scavenger gases, and a system for internal reporting of equipment malfunctions and unavailability;

4. Infection control procedures sufficient to adequately sterilize or appropriately disinfect all equipment components; and

5. Procedures for ensuring patient safety.

(d) **Conscious sedation.** The hospital shall develop and implement, with the assistance of the anesthesia services director, policies and procedures for the administration of conscious sedation, which shall be applicable hospital-wide. These policies and procedures shall be approved by appropriate members of the medical staff and shall include at least the following:

1. Designation of the licensed personnel authorized to administer conscious sedation and/or monitor the patient during conscious sedation;

2. Drugs approved for use in administering conscious sedation;

3. Patient monitoring requirements; and

4. Criteria for discharge.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.29
Authority: O.C.G.A. §§ 31-7-2.1, 43-22-21 and 43-26-11.1.
History. Original Rule entitled "Anesthesia Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.30. Nuclear Medicine Services.

If the hospital provides nuclear medicine services, those services shall be organized and effective. The nuclear medicine services shall be provided in a manner consistent with applicable state laws and regulations and generally accepted standards of practice.

(a) Radioactive materials used in the provision of nuclear medicine services shall be prepared by personnel authorized as defined by state law to prepare radiopharmaceuticals and shall be labeled, used, transported, stored, and disposed of in a manner consistent with the "Georgia Radiation Control Act," O.C.G.A. Chapter 31-13 *et seq.*, and applicable rules.

(b) If a clinical laboratory is utilized in the provision of nuclear medicine services, the laboratory shall be licensed to perform these services as required by the Rules and Regulations for Clinical Laboratories, Chapter 111-8-10.

(c) Nuclear medicine services shall be directed by a doctor of medicine or osteopathy who is a member of the medical staff qualified to perform and supervise those services. The director shall be responsible for the administration of nuclear medical services, including the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

(d) Nuclear medicine procedures shall be administered and/or supervised by licensed doctors of medicine or osteopathy as authorized by state law.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.30
Authority: O.C.G.A. §§ 31-7-2.1, 31-13-1*et seq.* and 31-22-1 *et seq.*
History. Original Rule entitled "Nuclear Medicine Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.31. Emergency Services.

The hospital shall provide, within its capabilities, services to persons in need of emergency care.

(a) **Full-time Emergency Services.** If the hospital offers emergency care as an organized service and/or holds itself out to the public as offering emergency services, the service shall be included in the scope of services submitted with the application for the hospital permit and shall be offered twenty-four (24) hours per day.

1. **Organization.** Supervision and organization of emergency services shall be under the direction of a qualified member of the medical staff.

(i) The director shall be responsible for the development of policies and procedures related to emergency services and the review and update of policies as necessary. The policies and procedures shall be approved by appropriate members of the medical staff.

(ii) The director shall implement systems to assess the effectiveness of the emergency service and to address improvement issues through the hospital's quality management program.

(iii) Staffing assignments shall provide for sufficient nursing, medical, and technical staff to meet the anticipated needs of emergency patient care. There shall be available to emergency room staff procedures for accessing additional staff on an as-needed basis to meet unanticipated needs.

(iv) Patient care responsibilities for emergency services staff shall be specified by written policies and procedures, which shall include training and experience requirements appropriate to the assigned responsibilities and clearly defined lines of authority.

2. **Delivery of Services.** When the hospital provides emergency services, the services shall comply with the following:

   (i) Policies and procedures for processing patients presenting for emergency care shall be in writing and shall include the procedures for initial patient assessment, prioritization for medical screening and treatment, and patient reassessment and monitoring.

   (ii) There shall be a central log of all patients presenting for emergency care, with the presenting complaint and the level of acuity or triage documented. Entries in the log must be retrievable by the date and time the patient presents for treatment;

   (iii) An emergency medical record shall be maintained for each patient which includes all assessment and treatment information about the patient from the time of presentation until the time of discharge or transfer;

   (iv) Written protocols and standards of practice to guide emergency interventions by non-physician staff shall be available in the emergency services area;

   (v) A licensed physician shall be available to cover basic emergency room services either on-site or by telephone. Where the licensed physician is providing such coverage by telephone, the physician must be able to arrive in the emergency room within thirty (30) minutes of the need for physician services having been determined;

   (vi) The emergency services area shall have operable equipment and sufficient and appropriate supplies and medications to support emergency care for patients of all ages, including at least:

      (I) An emergency call system;

      (II) Oxygen;

      (III) Manual breathing bags and masks;

      (IV) Cardiac monitoring and defibrillator equipment;

      (V) Laryngoscopes and endotracheal tubes;

      (VI) Suction equipment; and

      (VII) Emergency drugs and supplies as specified by the medical staff;

   (vii) The hospital shall integrate functions of the emergency services with other services of the hospital to ensure appropriate patient care and treatment

including those patients awaiting admission or transfer to another facility, placement in a hospital bed, or transfer to another facility;

(viii) Policies and procedures shall be developed and implemented for the appropriate transfer of emergency patients to other facilities or other areas of the hospital when appropriate;

(ix) The hospital shall have policies and procedures for the management of mass casualty situations which may require the coordination of the hospital's emergency services with other facilities, the local Emergency Management Agency (EMA), and local ambulance service providers;

(x) Emergency Services Where Maternity Services Are Customarily Offered. In addition to applicable federal laws regarding the treatment of persons requesting treatment for emergency medical conditions that are enforced by the federal government, state law requires any hospital which operates an emergency service to provide appropriate and necessary emergency services to any pregnant woman who is a resident of this state and who presents herself in active labor, to the hospital, if those services are usually and customarily provided in that facility. Such services shall be provided within the scope of generally accepted practice based upon the information furnished the hospital by the pregnant woman, including such information as the pregnant woman reveals concerning her prenatal care, diet, allergies, previous births, general health information, and other such information as the pregnant woman may furnish the hospital. If, in the medical judgment of the physician responsible for the emergency service, the hospital must transfer the patient because the hospital is unable to provide appropriate treatment, the hospital shall provide appropriate treatment as set forth in O.C.G.A. § 31-8-42; and

(xi) Diversion Status - Inability to Deliver Emergency Services. The hospital shall develop and implement a diversion policy in consultation with the medical staff which describes the process of handling those times when the hospital must temporarily divert ambulances from transporting patients requiring emergency services to the hospital. The policy must include the following: when diversion is authorized to be called, who is authorized to call and discontinue diversion, efforts the hospital will make to minimize the usage of diversion, and how diversion will be monitored and evaluated. In connection with going on diversion status, the hospital shall:

(I) Notify the ambulance zoning system when it is temporarily unable to deliver emergency services and is declaring itself on diversion;

(II) Notify the ambulance zoning system when diversion status is no longer determined to be necessary; and

(III) Monitor and evaluate its usage of diversion status and make changes within its control to minimize the use of diversion status.

(b) **Hospitals Without Organized Emergency Services.** Hospitals not providing an organized emergency service shall have current policies and procedures and sufficient qualified staff to provide for the appraisal and initial treatment of any patients or persons presenting with an emergency medical or psychiatric condition, within the capabilities of the hospital, and for referral of the patient for further treatment when appropriate.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.31
Authority: O.C.G.A. §§ 31-7-2.1, 31-7-3.1, 31-8-42 and 31-11-82.
History. Original Rule entitled "Emergency Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.32. Outpatient Services.

Outpatient services offered by the hospital, including but not limited to ambulatory care services and off-campus clinics, shall be integrated with other hospital services and systems and shall be provided in accordance with applicable rules in this Chapter for the specific service.

(a) **Organization of Outpatient Services.**

1. The hospital shall develop and implement policies and procedures to ensure that outpatient care provided meets the needs of patients in accordance with generally accepted standards of practice.

2. Each outpatient service shall be staffed with sufficient qualified personnel to promptly, safely, and effectively meet the care needs of patients. Staff providing care to outpatients shall meet the same qualification requirements as staff providing similar services to inpatients of the hospital.

3. The hospital shall assign responsibility for the periodic assessment of the quality and effectiveness of the outpatient services provided, and this assessment shall be a part of the hospital's quality management program.

(b) **Outpatient Service Delivery.**

1. Hospital services for outpatients shall be provided only on the order of a licensed physician, dentist, osteopath, physician's assistant, or advanced practice nurse as permitted by law in accordance with the system of accountability established by the medical staff.

2. Outpatient services shall be provided in a manner which ensures the privacy of each patient and the confidentiality of the patient's disclosures. Private rooms or cubicles shall be provided for the use of outpatients and staff for consultation purposes, as appropriate to the needs of the service.

3. Hospitals shall provide waiting areas for outpatients with sufficient seating for the expected volume of patients.

4. Each outpatient shall have an outpatient record, which shall be maintained and stored in a manner to be available for subsequent outpatient or inpatient hospital visits.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.32
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Outpatient Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.33. Rehabilitation Services.

The hospital shall define the scope of rehabilitation services provided to patients. The hospital may offer limited or comprehensive rehabilitation services including such services as physical therapy, occupational therapy, audiology, speech-language pathology, or other services.

(a) **Organization of Limited Rehabilitation Services.** Where a hospital chooses to offer limited rehabilitation services, which are typically single or stand-alone therapy discipline(s), the rehabilitation service(s) shall be coordinated by an appropriately qualified individual assigned responsibility for the clinical aspects of organization and delivery of the rehabilitation service(s) provided by the hospital. The coordinator shall be responsible for monitoring the quality and appropriateness of rehabilitation services and for ensuring that identified problems are addressed through the quality management program.

(b) **Organization of Comprehensive Rehabilitation Services.** Where a hospital chooses to offer a comprehensive rehabilitation service program which provides integrated and coordinated multidisciplinary therapy services as an organized inpatient service, the director must be a qualified member of the medical staff with appropriate training and experience.

(c) Professional and paraprofessional staff providing patient care shall meet licensing or registration requirements consistent with state law.

(d) Rehabilitation services shall be provided in accordance with orders from the licensed practitioner responsible for the patient's care. Orders for services shall be entered in the patient's medical record with the date of the order and shall be signed by the person

giving the order. If rehabilitation services are provided by the hospital on an outpatient basis, the hospital shall specify how orders from outside sources will be managed.

(e) Following assessment, treatment services shall be provided according to a written treatment plan, which specifies the goals of treatment and the frequency and expected duration of services.

(f) There shall be a functional system for recording in the patient's medical record the patient's response to treatment and for communicating information regarding the patient's response or progress to the ordering licensed practitioner.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.33
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Rehabilitation Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.34. Maternal and Newborn Services.

(1) No later than 90 days after the effective date of these rules, if the hospital offers an organized service for the provision of care for expectant mothers and newborns, it shall clearly define the level of services provided according to the levels described in these rules (basic, intermediate, or intensive) and comply with the rules set forth in this section.

(a) The hospital shall establish and utilize admission criteria for the maternal and newborn services that reflect the level of services offered by the hospital.

(b) The hospital shall have established mechanisms, through written agreement and other arrangement, for transfers to or consultations with facilities providing services at the higher levels of care for those maternal and newborn patients who require such care. The agreements or arrangements shall ensure that there is collaboration between the sending and receiving hospital concerning the transfer of such patients prior to the actual need for transfer and shall include mechanisms for the communication of information regarding the outcome of each transfer and for periodic review of the agreements or arrangements.

(c) All hospitals offering obstetrical care shall have facilities, staff, and equipment necessary for delivery, management, and stabilization of expectant women who present at the hospital in active labor and for whom delivery is imminent, regardless of the level of care anticipated for the newborn. The hospital shall have in place a system for communication and consultation with a board certified obstetrician or maternal-fetal medicine specialist and a board certified neonatologist for situations where transport of high-risk patients prior to delivery is not feasible.

(d) The hospital shall establish a system for receipt of prenatal records for admissions to the maternal and newborn service other than emergency admissions to include the results of any routine laboratory tests as required by the hospital.

(e) The hospital shall have written plans and procedures for transfer of expectant mothers or newborns presenting at the hospital who exceed the criteria for admission, which shall include mechanisms for accessing transportation appropriate to the needs of the patient(s).

(f) The hospital shall include in the internal quality management program a systematic review of the admissions and transfers for maternal and newborn services, with comparison to the established admission criteria, which shall prompt corrective action when indicated.

(g) With the exception of hospitals permitted as specialized children's hospitals, hospitals shall offer a level of services for maternal care comparable to the level of services offered for neonatal care.

(2) The hospital shall have sufficient staff, space, facilities, equipment, and supplies to support the range of maternal and infant services offered, according to generally accepted standards of practice.

(3) **Basic Maternal and Newborn Services.** All hospitals offering maternal and newborn services shall offer at least a basic level of those services. The basic level of maternal and newborn services shall provide comprehensive care for women with low-risk pregnancies, anticipated uncomplicated deliveries, and apparently normal developing fetuses with estimated gestation of thirty-six (36) weeks or greater and for newborns with anticipated birth weights of 2500 grams or greater. The maternal and newborn services of these hospitals shall meet the following minimum requirements:

(a) **Organization of Basic Maternal and Newborn Services.**

1. The director of obstetrical services shall be a board eligible or board certified obstetrician, or a board eligible or board certified family practitioner with obstetrical privileges, or shall be a credentialed member of the medical staff with obstetrical privileges with access to such board eligible or board certified specialists by consultation.

2. The director of newborn services shall be a member of the medical staff who is a board eligible or board certified pediatrician, or a board eligible or board certified family practitioner, or shall be a credentialed member of the medical staff with access to such specialists by consultation. The director of newborn services shall be responsible for ensuring that medical care is provided for all newborns.

3. The perinatal nurse manager shall be a licensed registered nurse with education and demonstrated knowledge and experience in perinatal nursing;

(b) **Delivery of Basic Maternal and Newborn Services.**

1. **Staffing Plan.** The hospital shall follow a staffing plan that ensures the availability of appropriate numbers of qualified staff for the perinatal services offered, according to generally accepted standards of practice and state licensing regulations.

(i) **Staffing for the Labor and Delivery Area.** For the delivery of newborns, the hospital shall provide for at least the following:

(I) A birth attendant, who may be an obstetrician, a physician with obstetrical privileges, or a certified nurse midwife who has been granted clinical privileges in accordance with these rules, present at the hospital or immediately available by telephone and able to be on-site within thirty (30) minutes;

(II) A registered nurse present to assist with each delivery;

(III) An individual credentialed in neonatal resuscitation to be present in the delivery room for each delivery for the purpose of receiving the newborn;

(IV) For Cesarean deliveries, an additional physician or certified nurse midwife, a registered nurse, or a surgical assistant or technician, able and qualified to assist with a Cesarean section, on-site or able to arrive in sufficient time to accommodate the time limit for emergency Cesarean section of thirty (30) minutes from the physician's decision to operate to the initial incision; and

(V) Professional staff qualified to administer anesthesia, on-site or able to arrive in sufficient time to accommodate the time limit for emergency Cesarean section of thirty (30) minutes from the physician's decision to operate to initial incision.

(ii) **Staffing for the Newborn Nursery.** The hospital shall provide for at least:

(I) A qualified registered nurse with experience or training in the care of newborns to supervise and be responsible for the quality of nursing care given to newborns, for nursing in-service programs in nursery issues, for assisting the director

of the newborn nursery in carrying out his or her duties, and for the maintenance of the nursery records;

(II) A licensed nurse on duty in the nursery at all times in hospitals with a daily newborn nursery census greater than ten (10) newborns; and

(III) A staff member trained in newborn service provision present in the newborn nursery when it is occupied by any newborn.

2. The directors of obstetrical and newborn services shall develop and implement written policies, procedures, and guidelines for the services that reflect current standards of practice and address at least:

   (i) Admission criteria for the services based on the level of service provided;

   (ii) Guidelines and mechanisms for specialty consultations and transfer for high-risk patients whose needs exceed the range of services offered at the hospital;

   (iii) The orientation program for maternal and newborn services staff;

   (iv) Patient care requirements for mothers and newborns, including but not limited to nursing assessments, gestational age assessment, newborn assessments including Apgar scoring immediately after delivery, assessment and management of nutritional needs including feedings for the newborn whether normal or gavage, umbilical and circumcision care, assessment of thermoregulation by the newborn, prevention of blindness, hypoglycemia, and hemorrhagic disease for the newborn, use of appropriate prophylaxes, patient monitoring needs, and assessment of educational needs of the mother;

   (v) Procedures for a family-centered environment (rooming-in) as an option for each patient unless contraindicated by the medical condition of the mother or infant or unless the hospital does not have sufficient facilities to accommodate all such requests;

   (vi) Room assignments and procedures for traffic control and security, including such security measures as are necessary to limit access to newborns by unauthorized persons and to prevent kidnapping of newborns;

(vii) Guidelines for the use of anesthetic agents for pain management and the requirements for the qualifications and responsibilities of persons who administer the agents and the required patient monitoring;

(viii) Guidelines for induction and augmentation of labor and for designation of qualified personnel who must be in attendance during these procedures;

(ix) Indicators and procedures for vaginal birth after Cesarean section (VBAC);

(x) Indicators and procedures for operative vaginal deliveries;

(xi) Staffing and procedural guidelines for management of obstetrical and newborn emergencies, including the availability of staff components to manage such emergencies twenty-four (24) hours per day;

(xii) Guidelines for the monitoring of newborns during the first twelve (12) hours after birth and until discharge;

(xiii) Procedures for infection control, including isolation procedures, visiting privileges, individualized infant hygiene care, and specific policies regarding the prevention and management of infectious diseases, including but not limited to Hepatitis B, Hepatitis C, Group B Streptococcal infections, tuberculosis, human immunodeficiency virus (HIV), and sexually transmitted diseases;

(xiv) Requirements for newborn screening tests for metabolic disorders and hemoglobinopathies and other screenings, as required by law.

(xv) Procedures for continuous and unquestionable identification of newborns;

(xvi) Procedures for completing birth and death certificates in accordance with Georgia's official vital records registration system; and

(xvii) Guidelines for discharge of mothers and newborns, including early discharge, and for assessment of education and other discharge needs.

(c) **Physical Environment for Maternal and Newborn Services.**

1. Obstetrical and newborn service areas shall be located, arranged, and utilized so as to provide for every reasonable protection from infection and from cross-infection. The physical arrangements shall separate the obstetric patients from other patients with the exception of non-infectious gynecological patients.

2. Rooms used for patients in labor shall be located with convenient access to the delivery room(s). If labor rooms also serve as birthing rooms, the rooms shall be equipped to handle obstetric and neonatal emergencies.

3. Delivery suites shall be used for no purpose other than for the care of obstetrical patients. Each room shall have the necessary equipment and facilities for infection control and for the management of obstetric and neonatal emergencies. Delivery suites shall be designed to include an anesthesia supply and equipment storage room and a communication system to ensure that emergency backup personnel can be summoned when needed.

4. A newborn stabilization area shall be located within each delivery room or birthing room and shall be equipped with oxygen and suction outlets.

5. The newborn nursery shall have an air temperature maintained at 75-80 degrees Fahrenheit, with a relative humidity of thirty percent to sixty percent (30% - 60%).

6. Air from other areas of the hospital shall not be recirculated into the newborn nursery. Ventilation of the nursery suite(s) shall provide the equivalent admixture of a minimum of six (6) total air changes per hour.

7. Life-sustaining nursery equipment and lighting for the nursery areas shall be connected to outlets with an automatic transfer capability to emergency power.

8. Each labor room, delivery room, birthing room, and nursery station shall be equipped with sufficient power outlets to handle the equipment required for the provision of patient care without the use of extension cords,"cheater" plugs, or multiple outlet adapters, which are prohibited.

(d) **Clinical Laboratory, X-Ray, and Ultrasound Services.** Diagnostic support services such as laboratory, x-ray, and ultrasound, shall be available on an on-call basis, with the capability to perform studies as needed for maternal and newborn care; and

(e) **Records Requirements.**

1. The medical record for each maternity patient shall be maintained in accordance with Section 111-8-40-.18 of these rules, with the following additions:

   (i) The medical record for each maternity patient shall contain a copy of the patient's prenatal records, submitted at or before the time of admission;

   (ii) The admission data shall include the date and time of notification of the birth attendant, the condition on admission of the mother and fetus, labor and membrane status, presence of bleeding, if any, fetal activity level, and time and content of the most recent meal ingested; and

   (iii) Labor and postpartum care notes shall be included.

2. The medical record for each newborn shall be cross-referenced with the mother's medical record and shall contain the following additional record information:

   (i) Physical assessment of the newborn, including Apgar scores, presence or absence of three cord vessels, and vital signs;

   (ii) Accommodation to extra uterine life including the ability to feed and description of maternal-newborn interaction;

   (iii) Treatments and care provided to the newborn to include the specimens collected, newborn screening tests performed, and appropriate prophylaxes;

   (iv) The infant's footprint and mother's fingerprint, or comparable positive newborn identification information; and

   (v) Report of the physical examination of the newborn prior to discharge, performed by an appropriately credentialed physician, physician's assistant, nurse practitioner, or nurse midwife.

3. The hospital shall maintain a register of births, in which is recorded the name of each patient admitted for delivery, the date of admission, date and time of birth, type of delivery, names of physicians or other birth attendants, assisting staff and anesthetists, the sex, weight, and gestational age of the infant, the location of the delivery, and the fetal outcome of the delivery.

4. The hospital shall maintain annual statistics regarding the number of births and number of infant deaths. Death statistics for infants shall include birth weights, gestational ages, race, sex, age at death, and cause of death.

(4) **Intermediate Maternal and Newborn Services.** The hospital offering intermediate maternal and newborn services shall offer comprehensive care for women with the potential or likelihood for only certain pre-defined high-risk complications and with anticipated delivery of a newborn at greater than thirty-two (32) weeks' gestation and birth weight greater than 1500 grams who are anticipated to have only such medical conditions which can be expected to resolve rapidly. The maternal and newborn service shall meet all of the requirements for provision of the basic services as described above in these rules, with the following additions or exceptions:

(a) **Organization of Intermediate Maternal and Newborn Services.**

1. The director of obstetric services shall be a member of the medical staff who is a board eligible or board certified obstetrician or board eligible or board certified maternal-fetal medicine specialist; provided, however, within five (5) years from the effective date of these rules, the director of obstetric services shall be a board certified obstetrician or board certified maternal-fetal medicine specialist.

2. The director of newborn services shall be a member of the medical staff who is board eligible or board certified pediatrician or board eligible or board certified neonatologist; provided, however, within five (5) years from the effective date of these rules, the director of newborn services shall be a board certified pediatrician or board certified neonatologist.

3. A board eligible or board certified neonatologist shall be available to participate in care for the neonates.

4. The perinatal nurse manager shall be a licensed registered nurse with the training and demonstrated knowledge and experience in care of high-risk maternal care and moderately ill newborns.

5. When a neonate is on mechanical ventilation or when a high risk maternity patient is being managed, a respiratory therapist, certified lab technician/blood gas technician, and an x-ray technologist shall be on-site and available to the maternal and newborn services area on a twenty-four (24) hour basis.

6. If the facility offers care for newborns requiring parenteral support, a licensed dietitian and a licensed pharmacist with parenteral experience shall be on staff.

(b) **Delivery of Intermediate Maternal and Newborn Services.** Service delivery shall meet the requirements of the basic maternal and newborn services, with the following additions or exceptions:

1. The hospital shall provide care for expectant mothers and newborns requiring the basic level of maternal and newborn services, as well as for those requiring an intermediate level of care;

2. Portable x-ray and ultrasound equipment and services shall be available on a twenty-four (24) hour basis;

3. The intermediate level nursery shall provide care to neonates expected to require no more than short-term mechanical ventilation or parenteral support. Such support, if needed for more than forty-eight (48) hours, shall be authorized daily by the consulting neonatologist, or the neonate shall be transferred to a facility with a higher (intensive) level of care; and

4. Written policies, procedures, protocols, and guidelines shall reflect the pre-defined level of care provided. Criteria for admission to and discharge from the intermediate level nursery shall be defined in the written policies and procedures.

(c) **Physical Environment for Intermediate Maternal and Newborn Services.** The physical environment shall meet the requirements of the basic maternal and newborn services, with the following additional requirements:

1. There shall be provided in the intermediate level nursery sufficient space between each patient station to allow for easy access for staff and visitors on three (3) sides of the patient bed and to allow for easy access with portable diagnostic and support equipment as may be required;

2. Each patient station in the intermediate level nursery shall have at least two (2) oxygen outlets, two (2) compressed air outlets, and two (2) suction outlets;

3. There shall be adequate lighting provided for patient care while avoiding extra illumination of adjacent neonates; and

4. The patient bed areas shall be designed to minimize the impact of noise on the infants.

(5) **Intensive Maternal and Newborn Services.** The hospital offering an intensive level of maternal and newborn services shall provide services for normal and high-risk maternal, fetal, and newborn conditions. The hospital providing the intensive level of services shall meet all requirements for basic and intermediate maternal and newborn services, with the following additions and/or exceptions:

(a) The director of intensive obstetric services shall be a member of the medical staff who is a board certified obstetrician or board certified maternal-fetal medicine specialist;

(b) The director of intensive newborn services shall be a member of the medical staff who is a board certified pediatrician or board certified neonatologist;

(c) The hospital shall have on call, on a twenty-four (24) hour basis, a board certified obstetrician or maternal-fetal medicine specialist to provide on-site supervision and management of maternal patients;

(d) The hospital shall have available for consultation a maternal-fetal medicine specialist;

(e) The hospital shall have on call, on a twenty-four (24) hour basis, a board certified neonatologist to provide on-site supervision and management of neonates;

(f) The hospital shall provide pediatric subspecialties on staff or have a mechanism to provide consultation and care for pediatric subspecialties in a timely manner;

(g) The nursery manager of the intensive care nursery shall have demonstrated knowledge, training, and experience in neonatal intensive care nursing and shall have a dedicated assignment to the intensive care nursery;

(h) The hospital shall have on staff pharmacology personnel competent in perinatal pharmacology. Total parenteral nutrition shall be available; and

(i) The hospital shall have on staff a licensed physical therapist or occupational therapist and a licensed dietitian with training and experience in neonatal care.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.34
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Maternal and Newborn Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.35. Pediatric Services.

Any hospital providing care to infants and children shall have facilities, equipment, and policies and procedures specific to the provision of services for pediatric patients.

(a) Hospital policies shall define the ages of patients considered to be appropriate for pediatric services and the scope of services to be provided to them.

(b) Staff providing services to pediatric patients shall have experience and training in serving the pediatric population and shall have documented in-service training at least annually on age-specific care issues for the pediatric population served by the hospital.

(c) Protocols for screening and assessment of pediatric patients shall be approved by the medical staff and shall be individualized for the age and presenting signs and symptoms of the patient. In addition to the screening and assessment information required for all patients, the general screening and assessment protocol for pediatric patients shall include at a minimum:

1. Chronological age, weight, and length or height;

2. For infants and young children, a measurement of head circumference;

3. Immunization history;

4. A statement as to the developmental age and growth of the child as related to established norms; and

5. Family relationships, including expected family involvement during treatment.

(d) The hospital shall establish and implement policies and procedures to prohibit access to pediatric patients by unauthorized persons and to prevent kidnapping or elopement of pediatric patients.

(e) The hospital shall provide space and equipment to allow for visitation of family members in the patient rooms and to allow for overnight stay of a parent or guardian where the parent or guardian's presence does not interfere with the course of treatment. The pediatric patient's medical record shall clearly indicate persons who are not permitted to visit the pediatric patient.

(f) Medical supplies and equipment including emergency equipment appropriate to the size and age of the pediatric patient shall be available in all areas of the hospital providing services to pediatric patients.

(g) The phone number for the Poison Control Center shall be available in a conspicuous place in the pediatric service area(s).

(h) Where pediatrics is provided as an organized service, there must be a qualified physician member of the medical staff with experience or training in pediatrics assigned responsibility for directing the clinical aspects of organization and delivery of all pediatric services provided by the hospital. The pediatric medical director shall be responsible for monitoring the quality and appropriateness of pediatric services in coordination with the hospital's quality management program and for ensuring that identified opportunities for improvement are addressed.

(i) Hospitals providing services to pediatric patients as an organized service shall have space, facilities, and appropriately sized equipment for providing those services apart from adult patient rooms and newborn units and shall provide for regular and routine cleaning of play equipment in the pediatric area according to protocols established for that purpose by the hospital's infection control program.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.35
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Pediatric Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.36. Dialysis Services.

(1) If the hospital provides acute inpatient dialysis services or outpatient services either directly or through contract arrangements, the scope and organization of those services shall be defined.

(2) **Organization and Administration of Renal Dialysis Services.** The hospital shall have an organizational plan for dialysis services which clearly defines lines of authority, responsibility, and accountability and which includes provision for adequate staffing to provide dialysis care according to generally accepted standards of practice.

(a) **Medical Director.** The medical director for dialysis services shall be a physician member of the medical staff qualified to provide oversight to the specialized care required for dialysis patients and the medical director shall have at least one-year's experience in care for patients with end stage renal disease.

(b) **Nursing Services.** A registered nurse with demonstrated clinical competencies in providing dialysis services for patients shall be available during all dialysis treatments. Nursing staff and dialysis care technicians providing dialysis services shall have evidence of education, training, and demonstrated competencies in the provision of appropriate dialysis services and emergency care of patients receiving dialysis.

(c) **Policies and Procedures for Dialysis Services.** Where the hospital provides dialysis services directly to its patients, the hospital shall develop and implement policies and procedures that address the special needs of dialysis patients and shall include at least the following:

1. Maintenance of dialysis equipment;

2. Water treatment system safety;

3. Infection control;

4. Reuse of dialyzers and dialysis supplies, if applicable, and

5. Care of dialysis patients experiencing common complications of dialysis treatments.

(d) **Contracted Services.** Where the hospital provides dialysis services through a contract arrangement, the hospital must contract with a Georgia-licensed End Stage Renal Disease Facility. The contract must outline what specific services shall be provided and include who will be responsible for the maintenance of the dialysis equipment, the water treatment safety system, infection control, reuse of dialyzers and supplies, if applicable, the clinical qualification of staff to be provided, and the clinical supervision that will be provided to dialysis patients during the administration of dialysis treatments.

(3) **Appropriate Treatment.** The hospital shall provide dialysis services in accordance with accepted standards of care for the persons requiring dialysis services.

(4) **Quality Improvement.** The hospital shall ensure that problems identified during the on-going monitoring of the dialysis services are addressed in the hospital quality improvement program. Contracted services must participate in the hospital quality improvement program.

(5) **Outpatient Chronic Dialysis Services.** A hospital choosing to provide outpatient dialysis services directly as an integral part of the hospital to persons with end stage renal disease on a regularly recurring basis must meet the rules set forth in the Rules and Regulations for End Stage Renal Disease Facilities, Chapter 111-8-22, which are herein incorporated by reference, except for .03, .04, and .19.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.36
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Dialysis Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.37. Psychiatric and Substance Abuse Services.

(1) If the hospital provides psychiatric and/or substance abuse treatment services as an organized service, the scope of those services, including whether the services are provided for inpatients, outpatients, or both, shall be defined in the hospital's application for permit and meet the requirements set forth in this section and generally accepted standards of care.

(2) **Organization and Administration of Psychiatric and Substance Abuse Services.** The hospital shall have a plan for the service which clearly defines lines of authority, responsibility, and accountability and which includes provision for adequate staffing to provide patient care according to generally accepted standards of practice.

(a) **Director of Psychiatric and Substance Abuse Services.** The director of psychiatric and substance abuse services shall be a licensed physician member of the medical staff appropriately trained and qualified to supervise the provision of these services.

1. If the hospital offers substance abuse services only, the director shall be a licensed physician member of the medical staff certified or eligible for certification in addiction medicine by the American Society of Addiction Medicine or the American Osteopathic Academy of Addiction Medicine or a licensed physician member of the medical staff appropriately trained and qualified to supervise the service. If the director of the substance abuse services meets this certification requirement but is not board certified in psychiatry, the hospital must have a board eligible or board certified psychiatrist on staff to be utilized for psychiatric consultation as needed.

2. The director of the psychiatric and/or substance abuse services shall be responsible for all clinical aspects of the organization and delivery of services and for the evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

(b) **Staffing for Psychiatric and Substance Abuse Services.** The hospital shall provide sufficient clinical and support staff to assess and address the needs of psychiatric and substance abuse patients and to ensure the maintenance of a safe therapeutic environment for patients and staff.

1. **Nursing Manager/Director.** The nursing care for the psychiatric and/or substance abuse services shall be supervised by a licensed registered nurse with at least three (3) years of clinical psychiatric and/or substance abuse experience. Authorization from the Georgia Board of Nursing to practice as a Clinical Nurse Specialist, Psychiatric/Mental Health may substitute for two (2) years of the required clinical experience.

2. **Counseling Services.** Counseling services for the psychiatric and substance abuse services shall be supervised by a master's level clinician licensed in social work, marriage and family therapy, professional counseling, or a clinical nurse specialist, psychiatric mental health.

3. **Clinical Psychologist.** A licensed clinical psychologist shall be available to provide testing and treatment consultation for patients as needed.

4. **Child Psychiatrist.** If psychiatric services are provided for children, a board eligible or board certified child psychiatrist shall be on staff.

5. **Special Staffing Requirements for Inpatient Psychiatric or Substance Abuse Services.** Hospitals providing inpatient psychiatric and/or substance abuse care shall provide:

(i) A physician, with training and qualifications appropriate to the services offered, present in the hospital or available on call on a twenty-four (24) hour basis;

(ii) At least one registered nurse on duty at all times; and

(iii) Rehabilitative and therapeutic activity staff, trained and qualified to meet the needs of the patients as specified in the patients' individualized service plans.

(c) **Policies and Procedures for Psychiatric and Substance Abuse Services.** In addition to hospital policies and procedures otherwise required by these rules, the hospital providing psychiatric and/or substance abuse services shall develop and implement policies and procedures that address the special needs of the population served, to include at least:

1. Admission and discharge criteria and procedures, which comply with Georgia laws concerning involuntary admissions or treatment;

2. Safety and security precautions for the prevention of suicide, assault, and patient injury;

3. The handling of medical emergencies, including but not limited to suicide attempts, cardiac arrest, aspiration, or seizures;

4. Special procedures, such as electro convulsive therapy (ECT) and medical detoxification, as applicable; and

5. Procedures for the use of seclusion and restraint in accordance with O.C.G.A. Chapters 3 and 7 of Title 37 and these rules.

(3) **Patient's Rights in Psychiatric and Substance Abuse Services.**

(a) In addition to the rights afforded all patients at the hospital, the hospital shall ensure that patients served by the psychiatric and substance abuse services shall have the right to:

1. Receive treatment in the hospital using the least restrictive methods possible; and

2. Participate to the extent possible in the development, implementation, and review of their individualized service plan.

(b) Any permissible restriction of patient rights by the hospital program shall be imposed only in order to protect the health and safety of the patient or others and

shall be temporary. The nature, extent, and reason for the restriction shall be entered into the patient's medical record as a written order by a physician or licensed psychologist and reviewed for necessity as required by state law.

(4) **Patient Assessment and Treatment.**

(a) In addition to other assessment and treatment procedures otherwise required by these rules, psychiatric and substance abuse service programs at the hospital shall provide:

1. For inpatients:

(i) With the admission assessments performed within twenty-four (24) hours of admission, a psychiatric or substance abuse evaluation as indicated by the reason for admission; and

(ii) An individualized service plan, initiated within the first twelve (12) hours after admission and updated as needs are identified through assessments;

2. For outpatients:

(i) Within seven (7) days following the initiation of outpatient services, a complete assessment of patient needs, including an evaluation sufficient to identify significant medical conditions which may impact the course of treatment; and

(ii) Within ten (10) days following initiation of outpatient services, an individualized service plan developed and implemented to address needs identified;

3. Each patient's individualized service plan shall be developed from the patient's needs as identified through psychological, medical, and social assessment and shall be an organized statement of the proposed treatment process which serves to guide the providers and patient through the duration of the service provision. The service plan shall reflect the following:

(i) The patient's participation, to the extent possible, in the development of the individualized service plan;

(ii) Measurable goals and/or objectives to be met toward the established discharge criteria; and

(iii) Regular review of the patient's progress toward goals and/or objectives in the individualized service plan, with modifications to the plan made in response to progress or lack of progress as

reflected in progress notes recorded at each visit which document the patient's status and response to treatment;

4. At the time of development of the patient's treatment plan and with the participation of the patient, a discharge plan shall be developed for each inpatient or an aftercare plan for each outpatient. The discharge/aftercare plan shall be re-evaluated periodically during treatment to identify any need for revision; and

5. All medications administered or prescribed for psychiatric or substance abuse patients shall be solely for the purpose of providing effective treatment or habilitation as described in the individualized service plan and/or for protecting the safety of the patient or others and shall not be used for punishment or for the convenience of staff.

(b) If the hospital is not able to meet the patient needs as identified, including any acute medical or surgical needs, the hospital shall assist the patient in locating and accessing services to meet those needs, which may include transfer to another facility.

(5) **Physical Space and Design Requirements for Inpatient Psychiatric and Substance Abuse Services.**

Hospitals providing inpatient psychiatric and substance abuse services shall have:

(a) At least one seclusion area must be available to be used for the involuntary confinement of patients when necessary. The seclusion area shall be large enough to provide access to the patient from all sides of the bed or mattress and to accommodate emergency life-sustaining equipment, have a door that opens outward, and have provision for direct patient observations at all times by staff;

(b) A design conforming to the suicide prevention recommendations from the *Guidelines for Design and Construction of Hospital and Healthcare Facilities*, produced by the American Institute of Architects' Academy of Architecture for Health with the assistance of the U.S. Department of Health and Human Services, which is hereby adopted by reference;

(c) A day room that allows for social interaction, dining, and group therapy activities;

(d) Space for storage of patient's personal belongings and for securing valuables;

(e) A system for summoning help from within the immediate service area or other areas of the hospital in the event of an emergency.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.37
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Psychiatric and Substance Abuse Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.38. Special Requirements for Critical Access Hospitals.

Critical access hospitals (CAHs) shall be required to comply with the entirety of this chapter, as applicable to the scope of services offered, with the following exceptions and/or additions:

(a) Prior to application for a hospital permit, the hospital shall be approved for critical access hospital status by the Georgia Department of Community Health.

(b) The CAH shall be a member of a rural health network having at least one (1) additional hospital that furnishes acute care hospital services, which will serve as an affiliate hospital for the CAH. The CAH shall have current written agreement(s) with affiliate hospital(s) which include provisions for:

1. Patient referral and transfer between the facilities, with the use of emergency and non-emergency transportation;

2. Credentialing of medical and professional staff; and

3. Participation in quality management activities.

(c) The CAH's organization, scope, and availability of patient care services shall be defined and approved by the governing body, medical staff, and affiliate hospital. The CAH shall have:

1. Operational policies for the CAH shall be developed with participation from one (1) or more licensed physicians, one (1) or more healthcare practitioners if on the staff of the critical access hospital, and at least one (1) member of the affiliated hospital's staff who is not on the staff of the CAH;

2. Operational policies for the CAH which describe the patient care services the CAH will provide directly and those that will be provided through contract or other arrangement;

3. No more than twenty-five (25) inpatient beds or as currently defined in federal regulations. Of these beds, at least two (2), but no more than fifteen (15), shall be used for acute inpatients. If the CAH has approved swing bed services, a maximum of twenty-three (23) beds may be utilized for swing bed patients;

4. An average length of stay for patients of no more than ninety-six (96) hours or as currently defined in federal regulations;

5. A mechanism in place to ensure that emergency care is available twenty-four (24) hours per day. The CAH shall not be required to remain open twenty-four (24) hours per day when it does not have inpatients.

   (i) The CAH shall, in accordance with the local emergency response systems, establish procedures under which a physician is immediately available by telephone or radio contact, on a 24-hour per day basis, to receive emergency calls, provide information or treatment of emergency patients, and refer patients to the CAH or other appropriate location for treatment.

   (ii) A physician or limited health care practitioner with training in emergency care shall be on-call and immediately available by telephone or radio contact and available to be on-site at the CAH within thirty (30) minutes.

   (iii) The CAH shall have equipment, supplies, and medications available for treating emergencies, as are required of other organized hospital emergency services.

   (iv) Staff assigned to provide emergency patient care shall have training in handling medical and non-medical emergencies; and

6. A registered nurse or licensed practical nurse shall be on duty whenever the critical access hospital has one (1) or more inpatients.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.38
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Special Requirements for Critical Access Hospitals" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-40-.39. Special Requirements for Rural Free Standing Emergency Departments.

Rural Free Standing Emergency Departments shall be required to comply with the entirety of this chapter, as applicable to the scope of services offered by the Rural Free Standing Emergency Department, with the following exceptions and/or additions:

(a) The Rural Free Standing Emergency Department shall make all reasonable efforts to secure written agreement(s) with hospital(s) within 35 miles which include provisions for patient referral and transfer between the facilities, with the use of emergency and non-emergency transportation.

(b) The Rural Free Standing Emergency Department's organization, scope, and availability of patient care services shall be defined and approved by the governing body.

(c) The Rural Free Standing Emergency Department shall have operational policies developed with participation from one (1) or more licensed physicians. The operational policies must describe the patient care services the Rural Free Standing Emergency Department will provide directly and those that will be provided through contract or other arrangement.

(d) A Rural Freestanding Emergency Department that is not otherwise subject to the federal Emergency Medical Treatment & Labor Act, 42 U.S.C. 1395 dd shall provide to each patient, without regard to the individual's ability to pay, an appropriate medical screening examination to determine whether an emergency medical condition exists, and if so, shall provide stabilizing treatment within its capability. If the Rural Freestanding Emergency Department is unable to stabilize the patient within its capability, or if the patient requests, it shall implement a transfer of the patient to another facility that has the capability of stabilizing the patient.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.39
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Physical Plant Design and Construction" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: Renumbered as 111-8-40-.40. New Rule entitled "Special Requirements for Rural Free Standing Emergency Departments" adopted. F. Apr. 29, 2014; eff. May 19, 2014.

Rule 111-8-40-.40. Physical Plant Design and Construction.

(1) **General.** The hospital shall be designed and constructed in accordance with the needs of the patients being served.

(a) The design and construction specifications for the hospital shall conform to those nationally accepted standards for hospital design and construction as set forth in the *Guidelines for Design and Construction of Hospital and Healthcare Facilities*, published by the American Institute of Architects' Press, which has been accepted for use by the Department and which are current, as determined by the Department to be applicable, at either:

1. The time of construction of the hospital when the initial permit was obtained; or

2. The time of request for approval for renovation(s) or addition(s) to areas of the hospital which impact patient care.

(b) Compliance with standards acceptable to the Department shall be determined by a state architect designated by the Department to review hospital design and construction specifications.

1. All parts of the facility shall be subject to the architect's review, including new and existing buildings, additions, alterations, or renovations to existing structures, any mobile, transportable, or relocatable units, and any off-site structures intended to house hospital services or functions.

2. The hospital shall notify the Department prior to initiating new construction, modifications, or additions and shall submit plans for such new construction for review and approval by the state architect designated by the Department.

(c) The hospital shall have evidence of a satisfactory inspection of all buildings and structures, including any mobile units, by the local representative of the state fire marshal, the local fire and building authorities (where required by local ordinance), and the state architect.

(d) Designated space for the laundry, power plant, mechanical equipment, ambulance entrance, autopsy or morgue, loading dock, incinerator, garbage can cleaning, and storage areas for garbage and trash shall be constructed or arranged to avoid unreasonable noise, steam, odors, hazards to patients, and unsightliness relative to patient bedrooms, dining rooms, and lounge areas.

(e) Electrical, mechanical, and plumbing work and equipment shall be designed and installed in accordance with local and state ordinances.

(2) **Special Requirements for Mobile, Transportable, and Relocatable Units.** If the hospital utilizes, by ownership or contract, mobile, relocatable, or transportable units for the provision of hospital services, the units shall meet the following requirements:

(a) If the unit is used to provide routine ancillary services for hospital inpatients or to provide services for the hospital emergency room, there shall be a covered or enclosed walkway from the hospital to the unit to ensure patient safety from the outside elements;

(b) The unit shall be located so as to prevent diesel or exhaust fumes from the tractor or unit generator from entering the fresh air intake of either the unit or the facility;

(c) The unit shall have means of preventing unit movement, either by blocking the wheels or use of pad anchors;

(d) The hospital shall provide waiting areas for the unit and, in close proximity to the unit, patient and staff toilet facilities for use by the staff providing services from the unit and for use by the patients accessing the services in the unit;

(e) Each unit shall be accessible to wheelchair and stretcher bound patients;

(f) The hospital shall provide access to hand washing facilities for staff in the unit, as appropriate to the services provided in the unit and sufficient to allow compliance with the hospital's infection control program;

(g) The hospital shall have a plan for the handling of emergencies that may occur in the unit. The unit shall be connected to the hospital communication system for access to emergency response services;

(h) Waste lines to the unit shall be designed and constructed to discharge into an approved sewage system. The hospital shall ensure that back-flow prevention is installed at the point of water connection on the unit;

(i) If stairs are used to access the unit, they shall have stable handrails; and

(j) The hospital shall ensure that approaches to the unit have adequate lighting for safe negotiation at all hours of operation.

(3) **Emergency Lighting and Power.** The hospital shall have access to emergency lighting and electrical power meeting the following requirements:

(a) Functioning automatic emergency lighting equipment in all corridors in nursing units and in each operating room, delivery room, emergency room, exit, elevator, and stairway; and

(b) A functioning emergency electrical system. The emergency electrical system shall be so controlled that after interruption of the normal electric power supply, the generator is brought to full voltage and frequency and connected within ten (10) seconds through one or more primary automatic transfer switches to all emergency lighting; all alarms; blood banks; nurses' call; equipment necessary for maintaining telephone service; pump for central suction system; and receptacles in operating rooms and delivery rooms, patient corridors, patient rooms, recovery rooms, intensive care nursing areas, and nurseries. All other lighting and equipment required to be connected to the emergency system shall either be connected through the above-described primary automatic transfer switching or shall be subsequently connected through other automatic or manual transfer switching. Receptacles connected to the emergency system shall be distinctively marked for identification. Storage-battery-powered lights, provided to augment the emergency lighting during the interim of transfer switching immediately following an interruption of the normal service supply, shall not be used as a substitute for the requirement of a generator. Where fuel is normally stored on the site, the storage capacity shall be sufficient for twenty-four (24) hour operation. Where fuel is normally piped underground to the site from a utility distribution system, storage facilities on the site will not be required.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.40
Authority: O.C.G.A. § 31-7-2.1.

History. Original Rule entitled "Requests for Waiver or Variance" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: Renumbered as 111-8-40-.41. New Rule entitled "Physical Plant Design and Construction" adopted. F. Apr. 29, 2014; eff. May 19, 2014.

Rule 111-8-40-.41. Requests for Waiver or Variance.

A hospital may request a waiver or variance of a specific rule by application on forms provided by the Department. A waiver or variance may be granted in accordance with the following considerations:

(a) The Department may grant or deny the request for waiver or variance at its discretion. If the waiver or variance is granted, the Department may establish conditions which must be met by the hospital in order to operate under the waiver or variance. Waivers or variances may be granted with consideration of the following:

1. **Variance.** A variance may be granted by the Department upon a showing by the applicant that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application would cause undue hardship. The applicant must also show that adequate standards exist for affording protection for the health, safety, and care of patients, and these existing standards would be met in lieu of the exact requirements of the rule or regulation.

2. **Waiver.** The Department may dispense altogether with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, and care of the patients.

3. **Experimental Waiver or Variance.**

   The Department may grant a waiver or variance to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant that the intended protections afforded by the rule or regulation in question are met and the innovative approach has the potential to improve service delivery;

(b) Waivers and variances granted by the Department shall be for a time certain, as determined by the Department; and

(c) Waivers and variances granted to a facility shall be recorded and shall be available to interested parties upon request.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.41
Authority: O.C.G.A. § 31-2-7.
History. Original Rule entitled "Enforcement of Rules and Regulations" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: Renumbered as 111-8-40-.42. New Rule entitled "Requests for Waiver or Variance" adopted. F. Apr. 29,

2014; eff. May 19, 2014.

Rule 111-8-40-.42. Enforcement of Rules and Regulations.

A hospital that fails to comply with these rules and regulations shall be subject to sanctions and/or permit revocation as provided by law. The enforcement and administration of these rules and regulations shall be as prescribed in the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25, pursuant to O.C.G.A. § 31-2-8.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.42
Authority: O.C.G.A. § 31-2-8.
History. Original Rule entitled "Severability of These Rules" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: Renumbered as 111-8-40-.43. New Rule entitled "Enforcement of Rules and Regulations" adopted. F. Apr. 29, 2014; eff. May 19, 2014.

Rule 111-8-40-.43. Severability of These Rules.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions of rules shall remain in full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-40-.43
Authority: O.C.G.A. §§ 31-2-1*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Severability of These Rules" adopted. F. Apr. 29, 2014; eff. May 19, 2014.

Subject 111-8-41. RULES AND REGULATIONS FOR HOSPITAL TRANSPARENCY.

Rule 111-8-41-.01. Legal Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated (O.C.G.A.) § 31-7-22 et seq. (effective Oct. 1, 2019).

Cite as Ga. Comp. R. & Regs. R. 111-8-41-.01
Authority: O.C.G.A. § 31-7-22.
History. Original Rule entitled "Legal Authority" adopted. F. Dec. 12, 2019; eff. Jan. 1, 2020.

Rule 111-8-41-.02. Applicability.

These rules shall apply to all Hospitals, any Affiliate, and any Subsidiary as defined in these Rules. This information is provided with the intent to give healthcare consumers the tools to make an informed decision in selecting a hospital.

Cite as Ga. Comp. R. & Regs. R. 111-8-41-.02
Authority: O.C.G.A. § 31-7-22.
History. Original Rule entitled "Applicability" adopted. F. Dec. 12, 2019; eff. Jan. 1, 2020.

Rule 111-8-41-.03. Definitions.

As used in these Rules, the term

(1) "Administrative Position" shall mean a non-clinical hospital employee or contractor, which shall include, but is not limited to, a management company or similar entity, with a gross annual salary or payment of $100,000 or more.

(2) "Affiliate" shall mean any hospital that is united; being in close connection, allied, associated, or attached as a member or branch to another hospital.

(3) "Captive Insurance Company" shall include any agency captive insurance company, association captive insurance company, captive insurance company, dormant captive insurance company, industrial insured captive insurance company, or pure captive insurance company as defined in O.C.G.A. § 33-41-2.

(4) "Hospital" shall mean a nonprofit hospital, a hospital owned or operated by a hospital authority, or a nonprofit corporation formed, created, or operated by or on behalf of a hospital authority.

(5) "Joint Venture" shall mean an enterprise shared between two or more entities. A joint venture is a business entity created by two or more business entities, which enter into an agreement to share funding, profits or losses, and control over the new entity.

(6) "Link" shall mean publicly-accessible single-click access from a prominent place on the webpage of either the Hospital or the department to the web location where the subject documents are posted.

(7) "Parent Corporation" shall mean a business entity that forms another business entity and retains ownership in the new entity. A parent corporation is a corporation that creates or acquires another business entity, retaining ownership or control in the new entity, which is the Subsidiary corporation.

(8) "Real Estate" shall mean the physical parcel of land, improvements to the land, improvements attached to the land, real fixtures, and appurtenances such as easements.

(9) "Real Property Holdings" shall mean the bundle of rights, interests, and benefits connected with the ownership of real estate. Real property does not include the intangible

benefits associated with the ownership of real estate, such as the goodwill of a going business concern.

(10) "State Funds" shall mean state dollars, but shall not include funding necessary for the continued state participation in the federal Medicaid program.

(11) "Subsidiary" shall mean a company or companies organized by a parent corporation.

(12) "Subsidiary Holding Company" shall mean a company or companies organized by a parent corporation or a Subsidiary corporation to the parent corporation.

Cite as Ga. Comp. R. & Regs. R. 111-8-41-.03
Authority: O.C.G.A. § 31-7-22.
History. Original Rule entitled "Definitions" adopted. F. Dec. 12, 2019; eff. Jan. 1, 2020.

Rule 111-8-41-.04. Required Documentation.

Beginning October 1, 2019, each Hospital in this state shall make public the most recent version of the following subject documents:

(1) Federal related disclosures:

(A) Copies of audited financial statements that are general purpose financial statements, which express the unqualified opinion of an independent certified public accounting firm for the most recently completed fiscal year for the Hospital; each of its Affiliates, except those Affiliates that were inactive or that had an immaterial amount of total assets; and the Hospital's parent corporation that include the following:

(i) A PDF version of all audited financial statements;

(ii) A note in the Hospital's audited financial statements that identifies individual amounts for such Hospital's gross patient revenue, allowances, charity care, and net patient revenue;

(iii) Audited consolidated financial statements for Hospitals with subsidiaries and consolidating financial statements that at a minimum contain a balance sheet and statement of operations and that provide a breakout of the Hospital's and each Subsidiary's numbers with a report from independent accountants on other financial information; and

(iv) Audited consolidated financial statements for the Hospital's parent corporation and consolidating financial statements that at a minimum contain a balance sheet and statement of operations and that provide a

breakout of the Hospital's and each Affiliate's numbers with a report from independent accountants on other financial information; and

(B) Copy of audited Internal Revenue Service Form 990, including Schedule H for hospitals and other applicable attachments; provided, however, that for any Hospital not required to file IRS Form 990, the department shall establish and provide a form that collects the same information as is contained in Internal Revenue Service Form 990, including Schedule H for hospitals, as applicable; and

(2) Georgia supplemental disclosures:

(A) Copy of the Hospital's completed annual hospital questionnaire, as required by the department;

(B) The community benefit report prepared pursuant to O.G.C.A. § 31-7-90.1, if applicable;

(C) The disproportionate share hospital survey, if applicable;

(D) Listing of all Real Property Holdings of the Hospital, including the location and size, parcel ID number, purchase price, current use, and any improvements made to such property;

(E) Listing of any ownership or interest the nonprofit Hospital has in any Joint Venture, partnership, Subsidiary Holding Company, or Captive Insurance Company; where any such entity is domiciled; and the value of any such ownership or interest;

(F) Listing of any bonded indebtedness, outstanding loans, and bond defaults, whether or not in forbearance; and any bond disclosure sites of the Hospital;

(G) A report that identifies by purpose, the ending fund balances of the net assets of the Hospital and each Affiliate as of the close of the most recently completed fiscal year, distinguishing between donor permanently restricted, donor temporarily restricted, board restricted and unrestricted fund balances. The Hospital's interest in its foundation shall be deducted from the foundation's total fund balance;

(H) Copy of all going concern statements regarding the Hospital;

(I) The most recent legal chart of corporate structure, including the Hospital, each of its Affiliates and Subsidiaries, and its Parent Corporation, duly dated;

(J) Report listing the salaries and fringe benefits for the ten highest paid Administrative Positions in the Hospital. Each position shall be identified by its

complete, unabbreviated title. Fringe benefits shall include all forms of compensation, whether actual or deferred, made to or on behalf of the employee, whether full or part-time;

(K) Evidence of accreditation by accrediting bodies, including, but not limited to, the Joint Commission and DNV; and

(L) Copy of the Hospital's policies regarding the provision of charity care and reduced cost services to the indigent, excluding medical assistance recipients, and its debt collection practices.

Cite as Ga. Comp. R. & Regs. R. 111-8-41-.04
Authority: O.C.G.A. § 31-7-22.
History. Original Rule entitled "Required Documentation" adopted. F. Dec. 12, 2019; eff. Jan. 1, 2020.

Rule 111-8-41-.05. Posting Requirements.

(1) Each Hospital shall post a Link entitled "Hospital Transparency Information" in a prominent location on the main page of its website to the documents listed in Rule 111-8-41-.04 on July 1 of each year or more frequently at its discretion. Documents from prior years shall remain posted and accessible on the Hospital's website indefinitely.

(2) All documents listed in Rule 111-8-41-.03 shall be prepared in accordance with generally accepted accounting principles, as applicable.

(3) Each Hospital shall provide the Link to the department annually and in the manner requested.

(4) The department shall post the Link in a prominent location on its website for each Hospital in this state.

Cite as Ga. Comp. R. & Regs. R. 111-8-41-.05
Authority: O.C.G.A. § 31-7-22.
History. Original Rule entitled "Posting Requirements" adopted. F. Dec. 12, 2019; eff. Jan. 1, 2020.

Rule 111-8-41-.06. Enforcement.

(1) Any Hospital that fails to post the documents required by these Rules within 30 days of the dates required in this Rule section shall be suspended from receiving any State Funds or any donations pursuant to O.C.G.A. § 48-7-29.20; provided, however, that the department shall provide a hospital notice of any deficiency and opportunity to correct such deficiency prior to any suspension of funds pursuant to this subsection.

(2) Any hearing under these Rules shall be held in accordance with the Georgia Administrative Procedure Act.

(3) Any person who knowingly and willfully includes false, fictitious, or fraudulent information in any documents required to be posted pursuant to O.C.G.A. § 31-7-22 and these Rules shall be subject to a violation of O.C.G.A. § 16-10-20 and be referred by the department to the Office of the Attorney General for investigation.

Cite as Ga. Comp. R. & Regs. R. 111-8-41-.06
Authority: O.C.G.A. § 31-7-22.
History. Original Rule entitled "Enforcement" adopted. F. Dec. 12, 2019; eff. Jan. 1, 2020.

Subject 111-8-47. INTERMEDIATE CARE HOMES.

Rule 111-8-47-.01. Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them; except, however, same do not apply to facilities owned or operated by the federal government:

(a) An "Intermediate Care Home" is a facility which admits residents on medical referral; it maintains the services and facilities for institutional care and has a satisfactory agreement with a physician and dentist who will provide continuing supervision including emergencies; it otherwise complies with these rules and regulations;

(b) The term "Intermediate Care" means the provision of food, including special diets when required, shelter, laundry and personal care services, such as help with dressing, getting in and out of bed, bathing, feeding, medications and similar assistance, such services being under the supervision of a registered, licensed undergraduate, or licensed practical nurse.1. Intermediate care does not normally include providing care for bed patients except on an emergency or temporary basis, the insertion or changing of catheters, handfeeding of patients, and the care of patients who cannot go to the medication area without assistance.

(c) The term "Distinct Part" means a physically identifiable unit of a medical facility such as an entire ward or contiguous wards, wing, floor, or building. It consists of all beds and related facilities in the unit;

(d) The term "Intermediate Care Unit" means a clearly defined administrative unit within which is located a specified number of resident beds and supportive services;

(e) The term "Medication Area" means a circumscribed space within the Intermediate Care Unit containing equipment for proper storage, preparation and administration of medicines prescribed by the residents' physician or dentist;

(f) The term "Resident" means any person residing in and receiving care in an Intermediate Care Home. Residents are individuals who because of their physical or mental condition (or both) require living accommodations and care which, as a practical matter, can be made available to them only through institutional facilities; and who do not have such an illness, disease, injury or other condition as to require the degree of care and treatment which a hospital or nursing home is designed to provide;

(g) The term "Resident Activities Program" means a schedule of events which are regularly planned for all residents, including social and recreational activities involving active participation by the residents, entertainment of appropriate frequency and character and opportunities for participation in community activities as possible and appropriate;

(h) The term "Transfer Agreement" means a written contract with other facilities providing for transfer of residents between the facilities and for interchange of medical and other information, when the facility cannot provide the level of care needed by the resident;

(i) "Physician" shall mean a doctor of medicine and/or a doctor of osteopathy duly licensed to practice in this State by the Georgia Composite Medical Board, under the provisions of the Georgia Medical Practice Act (O.C.G.A. § 43-34-1 et seq.);

(j) "Dentist" means any person who is licensed to practice in this State under the provisions of the Dentists and Dental Hygienists Act;

(k) "Pharmacist" shall mean an individual licensed to practice pharmacy in accordance with the provisions of the Pharmacy Practice Act, O.C.G.A. § 26-4-1 et seq.;

(l) "Physical Therapist" shall mean an individual who practices physical therapy and who is registered with the Board of Physical Therapy of the State of Georgia (O.C.G.A. § 43-33-1 et seq.);

(m) A "Registered Nurse" is a person who holds a current and valid license as a registered nurse issued by the State of Georgia;

(n) A "Licensed Undergraduate Nurse" is a person who holds a current and valid license as a licensed undergraduate nurse issued by the State of Georgia;

(o) A "Licensed Practical Nurse" is a person who holds a current and valid license as a licensed practical nurse issued by the State of Georgia;

(p) The term "Full-time Employee" means any person employed who normally works at least forty (40) hours per week in the home;

(q) The term "Governing Body" means the Board of Trustees, the partnership, the corporation, the association, the person or group of persons who maintain and control the home and who is legally responsible for the operation;

(r) The term "Administrator" means an individual who is licensed by the Georgia State Board of Nursing Home Administrators and who has the necessary authority and responsibility for management of the home;

(s) "Permit" means authorization by the Department to the Governing Body to operate a home and signifies satisfactory compliance with these rules and regulations.

(t) "Provisional Permit" means authorization by the Department to the Governing Body to operate a home on a conditional basis for a period not to exceed six months to allow a newly established home a reasonable but limited period of time to demonstrate operational procedures in satisfactory compliance with these rules and regulations; or to allow an existing home a reasonable length of time to comply with these rules and regulations, provided said home shall first present a plan of improvement acceptable to the Department. Successive Provisional Permits may be granted to any home having deficiencies only in exceptional cases, in which cases the governing body must present a plan of improvement acceptable to the Department;

(u) The term "Plan of Improvement" means a written plan submitted by the Governing Body and acceptable to the Department. The plan shall identify the existing noncompliances of the institution, the proposed procedures, methods, means and period of time to correct the noncompliances;

(v) The term "Board" means the Board of Community Health;

(w) The term "Department" means the Department of Community Health;

(x) The term "Commissioner" means the chief executive of the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.01
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Definitions" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.02. Governing Body.

(1) There shall be a governing body which assumes full legal responsibility for the overall conduct of the facility.

(2) The ownership of the facility shall be fully disclosed to the Department. In the case of corporations, partnerships and other bodies created by statute, the corporate officers and all others owning ten percent or more of the corporate stock or ownership shall be made known to the Department.

(3) The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to the facility.

(4) The governing body shall certify to the Commissioner, the name of the person to whom is delegated the responsibility for the management of the facility, including the carrying out of rules and policies adopted by the governing body. This person shall be known as the administrator.

(5) The word hospital, sanitorium or sanitarium shall not be used in the official title of any home permitted under the provisions of these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.02
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Governing Body" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.03. Administration.

(1) Each intermediate care home shall be under the supervision of a licensed nursing home administrator. An administrator may serve as the administrator of not more than one facility, except that two facilities having common ownership or management located on the same premises may be served by a single administrator. Distinct part facilities sharing a common roof shall be considered one facility. In exceptional circumstances, a waiver may be granted by the Department for a period of six months.

(2) Each home shall be operated in accordance with policies approved by the Department. These policies shall include but not be limited to those governing admissions, transfers, discharges, physicians' and dental services, social services, intermediate resident care services, housekeeping, environmental sanitation, recreational services and health records.

(3) Each facility shall have a written transfer agreement in effect with one or more hospitals and nursing homes. Intermediate care homes that are a Distinct Part of a hospital or skilled nursing home will be considered to meet this requirement if acceptable provisions for the transfer of residents are included in the home's policies.

(4) There shall be a separate personnel folder maintained for each employee. This folder shall contain all personal information concerning the employee, including the application and qualifications for employment, physical examination and job title assigned. A current job description shall be available for each classification of employee, but may be maintained separately from the personnel folder.

(5) The facility and its premises shall be used only for those purposes for which the facility is operated and permitted.

(6) In response to a reasonable request by a resident or visitor, privacy shall be afforded for private conversation and/or consultations.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.03
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Administration" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.04. Personal Care Services.

(1) A registered nurse, licensed undergraduate nurse, or a licensed practical nurse, shall be employed full time as supervisor of care.

(2) In addition to the supervisor of care, there shall be sufficient staff members on duty at all times to assure each resident proper care according to his needs. This includes staff members awake and on duty all night. Proper care includes, but is not limited to: assistance with activities of daily living, clean and proper clothing, good grooming, free of body odor, clean hair and scalp, clean and trimmed finger and toe nails, daily mouth care and barber services, including shaves.

(3) All resident care and related services shall be carried out in accordance with written resident care policies which are assembled, available and understood by all staff and including but not limited to:

   (a) Clearly established lines of administrative and supervisory responsibility;

   (b) Clearly defined duties which are assigned to staff members and consistent with their training and experience.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.04
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Personal Care Services" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.05. Professional Service.

(1) Residents shall be admitted only on medical evaluation and referral.

(2) Each resident's health care is under the continuing supervision of a physician who sees the resident as needed and in no case less often than sixty (60) days, unless justified otherwise and documented by the attending physician.

(3) There shall be a physician and dentist on call who will provide for the resident's medical and/or dental needs when his attending physician or dentist is not available.

(4) A home shall admit only those residents for whom it can provide the care needed and for which it holds a permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.05
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Professional Service" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.06. Dietary Service.

(1) If an intermediate care home accepts or retains residents in need of medically prescribed special diets, the menus for such diets shall be planned by a qualified dietitian (American Dietetic Association or equivalent qualifications), or shall be reviewed and approved in writing by the attending physician.

(2) Meals, adequate as to quantity and quality, shall be served in sufficient numbers with a maximum of five (5) hours apart with no longer than fourteen (14) hours between the evening meal and breakfast. Between meal and bedtime snacks shall be offered to each resident.

(3) A nutritionally adequate diet shall be provided all residents and adjusted to resident's age, sex, activity, and physical condition. Nutrient concentrates and supplements shall be given only on written order of a physician.

(4) Menus shall be planned and dated. Used menus shall be kept on file for a period of thirty days for reference by the resident's physician and personnel of the home.

(5) Modified diets shall be provided in accordance with written orders of a physician or dentist. An approved diet manual shall be readily available to food service personnel.

(6) Sufficient perishable foods for a twenty-four hour period and nonperishable foods for a three-day period shall be on the premises for use in an emergency.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.06
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Dietary Service" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.07. Social Service.

(1) Each home shall provide services to assist all residents in dealing with social and related problems through one or more caseworkers on the staff of the facility or through arrangements with an appropriate outside agency.

(2) Social service information concerning each resident shall be obtained and kept. This information shall cover social and emotional factors related to the resident's condition and

information concerning his home situation, financial resources and relationships with other people.

(3) All employees having contact with residents shall receive social service orientation and inservice training toward understanding emotional problems and social needs of residents.

(4) One person in each home shall be designated as being responsible for the social services aspects of care in the home.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.07
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Social Service" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.08. Medications.

Each facility shall insure that the handling of patient medication is in full compliance with state and federal laws and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.08
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Medications" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.09. Physical Therapy Service.

(1) When a home has a physical therapy program, the services must be provided or directly supervised by a physical therapist.

(2) A therapy record will be kept as part of the health folder on each resident receiving physical therapy. Information in the health folder shall include referral, diagnosis, precautions, initial physical therapy evaluation, treatment plans and objectives, frequency and dates of medical reevaluation.

(3) The physical therapist shall keep progress notes on each resident including progress or lack of progress, symptoms noted, and changes in treatment plans.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.09
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Physical Therapy Service" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.10. Resident Care.

(1) Each resident shall have a physician's written statement of his or her condition at time of admission or within forty-eight (48) hours thereafter and it shall be kept on file in the resident's health folder.

(a) Physicians' prescriptions for medications for residents needing medication shall accompany the resident upon admission to the facility;

(b) The physician's statement of the resident's condition should state any special care required including special diets.

(2) Each home shall have a written agreement with a physician and a dentist who will be available to the home for emergencies, and who will provide the home with consultation concerning medical and dental problems.

(3) Each home shall maintain a plan of care for each resident. This plan shall be kept current and will show, as a minimum, the name and frequency of medications, kind of diet, social problems, special care required, and ability to provide self-care. The plan of care shall be available to all personnel.

(4) Reports of all resident evaluations and examinations shall be kept in the individual health folder.

(5) The home shall have a microbial and infection control program. Policies and procedures for infection control shall be written, assembled and available to all staff members. Procedures shall be specific for practice in the home and shall be included in the training of every staff member. As a minimum, procedures shall include the following control measures:

(a) Prevention of spread of infection from personnel to resident: Any person whose duties include direct resident care, handling food, or handling clean linen, and who has an acute illness such as "strep" throat, or an open sore or boil, shall not be allowed to work until he is fully recovered;

(b) Prevention of spread of infection from visitors to residents;

(c) Prevention of spread of infection from resident to personnel or other residents. Isolation techniques to be observed according to the source of infection and the method of spread; and

(d) Reporting of communicable diseases as required by the rules and regulations for notification of diseases which have been promulgated by the Department of Public Health.

(6) Restraint and/or forcible seclusion of a resident will be permitted only on a signed order of a physician, except in an emergency and then only until the advice of a physician can be obtained.

(7) Provisions shall be made for proper sterilization of supplies, utensils, instruments and other materials as needed for the residents.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.10
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Resident Care" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.11. Records.

(1) There shall be an individual health folder for each resident including:

(a) The name, address and telephone number of his physician and dentist;

(b) A record of the physician's findings and recommendations including the preadmission evaluation of the resident's condition and subsequent reevaluations and all orders and recommendations of the physician for care; and

(c) All symptoms and other indications of illness or injury brought to the attention of the staff by the residents, or from other sources, including the date, time and action taken regarding each.

(2) Each facility shall keep resident statistics, including admissions, discharges, deaths, resident days, and percent of occupancy. Statistical records shall be open for inspection, and upon request, data shall be submitted to the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.11
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Records" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.12. Equipment.

(1) Resident beds shall be single, at least thirty-six (36) inches wide, with firm even springs covered by a mattress not less than four inches thick.

(2) The home shall provide all linens and blankets essential to the treatment and comfort of residents.

(3) Wheelchairs and walkers shall be provided by the home when needed.

(4) Each resident shall have necessary furniture which shall include a bedside table, a reading lamp, a chair, drawer space for clothes, enclosed space for hanging clothing, individual

towel rack, soap dish, drinking glass, and access to a mirror. Each resident shall have a suitable signaling device.

(5) Individual equipment shall be cleaned after each use and disinfected at least once each week. Equipment such as bedpans, urinals and wash basins, if not individual, should be disinfected after each use.

(6) Each resident shall be provided adequate supplies and equipment for proper oral hygiene including a toothbrush or a denture brush and denture receptacle when needed.

(7) Bedrails shall be available for use as required by the resident's condition.

(8) There shall be an electric clock with a bold face that can be read from a distance of twenty (20) feet installed in the lobby of each home.

(9) Disposable equipment and supplies shall be used only once and disposed of in an approved manner.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.12
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Equipment" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.13. Safety.

(1) All buildings and equipment shall be maintained in such condition that no hazards to the life and safety of the patients exist.

(2) Adequate parking shall be available nearby. Parking areas and service entrances shall be so designated that fire fighting equipment will have unobstructed access to all parts of the building.

(3) Handrails shall be provided on all stairways and ramps. Stairtreads shall be made of or covered with safe nonslip material. Doors opening onto stairways shall not open directly onto risers, but shall open onto a landing not less than the width of the door.

(4) Safety barriers at the head of stairways, and handrails in hallways shall be provided. There shall be no low windows, open porches, changes in floor levels or similar hazards.

(5) Doors to rooms used by residents shall be equipped with locks or other devices which will not allow the room to be locked from the inside.

(6) Floor surfaces shall be smooth and level; scatter rugs and highly polished floors in resident areas are prohibited.

(7) Showers, tubs, and toilets shall have grab bars firmly installed convenient to resident use; the floor in bathing areas shall be provided with a nonslip surface. No resident shall be permitted to bathe without an attendant available to regulate water temperature and to provide generally for the safety of the resident, unless the resident's physician has provided a written statement to the effect that the resident is sufficiently responsible to bathe himself. Shower heads shall not be installed above bathtubs.

(8) Warning signs shall be posted prohibiting smoking or open flames of any kind in areas where oxygen is in use or stored.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.13
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Safety" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.14. Environmental Sanitation and Housekeeping.

(1) Equipment and supplies for proper sanitation will be maintained on the premises.

(2) Laundry shall be handled, stored and processed so that spread of infection will be minimized. A sufficient clean linen supply shall be insured at all times. Soiled linen shall not be permitted to accumulate.

(3) The premises and all areas within the home shall be kept clean and free from debris. Ventilation openings, such as ports for exhaust fans, shall be equipped with covers that close automatically when the fan is not in operation. Doors and other openings shall be equipped and maintained to minimize the ingress of flies, insects and rodents.

(4) Provision shall be made to maintain clean containers and store garbage in areas that are separate from food handling, food preparation and food storage area.

(5) Sanitary containers, sputum cups, and other satisfactory individual containers must be provided when needed.

(6) Each home shall have an infection control program which provides for policies, procedures and training programs. Great care should be exercised to prevent spread of infection by fomites or by infected person to person.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.14
Authority: Ga. L. 1964, pp. 507. 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Environmental Sanitation and Housekeeping" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.15. Health of Employees.

Each home shall require that each employee receive a physical examination upon employment. The examination shall be in sufficient detail, with pertinent laboratory and X-ray data to insure that the employee is physically and mentally qualified to perform the job to which he is assigned. An annual physical examination thereafter is recommended. However, as a minimum, on an annual basis each employee will have a physical inspection to help insure freedom from communicable disease. As part of the annual examination or inspection a tuberculin skin test will be given to all previous negative reactors. If the skin test is positive, a chest X-ray will be required and the individual referred to his physician or appropriate health authority for possible prophylaxis treatment. Copies or certificates of physical examinations shall be kept in the employee's personnel folder.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.15
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Health of Employees" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.16. Recreation.

(1) An individual shall be designated as being in charge of resident activities. This individual shall have experience and/or training in group activities, or shall have consultation made available from a qualified recreational therapist or group activity leader.

(2) Provisions shall be made for suitable recreational and entertainment activities for residents according to their needs and interests. These activities are an important adjunct to daily living and are to encourage restoration to self-care and resumption of normal activities. Variety in planning shall include some outing activities in suitable weather.

(3) Residents shall be encouraged but not forced to participate in patient activities.

(4) The facility shall make available a variety of supplies and equipment adequate to satisfy the individual interests of residents. Examples are: books, magazines, daily newspapers, games, stationery, radio, television, and the like.

(5) An active resident activities program shall be carried out that will meet the needs of all residents.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.16
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Recreation" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.17. Resident Capacity.

(1) The number of beds provided shall be indicated on each permit and provisional permit.

(2) The number of residents receiving care within the home shall not exceed the number of beds shown on the permit. In exceptional cases, temporary waivers, not to exceed thirty (30) days, may be granted by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.17
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq, Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Resident Capacity" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.18. Physical Plant Standards.

(1) Requirements under this rule "Physical Plant Standards" will be enforced with the effective date of these regulations. In exceptional cases and upon application to the Department by the governing body of the home, variances may be granted at the discretion of the Department if it is determined that these requirements will place an undue burden or extreme hardship on the home or its occupants, provided that the health or safety of the residents is not jeopardized.

(2) At least two rooms per fifty (50) beds shall be designed for single occupancy (one bed). At least one room designed for single occupancy shall have an adjoining private bathroom, containing a lavatory, water closet and a bathtub or shower equipped with grab bars. Intermediate care homes which are a Distinct Part of a nursing home may utilize the single occupancy rooms of the nursing home, provided that there are at least two single occupancy rooms per each fifty (50) beds for the combined patient and resident capacities.

(3) All resident rooms shall open into corridors leading to the exterior of the building. No resident room will be so located as to make it necessary for a resident to pass through another room to gain entrance to a corridor leading to the exterior.

(4) Each resident room shall be an outside room with window space equal to at least one-eighth of the floor area with opening in area large enough to remove resident by mattress.

(5) Resident bedrooms shall contain not less than one hundred (100) square feet of usable floor space in private or single rooms and no less than eighty (80) square feet per bed of usable floor space in multibed rooms. Usable floor space is in addition to area provided for closets, toilet rooms and entry ways.

(6) Not less than three (3) feet or space shall be provided between beds and between the foot of the bed and wall or other obstruction. There shall be sufficient space so beds may be made accessible from both sides for nursing care when needed.

(7) An individual clothes closet or wardrobe with door shall be provided per bed in every resident room. Clothes closets or wardrobes shall be at least twenty-two (22) inches deep and twenty (20) inches wide with at least one shelf above a hanging space equipped with a device for clothes hangers.

(8) There shall be sufficient bedside screens available to provide privacy for residents when needed or requested. Bedside screens shall be rendered and maintained flame resistant.

(9) Employees, staff, and visitors shall not use water closets provided for residents. Toilets, including a water closet, lavatory, soap, paper towels and dispensers shall be provided near or adjacent to the following locations:

(a) Medication area;

(b) Kitchen;

(c) Lobby area or waiting room.

(10) Resident bathing and toilet facilities:

(a) Unless there is a bathroom adjoining each resident's room containing a lavatory, water closet and a bathtub or shower there shall be a general bathing area in each Intermediate Care Unit. This area shall contain at least one bathtub accessible from three sides, one stall shower with adjacent drying space, one lavatory, with soap, paper towels and dispenser, and one water closet. This unit shall be of sufficient size to provide space for dressing, a wheelchair, and an attendant. Unless the bathing fixtures are located in separate rooms, compartments must be provided to permit independent use to afford privacy for each sex. Special institutional tubs or showers may be approved for use if the program of service indicates;

(b) At least one enclosed water closet and one lavatory shall be provided for each eight beds or major fraction thereof;

(c) At least one bathing facility (bathtub or shower) shall be provided for each fifteen (15) beds, or major fraction thereof, located in patient bedrooms that do not adjoin a toilet room in which a bathing facility is located;

(d) Unless bathtubs in bathrooms adjoining resident rooms are located so as to be accessible from three sides, handrails or grab bars on the tub or on the wall by the tub shall be provided;

(e) All shower stalls shall be at least four feet by four feet square and must have handrails on three sides, be equipped with curtains and be designed for wheelchair use. Thresholds to showers must be flush with the floor. The floor of the shower stall shall drain properly;

(f) Grab bars, securely attached to walls and conveniently located, adjacent to all bathtubs, showers, and water closets intended for resident use shall be provided.

(11) A medication area shall be provided in each Intermediate Care Unit. It shall contain a call system, charting desk and supplies, medicine storage, lavatory with soap, towels and towel dispenser, preparation area and a refrigerator.

(12) There shall be a floor pantry in each Intermediate Care Unit located near or adjacent to the medication area. The floor pantry shall contain a hot plate, sink, counter, cabinets and a refrigerator that shall not be used to store drugs, biologicals, or laboratory specimens.

(13) There shall be separate clean and soiled utility rooms in each Intermediate Care Unit located near the medication area. The clean utility room shall contain wall and base cabinets and stain resistant counter top, a small sink set into the counter or with drain boards. The soiled utility room shall contain a counter with a stain resistant top and storage cabinets underneath. In addition, it shall contain a deep service sink with stopper for chemical sterilization of bedpans, urinals and commode pails. The deep service sink with stopper may be omitted if a steam autoclave for sterilizing is available to the home.

(14) At least one bedpan cleansing device shall be provided in each Intermediate Care Unit. It may be located in the soiled utility room or in a special bedpan closet conveniently located. The bedpan cleansing device may be omitted if water closets in residents' toilets are equipped with bedpan lugs, spray hose and elevated vacuum breaker.

(15) Sufficient space shall be provided in each Intermediate Care Unit for stretcher and wheelchair parking. Such space shall be out of corridor traffic.

(16) A drinking fountain which shall not impair any passageway shall be provided in each Intermediate Care Unit.

(17) There shall be a treatment room convenient to resident rooms containing a treatment table, lavatory equipped with soap, paper towels and dispenser, instrument table and storage cabinet, and providing adequate room for transfer of residents. A treatment room may be used for consultation if appropriately enlarged. Intermediate care homes that are a Distinct Part of a hospital or nursing home may utilize the treatment room in the other facility.

(18) There shall be a resident dining and recreation area provided in each facility. The minimum total area shall be twenty (20) square feet of floor space per bed. One-half the required space shall be for dining. Intermediate care facilities that are a Distinct Part of a nursing home may utilize the dining facilities of the other facility if the dining facilities are of sufficient size to accommodate the total patient and resident capacity.

(19) A room with sufficient space for residents' active exercise regimens including such equipment as a full-length mirror, parallel bars, steps, a wall-mounted wheel, and an

exercise table shall be provided. The room shall also contain a lavatory with gooseneck spout and wrist controls. Soap, paper towels and towel dispenser shall also be provided.

(20) There shall be a lobby and/or waiting room in each facility. The size of this area shall be determined according to the size of the facility and the program of service. Intermediate care homes that are a Distinct Part of a nursing home may utilize the lobby or waiting room of the other facility.

(21) There shall be at least one building exit at ground level and at least one building exit shall be provided with a suitable ramp designed for a stretcher or a wheelchair. There shall be one such exit leading to the outdoor recreation area.

(22) A public telephone shall be located near the lobby. At least one telephone shall be arranged to be convenient for a wheelchair user.

(23) The central kitchen area shall be located to permit efficient service to the dining rooms and the Intermediate Care Units. It must be arranged and equipped for adequate food storage; preparation and serving of food in proper sequence; dish and utensil cleaning and storage; and refuse storage and removal. Homes that are a Distinct Part of another facility may utilize the service of a central kitchen provided it is of adequate size and adequately equipped to serve the total patient/resident population. Storage space shall be sufficient to store a 24-hour supply of perishable foods and a 3-day supply of nonperishable foods.

(24) Each facility shall have a laundry room with adequate washing and drying equipment for the use of residents to launder their personal clothing.

(25) Separate and adequate clean laundry storage and separate and adequate soiled laundry storage rooms shall be provided appropriate to the frequency of deliveries and linen needs.

(26) Janitor's closets shall be provided on the basis of at least one closet for the dietary area and one for the remainder of the home. This room shall be of sufficient size to include racks for equipment, storage space, and a service sink.

(27) General storage space for the storage of supplies, furniture, equipment and residents' possessions shall be provided. Such space may be provided in one or more rooms and shall be commensurate with the needs of the home, but not less than five (5) square feet per bed.

(28) Maintenance area or areas commensurate with the needs of the home, including storage space for building and grounds maintenance equipment, tools, supplies and materials and shop space for mechanical, painting and carpentry work shall be provided.

(29) Floor, wall and ceiling finishes shall be smooth, easily cleaned and be wear-resistant appropriate to location. In addition, the floors of the following spaces shall be waterproof: toilets, baths, bedpan rooms, floor of pantries, kitchens, utility rooms,

janitors' closets and treatment rooms. Areas subject to wetting shall have nonslip flooring. Carpeting, wall and ceiling finishes shall be approved by the State Fire Marshal.

(30) Stairways, door and corridors:

(a) Stairways serving resident areas shall not be less than forty-four (44) inches in clean width;

(b) Stairs shall be individually enclosed and be separated from any public hall;

(c) A landing shall be provided at the top and bottom of every stair run. Doors shall swing with exit travel to provide safe exit;

(d) The minimum dimension of landing shall be as wide as the required width of the stairway it serves. A door swinging into a landing, when open, shall not overlap the required width of the landing;

(e) The width of stair to risers shall not be less than ten (10) inches plus a one inch nosing;

(f) Winders and single risers are not acceptable;

(g) Stairs and landings shall have a nonslippery finish;

(h) Residents' room corridor entrances and all required exits shall be not less than forty-four (44) inches in clean width. All other doors through which residents must pass shall be not less than thirty-six (36) inches in clean width except that doors to toilets in resident bedrooms may be not less than thirty-two (32) inches wide. Doors through which residents or equipment do not pass shall be not less than thirty (30) inches wide, except that doors to resident closets may not be less than twenty (20) inches wide;

(i) When a door swings out on any platform, balcony, or porch or terrace, the minimum width of the platform, balcony, porch or terrace shall be thirty (30) inches plus the width of the door, measured at right angles to the wall containing the door. Exit doors, other than for living units shall swing in the direction of exit from the structure;

(j) Corridors in areas used by residents shall be not less than eight (8) feet in clean width. Handrails may project into corridors, but drinking fountains, desk or other projections or obstructions may not reduce the eight (8) foot minimum dimension;

(k) Ramps shall be not less than forty-four (44) inches wide. Where ramps provide a change of corridor level, the minimum width shall be not less than that of the corridor;

(l) The maximum slope of ramps shall be not greater than ten (10) percent. Changes in direction, if any, shall be on level landings with a minimum width the same as the ramp width;

(m) Ramps shall have a nonslip finish. Ramps serving as a required means of egress shall be enclosed or protected as indicated for required stairways;

(n) Handrails shall be provided on each side of all resident corridors and on each side of stairways and ramps.

(31) Light and Ventilation:

(a) The total glass area in resident bedrooms shall be not less than one-eighth of the floor area of the room. The ventilating area shall be not less than four (4) percent of the floor area;

(b) Openings providing required natural light, which open on a covered porch whose depth exceeds four (4) feet, shall be increased in area ten (10) percent per foot of depth over four (4) feet;

(c) The heads of windows (sash opening) shall not be more than one foot below the finished ceiling unless they are at least six (6) feet, eight (8) inches above the finished floor. The lower level of the window glass shall be not more than forty-eight (48) inches above the floor level;

(d) Ceiling heights shall be not less than eight (8) feet except that seven (7) feet six (6) inches may be used in corridors, halls, toilet rooms and bathrooms;

(e) The lower edge of resident bedroom windows shall in every instance be above grade.

(32) Mechanical:

(a) All bathrooms and toilet rooms shall be provided with mechanical ventilation capable of producing a minimum of ten (10) air changes per hour. Utility rooms, community rooms and corridors shall be provided with not less than four (4) changes per hour with at least two (2) of the air changes being outside air. Ducts ventilating bathrooms or toilet rooms shall not be interconnected with other duct systems but shall be discharged to the outside. Resident rooms shall be provided with at least two (2) air changes per hour of outside air. Corridors and exit halls shall not be used as a plenum for supply or return air to heating or air-conditioning systems;

(b) Kitchens, laundries, non-refrigerated garbage storage rooms, and rooms used to store combustible materials, shall be provided with an independent system of mechanical ventilation discharging above the roof and remote from any window.

A minimum of ten (10) air changes per hour shall be provided. Exhaust hoods shall be installed over cooking ranges;

(c) All buildings shall be provided with a heating system designed to maintain a temperature of 75 degrees Fahrenheit in all habitable rooms and corridors when the outside temperature is at design level. The heating system should provide warm floors;

(d) All steam-operated equipment such as sterilizers, laundry and kitchen units, shall be provided with steam at temperatures and pressures as recommended by the equipment manufacturers;

(e) The quality and quantity of the water supply and the method of sewage disposal shall have the approval of the Department;

(f) A safe method shall be employed to heat water to provide an adequate supply of hot water at necessary temperatures for all purposes;

(g) Temperature controls shall be provided so that hot water for personal uses shall not exceed 110 degrees Fahrenheit;

(h) Hot water temperatures for other uses shall be as required by the equipment served;

(i) The quantity of hot water for kitchens and laundries shall be adequate to serve the equipment installed;

(j) Wrist control handles shall be provided for sinks or lavatories in floor pantries, medicine preparation rooms, clean utility rooms, soiled utility rooms, treatment or examination rooms, rehabilitation or physical therapy rooms and at handwashing fixtures in the kitchen area;

(k) Gooseneck spouts shall be provided for sinks or lavatories in treatment or examination rooms, physical therapy or rehabilitation rooms and at handwashing fixtures in the kitchen area;

(l) Vacuum breakers shall be provided for any plumbing fixture having a hose or hoses attached or to any plumbing fixture having trim to which a hose may be attached, including shampoo sinks, service sinks, combination hot and cold water outlets at can wash areas and hose bibs for clean-up purposes in the dishwashing area of kitchens;

(m) Aerators shall not be included as part of trim for plumbing fixtures;

(n) With relationship to adjacent areas, a positive air pressure shall be provided for clean utility rooms, floor pantries and medicine preparation rooms;

(o) With relationship to adjacent areas, a negative air pressure shall be provided for soiled utility rooms, physical therapy or rehabilitation rooms, janitor's closets, soiled laundry rooms and bathrooms or toilets. Air from these rooms shall not be recirculated; air shall be exhausted;

(p) Floor grilles shall not be used for supply or return air openings in heating, air-conditioning or ventilating systems;

(q) Ventilation openings, such as ports for exhaust fans, etc., shall be equipped with covers that close automatically when the fan is not in operation;

(r) Intake air ducts shall be designed and maintained so as to prevent the entrance of dust and insects;

(s) Hot air ducts from the heating system shall not emit temperatures in excess of 150 degrees Fahrenheit.

(33) Electrical:

(a) All areas shall be adequately lighted as required by duties performed in each space. Bedrooms and combination living-bedrooms shall have a night light, a light for general illumination and a reading light at the head of each bed. The outlets for general illumination and night lights shall be switched at the door. The reading light shall be controlled at the bedside. Each stairway, hall, corridor, or general passage shall have five (5) foot candles of illumination, doubled at building and stair entrance, or change of floor level, or at ramps;

(b) Receptacles appropriate for the designed space use shall be located where plug-in service is required. There shall be not less than one duplex receptacle at the head or near the head of each bed. All other spaces shall have general and special purpose outlets suited to the need of the space; including an outlet in the lobby for an electric clock and receptacles for cleaning and maintenance equipment spaced not more than fifty (50) feet apart in corridors;

(c) Emergency lighting shall be provided for exits, stairs, and corridors which shall be supplied by an emergency generator or a battery with automatic switch;

(d) Each toilet room and bathroom and each bed location shall be furnished with an electrical or mechanical call signal audible or visible at the medication area. A duplex unit may be used for two beds.

(34) Elevators and Dumbwaiters:

(a) Where residents' rooms are located on more than one floor at least one elevator shall be provided. Other elevators shall be provided, depending upon the needs and size of the home;

(b) At least one elevator in multistory buildings shall be arranged of sufficient size to admit a stretcher and an attendant;

(c) Elevator doors shall be automatic slide type with safety interlock. Elevators shall be equipped with grab bars and an automatic self-leveling control which will automatically bring car platforms level with the landing;

(d) Dumbwaiter cabs shall be not less than twenty-four (24) by twenty-four (24) by thirty-six (36) inches of steel with one shelf.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.18
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Physical Plant Standards" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.19. Application for Permit.

(1) The governing body shall submit to the Department an application for a permit.

(2) The application for a permit shall be made on forms provided by the Department and shall be filed at least thirty (30) days prior to the anticipated date of opening and commencement of operation of a new home.

(3) A letter from the physician and dentist who have agreed to provide emergency service and the names of the administrator and supervisor of care shall accompany the application.

(4) A plan for progressive employment of personnel to match increasing occupancy and to assure compliance with these rules and regulations shall be submitted at the time established for the preopening inspection.

(5) Proof of ownership shall accompany the application.

(a) Corporations shall submit a copy of their charter and the name and address of all owners with ten (10) percent or more of the stock and shall identify each corporate officer;

(b) Nonprofit associations and hospital authorities shall submit legal proof of the organization, the name and address of each trustee and the office held, if any;

(c) All others shall submit the name and address of each person owning any part of the facility.

(6) Proof of an active liability insurance policy or a self-insurance trust for the home's benefit for a nursing home claim.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.19
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Application for Permit" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.20. Permits.

(1) To be eligible for a permit the home must be in satisfactory compliance with these rules and regulations and the provisions at law which apply to the locations, construction, and maintenance of homes and the safety of the patients therein.

(2) Prior to the issuance of a permit and at the request of the Commissioner, the governing body shall furnish to the Department evidence of satisfactory compliance with any laws or regulations thereunder applicable to homes but the enforcement of which is the responsibility of a department or agency of government other than the Department.

(3) Each home shall, as a condition precedent to obtaining or maintaining a permit to operate an intermediate care home, carry or be covered by liability insurance coverages or establish or have established for its benefit a self-insurance trust for a nursing home claim. If a home fails to carry or be covered by liability insurance coverages or establish or have established for its benefit a self-insurance trust for a nursing home claim, the Department shall provide notice to such home of its noncompliance and allow such home 60 days in which to comply. A home's failure to maintain such coverage or establish such trust shall result in the Department:

   (a) Revoking such home's permit issued to operate the intermediate care home;

   (b) Denying any application to renew such permit; and

   (c) Denying any application for a change of ownership of the intermediate care home.

(4) The permit shall be framed and publicly displayed at all times.

(5) Permits are not transferable from one governing body to another, nor valid when the home is moved from one location to another.

(6) The permit shall be returned to the Department when the home ceases to operate, or is moved to another location or the ownership changes or the governing body is significantly changed or the permit is suspended or revoked.

(7) A permit shall be required for each home located on different premises where more than one home is operated under the same governing body. When a home operates as distinct parts, then a permit shall be required for each distinct part.

(8) Each home shall be in compliance with O.C.G.A. § 26-2-370 et seq. entitled "Food Service Establishments" and the Rules and Regulations as adopted and promulgated

thereunder, entitled "Rules and Regulations for Food Service" and with any amendment to the law or rules promulgated thereunder.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.20
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A.§§ 26-2-370 et seq., 31-2-4 et seq., 31-7-1 et seq., 31-2A-2 et seq.
History. Original Rule entitled "Permits" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.21. Provisional Permits.

(1) Provisional permits may be granted to the governing body of a newly established home to demonstrate operational procedures in satisfactory compliance.

(2) A provisional permit may be granted to the governing body of an existing home to demonstrate operational procedures in satisfactory compliance.

(3) Provisional permits granted to allow a reasonable time to demonstrate satisfactory compliance of operational procedures shall be limited to a period of not more than six (6) months.

(4) A provisional permit may be granted to the governing body of an existing home to give reasonable time to comply with regulations and standards which relate to the structural or physical condition of the home.

(5) No provisional permits shall be granted to the governing body of a newly established home which is in substantial noncompliance with rules, regulations and standards relating to the structural or physical condition of the home. Provisional permits granted to allow time for correction of structural or physical conditions shall not exceed twelve (12) months.

(6) A provisional permit shall not be issued when there are noncompliances of any type which present an immediate hazard to the life, health or safety of the patients.

(7) No provisional permit shall be granted to an existing home unless the governing body shall first present to the Commissioner a plan of improvement which shall list each noncompliance to be corrected, the time required to demonstrate acceptable operational procedures or to correct noncompliances which relate to the structural or physical condition of the home and the means, methods and procedures to be used in the correction of the noncompliances.

(8) The governing body of a home operating under a provisional permit may petition the Department for an extension of time if needed to correct noncompliances where the failure to make such corrections within the time allotted is an extenuating circumstance beyond the control of the governing body. Such petitions shall be submitted to the Department at least thirty (30) days prior to expiration date of the provisional permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.21
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Provisional Permits" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.22. Inspections.

(1) The home shall be available at reasonable hours for observation and examination by properly identified representatives of the Department.

(2) The administrator or authorized representative shall notify the Department of the anticipated opening date of a newly constructed home in order that a preopening licensure survey of the home may be conducted to determine compliance with these rules and regulations.

(3) The administrator or his representative shall accompany the Department representative on tours of inspection.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.22
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "Inspections" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.23. New Construction.

(1) General Requirements:

(a) A program narrative and all plans and specifications for construction, including additions, alterations, and renovations, shall be approved by the Department prior to commencing work on the building;

(b) The program narrative shall be submitted prior to or along with the schematic or initial plans for construction. The program narrative should include the following:

1. The names and addresses of each owner. If the owner is a public stock corporation, the names and addresses of each officer shall be included;

2. The geographical area to be served;

3. Admission policies;

4. Cooperative programs of service with local agencies, including hospitals and nursing homes;

5. Arrangements for medical and dental care, e.g., physicians on contract and agreements with hospitals, nursing homes and home health agencies for resident referral;

6. List of personnel by types of employees and proposed salaries;

7. Plans for securing the services of professional personnel including registered nurses, licensed practical nurses, social workers, dietitians, pharmacists, physicians and therapists;

8. A description of the service to be provided the community, i.e., the level of care to be provided and the economic segments of the population to be served;

9. Source and amount of financing;

10. Anticipated first two-year cost of operation, income and source of operating funds;

11. Exact location of proposed site;

12. Utilities available, i.e., electricity, gas, water, sewage and waste disposal, and transportation;

13. The name, address and telephone number of the person selected to represent the owner during the period of planning and construction.

(c) Any individual or group planning construction shall submit complete architectural, structural, mechanical and electrical plans and specifications to the Department for review and approval prior to any new construction, addition, alteration or renovation. Final plans submitted shall be in sufficient detail to show the building site, driveways and parking areas, type of construction, mechanical and electrical systems, the type and location of major items of equipment, the intended use of each room, the proposed location of beds, the type and source of utilities, food service system, and the proposed system of garbage and refuse disposal;

(d) Plans for addition and/or remodeling of an existing building will be submitted in sufficient detail to include type of construction and layout of the existing building to show overall relationship. Any changes in the approved final plans shall also be submitted to the Department for approval.

(2) Location and site:

(a) The site shall be approved by the Department;

(b) The site shall have proper drainage. Sewage disposal, water, electrical telephone, and other necessary facilities shall be available to the site.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.23
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq.
History. Original Rule entitled "New Construction" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-47-.24. Enforcement.

The administration and enforcement of these rules and regulations shall be as prescribed in O.C.G.A. § 31-2-8 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

Cite as Ga. Comp. R. & Regs. R. 111-8-47-.24
Authority: Ga. L. 1964, pp. 507, 612, as amended by Ga. L. 1969, p. 715 et seq., Ga. L. 1972, p. 1015 et seq., O.C.G.A. §§ 31-2-4, 31-2-8, 31-7-1 et seq.
History. Original Rule entitled "Enforcement" adopted. F. Jan. 27, 2017; eff. Feb. 16, 2017.

Subject 111-8-50. LONG-TERM CARE FACILITIES: RESIDENTS' BILL OF RIGHTS.

Rule 111-8-50-.01. Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereafter respectively ascribed to them:

(a) "Administrator" means an individual who is licensed by the Georgia State Board of Nursing Home Administrators and who has the necessary authority and responsibility for management of the facility;

(b) "Department" means the Department of Community Health of the State of Georgia;

(c) "Long-term Care Facility" or "Facility" means any intermediate care home, skilled nursing home or intermingled home now or hereafter subject to regulation and licensure by the Department;

(d) "Resident" means any person residing in and receiving treatment in a long-term care facility;

(e) "Guardian" means a resident's legal guardian or conservator, or the parent of a minor resident who does not have a duly appointed guardian;

(f) "Representative" means a person authorized by a resident or his guardian to act for the resident as an official delegate or agent;

(g) "Long-term Care Ombudsman" or "Ombudsman" means a person certified as a community ombudsman or the state ombudsman pursuant to O.C.G.A. § 31-8-52*et seq.*;

(h) "Complainant" means resident, applicant for residency, guardian or representative, who presents a grievance or complaint;

(i) "Physician" shall mean a person duly licensed to practice in this State by the Composite State Board of Medical Examiners, under the provisions of O.C.G.A. § 43-34-1*et seq.*;

(j) "Person in Charge" means either the administrator of a facility or the person authorized by the administrator to be in charge when the administrator is not present;

(k) "Medical Necessity Review" means a review of the social and medical needs of a resident, whose stay is being paid by Medicaid or Medicare or other third party payor, to determine the appropriate level of care of such resident;

(l) "Referee" means a volunteer jointly chosen by the complainant and the administrator;

(m) "Grievance" means a complaint presented pursuant to Rule .14 of these regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.01
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-102, 31-8-124 and 31-8-127.
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.02. Administration.

(1) Each facility shall establish written policies and procedures to provide that it complies with these rules and regulations and provides for implementation of these rules and regulations at the facility. Such written policies and procedures shall not conflict with the intent of the Act nor these rules and regulations and shall not be more restrictive than these rules and regulations except where specifically provided.

(2) Each facility must conduct training or make provision for the training of all staff on a quarterly basis, and for new staff, as employed. The content of the training may vary from quarter to quarter as long as it provides that all staff are familiar with the Long-term Care Facilities: Residents' Bill of Rights. O.C.G.A. § 31-8-100*et seq.* and these rules and regulations. Such training may be combined with any other quarterly training required to be done for staff of long-term care facilities. The facility shall document the dates, topics, and staff attending such training.

(3) Each facility must provide a written explanation of the rights, grievance procedures, and enforcement procedures to each resident and guardian, or representative if the resident does not have a guardian.

(4) A facility must bill for all charges at least once each month, unless otherwise agreed to in writing by the facility and the resident or guardian. Each bill must itemize charges for daily or monthly rates and for all extra charges.

(5) Each facility must post in the most frequented and conspicuous places, accessible to all residents, notices of residents' rights prepared by the Department.

(6) Copies of these rules and regulations shall be kept by the facility and shall be available for examination by any resident, guardian or representative.

(7) Upon the request of the resident, guardian or representative, the facility shall provide such person making the request with the name, address and telephone number of the resident's physician.

(8) Each resident or guardian shall he entitled to have reported promptly to persons of the resident's choice significant changes in the resident's health status. A resident or guardian who desires that family members or other persons of their choice be notified in the case of significant changes in the resident's health status shall either:

(a) Notify the administrator in advance that he desires that certain persons be notified in the event of any significant change in the resident's health status, with such notification being made part of the resident's personal file; or

(b) If such advance notification has not been given, a resident or guardian may inform the physician or administrator at any time that he desires that certain persons be notified of significant current changes. In the case of a resident unable to communicate who does not have a legally appointed guardian, the physician or administrator shall immediately contact family members or other interested persons concerning any significant change in the resident's health status.

(9) Upon a resident's request or a request of his or her guardian or representative, the facility must provide him or her with a current list of all services and charges. Current charges must be posted in the most frequented places, conspicuous, and accessible to all residents.

(10) The facility must inform each resident in writing, at least 30 days in advance of the effective date of any changes in the rates or the services that these rates cover.

(11) Each resident or his guardian or authorized representative shall be entitled to inspect and receive a copy of the resident' s non-medical records kept by the facility. The facility may charge a reasonable fee for duplication, not to exceed actual cost.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.02
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-104, 31-8-106, 31-8-108, 31-8-122 and 31-8-127.

History. Original Rule entitled "Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.03. Notification of Rights.

(1) At or before being admitted to a facility, each resident and guardian, or representative if there is no guardian, must be given a copy of the written explanation of the resident's rights, grievance procedure and enforcement procedures. A staff member must also orally explain to such persons the resident's rights, grievance procedures and enforcement procedures. Written acknowledgement of this written and oral explanation must be given by the resident, or in the case of a resident unable to give a written acknowledgement, by the resident's guardian or representative if there is no guardian. Such written acknowledgement shall be kept in the resident's file.

(2) At the time of admission to a facility, each resident, guardian, or representative must be provided with the following information in writing:

(a) The basic daily or monthly rate of the facility for the level of care to be received by the resident;

(b) A list of the services of the facility. Such list must show which services are offered as a part of the daily rate and which services are offered on an as-needed basis along with the related charges for such services. Such list must also show which services are not covered under Medicare or Medicaid programs and for which there are extra charges;

(c) A statement disclosing the facility's name and business address and the administrator's name and business address. The statement should also disclose that upon request at any time during normal business hours, a resident or a person applying to be a resident must be given a current copy of the annual disclosure statement filed with the Department of Medical Assistance.

(d) Notice of right of access to the written policies and procedures of the facility adopted pursuant to .02(1) of these rules and regulations during normal business hours;

(e) The right to select at admission, or to change at any time, the pharmacy or pharmacist of the resident's choice for those pharmaceutical supplies and services not provided as a part of the facility's basic rate. If the facility uses a specific type of unit dose drug system, any pharmacy or pharmacist chosen by the resident must be able to provide pharmaceuticals under such a system. Such notice at the time of admission shall also include a list of which pharmaceutical supplies and services are not provided by the facility.

(3) Provisions of these rules and regulations shall apply to current as well as future residents.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.03
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-104, 31-8-106, 31-8-110, 31-8-118 and 31-8-127.
History. Original Rule entitled "Notification of Rights" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.04. Citizenship and Personal Choice.

Residents shall be free from any duty to perform services for the facility and must be permitted to exercise all rights of citizenship and of personal choice in accordance with the following:

(a) All residents legally eligible to vote must be permitted to vote in all primary, special and general elections and in referenda. If requested by the resident, the facility must assist in obtaining voter registration forms, applications for absentee ballots and in obtaining such ballots and assist the resident in meeting all other legal requirements in order to be able to vote. The facility shall not interfere with nor attempt to influence the actual casting of the resident's vote.

(b) All residents must be free to practice their religion and religious beliefs as they choose.

All residents must also be free from the imposition, by the facility or any of its employees, of any religious beliefs and practices if they so choose.

(c) All residents must be free to associate, meet and communicate in private with persons of the resident's choice. Residents must be permitted to participate in social, familial, religious, and community group activities of their choice either on or off of the facility grounds, provided that if such event occurs off the facility grounds, the right to leave the facility shall be subject to .10 of these rules and regulations.

(d) All residents shall be permitted (subject to .10 of these rules and regulations) to rise and retire at any time of their choice, provided the resident does not interfere with the rights of others.

(e) Subject to applicable state law and the written policies of the facility given and explained to the resident, guardian and/or representative at the time of admission, all residents must be permitted to use tobacco and to consume alcoholic beverages, as long as the resident does not interfere with the rights of others. This right is subject to .10 of these rules and regulations. Residents shall be notified 30 days in advance of any change in the facility's policies affecting the use of tobacco or consumption of alcoholic beverages;

(f) Subject to .10 of these rules and regulations, all residents must be free to enter and leave the facility grounds as the resident chooses. If the facility desires, as stated in its written policies, it may require a resident to inform the facility at the times he is leaving and re-entering the facility grounds.

(g) The facility must have visiting hours of at least 12 continuous hours in any 24-hour period, seven days a week.

(h) Visitors must be granted access to residents during normal visiting hours provided that each visitor entering a facility promptly discloses his presence and identifies himself to the person in charge and enters the immediate living quarters of a resident only after identifying himself and receiving permission to enter. Place of visitation shall be any place of the resident's choice so long as it does not disrupt the normal operation of the facility or disturb the other residents. Residents may terminate visits at any time. The person in charge may refuse a visitor access or require such a visitor to leave only if:

1. The person in charge has reason to believe that the presence of such visitor would result in severe harm to a resident's health, safety or property; or

2. Access is sought for financial solicitation or commercial purposes; or

3. A resident does not wish such visitor to stay. If access by a visitor is denied, the person in charge shall document such denial, along with the reasons therefore. This section does not limit the power of any public agency, ombudsman, persons from federally mandated advocacy programs, or other persons permitted or required by state or federal law to enter or inspect a facility.

(i) Residents must be permitted to form resident councils to address any issues they may feel are appropriate or for other purposes and to meet without staff, if residents so desire. The facility must provide sufficient space for meetings of such resident councils and shall assist in attending such meetings those residents who request such assistance. The facility shall not compel the attendance of any residents at such meetings.

(j) Each resident must be permitted to voice complaints and recommend changes in policies, procedures, and services to the administrator, his or her designee, or the residents' counsel.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.04
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-111, 31-8-112, 31-8-114, 31-8-117 and 31-8-127.
History. Original Rule entitled "Citizenship and Personal Choice" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.05. Privacy.

All residents shall enjoy privacy in their rooms and in their portions of any room which they share.

(a) Staff shall not enter a resident's room without first making their presence known before entering unless such staff member has reason to believe that the resident is asleep or it is an emergency which threatens the health or safety of the resident or unless it is required by the resident's care plan and documented in said plan.

(b) A resident shall be entitled to an available private room and a personal sitter if the resident pays the difference between the facility's charge for such a room and/or sitter and

the amount reimbursed through Medicaid or Medicare provided that this provision is not prohibited by overriding Federal law or regulations.

(c) A resident shall have the right to visit privately with the resident's spouse. A resident and spouse shall be permitted to share a room if both are residents of the facility and space permits.

(d) Residents shall enjoy the right of freedom from eavesdropping, and the right to unimpeded, private and uncensored communication with anyone of the resident's choice by mail, telephone and visit. The administrator shall provide that mail is received and mailed on regular postal days. Public telephones must be available and accessible to residents, including those in wheelchairs, and must permit and be conducive to private conversation. Residents shall have the right to refuse any telephone call or correspondence. Such refusal shall be documented in the resident's file.

(e) The facility must provide at least one place for private visitation during normal visiting hours. This place must be provided in addition to the residents' rooms.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.05
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-114 and 31-8-127.
History. Original Rule entitled "Privacy" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.06. Management of Personal Property and Financial Affairs.

(1) Each resident must be permitted to retain and use his/her personal property in his/her immediate living quarters subject to space limitations and state and federal safety laws and regulations.

(2) Upon request, the facility shall provide a means of securing the resident's property in his/her room or another convenient location in the facility, subject to the following:

   (a) The resident must have access to the secured items at least during all normal business hours and where facility policy allows, on weekends and holidays;

   (b) The facility shall keep an updated written record of all personal belongings which a resident has requested that the facility keep in a secure place.

(3) The facility shall have procedures for investigating complaints and allegations of thefts of residents' property. Such procedures must provide that the facility promptly investigate complaints of theft, and the facility report the results of its investigation to the complainant within two weeks.

(4) All payments made to or on behalf of a resident, regardless of the source, shall be used only for the benefit of that resident, unless state or federal law provides otherwise.

(5) Every resident or guardian shall be permitted to manage his own financial affairs. The facility may establish a personal account, consistent with federal regulations, for each resident at the facility. The resident or guardian may authorize the administrator or designated employee of the facility to help in managing the resident's financial affairs subject to the following:

(a) The resident or guardian must authorize the facility in writing to help in the management of all or the part specified of the resident's finances. Such written authorization must be kept in the resident's file;

(b) The facility may expend funds for the resident only at the specific written or oral request of the resident or guardian and only for the purpose designated by the resident or guardian.

(c) The resident or his guardian shall be given any portion or all of the resident's funds upon request of the resident or guardian. The resident or guardian may authorize in writing a representative to withdraw funds from the resident's account. Such authorization must contain a specific amount permitted to be withdrawn and the date such authorization expires.

(d) A current written record of all financial arrangements and transactions made to or on behalf of the resident must be maintained by the facility either individually in each resident's file or individually in a separate file for all transactions made to or in behalf of each resident. A resident or guardian shall be permitted to inspect and duplicate at cost such current record for that resident.

(e) The facility shall issue to each resident or guardian a written quarterly statement, and prior to any change in ownership of the facility, showing the current balance and an itemized listing of all transactions made to or on behalf of the resident.

(6) Funds received from a resident on his behalf may be deposited in an interest bearing account. All funds not needed for the ordinary use by a resident on a daily basis above $150.00 per resident must be kept in an account insured by agencies of or corporations chartered by the state or federal government. Such account must clearly show that the facility has only a fiduciary interest in the funds in such account. All interest earned upon such account must accrue to the resident, with each resident being credited with the portion of the interest attributable to his portion of the account.

(7) To guarantee the security of residents' funds, each facility shall obtain an irrevocable letter of credit from a bank or savings and loan association, as defined in O.C.G.A. § 7-1-4, or purchase a surety bond at least equal to the amount of all funds in the residents' accounts maintained by the facility.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.06
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-113, 31-8-115 and 31-8-127.
History. Original Rule entitled "Management of Personal Property and Financial Affairs" adopted. F. Feb. 20, 2013;

eff. Mar. 12, 2013.

Rule 111-8-50-.07. Residential Care and Treatment.

Each resident must receive care, treatment and services which are adequate and appropriate for the condition of the resident, as determined by periodic review of each resident's treatment plan. Such care, treatment, and services must be provided with reasonable care and skill and in compliance with all applicable laws and regulations and with the goal of the resident's return home or to a less restrictive environment.

(a) The quality of a particular service or treatment must be the same to all residents without regard to the source of payment for such service or treatment. In particular, the quality of care provided to a resident whose care is being paid for from Medicaid or Medicare funds must be that same quality of care provided to those residents whose care is being paid for from other sources.

(b) Care, treatment and services must be provided with respect for the resident's personal dignity and privacy subject to the following:

1. All aspects of a resident's medical, personal and bodily care program shall be conducted in private and kept confidential. Any persons not directly involved in the particular aspect of care being provided to a resident must have the resident's permission to be present at the time that component of the resident's care is being provided;

2. A resident's personal and medical records must be kept confidential. Only the resident or guardian may approve the release or disclosure of such records to persons or agencies outside the facility which must be in writing, unless it is a case of the resident's transfer to another health care facility or during Medicare, Medicaid, licensure, medical care foundation, or peer review surveys, or as otherwise provided by law or third-party payment contract;

3. Each resident or guardian shall have the right of access to all information in the medical and personal records of that resident and to have given to him by the physician a complete and current explanation of his medical diagnosis, treatment and prognosis in language the resident can understand. Each resident or guardian shall have the right to inspect and receive a copy of such records unless said right is suspended in accordance with .10 of these rules and regulations. The facility may charge a reasonable fee for duplication of the medical records, not to exceed actual cost.

(c) Each resident or guardian shall be entitled to choose or change at any time the resident's physician(s). A physician so chosen shall inform the resident in advance whether or not the physician's fees can be paid for by Medicaid, Medicare, or from any other public or

private benefits and agree to and provide documentation to any third party payor as required by law, regulations or contract.

(d) The resident or guardian shall be entitled to participate in the development of the resident's care plan and in the provision of treatment under the plan. The resident or guardian shall be informed of the right to participate in the planning of care and treatment each time a substantial change in the treatment is needed.

(e) A resident shall not take part in any experimental research or be the recipient of any experimental treatment unless informed written consent (consistent with O.C.G.A. § 31-9-1*et seq.*) is given by the resident or guardian. Such written consent shall be made a part of the resident's medical record.

(f) Subject to the resident's choice of pharmacy or pharmacist, pursuant to .03(2)(e) of these rules and regulations, each resident shall receive pharmaceutical supplies and services at reasonable prices not exceeding applicable and normally accepted prices for comparably packaged pharmaceutical supplies and services within the community.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.07
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-108, 31-8-114 and 31-8-127.
History. Original Rule entitled "Resident Care and Treatment" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.08. Refusal of Medical Treatment, Dietary Restrictions and Medications.

Each resident or guardian shall have the right to refuse any aspect of medical treatment, dietary restriction or any medication, subject to the following:

(a) When a resident or guardian makes such refusal such person shall be notified by the appropriate facility staff person or physician of the immediate and possible long-term consequences of the refusal. The refusal shall be documented in the resident's record as shall the possible consequences of the refusal, and the resident's physician shall be notified as soon as practical.

(b) If such refusal would result in serious injury, illness or death, the facility shall:

1. Promptly notify the resident's physician and if serious injury, illness or death is imminent, transport the resident to a hospital; and

2. Notify the resident's guardian, representative or responsible family member in that order of priority as specified in O.C.G.A. § 31-9-2 or if no such persons are immediately available, notify the director of the County Department of Family and Children Services or his designee. The director or designee shall document such notification and take appropriate protective measures.

(c) If such refusal would result in injury, illness or death to any other person, such resident or guardian shall not enjoy this right of refusal. The likelihood of injury, illness, or death to any other person must be documented in the resident's records by the resident's physician.

(d) Any facility or employee of a facility acting in accordance with this section shall be immune from all liability resulting from such refusal in accord with Ga. Code Ann; 88-1914B.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.08
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-108 and 31-8-127.
History. Original Rule entitled "Refusal of Medical Treatment, Dietary Restrictions and Medications" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.09. Use of Restraints, Isolation and Restrictions.

Each resident must be free from actual or threatened physical restraints, isolation or restrictions on mobility within or outside the facility grounds, including the use of drugs to limit mobility, activity and functional capacity or the use of any other restrictions, except to the minimum extent necessary to protect the resident from immediate injury to the resident or to any other person. Restraints are defined to include, but not limited to, any contrivance, situation, safety device, or medication that has the purposeful or incidental effect of restricting a resident's mobility within or outside of the facility grounds. All authorization and use of restraints, restrictions, or isolation must be documented in the resident's medical file.

(a) Restraints, restrictions, or isolation may not be used for punishment, incentive, behavior conditioning or modification, convenience of the facility or any purpose other than to protect the resident from immediate injury to himself or to any other person.

(b) Except in an emergency situation described in subsection (c) of this rule, below, restraints, restrictions, or isolation must be authorized as follows:

1. Prior to authorizing restraints, restrictions, or isolation, the attending physician shall make a personal examination and individualized determination that such restraint, restriction, or isolation is necessary to protect the resident or other persons from immediate injury; and

2. The physician shall specify the length of time for which such restraint, restriction, or isolation is authorized. Such authorization may not exceed 65 days for intermediate care home residents or 35 days for skilled nursing home residents, but in no event shall such restraint, restriction, or isolation be used beyond the period of actual need to protect the resident or other persons from immediate injury. Any period beyond that specified shall be regarded as a new period and all requirements for the use of such restraints, restriction or isolation must be met.

(c) In an emergency situation severely threatening the health or safety of the resident or others, restraints, restrictions, or isolation may be authorized only by the person in charge. In an emergency situation, restraints, restrictions or isolation may be used only for 12 hours from the time of onset of the emergency situation. Beyond the 12-hour period, restraints, restrictions, or isolation may not be used unless it is in accordance with subsection (b) of this rule.

(d) The resident and guardian or persons designated by the resident, if any, shall be immediately informed of the need for such restraints, restrictions or isolation, the reasons for such use, and the time specified for such use.

(e) A restrained or isolated resident shall be monitored by staff at least every hour. A restrained or isolated resident must be released and exercised every two hours except during normal sleeping hours. Such activities shall be documented in the resident's record.

(f) A resident who is restrained, restricted or isolated pursuant to this section shall retain all other rights and responsibilities provided by these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.09
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-109 and 31-8-127.
History. Original Rule entitled "Use of Restraints, Isolation or Restrictions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.10. Temporary Suspension of Rights.

Convenience to the facility shall not justify the suspension of any rights to individual residents.

(a) Only the following rights may be temporarily suspended:

1. The right to rise and retire as the resident chooses, pursuant to .04(d) of these rules and regulations;

2. The right to use tobacco and consume alcoholic beverages, pursuant to .04(e) of these rules and regulations;

3. The right of access to his own medical records and explanation of condition, treatment and diagnosis, pursuant to .07(b)3 of these rules and regulations; and

4. The right to enter and leave as desired, pursuant to .04(f) of these rules and regulations.

(b) The above rights may be temporarily suspended only after the following:

1. The physician must personally examine the resident and document in the resident's file that the exercise of such right or rights endangers the health or safety of other residents or imposes an immediate and substantial danger to the resident;

2. Prior to or at the time of such suspension, the resident and guardian or representative if there be no guardian, shall be notified of such suspension, its duration and of the resident's right to meet with legal counsel, ombudsman, family members, his guardian, or any other person of the resident's choice;

3. If the threatened danger is only to the resident and not to the health or safety to other residents, and the resident has had the reasons for the proposed suspension fully explained to him along with the danger if that right is exercised, the resident's rights shall not be suspended pursuant to this regulation if the resident or guardian understands the danger and insists on the exercise of the right. This fact must be documented in the resident's file.

(c) A temporary suspension of rights may be authorized for a maximum of 65 days for residents of intermediate care homes and for 35 days for residents of nursing homes. In no event shall the suspension of such right or rights be authorized for a period longer than actual need. Any additional period shall be considered a new suspension, for which all provisions and requirements of this section shall be met.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.10
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-117 and 31-8-127.
History. Original Rule entitled "Temporary Suspension of Rights" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.11. Transfer and Discharge.

(1) In an emergency situation where the resident or other residents are subject to an imminent and substantial danger that only immediate transfer or discharge will relieve, the facility may involuntarily transfer the resident to another health facility. The person in charge shall document in the resident's file the reasons for such emergency transfer and shall immediately inform the resident, guardian and other persons of the resident's choice regarding such transfer and the place where the resident is to be transferred.

(2) In all other situations an involuntary transfer or discharge must be in accordance with any of the following reasons and procedures and only after all other reasonable alternatives to transfer have been exhausted:

(a) The resident's physician or, if unavailable, another physician determines that failure to transfer the resident will result in injury or illness to the resident or others. The resident's physician shall be kept informed of actions taken. The attending physician must document that determination in the resident's record. If the basis for the transfer or discharge is the threat of injury or illness to the

resident only, the resident cannot be transferred or discharged unless the physician documents in the resident's medical record that such transfer or discharge is not expected to endanger the resident to a greater extent than remaining in the facility; or

(b) The facility does not participate in, or voluntarily or involuntarily ceases to operate or participate in the program which reimburses for the resident's care. In the event that a facility voluntarily or involuntarily ceases to operate or participate in the program which reimburses for the resident's care and proposes to transfer or discharge a resident because of that fact, the facility must cooperate fully with and take all reasonable directives from the State Medicaid Agency and the Health Care Financing Administration Regional Office in the implementation of any transfer planning and transfer counseling conducted by these agencies; or

(c) Nonpayment of allowable fees has occurred. When a resident has been converted from full or private pay status to Medicaid eligibility due to exhaustion of personal financial resources, nonpayment of allowable fees has not occurred so long as the facility participates in the Medicaid program. Similarly, conversion from Medicare/Medicaid eligibility status does not constitute nonpayment of allowable fees; or

(d) The findings of a Medicare or Medicaid medical necessity review determine that the resident no longer requires the level of care presently being provided, subject to the right of the resident to any appeal procedure available to challenge the determination of medical necessity review. Where space permits, the resident must be given the option of staying at the facility, if the facility is certified to provide the new level of care.

(3) The facility must give written notice to the resident, guardian or representative, if there is no guardian, and the resident's physician at least 30 days before any proposed transfer or discharge is made in accordance with subsections (2)(a), (2)(b), or (2)(c) of this rule. The written notice must contain the following information: the reasons for the proposed transfer or discharge; the effective date of the proposed transfer or discharge; the location or other facility to which the facility proposes to transfer or discharge the resident; and notice of the right to a hearing pursuant to the Georgia Administrative Procedure Act and Section .15 of these rules and regulations, and of the right to representation by legal counsel. If the resident so desires, the facility shall also send a copy of such notice to the community ombudsman, or state ombudsman if there is no community ombudsman.

(4) If two residents are married and the facility proposes to transfer one spouse to another facility at a similar level of care, notice must be given to the other spouse of the right to be transferred to the same facility if the other spouse makes a request to that facility in writing. Married residents must be transferred on the same day, pending availability of accommodations. If also available, that facility shall place both residents in the same room if the residents so desire.

(5) In the event of an involuntary transfer pursuant to subsections (2)(a), (2)(b), or (2)(c) of this rule, the facility must assist the resident and guardian in finding a reasonably appropriate alternative placement prior to the proposed transfer or discharge by developing a plan designed to minimize any transfer stress to the resident. Such plan shall include counseling the resident, guardian, or representative, regarding available community resources and informing the appropriate state or social service organizations, including, but not limited to, the community or state long-term care ombudsman and assisting in arranging for the transfer.

(6) In the event that the facility proposes an involuntary transfer of the resident to another bed in the same facility, the resident and guardian shall receive 15 days written notice prior to such change.

(7) A resident shall be voluntarily discharged from a facility when the resident or guardian gives the person in charge notice of the resident's intention to be discharged and the expected date of departure. In the case of a resident without a guardian, the facility may not require that the resident be "signed out" or authorized to be discharged by any person or agency other than the resident. Notice of the resident's or guardian's intention to be discharged, and the expected and actual dates of departure shall be documented in the resident's record. If the resident appears to be capable of living independently of the facility, upon such discharge, the facility is relieved of any further responsibility for the resident's care, safety, or well-being.

(8) If a resident being voluntarily discharged into the community, appears to be incapable of living independently of the facility, in addition to the requirements under section (7) of this rule, the facility shall also do the following:

(a) Notify the Department of Human Services in order to obtain social or protective services for the resident immediately after the facility receives notice of the resident's intention to be discharged;

(b) Document such notice to the Department of Human Services in the resident's record along with the resident's notice of intention to be discharged and the expected and actual dates of departure;

(c) Upon notice to the Department of Human Services and upon actual discharge of the resident, the facility shall be relieved of any further responsibility for the resident's care, safety, or well-being.

(9) Each resident transferred from a facility to a hospital, other health care facility, or trial alternative living placement shall have the right to return to the facility immediately upon discharge from the hospital, other health care facility or upon termination of the trial living placement, provided that the resident has continued to pay the facility or payment on behalf of the resident by another person or agency has been provided for the period of the resident's absence. If payment is provided for the period of absence, the facility shall continue the same room assignment for such resident. In cases of nonpayment to the facility during such absence, a resident who requests to return to a facility from a hospital

shall be admitted to the facility to the first bed available, with priority over any existing waiting list.

(10) Whenever allowed by the resident's health condition, a resident shall be provided treatment and care, rehabilitative services, and assistance by the facility to prepare the resident to return to the resident's home or other living situation less restrictive than the facility. Upon the request of the resident, guardian, or representative, the facility shall provide him with information regarding available resources and inform him of the appropriate state or social service organizations.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.11
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-101, 31-8-116 and 31-8-127.
History. Original Rule entitled "Transfer and Discharge" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.12. Contributions to the Facility.

No resident, resident's family, guardian or representative shall be coerced directly or indirectly into contributing to a resident, facility, staff person, or corporation or agency with any financial interest in the facility.

(a) Free will contributions may be made for general or restricted purposes. When free will contributions are made by a person for a restricted purpose, such contribution must be used only for the purpose so designated.

(b) When a free will contribution is made, a signed receipt shall be issued to the person making the contribution and shall contain the following information:

1. The name of the person making the contribution;
2. The date the contribution is made;
3. The amount and type of the contribution;
4. The restricted purpose, if any, for which the contribution is intended.

(c) The facility shall keep in a central file, copies of all receipts issued in accordance with section (b) of this rule.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.12
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-119 and 31-8-127.
History. Original Rule entitled "Contributions to the Facility" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.13. Nondiscrimination.

(1) Each resident or person requesting admission to a facility shall be free from discrimination by the facility through its refusing admission or continued residency on the basis of the resident's or applicant's history or condition of mental or physical disease or disability unless either:

(a) Such admission would cause the facility or any resident or applicant to lose eligibility for any state or federal program of financial assistance; or

(b) The facility cannot provide adequate and appropriate care, treatment, and services to the resident or applicant due to such disease or disability, provided such exclusion is not contrary to federal or state law and regulation prohibiting such discrimination nor contrary to federal or state law or regulation requiring that care must be provided if the facility participates in a financial program requiring such admittance or continued residency.

(2) A facility shall not discriminate in the provision of a service to a resident based upon the source of payment for the service.

(3) No person shall be discriminated against as to admission or continued residency on the basis of the person's choice of pharmacy, pharmacist and/or physician.

(4) No person shall be discriminated against as to admission or continued residency and as to care, treatment and services on the basis of failure or refusal by the resident, guardian or representative to make contributions to a resident, facility, staff person, or corporation or agency with a financial interest in a facility.

(5) No person shall be discriminated against in any manner whatsoever for exercising any of the rights described in these rules and regulations, nor shall any form of restraint, interference, or coercion be used against any person for exercising any of the rights described in these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.13
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-108, 31-8-110, 31-8-118 and 31-8-127.
History. Original Rule entitled "Nondiscrimination" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.14. Grievance Procedure.

Any resident, guardian or representative who believes his rights or, in the case of a guardian or representative, the rights of the resident, have been violated, may present a grievance. The grievance procedure shall be in accordance with the following:

(a) The facility shall maintain a confidential central file of documents and materials pertaining to grievances. Any resident, guardian or representative shall be free to review any document or materials pertaining to that resident. All documents and materials pertaining to grievances shall be available to the Department.

(b) To initiate a grievance, the resident, guardian, or representative must submit an oral or written complaint to the administrator or his designee, who, in the event of an oral complaint, shall promptly reduce the substance of the complaint to writing. The administrator shall also promptly act to resolve the complaint. If the complaint is not resolved within three business days, the administrator or designee shall give a written response to the complainant. The content of such response shall include:

1. The names of the complainant and of the person making the written response;
2. The date the grievance was commenced and the date of the written response;
3. A complete description of the complaint;
4. The facility's position in regard to the complaint; and
5. A description of the review and appeal rights including the name and telephone number of the community ombudsman or state ombudsman, if there is no community ombudsman.

(c) If the complainant is not satisfied with the resolution or written response of the administrator or designee, he shall submit an oral or written complaint to the community or state ombudsman, pursuant to O.C.G.A. § 31-8-124 and 31-8-150 et. seq.

(d) If the ombudsman is unable to resolve the grievance to the complainant's satisfaction within 10 calendar days of submission to such ombudsman, the complainant may submit the grievance to an impartial referee, jointly chosen by the administrator or his designee and the complainant. The referee may be any person who is mutually acceptable to the complainant and the administrator or designee.

(e) Within 14 calendar days after the complainant has requested a hearing before an impartial referee, such hearing shall be held at a time convenient to the administrator, complainant and referee and such hearing shall be held at the facility. The complainant and the administrator may review relevant records and documents, present evidence, call witnesses, cross-examine witnesses, make oral arguments, and be represented by any persons of their choice. The referee may ask questions of any person, review relevant records and documents, call witnesses, and receive other evidence as appropriate. The referee shall keep a record of the proceedings, which may be a sound recording. In the event that the complainant and the administrator/designee cannot agree upon an imparital referee within seven calendar days after the complainant has requested a referee's hearing, the complainant shall have the right to an administrative hearing pursuant to .15 of these rules and regulations.

(f) Within 72 hours after the hearing before the referee, the referee shall render a written decision, on forms to be provided by the Department. Copies of the decision shall be given to the complainant, to the administrator for filing in the central file for that purpose, and a copy shall be sent to the Department. The decision shall be divided as follows:

1. Contentions of the parties;

2. Findings of the relevant and significant facts;

3. Decisions of the referee as to whether a violation of resident's rights has occurred, along with a recommendation to the Department for corrective action and the date by which the correction should be made; and

4. A complete description of the right and manner in which to appeal the referee's decision in accordance with .15 of these rules and regulations

(g) The decision of the impartial referee shall be binding upon all the parties unless reversed upon appeal.

(h) If a resident or complainant is unable for any reason to understand any writing or communication pertinent to this section, such information shall be communicated to him in a manner that takes into account any communication impairment he may have.

(i) A resident, guardian or representative who elects not to proceed under this section shall not be prohibited from proceeding under .15 or .16 of these rules and regulations. Nothing in these rules and regulations is meant to modify or diminish any complaint procedure set up or in operation pursuant to O.C.G.A. § 31-8-80*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.14
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-50 *et seq.*, 31-8-80 *et seq.*, 31-8-101, 31-8-124 and 31-8-127.
History. Original Rule entitled "Grievance Procedure" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.15. Administrative Hearing.

Any resident, guardian or representative or administrator who is dissatisfied with the decision of the impartial referee or any resident, guardian or representative who is unable to agree upon an impartial referee, or who be believes that any of his rights under these rules and regulations have been violated, shall have the right to request a hearing from the Department pursuant to the Georgia Administrative Procedure Act O.C.G.A. § 50-13-1*et seq.* in conjunction with the statute, Long-term Care Facilities: Residents' Bill of Rights O.C.G.A. § 31-8-125.

(a) The Department is authorized to hold such hearings and in the cases of an appeal from the decision of a referee, the Department may hold such hearings by review of the record of the hearing provided by the referee.

(b) A person desiring a hearing under this section may request such a hearing in writing to the Department. The request shall include the person's name, the name of the facility and the reason the hearing is requested. The request shall be mailed or delivered to the Department of Community Health.

(c) The hearing shall be conducted within 45 calendar days of the receipt by the Department of the request for the hearing. The Department shall send written notice to the administrator and complainant confirming the date, time and location (which shall be the facility unless the resident's medical condition requires a different location) of the hearing. Except where the ombudsman has been unable to resolve the matter at issue, the Department shall refer the complaint to the state or community ombudsman for informal resolution pending the hearing.

(d) Except in the event of an emergency situation in which the resident or other residents are subject to imminent and substantial danger that only immediate transfer will reduce, o except in case of nonpayment under subsection .11(2)(c), of these rules and regulations, no transfer shall take place until all appeal rights are exhausted. However, if a resident is transferred before exhaustion of all appeal rights, such resident in no way relinquishes any appeal rights under these rules and regulations.

(e) Where two or more residents in a facility allege a common complaint, the Department may, at the resident's request, schedule a common hearing.

(f) The decision of the hearing officer shall be made within 30 calendar days from the date of the hearing and shall be based upon whether or not a violation has been found. The decision shall be divided as follows:

1. The issues to be decided;
2. A summary of any actions already taken;
3. The contentions of the parties;
4. The findings of the hearing officer including whether a violation has occurred;
5. If a violation has occurred, the corrective action to be taken, and the date by which such corrective action shall be taken; and
6. The right to appeal the decision to the Superior Court of the county in which the facility is located or as provided otherwise by law.

(g) Upon the failure to correct any violations found within the time specified, the Department may impose appropriate civil penalties as provided in .16 of these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.15
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-125 and 31-8-127.
History. Original Rule entitled "Administrative Hearing" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-50-.16. Enforcement.

Any person or persons aggrieved because a long-term care facility has violated or failed to provide any rights granted under O.C.G.A. § 31-8-100*et seq.* or these rules and regulations shall have a cause of action against such facility for damages and such other relief as the court having jurisdiction of the action deems proper. No person shall be prohibited from maintaining such an action for failure to exhaust any rights to administrative or other relief granted under O.C.G.A. § 31-8-100*et seq.* or these rules and regulations. In addition to all other penalties or remedies that may be imposed by these rules and regulations, or any state or federal law, the Department is authorized to impose civil penalties as follows:

(a) If a violation has occurred, the Department shall order the facility to correct such violation by a specified date. It shall be presumed for the purposes of this section that a violation has occurred when any of the following findings are made:

1. An impartial referee has rendered a decision pursuant to subsection .14(f)3 that a violation has occurred and such finding is not reversed upon appeal; or

2. A hearing officer determines pursuant to subsection .15(f) that a violation has occurred and such finding is not reversed upon appeal; or

3. A superior court judge, pursuant to an action under O.C.G.A. § 31-8-126, finds that a facility has violated or failed to provide any rights under O.C.G.A. § 31-8-100*et seq.*, and such finding is not reversed upon appeal; or

4. The Department determines in any inspection, required or permitted by law or regulation, that a violation has occurred.

(b) If an impartial referee, hearing officer, superior court judge, or the Department finds a violation pursuant to section (a) of this rule, the facility shall correct such violation within the time specified by the Department. If the facility does not correct the violation within the time specified or within a reasonable time, as established by the Department, the Department shall have the power to order the facility to discontinue admitting residents to such facility until such violation has been corrected. The Department shall have the authority to visit and inspect the facility to determine if a known or alleged violation has been corrected.

(c) In cases of violation repeated by a facility under the same license within a 12-month period, the Department may assess a civil penalty not to exceed $75.00 per violation for each day in which the violation continues, except that the maximum civil penalty for each violation within a 12-month period shall not exceed $2,500.00. If a facility commits a violation against an individual or group of individuals and commits the same violation within a 12-month period against another individual or group of individuals, such violation shall be considered a repeat violation for the purpose of imposing civil penalties under this section. In imposing such civil penalties, the Department shall consider all relevant factors including, but not limited to:

1. The amount of assessment necessary to insure immediate and continued compliance;

2. The character and degree of impact of the violation on the health, safety, and welfare of any resident in the facility;

3. The conduct of the person or facility against whom the citation is issued in taking all feasible steps or procedures necessary or appropriate to comply or to correct the violations;

4. Any prior violations by the facility of statutes, regulations, or orders administered, adopted, or issued by the Department.

(d) No civil penalty shall be collected by the Department until notice and opportunity for hearing are afforded pursuant to O.C.G.A. § 31-2-8. Any person or facility subject to a civil penalty is entitled to review pursuant to O.C.G.A. § 50-13-19. Nothing in these regulations shall be construed to preempt any other law or regulations or to deny any rights or remedies which are provided under any other law or regulations.

(e) All civil penalties recovered by the Department shall be paid into the State Treasury.

Cite as Ga. Comp. R. & Regs. R. 111-8-50-.16
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-8-126, 31-8-127 and 50-13-1 *et seq.*
History. Original Rule entitled "Enforcement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-53. RULES AND REGULATIONS FOR NARCOTIC TREATMENT PROGRAMS.

Rule 111-8-53-.01. Legal Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated § 26-5-2*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.01
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5 and 31-2-7.
History. Original Rule entitled "Legal Authority" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-53-.02. Title and Purpose.

These rules shall be known as the Rules and Regulations for Narcotic Treatment Programs. The purpose of these rules is to provide for the licensing and inspection of narcotic treatment programs.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.02
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5 and 31-2-7.
History. Original Rule entitled "Title and Purpose" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013

Rule 111-8-53-.03. Definitions.

Unless the context otherwise requires, as used in these rules the term:

(a) "Administrator" means the individual designated by the program's governing body who is responsible for the on-going and day-to-day operations of the program, for overall compliance with federal, state, and local laws and regulations regarding the operation of narcotic treatment programs, and for all program employees including practitioners, agents, or other persons providing services at the program;

(b) "Applicant" means any individual affiliated with a partnership, corporation, association or individuals or groups of individuals submitting an application to operate a narcotic treatment program under this article.

(c) "Clinical director" means the individual designated by the program's governing body who is responsible for the on-going and day-to-day clinical aspects of treatment for those patients admitted to the program;

(d) "Clinical staff" means registered nurses, licensed practical nurses, and registered pharmacists, all operating within their respective scope of practice as authorized by law and regulation, as well as those members of the medical staff as such term is defined by these rules;

(e) "Counselor" means an individual who is qualified by education, training, and experience to provide substance abuse counseling and who is licensed or certified if required by state practice acts or these rules;

(f) "Crime" means the commission of any of the following offenses:

1. A violation of Code Section 30-5-8, relating to abuse, neglect, or exploitation of a disabled adult or elder person;

2. A violation of Code Section 16-5-1, relating to murder;

3. A violation of Code Section 16-5-2, relating to voluntary manslaughter;

4. A violation of Code Section 16-5-21, relating to aggravated assault;

5. A violation of Code Section 16-8-41, relating to armed robbery with a firearm;

6. A violation of Code Section 16-6-21, relating to aggravated sexual battery;

7. A violation of Code Section 16-6-5, relating to enticing a child for indecent purposes;

8. A violation of Code Section 16-5-70, relating to cruelty to children;

9. A violation of Code Section 16-5-101, relating to cruelty to a person 65 years of age or older or a disabled adult;

10. A violation of Code Section 16-6-1, relating to rape;

11. A violation of Code Section 16-6-4, relating to child molestation;

12. A felony violation of Code Section 16-8-2, relating to theft by taking;

13. A felony violation of Code Section 16-8-3, relating to theft by deception;

14. A felony violation of Code Section 16-8-4, relating to theft by conversion;

15. A felony violation of Code Section 16-9-1, relating to forgery;

16. A violation of Code Section 16-8-40, relating to robbery;

17. A felony violation of Chapter 13 of Title 16, relating to controlled substances;

18. A felony violation of Code Section 16-5-23.1, relating to battery; or

19. Any other offense committed in another jurisdiction which, if committed in this state, would be deemed to be such a crime without regard to its designation elsewhere.

    Any other criminal offense as determined by the Department and established by rule adopted pursuant to Chapter 13 of Title 50, the "Georgia Administrative Procedure Act," that would indicate the unfitness of an individual to be involved in the operations or activities of a narcotic treatment program.

(g) "Criminal history background check" means a search as required by law of the criminal records maintained by law enforcement authorities to determine whether the individual has a criminal record as defined in these rules.

(h) "Criminal record" means:

1. Conviction of a crime; or

2. Arrest, charge, and sentencing for a crime where:

   (i) A plea of nolo contendere was entered to the charge; or

(ii) First offender treatment without adjudication of guilt pursuant to the charge was granted; or

(iii) Adjudication or sentence was otherwise withheld or not entered on the charge; or

3. Arrest and being charged for a crime if the charge is pending, unless the time for prosecuting such crime has expired pursuant to Chapter 3 of Title 17 O.C.G.A.

(i) "Department" means the Department of Community Health, operating through the Division of Healthcare Facility Regulation, or its successor;

(j) "Director of Pharmacy Services" means a pharmacist licensed by the Georgia Board of Pharmacy who has been designated by the governing body of the narcotic treatment program to direct, oversee, establish protocols and be responsible for all pharmacy related transactions of the narcotic treatment program;

(k) "Final administrative decision" means the issuance of a ruling by the Commissioner of the Department of Community Health or his or her designee or any appeal from a decision of an administrative law judge pursuant to a contested case involving the imposition of a sanction; a decision of an administrative law judge finalized by operation of law where no appeal is made to the Commissioner of the Department of Community Health; the disposition of a contested case through settlement by the parties; or a sanction imposed by the Department that is uncontested by a facility within the allotted time period;

(l) "Governing body" means the county board of health, the partnership, the corporation, the association, or the person or group of persons who maintains and controls a narcotic treatment program, who is legally responsible for its operation, and who holds the license to operate that program;

(m) "Individual treatment plan" means a comprehensive plan that outlines for each patient attainable short-term and long-term treatment goals that are mutually acceptable to the patient and the narcotic treatment program and that specify the services to be provided and the frequency and schedule for such provision;

(n) "Inspection" means any examination by the Department or its representatives of a provider, including, but not limited to, the premises, staff, persons in care, and documents pertinent to initial and continued licensing so that the Department may determine whether a provider is operating in compliance with licensing requirements or has violated any licensing requirements. The term inspection includes any survey, monitoring visit, complaint investigation, or other inquiry conducted for the purposes of making a compliance determination with respect to licensing requirements;

(o) "License" means the official permit issued by the Department that authorizes the holder to operate a narcotic treatment program for the term provided therein;

(p) "Medical director" means a physician licensed by the Georgia Composite Medical Board who has been designated by the governing body of the narcotic treatment program to be responsible for the administration of all medical services performed by the narcotic treatment program, including compliance with all federal, state, and local laws and rules regarding medical treatment of narcotic addiction;

(q) "Medical staff" means the physicians licensed in the State of Georgia who are responsible for the medical treatment being provided to patients through a licensed narcotic treatment program. In limited circumstances, as defined in these rules, medical staff may also include a nurse practitioner, operating under an approved written protocol, and a physician's assistant, operating under an approved job description, supervised by either the program physician or medical director;

(r) "Methadone" means an opioid agonist treatment medication as approved by the Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355, for use in the treatment of opiate addiction;

(s) "Narcotic treatment program" means any system of treatment provided for chronic heroin or opiate-like drug-dependent individuals that administers narcotic drugs under physicians' orders either for detoxification purposes or for maintenance treatment in a rehabilitative context offered by any county board of health, partnership, corporation, association, or person or groups of persons engaged in such administration;

(t) "Owner" means any individual or any person affiliated with the corporation, partnership, or association with 10 percent or greater ownership interest in a business or agency licensed as a narcotic treatment program and who:

1. Purports to or exercises authority of an owner in the business or agency;

2. Applies to operate or operates the business or agency; or

3. Enters into a contract to acquire ownership of such a business or agency.

(u) "Patient" means any individual who undergoes treatment in a narcotic treatment program;

(v) "Program physician" means any physician licensed in the State of Georgia, including the medical director, who is employed by a narcotic treatment program to provide medical services to patients;

(w) "Registered Nurse" means a person who holds a current and valid license as a registered nurse issued by the State of Georgia;

(x) "Records check application" means two sets of classifiable fingerprints, a records search fee to be established by the Department by rule and regulation, payable in such form as

the Department may direct to cover the cost of a fingerprint records check, and an affidavit by the applicant disclosing the nature and date of any arrest, charge, or conviction of the applicant for the violation of any law, except for motor vehicle parking violations, whether or not the violation occurred in this state, and such additional information as the Department may require;

(y) "Region" means one of the 49 geographical areas specified in O.C.G.A. § 26-5-48(h);

(z) "Satisfactory criminal history background check determination" means a written determination that a person for whom a records check was performed was found to have no criminal record which includes one of the covered crimes outlined in paragraph (f) of this section, if applicable;

(aa) "State Board of Pharmacy" means the board created to regulate the practice of pharmacy pursuant to Article 2 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated and the Rules and Regulations of the Georgia State Board of Pharmacy, Chapter 480-18; and

(bb) "Unsatisfactory criminal history background check determination" means a written determination that a person for whom a records check was performed has a criminal record which includes one of the covered crimes outlined in paragraph (f) of this section, if applicable.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.03
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Definitions" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.04. Governing Body.

Each licensed program shall have a clearly identified governing body that accepts responsibility for operating the narcotic treatment program in accordance with applicable laws, rules, and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.04
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5 and 31-2-7.
History. Original Rule entitled "Governing Body" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-53-.05. Licenses.

No governing body may operate a narcotic treatment program in the state without first obtaining a license from the Department.

(a) License. A license will be issued, upon presentation of evidence satisfactory to the Department, that the program is in compliance with these rules and all applicable federal and state laws for the handling and dispensing of drugs and all state and local health, safety, sanitation, building, and zoning requirements. Unless suspended or revoked by the Department, a license shall remain in force and effect for a period determined by the Department based upon outcomes and a program's compliance history with these rules. Effective July 1, 2017, the Department shall limit licenses to four (4) per Region unless a waiver is approved pursuant to Rule 111-8-53-.07(12).

(b) Compliance with Requirements of Other State and Federal Agencies. To obtain a license, a program must submit evidence satisfactory to the Department that it will operate in compliance with the requirements of the Substance Abuse and Mental Health Services Administration (SAMHSA), the Drug Enforcement Administration (DEA), the Georgia State Board of Pharmacy, and any other applicable federal or state agency.

(c) License is Nontransferable. A license to operate a narcotic treatment program is nontransferable for a change of location or governing body. Each license shall be returned to the Department in cases of changes in location or governing body or if suspended or revoked. When a licensee intends to relocate or there is change in governing body, it must notify the Department and submit an application in accordance with these rules. The program may be subjected to an on-site visit by the Department prior to the issuance of a license at the discretion of the Department.

(d) Exceptions for programs licensed prior to May 4, 2017. Programs licensed prior to May 4, 2017 must submit an application only in the event of a change of governing body or location. If such program is in good standing with the Department and the change of location is within the program's Region, the requirements of Rule 111-8-53-.07 shall not apply except for 111-8-53-.07(4)(b) and (4)(n). Upon application for an additional program by a current licensee, each location operated by such licensee shall be inspected, except that any such location inspected within the preceding 36 months shall be exempt from the requirement of an on-site inspection.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.05
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Licenses" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.06. Provisional Licenses.

(1) Provisional licenses may be issued for a period not to exceed 90 days to the governing body of a new narcotic treatment program that is in substantial compliance with these rules or of an existing program that is in substantial compliance with these rules as a result of having submitted an acceptable plan of correction to the Department.

(2) A provisional license shall not be issued to a narcotic treatment program in which there are conditions that present an immediate hazard to the life, health, or safety of patients or staff.

(3) Provisional licenses shall be renewed at the discretion of the Department only in cases of extreme hardship and in no case for longer than 90 days.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.06
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5 and 31-2-7.
History. Original Rule entitled "Provisional Licenses" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-53-.07. Applications.

(1) Mandatory Information Forum. Potential applicants must send at least one representative to attend the Information Forum which shall be held at least fourteen (14) days prior to the start of the Open Enrollment Period. Failure to attend the Information Forum shall disqualify any applicant from consideration during open enrollment.

(2) Letter of Intent. Applicants for licensure must submit a letter of intent stating such applicant's intention to apply for a narcotic treatment program license. Such letter of intent shall include the intended address and Region location. The letter shall be delivered to the Department at least seven (7) days prior to the beginning of the Open Enrollment Period.

(3) The first Open Enrollment Period shall be held December 1, 2017 through December 31, 2017. Thereafter, the Open Enrollment Period shall be held in the month of December of each following year unless the Department issues a Public Notice prior to December 1 specifying an alternate time frame for enrollment.

(4) No later than the last day of the Open Enrollment Period, an application for a license to operate a narcotic treatment program must be submitted by the governing body to the Department on forms provided by the Department and must contain all information and documents designated by the Department, including, at a minimum:

   (a) Data and details regarding treatment and counseling plans;

   (b) Written operating standards that demonstrate an organizational capability to meet these rules;

   (c) Biographical and qualifications of owners, medical directors, counselors, and other required staff;

   (d) A listing of all currently licensed narcotic treatment programs within the Region of proposed location and within a 75 mile radius, whether or not such other programs are outside of the Region.

(e) Patient levels of currently licensed programs in the proposed Region of care and within 75 miles, including

1. The number of patients admitted to current narcotic treatment programs in the most recent month; and

2. The number of patients served by current narcotic treatment programs in the most recent month,

(f) Data on demographic, social, health, economic, alcohol and drug related crimes, alcohol and drug overdoses, and hospital and emergency department admission of individuals addicted to opioids for the program location;

(g) Applicant experience operating a narcotic treatment program or working at such program, including complete history of such experience both within this state and in any other state;

(h) Program ownership in other locations, if any, including a complete and accurate description of narcotic treatment program experience, including whether the applicant currently holds, has held, or had revoked any licenses, registrations, enrollments, accreditations, contracts, and network memberships. The applicant shall disclose any adverse actions against the applicant while employed by or as a result of ownership of a narcotic treatment program;

(i) Evidence the applicant sought community input for the proposed location from substance abuse advocacy organizations, civic organizations, neighborhood associations, locally elected officials, and other groups;

(j) Proof of notification of intent to file an application with all law enforcement offices within a 25 mile radius of the proposed program location;

(k) Proof of notification of intent to file an application with all drug courts within a 75 mile radius of the proposed program location;

(l) A narrative description of and information about adjoining businesses and occupancies within 200 feet of the facility, including a description of transportation access, traffic patterns, security features, local area police and crime reports, and neighborhood safety;

(m) A complete description of the facility's parking arrangements for staff and patients; and

(n) Assurances satisfactory to the Department that the program is in compliance with all applicable federal and state laws for the handling and dispensing of drugs and all state and local health, safety, sanitation, building, and zoning requirements.

(5) Approval by SAMHSA, the DEA, and the Georgia State Board of Pharmacy. An application must include assurances satisfactory to the Department that the program will meet the requirements for approval by SAMHSA or other applicable federal agency, the DEA, and the Georgia State Board of Pharmacy.

(6) False or Misleading Information. An application for a license must be truthfully and fully completed. In the event that the Department has reason to believe that an application has not been completed truthfully, the Department may require additional verification of the facts alleged. The Department may revoke a license or refuse to issue a license where material false statements have been made on or in connection with an application.

(7) History of Compliance. When an existing licensee applies to operate another program, the Department will consider the licensee's history of compliance in Georgia and may consider the licensee's compliance in any other state when determining the applicant's eligibility for another license. When an applicant that has previously operated a program applies to operate a new program, the Department will consider the compliance history of the applicant in Georgia and may consider the compliance history of the applicant in any other state.

(8) No license shall be issued to any governing body that has been denied a license by the Department during the previous 12 months. No license shall be issued to any governing body that has had a license revoked by the Department during the previous 12 months.

(9) Criminal Background Checks for Applicant/Owner. Prior to the issuance of any new license, the applicant of the business or agency applying for the license shall be required to submit a records check application so as to permit the Department to obtain a criminal history background check. After initial licensure, the owner shall be required to submit evidence of a satisfactory background check to the Department every three (3) years.

(a) At the time of initial licensure, in lieu of a records check application, the applicant may submit evidence, satisfactory to the Department, that within the immediately preceding 12 months the owner has received a satisfactory narcotic treatment program criminal records check determination.

(b) A narcotic treatment program license shall not be issued, and any issued license shall be revoked, where it has been determined that the applicant/owner has received an unsatisfactory criminal records check determination involving any of the covered crimes, as defined in paragraph (f) of Rule 111-8-53-.03.

(c) An owner with a valid narcotic treatment program license who acquires a criminal record for any of the crimes listed in paragraph (f) of Rule 111-8-53-.03 subsequent to the effective date of the license shall disclose the criminal record to the Department.

(d) If at any time the Department has reason to believe an owner holding a valid license has been arrested, charged, or convicted of any of the covered crimes listed in paragraph (f) of Rule 111-8-53-.03, the Department shall require the owner to

submit a records check application immediately for determination of whether a revocation action is necessary.

(e) An owner holding a valid narcotic treatment program license issued prior to May 4, 2017 shall not be subject to any of the background check requirements stated in this Rule 111-8-53-.07(9). However, if there is a change in the governing body of a program licensed prior to May 4, 2017, any new individuals with an ownership interest in the program shall be subject to the requirements of this Rule 111-8-53-.07(9).

(10) Application Review Committee. Where more applications are received for a particular Region during the Open Enrollment Period than are permissible under these rules, the Department shall first review the applications to determine that all information required under subsections (1) - (9) above has been submitted. All complete applications will then be sent to the Application Review Committee to be scored based on the following criteria:

(a) Compliance with all state and federal laws and regulations;

(b) Compliance with all applicable standards of practice;

(c) Program structure for successful service delivery; and

(d) Impact on the delivery of opioid treatment services of the applicant in the applicable population.

(11) Notice of Intent to Issue License/Notice of Appeal Rights. Programs selected for licensure by the Application Review Committee shall receive a notice of the Department's intent to issue a license. Programs not selected shall receive notice of the right to an administrative hearing. Upon waiver of or exhaustion of administrative appeal rights, the Department shall issue license(s) to the selected program(s).

(12) Waiver Applications under O.C.G.A. § 26-5-48(f). The Department, in its discretion, may grant a waiver to an applicant to allow an application to be submitted for review in a Region that has four or more licensed narcotic treatment programs. The Application Review Committee shall consider such waiver applications based on criteria developed jointly by the Department and the Department of Behavioral Health and Developmental Disabilities with emphasis on the needs assessment and/or justification for the establishment of a new program (including identification of treatment gaps), as well as community stakeholder support.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.07
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Applications" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.08. Inspections and Plans of Correction.

(1) The Department is authorized to conduct on-site inspections of any program to verify compliance with these rules and all relevant laws or regulations at any time. A program shall permit any authorized representative of the Department to enter upon and inspect any and all program premises which, for the purpose of these rules, shall include access to all parts of the facility, staff, persons in care, and all records pertinent to initial and continued licensure. For the purpose of conducting any investigation, inspection, or survey, the Department shall have the authority to require the production of any books, records, papers, including all patient records or other information related to the initial or continued licensing of any program. The Department may require at reasonable intervals that each licensee shall furnish copies of complete records of each person treated or advised by the program, provided, however, that patient identifying information shall be redacted from such records prior to submission to the Department. Failure to permit entry and inspection is a violation of these rules and may result in the denial of any license applied for or in the suspension or revocation of a license.

(2) If, as a result of an inspection, violations of these rules requiring corrective action are identified, the Department shall issue a written inspection report that identifies the rules violated and requires the program to submit a written plan of correction that states what the program will do to correct each of the violations identified. The program may offer an explanation or dispute the findings of violations in the written plan of correction so long as an acceptable plan of correction is submitted within 10 days of the receipt of the inspection report. Failure to submit an acceptable plan of correction may constitute cause for the Department to deny a license or suspend or revoke a license. Upon the discovery of any violation of these rules, the Department may proceed to suspend or revoke a program's license in accordance with these rules. In determining whether to suspend or revoke a license, the Department may consider whether the violations can be corrected, the program's history of compliance, the nature and seriousness of the violations, the impact of the violations on the safety and welfare or the program's patients and the surrounding community and any other relevant circumstances.

(3) Programs shall also cooperate with interested parties seeking to apply for licensure by providing the information detailed in Rule 111-8-53-.07(4)(e) within a reasonable period of time.

(4) After initial licensure, the Department shall conduct on-site inspections of each program on an annual basis. The Department may authorize third party audits or inspections of programs for the purpose of determining whether or not a program is in compliance with these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.08
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Inspections and Plans of Correction" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.09. Administration.

(1) Program Purpose. A licensed program shall operate, in accordance with these rules, under written policies and procedures that define its philosophy, purpose, program orientation, and procedures. Such policies and procedures must identify the types of drug-dependent individuals and the ages of the patients that the program serves, including referral sources.

(2) Program Description. A licensed program shall develop and fully implement written policies and procedures that describe the range of treatment and services provided by the program. These policies and procedures must describe how identified treatment and services will be provided and how such treatment and services will be assessed and evaluated. A program description must show what services are provided directly by the program and what treatment and services are provided in cooperation with available community or contract resources.

(3) Finances. The governing body shall provide for the preparation of an annual budget and approve such budget. Copies of the current year's budget and expenditure records must be made available to the Department for examination and review by the Department upon request.

(4) Fees. The program shall develop and implement a written schedule of patient fees. The schedule must identify all fees that are chargeable to patients and a copy of the current schedule shall be posted in a conspicuous place so as to inform patients and their parents, guardians, or responsible parties of such schedule of fees.

(5) Patient Records. The patient record must accurately reflect the course of appropriate treatment provided to the patients. Programs must organize and coordinate patient records in a manner that demonstrates that all pertinent patient information is accessible to all appropriate staff and to the Department. The patient's Central Registry I.D. number must be maintained in each patient record and some form of a patient identification must appear on each page of the record. Each patient record must contain, at a minimum, the following:

(a) Basic identifying information including name, current address, current telephone number, date of birth, sex, and race;

(b) If applicable, the names, addresses, and telephone number of parents, or guardians, or responsible parties;

(c) Persons to notify in case of an emergency if different from above;

(d) Appropriate evidence of a history of opiate addiction prior to entry into the program;

(e) Records of screening and assessment, including information about expected charges for services;

(f) If applicable, documentation of why the patient was not admitted for treatment and suggested referrals given to patient;

(g) Written consents, signed by the patient and dated and witnessed, as required in Rule 111-8-53-.12(1)(c)1.;

(h) Documentation of Central Registry clearance as required in Rule 111-8-53-.19;

(i) Documentation of orientation as required in Rule 111-8-53-.12(1)(c)3.;

(j) The individual treatment plan and documentation of patient involvement in the development of the individual treatment plan;

(k) Medical reports, nursing notes, laboratory results including reports of drug screens, progress notes, and documentation of current dose and other dosage data, with all entries signed and dated by the appropriate professional staff;

(l) Dated and signed case entries of all significant contacts with or concerning patients, including a record of each counseling session in chronological order, as well as dated and signed forms and assessments;

(m) Correspondence with the patient, his or her family members, and other individuals and record of each referral for service and the results thereof;

(n) Documentation by appropriate professional staff that supports the course of treatment being provided; and

(o) Discharge summary, including reasons for discharge and any referral.

(6) Confidentiality of Patient Records. Written policies and procedures shall be established and implemented for the maintenance and security of patient records specifying who shall supervise the maintenance of such records, who shall have custody of such records, and to whom records may be released. Confidentiality of patient records and release of such records must comply with 42 CFR, Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records and any applicable state laws, including but not limited to O.C.G.A. § 26-5-56. Patients shall be informed that all clinical records are subject to inspection by the Department in connection with the initial and on-going licensure of the program.

(7) Drug Records. Medication orders and dosage changes must be written or printed on a physician's order sheet or a form that clearly displays the physician's signature and tracks orders over time. Dosage dispensed, prepared, or received must be recorded and accounted for by written or printed notation in a manner that reflects an accurate inventory at all times. Every dose shall be recorded in the patient's individual medication record at the time the dose is dispensed or administered and shall be properly authenticated by the licensed person administering such dose. Where computerized systems are used, authentication procedures will be strictly enforced. If initials are used,

the full signature and credentials of the qualified person administering or dispensing must appear at the end of each page of the medication sheet. The perpetual inventory must be totaled and recorded in milligrams daily. Methadone and related drugs shall be counted and reconciled with the written inventory at the beginning and end of each dosing day with all discrepancies satisfactorily resolved.

(8) Personnel Records. A program shall maintain written and verified records for each employee. Each employee file shall include:

(a) Identifying information including name, current address, current telephone number, and emergency contact persons;

(b) A five-year employment history or a complete employment history if the person has not worked five years;

(c) Evidence of a criminal record check obtained from a state or local law enforcement agency that reflects the individual does not have any convictions of a crime, as defined in paragraph (f) of Rule 111-8-53-.03, within the previous five years; for employees working in an administrative capacity who are not providing care to patients and for employees working as peer counselors, the program may accept a criminal record check which includes conviction of a nonviolent crime such as those listed in 111-8-53-.03(f)(12) - (17);

(d) Records of educational qualifications if applicable;

(e) Date of employment;

(f) The person's job description or statements of the person's duties and responsibilities;

(g) Documentation of training and orientation required by these rules;

(h) Any records relevant to the employee's performance, including an appropriate health status of the employee; and

(i) Evidence that any professional license required as a condition of employment is current and in good standing.

(9) Referral to Other Programs. Each program shall have arrangements for referral of patients to other programs that offer different treatment modalities.

(10) Closing of a Program. A program that intends to close the program voluntarily shall notify the Department no later than sixty (60) days prior to closure. Any program that closes, either voluntarily or involuntarily, shall submit satisfactory evidence to the Department that the program has developed a transition plan for the continuity of care for its patients. Such transition plan shall include, at a minimum:

(a) Written notice to all current patients of record that the program is closing. Such notice shall be provided to patients at least thirty (30) days prior to closure and shall include information on other programs in close proximity which have availability to treat new patients;

(b) Coordination with other programs to ensure continuity of care for patients that need assistance in locating a new treatment program;

(c) Use of the Central Registry to transfer patients to the receiving program;

(d) A plan for the transfer of appropriate clinical/treatment records to the receiving program in a manner that complies with state and federal privacy laws;

(e) A timeline for management of closure-related activities; and

(f) A protocol for securing all medications to ensure that there is no diversion and to transfer any excess medications to the U.S. Drug Enforcement Administration.

(11) Hours of Operation. Program hours of operation shall accommodate persons involved in activities such as school, homemaking, childcare, and variable-shift work. Programs shall offer comprehensive services, including, but not limited to, individual and group counseling, medical services, and referral services, at least five days per week. A program may close on Sundays and state and federal holidays provided appropriate treatment arrangements are made for patients. In order to accommodate patients for whom take-home medication has not been authorized, the program shall dispense medication at least seven days per week when necessary. Programs shall further develop a plan for contingencies, emergencies, etc., including 24 hour emergency services during non-operating hours to assist patients in crisis situations.

(12) Community Liaison and Concerns. A program shall schedule and provide services to its patients in such a manner as to minimize the impact on local community services.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.09
Authority: O.C.G.A. §§ 26-5-2*et seq*., 31-2-5, 31-2-7.
History. Original Rule entitled "Administration" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.10. Staffing.

(1) Staff Ratios and Responsibilities. The program shall have sufficient and appropriate types and numbers of staff to provide the treatment and services as required by applicable state law and regulation and as outlined in its program description. When the program is open to provide treatment, there shall be a minimum of one clinical staff member and at least one additional staff member on site at all times. Patient-staff ratios shall be adjusted to

ensure reasonable and prompt access to medical staff and counselors by patients and to provide the frequency and intensity of medical and counseling services required by the patients.

(a) Administrator. The governing body of each program shall designate in writing an administrator. The administrator shall be responsible for the on-going and day-to-day operations of the program, for overall compliance with federal, state, and local laws and regulations regarding the operation of narcotic treatment programs, and for all program employees including practitioners, agents, or other persons providing services at the program. The administrator must be at least 21 years of age, must have at least one year of supervisory and administrative experience in the field of substance abuse treatment, and must have at least one year of experience working in a narcotic treatment program. Programs must notify the Department in writing within 10 calendar days whenever there is a change in administrator.

(i) Criminal History Background Check - Administrators. The program must obtain a satisfactory criminal history background check for the person being considered for employment as an administrator and must obtain a new background check for the employed administrator every three (3) years thereafter. The records check must be performed as prescribed in these rules. Programs licensed prior to May 4, 2017 shall only be subject to the requirements of Rule 111-8-53-.10(a)(i) - (iv) if there is a change in the administrator.

(ii) At the time of initial employment, in lieu of a records check application, the program may submit evidence, satisfactory to the Department, that within the immediately preceding 12 months the administrator has received a satisfactory narcotic treatment program criminal records check determination.

(iii) A person with an unsatisfactory criminal history background check determination must not serve as an administrator of a licensed narcotic treatment program. Failure to satisfy this requirement may result in enforcement action against the facility as prescribed in Chapter 111-8-25.

(iv) The administrator must immediately submit to an additional criminal history background check when the Department provides the administrator with written notice of any one of the following:

1. There is reason to believe that the administrator has acquired a criminal record as defined by these rules; or

2. The criminal history background check is required in connection with a complaint investigation being conducted by the Department.

(b) Clinical Director. The governing body of each program shall designate in writing a clinical director. The clinical director shall be responsible for the day-to-day and on-going clinical aspects of the program and of the treatment for those patients admitted to the program. Programs must notify the Department in writing within 10 calendar days whenever there is a change in clinical director.

(c) Medical Director. The governing body of each program shall designate in writing a medical director to be responsible for the administration of all medical services, including compliance with all federal, state, and local laws and regulations regarding the medical treatment of narcotic addiction. A physician may serve as medical director of no more than two narcotic treatment programs provided that all such programs are in substantial compliance with these rules and are within 50 miles of the physician's primary residence or primary office location. Programs must notify the Department in writing within 10 calendar days whenever there is a change in medical director.

(d) Program Physician. Programs are required to provide sufficient physician coverage to provide the medical treatment and oversight necessary to serve patient needs. A program physician's responsibilities for each patient include, but are not limited to, performing medical history and physical exams, determination of diagnosis under current DSM criteria, determination of narcotic dependence, reviewing treatment plans determining dosage and all changes in doses, ordering take-home privileges, discussing cases with the treatment team, and issuing any emergency or verbal orders relating to patient care. At all times a program is open and a physician is not present on site, a program physician must be available on call for consultation and emergency orders. Programs must be able to document a referral agreement with a local hospital or health care facility. Any program physician who is not a medical director must work under the supervision of the program's medical director.

(e) Physician's Assistants and Nurse Practitioners. Licensed physician's assistants and certified nurse practitioners may be employed by programs and perform any functions permitted under Georgia law.

(f) Nurses. Programs shall ensure that appropriate nursing care is provided at all times the program is in operation and that an appropriately licensed and qualified health care professional is present at all times medication is administered at the program.

(g) Counselors. There must be at least one full-time counselor for every 50 patients. To be considered "full-time," a counselor must work a minimum

of 35 hours per week. The program shall assign no more than 40 patients to counselors in training who are not yet certified.

(2) Staff Qualifications.

(a) Medical Director. All medical directors shall be licensed to practice medicine in Georgia, shall maintain their licenses in good standing and shall have had, at a minimum, 12 hours of training in narcotic-addiction treatment within the 12 months preceding the date of hire when hired after the effective date of these rules.

(b) Program Physician. All program physicians must be licensed to practice medicine in the State of Georgia, must maintain their licenses in good standing, and must have had, at a minimum, 12 hours of training in narcotic-addiction treatment within the 12 months preceding the date of hire when hired after the effective date of these rules. If the program physician has not had such training, he or she must be working under the direction of a qualified medical director with an acceptable training plan, completed within 12 months of the date of hire, that consists of a combination of continuing education in addiction medicine and in-service training by the program's medical director.

(c) Medical staff. All medical staff must be licensed and in good standing to practice their respective professions in the State of Georgia, have 12 hours of training in narcotic-addiction treatment within the 12 months preceding the date of hire when hired after the effective date of these rules, and practicing within the scope authorized by law. If any member of the medical staff has not had such training, he or she must be working under the direction of a qualified medical director with an acceptable training plan, completed within 12 months of the date of hire, that consists of a combination of continuing education in addiction medicine and in-service training by the program's medical director.

(d) Nurses. All registered nurses and licensed practical nurses must be licensed to practice in Georgia in compliance with Chapter 26 of Title 43 of the Official Code of Georgia Annotated, the "Georgia Registered Professional Nurse Practice Act," and must maintain their licenses in good standing.

(e) Counselors. All counselors must be certified in addiction counseling pursuant to Section 7(b)(15) of Chapter 10A of Title 43 of the Official Code of Georgia Annotated within three (3) years of employment by the program. Programs licensed prior to May 4, 2017 shall have three (3) years to comply with this requirement.

(f) Clinical Directors. All clinical directors must be licensed to practice medicine in the State of Georgia, licensed as a practitioner to provide treatment, therapeutic advice, or counseling for the rehabilitation of drug-dependent persons in compliance with state practice acts, or certified as an addiction counselor, must be

at least 21 years of age, and must have at least one year of supervisory and administrative experience in the field of substance abuse treatment.

(g) Professional Practice. All professional staff members, including, but not limited to, physicians, pharmacists, physicians' assistants, nurse practitioners, registered nurses, licensed practical nurses, and counselors, may perform only those duties that are within the scope of their applicable professional practice acts and Georgia licenses.

(3) Medical Staff Supervision. Programs that do not employ a registered nurse to supervise the nursing staff must ensure that licensed practical nurses adhere to written protocols and are supervised by the Medical Director to ensure that nursing services are being appropriately delivered.

(a) Supervision by Medical Director must occur at least one time per month, be documented in writing, reviewed with the Administrator and Clinical Director, and include the following areas:

1. the written policies and procedures required in Rule 111-8-53-.15;

2. changes made to policies and procedures required in Rule 111-8-53-.15; and

3. areas identified by Administrator, Clinical Director, Director of Pharmacy Services, Medical Director or Program Physician as requiring training for all licensed practical nurses;

(4) Staff Training and Orientation. Prior to working with patients, all staff members who provide treatment and services must be oriented in accordance with these rules and must thereafter receive additional training in accordance with these rules.

(a) Orientation must include instruction in:

1. The program's written policies and procedures that are relevant to the employee's range of duties and responsibilities;

2. The employee's assigned duties and responsibilities;

3. Reporting patient progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services; and

4. Customer service.

(b) Additional training consisting of a minimum of 16 hours of training or instruction must be provided annually for each staff member who provides treatment services to patients. Such training must be in subjects that relate to the employee's assigned

duties and responsibilities and in subjects about current clinical practice guidelines for narcotic treatment, such as dosage based on a physician's clinical decision making and an individual patient's needs; drug screens; take-home medication practices; phases of treatment; treating abusers of multiple substances; narcotic treatment during pregnancy; HIV and other infectious diseases; co-morbid psychiatric conditions; and referring patients for primary care or other specialized services. Programs shall maintain records documenting that each staff member has received the required annual training.

(5) Employee Drug Testing. Programs shall establish and implement written policies and procedures for pre-employment and ongoing random drug testing of all program employees. Each sample must be collected and handled in accordance with accepted standards of clinical laboratory practice and tested for opiates, methadone and related drugs, amphetamines, cocaine, benzodiazepines, THC, and other drugs with satisfactory documentation of the results retained by the program.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.10
Authority: O.C.G.A. §§ 26-5-2*et seq*., 31-2-5, 31-2-7.
History. Original Rule entitled "Staffing" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.11. Physical Plant and Safety.

(1) A program shall be in compliance with all applicable local health, safety, sanitation, building, and zoning requirements.

(2) A program shall be in compliance with all applicable laws and rules issued by the state fire marshal and the proper local fire marshal or state inspector and shall have a certificate of occupancy, if required.

(3) All buildings and grounds must be accessible by the disabled and constructed and maintained in a safe manner in accordance with these rules.

(4) A program shall have appropriate and sufficient space to meet the programmatic needs of its patients, and carry out the program's array of services. Such space must include areas conducive to privacy for dosing, counseling and group activities, reception/waiting areas, and bathrooms that ensure privacy for collection of urine specimens.

(5) Medications shall be separately and appropriately stored. Medical specimens and food will be stored separately and appropriately to prevent cross-contamination.

(6) Facilities shall have NARCAN, or other medically appropriate emergency narcotic antagonists, available on site when care is being provided to patients; and

(7) Any laboratory functions performed by the program shall conform to the Rules and Regulations for Licensure of Clinical Laboratories, Chapter 111-8-10.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.11
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Physical Plant and Safety" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.12. Patient Screening, Assessment, and Admission.

(1) A program may only admit and retain patients whose known needs can be met by the program in accordance with its program purpose and description and applicable federal and state laws and regulations. Written policies and procedures for patient referral, intake, screening, assessment, and admission must be established and implemented and must include the following provisions or requirements.

(a) Screening. All applicants for admission must be initially screened by program staff to determine eligibility for admission. No applicant may be admitted until it has been verified that he or she meets all applicable criteria and that the sources and methods of verification have been recorded in the applicant's case folder. The screening process must include:

1. Verification, to the extent possible, of an applicant's identity, including name, address, date of birth, and other identifying data;

2. Drug history and current status, including determination and substantiation, to the extent possible, of the duration of substance dependence;

3. If an applicant has been previously discharged from treatment at another narcotic treatment program, the admitting program must initiate an investigation into the applicant's prior treatment history, inquiring of the last program attended the reasons for discharge from treatment;

4. If an applicant is 18 years of age or older, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of one year; and

5. If an applicant is under 18 years of age, verification that the applicant has had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12 month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible party consents in writing to such treatment.

(b) Assessment. Each patient admitted to the program must be assessed by the medical director, the program physician, or an appropriately licensed and qualified member of the medical staff who has been determined to be qualified by law, education, training, and experience to perform or coordinate the provision of such assessments. A program shall not admit a patient for a maintenance program unless it is the most appropriate treatment modality. Before any medication is prescribed or administered, a patient who is admitted to a program shall be assessed by the medical director, the program physician, or an appropriately licensed and qualified member of the medical staff who has been determined to be qualified by law, education, training, and experience to perform or coordinate the provision of such assessments. The assessment must include:

1. Medical history, including HIV status, pregnancy, current medications (prescription and non-prescription), and active medical complications;

2. Psychiatric history and current medical status examination;

3. Determination if the applicant needs special services, such as treatment for alcoholism, or psychiatric services, and determination that the program is capable of addressing these needs either directly or through referral;

4. Explanation of treatment options, detoxification rights, and program charges, including fee agreement, signed by the applicant; and

5. An in-person physical examination in accordance with current and accepted standards of medical practice, complete with laboratory tests, including drug screens, HIV status (if the applicant consents to be tested), CBC and chemistry profile, and pregnancy, STD, and Mantoux TB tests, to determine dependence on opium, morphine, heroin, or any derivative or synthetic drug of that group and to determine current DSM diagnosis. The purpose of such assessments shall be to determine whether narcotic substitution, short-term detoxification, long-term detoxification, or drug-free treatment will be the most appropriate treatment modality for the patient and to establish additional educational, vocational, and treatment needs of the patient. In lieu of a complete physical examination being performed by the program physician, the individual may present a complete physical examination, dated within 90 days of admission, performed by a physician licensed in good standing in the State of Georgia. Such examination shall be updated as necessary to reflect the individual's current condition at the time of admission, including updated laboratory tests.

(c) Admission.

1. Consent. Except as otherwise authorized by law, no person may be admitted for treatment without written authorization from the patient and parent, guardian, or responsible party, if applicable. The following information

must be explained by a trained staff person to the patient and other consenters, signed by the patient and such other consenters, and documented in the patient file:

(i) The program's services and treatment;

(ii) The specific condition that will be treated;

(iii) The expected charges for service including any charges that might be billed separately to the patient or other parties; and

(iv) The program's rules regarding patient conduct and responsibilities.

2. Admission Clearance. No person may receive medications unless the program first conducts an inquiry with the Central Registry in accordance with Rule 111-8-53-.19 and receives clearance from the Central Registry that the person is not simultaneously enrolled in another program.

3. Orientation. The program shall provide orientation to patients who are admitted for treatment within 24 hours of admission. Orientation must be done by a staff person who has been determined to be qualified by education, training, and experience to perform the task. Patients must be reoriented as needed to ensure an understanding of the program. Programs shall ensure that each patient signs a statement confirming that the following has been explained to the patient:

(i) The expected benefits of the treatment that the patient is expected to receive;

(ii) The patient's responsibilities for adhering to the treatment regimen and the consequences of non-adherence;

(iii) An explanation of individual treatment planning;

(iv) The identification of the staff person who is expected to provide treatment or coordinate the treatment;

(v) Program rules including requirements for conduct and the consequences of infractions, including involuntary discharge;

(vi) Patient's rights and responsibilities;

(vii) Procedures for complaining to the program and to the Department of Community Health;

(viii) Drug screening policies and procedures;

(ix) HIV education; and

(x) Community awareness.

4. Programs shall ensure that patients receive a written copy of the orientation information.

(2) Any program licensed or funded by the Department shall implement a priority admissions policy for the treatment of drug dependent pregnant females which provides for immediate access to services for any such female applying for admission, which access shall be contingent only upon the availability of space. The program must coordinate the treatment of the pregnant female with appropriate health care providers monitoring the progress of the pregnancy. Pregnancy tests for females must be conducted at admission, unless otherwise indicated.

(3) No program may provide a bounty, free services, medication, or other reward for referral of potential patients to the program.

(4) No program may provide temporary discounted financial incentives to a potential patient that does not conform to the schedule of fees established by such program as required by these rules. No program shall provide discounted fees for services during the first ninety (90) days of treatment. This paragraph (4) shall not apply to drug dependent pregnant females.

(5) Non-Admissions. The program shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. Such logs must identify the reasons why the persons were not admitted and what referrals were made for them by the program.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.12
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Patient Screening, Assessment, and Admission" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.13. Individual Treatment Plan.

A program must develop a preliminary individual treatment plan for each patient within 10 days of admission, which includes an initial treatment recommendation. A complete individual treatment plan for each patient must be developed within 30 days of admission. Patients must be involved in the development of their treatment plans. Treatment plans must document a consistent pattern of substance abuse treatment services and medical care appropriate to individual patient needs and must meet the requirements of 42 C.F.R. § 8.12(f)(4).

(a) Medical care, including referral for necessary medical service, and evaluation and follow-up of patient complaints must be compatible with current and accepted standards of medical practice. All patients must receive a physical examination by the medical director, the program physician, or an appropriately licensed and qualified member of the medical staff at least annually. All other medical procedures performed at the time of admission must be reviewed by the medical staff on an annual basis, and all clinically indicated tests must be repeated. The medical director or program physician shall evaluate the results of this annual medical examination and review of patient medical records and document such evaluation in each patient's record.

(b) In recognition of the varied medical needs of patients, the case history and individual treatment plans must be reviewed at least every 90 days for patients in treatment less than one year and at least annually for patients in treatment more that one year. This review will be conducted by the medical director or program physician along with the primary counselor and other appropriate members of the treatment team for general quality controls and evaluation of the appropriateness of continuing the form of treatment on an ongoing basis. This review must also include an assessment of the current dosage and schedule and the rehabilitative progress of the patient, as part of determination of whether additional medical services are indicated. If such review results in a determination that additional or different medical services are indicated, the program must ensure that such services are made available to the patient and appropriate referrals for additional care are made.

(c) When the program physician prescribes other controlled substances to patients in the program, the program physician shall ensure that such prescriptions are in accordance with all applicable statutes and regulation and with current and accepted standards of medical practice. Such prescriptions shall not be issued to any patient unless the medical director, the program physician, or a member of the medical staff first sees the patient and assesses the patient's potential for abuse of such medications.

(d) As part of the rehabilitative services provided by the program, each patient must be provided with individual or group counseling appropriate to his or her needs. The frequency and duration of counseling provided to patients must be determined by appropriate program staff and be consistent with the individual treatment plan. Individual treatment plans must indicate a specific level of counseling services needed by the patient as part of the rehabilitative process.

(e) All patients shall receive HIV risk reduction education appropriate to their needs.

(f) When appropriate, each patient must be enrolled in an education program, or be engaged in a vocational activity (vocational evaluation, education, or skill training), or make documented efforts to seek gainful employment. Deviations from compliance with these requirements must be explained in the patient's record. Each program shall take steps to ensure that a comprehensive range of rehabilitative services, including vocational, educational, legal, mental health, alcoholism, and social services are made available to patients who demonstrate a need for such services. The program can fulfill such

responsibility by providing support services directly or by appropriate referral. Support services recommended and utilized must be documented in the patient record.

(g) All programs will develop and implement policies for matching patient needs to treatment and providing treatment in accordance with current and accepted standards of medical practice. These policies shall include treatment phasing, in which the intensity of medical, counseling, and rehabilitative services provided to a patient varies depending upon the patient's phase of treatment. Phases of treatment may include intensive stabilization for new patients and those in need of acute care, graduated rehabilitation phases, and medical maintenance or appropriate treatment-tapering phases for long-term stable patients.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.13
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Individual Treatment Plan" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.14. Discharge and Aftercare Plans.

(1) A program must complete, in accordance with accepted standards of practice, an individual discharge and aftercare plan prior to discharge for patients who leave the program with notice. The patient and, as applicable, his or her parents, guardian, or responsible persons must participate in discharge and aftercare planning.

(2) A discharge summary must be completed within seven days of discharge of a patient and must include a final assessment of the patient's status at the time of discharge and a description of aftercare plans for patients; and

(3) The program must establish and maintain a formal plan of cooperation with other programs in the State to allow for continuity of care for drug dependent persons.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.14
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Discharge and Aftercare Plans" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.15. Narcotic Drugs.

Programs shall develop and implement written policies and procedures for prescription and administration of narcotic drugs and their security. These policies and procedures must include the following:

(a) Administration.

1. The program physician shall determine the patient's initial and subsequent dose and schedule. If the program physician did not perform the medical assessment required in Rule 111-8-53-.12, the program physician must consult with the person who performed the assessment before determining the patient's initial dose and schedule. The program physician shall communicate the initial and subsequent doses and schedule to the pharmacy or the person supervising medication. The program physician may assign such dose and schedule by verbal order; however, the program physician must confirm all such orders in writing within 72 hours.

2. Individual doses shall be based on the clinical judgment of the program physician who has personally reviewed the patient's record and who has considered all available relevant information, including, but not limited to, drug screens, quantitative levels of methadone and related drugs, patient interview, and specific circumstances pertaining to the individual patient.

3. A program shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosage requirements are met:

   (i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse;

   (ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms; and

   (iii) For the use of any other approved opioid agonist treatment medication, the program shall ensure that the dosage form and initial dosage requirements are in accordance with currently accepted standards of treatment.

4. Patients are stabilized on methadone or a related drug when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the patient comfortable for at least 24 hours with no need to resort to illicit opiates to satisfy opiate cravings.

5. The dose must either be administered by a licensed medical professional authorized by law to do so or be self-administered by the patient while under the supervision of a licensed medical professional. No methadone or any other drug may be administered unless the applicant has undergone all of the screening and admission procedures required, unless there is an emergency situation that is fully documented in the records. In that case, intake procedures must be completed on the next working day. No take-home medication may be given in such an emergency.

6. The program shall be responsible for ensuring that all dosages are within therapeutically acceptable limits;

(b) Any narcotic drug prescribed and administered shall be documented on an individual medication administration record that is maintained on site and stored when complete in the patient's clinical record. The record must include:

1. Name of medication;
2. Date prescribed;
3. Dosage;
4. Frequency;
5. Route of administration;
6. Date and time administered; and
7. Signed documentation of staff administering medication or supervising self-administration;

(c) Take-home doses of methadone shall be handled in accordance with applicable rules of SAMHSA or other applicable federal agency. A narcotic treatment program shall permit take-home doses of methadone according to these rules and the following restrictions:

1. During the first 90 days of treatment for a patient, the take-home supply shall be limited to a single dose per week, not to include any single take-home supply given to the patient for a day that the clinic is legitimately closed for business, including Sundays and state and federal holidays;
2. During the second 90 days of treatment for a patient, the take-home supply shall be limited to two doses per week, not to include any single take-home supply given to the patient for a day that the clinic is legitimately closed for business, including Sundays and state and federal holidays;
3. During the third 90 days of treatment for a patient, the take-home supply shall be limited to three doses per week, not to include any single take-home supply given to the patient for a day that the clinic is legitimately closed for business, including Sundays and state and federal holidays;
4. During the remaining months of the first year of treatment for a patient, the take-home supply shall be limited to no more than a six-day supply;
5. After one year of continuous treatment for a patient, the take-home supply shall be limited to no more than a two-week supply; and
6. After two years of continuous treatment for a patient, the take-home supply shall be limited to no more than a one-month supply, provided that the patient makes at least one visit per month;

(d) Adverse drug reaction and medication administration errors must be documented and reported to a program physician immediately and corrective action initiated. The adverse reaction or error also must be recorded in the drug administration record and the nurse progress notes and the Medical Director must be alerted;

(e) No drug shall be dispensed or administered except upon receipt of a medication drug order written by a licensed medical practitioner granted rights to prescribe such medication under the Rules and Regulations of the Georgia State Board of Pharmacy, Chapter 480-18-.07;

(f) All medications must be appropriately stored in a locked safe when not being administered or self-administered; and

(g) Emergency medications, such as NARCAN or other medically appropriate emergency narcotic antagonists, must be kept available for appropriate use.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.15
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Narcotic Drugs" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.16. Drug-Screen Tests.

The program shall develop and implement written policies and procedures for random drug-screen tests. These policies and procedures will be for the purposes of assessing the patient abuse of drugs and making decisions about the patient's treatment. These policies and procedures must include the following provisions:

(a) Clinically appropriate drug-screen tests done in accordance with current and accepted standards of medical practice must be conducted initially upon admission and on a random basis bi-weekly for new patients during the first 30 days of treatment and at least monthly thereafter. However, patients on a monthly schedule who fail the drug-screen tests will be returned to a bi-weekly schedule for at least two weeks or longer if clinically indicated;

(b) Each sample collected must be screened for opiates, oxycodone, methadone, methadone metabolite; amphetamines, cocaine, benzodiazepines, THC, and other drugs as indicated by individual patient use patterns or that are heavily used in the locale of the patient; and

(c) Programs shall develop and enforce policies for the proper collection and handling of drug-screen test samples to ensure that samples collected from patients are properly handled, are actually collected from the patient being tested, and are unadulterated. Such policies may include random direct observation, which shall be conducted professionally, ethically, and in a manner that respects patients' privacy.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.16
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Drug-Screen Tests" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.17. Quality Improvement.

(1) Programs shall develop and implement a written quality improvement plan that provides for the delivery of care in accordance with accepted standards of practice. At a minimum, the plan must include the following areas:

   (a) A service delivery assessment that evaluates appropriateness of treatment plans and services delivered, completeness of documentation in patient records, quality of and participation in staff training programs, linkage to and utilization of primary care and other out-of-program services, patient grievance procedures, availability of services and medications for other conditions, and at least one indicator to evaluate the effectiveness of services at the program; and

   (b) A documented assessment of medication-related issues including take-home procedures, security, inventory, and dosage issues completed with the Director of Pharmacy Services or an appropriate delegate.

(2) Such plan shall serve to continuously monitor the program's compliance with the requirements set forth in these rules. Responsibility for administering and coordinating the quality improvement plan must be delegated to a staff person who has been determined to be qualified by education, training, and experience to perform such tasks. The medical director shall be actively involved in the development, full implementation, and continuous monitoring of the plan.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.17
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Quality Improvement" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.18. Patient Rights, Responsibilities, and Complaints.

(1) Programs shall develop and implement written policies and procedures regarding the rights and responsibilities of patients and the handling and resolution of complaints. These policies and procedures must include a written notice of rights and responsibilities provided to each patient at orientation. The required notice must contain the following items:

   (a) Right to humane treatment that affords reasonable protection from harm, exploitation, and coercion;

(b) Right to be free from physical and verbal abuse;

(c) Right to be informed about the individual treatment plan and to participate in the planning, as able;

(d) Right to be promptly and fully informed of any changes in the plan of treatment;

(e) Right to accept or refuse treatment;

(f) Right to confidentiality of patient records;

(g) Right to be informed of the program's complaint policy and procedures and the right to submit complaints without fear of discrimination or retaliation and to have them investigated by the program within a reasonable period of time;

(h) Right to receive a written notice of the address and telephone number of the state licensing authority, i.e. the Department, and the right to file a complaint with the Department;

(i) Right to obtain a copy of the program's most recent completed report of licensing inspection from the program upon written request. The program is not required to release a report until the program has had the opportunity to file a written plan of correction for the violations as provided for in these rules; and

(j) Right to an informal review and appeal of any involuntary discharge.

(2) These policies and procedures shall also include provisions for patients and others to present complaints to the program, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.

(3) The program shall provide services in a manner that respects the rights and responsibilities of patients.

(4) The program shall post the name and phone number of the Complaint Intake Line for the Department of Community Health and the most recent inspection report issued by the Department in an area visible to the patients.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.18
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5 and 31-2-7.
History. Original Rule entitled "Patient Rights, Responsibilities, and Complaints" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-53-.19. Central Registry.

(1) To prevent simultaneous enrollment of a patient in more than one program, all programs shall participate in the Central Registry approved by the Department and operated by the Department of Behavioral Health and Developmental Disabilities and shall comply with any policies, procedures or rules of the Department of Behavioral Health and Developmental Disabilities which are associated with the Central Registry. The Central Registry shall require each program to provide the social security number and other identifying information of each patient. Patients must be informed of the program's participation in the Central Registry, and prior to initiating a Central Registry inquiry, the program must obtain the patient's signed consent. Within 24 hours of accepting patient for treatment, and prior to the administration of any medication, the program shall initiate a clearance inquiry by submitting to the approved Central Registry the patient's name, date of birth, social security number, anticipated date of admission, and any other relevant information required for the clearance procedure. All such information shall be considered confidential. No individual shall receive medication from a program if that individual is reported by the Central Registry to be participating in another such program. In the event a dual enrollment is discovered, the patient must be discharged from one program in order to continue enrollment at another program. Reports received by the Central Registry shall be treated as confidential and shall not be released except to a licensed program or as required by law. Information made available by the Central Registry to programs shall also be treated as confidential.

(2) To prevent simultaneous enrollment of persons in different programs located in different states, if a program operates within 125 miles of any adjoining state and that state also has a Central Registry, the program shall participate in the Central Registry of the adjoining state, if available.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.19
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Central Registry" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.20. Reporting to the Department.

(1) A narcotic treatment program shall report to the Department within 24 hours and also follow the Department of Behavioral Health and Developmental Disabilities reporting protocol whenever any of the following incidents involving patients occurs or the program has reasonable cause to believe that such an incident involving a patient has occurred:

(a) Any death of a patient;

(b) Any rape that occurs in the program;

(c) Any serious injury to a patient while at the program that requires medical attention;

(d) Any assault on a patient, any battery on a patient, or any abuse, neglect, or exploitation of a patient by program staff; and

(e) An external disaster or other emergency situation that affects the continued safe operation of the program.

(2) The report shall be received by the Department in confidence and shall include at least:

(a) The name of the program and the name of the administrator or clinical director;

(b) The date of the incident and the date the program became aware of the incident;

(c) The type of incident suspected, with a brief description of the incident; and

(d) Any immediate corrective or preventative action taken by the program to ensure against the replication of the incident.

(3) Where the Department determines that a rule violation related to the incident has occurred, the Department will initiate a separate complaint investigation of the incident. The complaint investigation report and the report of any rule violation compiled by the Department arising either from the initial report received from the program or an independent source shall be subject to disclosure in accordance with applicable laws.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.20
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Reporting to the Department" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Amended: F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.21. Enforcement and Penalties.

(1) When the Department finds that an applicant for a license fails to fulfill the requirements of these rules, the Department may, subject to notice and opportunity for a hearing, refuse to grant the license. The Department is not required to hold a hearing prior to taking such action.

(2) When the Department finds that any licensed program violates any requirements of these rules, the Department may, subject to notice and opportunity for a hearing, suspend or revoke the license.

(a) License Suspension.

1. The Department may suspend any license for a definite period calculated by the period necessary for the facility to implement long-term corrective measures and for the facility to be deterred from lapsing into noncompliance in the future. As an alternative to suspending a license for a definite period,

the Department may suspend the license for an indefinite period in connection with the imposition of any condition or conditions reasonably calculated to elicit long-term compliance with licensing requirements that the program must meet and demonstrate before it may regain its license.

2. In lieu of a full suspension, the Department, in its discretion, may suspend the authority of the narcotic treatment program to operate a portion of the program, e.g. granting take-home medication privileges or admitting new patients.

3. If the sanction of license suspension is finally imposed, as defined by a final administrative decision, the program must return its license to the Department. Upon the expiration of any period of suspension, and upon a showing by the program that it is capable of achieving compliance with licensing requirements, the Department shall reissue the program license. Where the license was suspended for an indefinite period in connection with conditions for the re-issuance of a license, once the program can show that any and all conditions imposed by the Department have been met, the Department shall reissue the program license.

(b) License Revocation. If the sanction of license revocation is finally imposed, as defined by a final administrative decision, the program must return its license to the Department.

(c) Notice. The Department shall provide notice of its actions to revoke the license or seek an emergency suspension of the program's license to operate to patients and to their legal guardians, if any, as follows:

1. The notice, together with the Department's complaint intake phone number and website, shall be provided to patients and to their legal guardians, if any, through the following methods:

   (i) The posting of the official notice of the revocation or emergency suspension action and any final resolution at the program by Departmental staff in an area that is visible to the patients and to their legal guardians, if any;

   (ii) The posting of the official notice of the revocation or emergency suspension action and any final resolution on the Department's website; and

   (iii) The distribution by Departmental staff of a brief notice of the initial filing of actions to revoke or suspend the program's license to the patients and to their legal guardians, if any, who are receiving

services at the program location at the time that the notice of revocation or emergency suspension is posted by the Department;

2. The Department may share any notice of the revocation or emergency suspension action and any information pertaining thereto with any other agencies that may have an interest in the welfare of the patients in care at the program;

3. When the Department has posted a notice of the revocation and/or emergency suspension actions in the program, the program shall ensure that the notice at the program continues to be visible to the patients and to their legal guardians, if any, throughout the pendency of the revocation and emergency suspension actions including any appeals;

4. The program shall have posted at the program in an area that is readily visible to the patients and to their legal guardians, if any, any inspection reports that are prepared by the Department during the pendency of any revocation or emergency suspension action; and

5. It shall be a violation of these rules for the program to permit the removal or obliteration of any notices of revocation, emergency suspension action, resolution, or inspection survey reports posted by the Department on the premises of the program during the pendency of any revocation or emergency suspension action.

(3) The Department is authorized to take emergency actions against any program when it determines that the public health, safety, or welfare requires such action.

(4) All enforcement actions shall be administered in accordance with Chapter 13 of Title 50 of the Official Code of Georgia Annotated, the "Georgia Administrative Procedure Act" and the Rules and Regulations for Enforcement of General Licensing and Enforcement Requirements, Chapter 111-8-25. Any requests for hearings in response to enforcement actions must be in writing and must be submitted to the Department no later than 10 calendar days from the date of receipt of any notice of intent by the Department to impose an enforcement action.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.21
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7, 50-13-1 *et seq.*
History. Original Rule entitled "Enforcement and Penalties" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-53-.22. Variance and Waiver.

(1) The Department may, in its discretion, grant variances and waivers of specific rules upon application or petition filed on forms provided by the Department. The Department may establish conditions which must be met by the program in order to operate under the variance or waiver granted.

(a) Variance. A variance may be granted by the Department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety, and care of patients exist and will be met in lieu of the exact requirements of the rule or regulations in question. The Department may require additional documentation by the program to support its application for a variance or waiver.

(b) Waiver. The Department, in its discretion, may dispense entirely with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, and care of patients.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.22
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Severability" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.
Repealed: New Rule entitled "Variance and Waiver" adopted. F. Feb. 15, 2018; eff. Mar. 7, 2018.

Rule 111-8-53-.23. Severability.

In the event that any rule, sentence, clause, or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions of rules shall remain in full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-53-.23
Authority: O.C.G.A. §§ 26-5-2*et seq.*, 31-2-5, 31-2-7.
History. Original Rule entitled "Severability" adopted. F. Feb. 15, 2018; eff. Mar. 7, 2018.

Subject 111-8-56. NURSING HOMES.

Rule 111-8-56-.01. Definitions.

Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereafter respectively ascribed to them; except, however, same do not apply to nursing homes owned or operated by the Federal Government:

(a) "Nursing Home" is a facility which admits patients on medical referral only and for whom arrangements have been made for continuous medical supervision; it maintains the services and facilities for skilled nursing care, rehabilitative nursing care, and has a satisfactory agreement with a physician and dentist who will be available for any medical and/or dental emergency and who will be responsible for the general medical and dental supervision of the home; it otherwise complies with these rules and regulations;

(b) "Skilled Nursing Care" means the application of recognized nursing methods, procedures, and actions directed toward implementation of the physician's prescribed therapeutic and diagnostic plan, detection of changes in the human body's regulatory system, preservation of such body defenses, prevention of complications, and promotion of emotional well-being, including but not limited to the following:

1. The administration of oral or injectable medications which cannot be self-administered. Other examples include the administration of oxygen, the use of suction, the insertion or changing of catheters, the application of medicated dressings, the use of aseptic technique and preparation of the patient for special procedures;

2. Observation in the care of the patient for symptoms and/or physical and mental signs that may develop and which will require attention of the physician and a revision in the patient's treatment regimen.

(c) "Rehabilitative Nursing" means the use of nursing skills and techniques to combat deformities and helplessness, to maintain or restore body functions, and to promote independence in self-care. Such techniques will include but not be limited to the following:

1. Positioning patients in or out of bed to maintain good body alignment (unless contraindicated by physician's orders), the use of range of motion exercises to maintain joint mobility;

2. Arranging a progression of self-care activities such as transfer and walking, and attention to bowel and bladder schedules together with retraining when indicated.

(d) The term "Distinct Part" means a physically identifiable unit of a medical facility such as an entire ward or contiguous wards, wing, floor, or building. It consists of all beds and related facilities in the unit;

(e) The term "Nursing Unit" means the number of patient beds assigned to a nurses' station;

(f) The term "Nurses' Station" means a circumscribed location containing communication and recording tools and equipment essential for the operation of nursing services;

(g) The terms "Patient" and "Resident" mean any person residing in and receiving care or treatment in a nursing home;

(h) The terms "Patient Care Plan" or "Plan of Care" mean a personalized daily plan of care indicating what care is needed, how it can be best accomplished for each patient, how each patient likes things done, what methods and approaches are most successful, and what modifications are necessary to ensure best results;

(i) The term "Patient Activities Program" means a schedule of events which are regularly planned and available for all patients, including social and recreational activities involving active participation by the patient, entertainment of appropriate frequency and character, and opportunities for participation in community activities as possible and appropriate;

(j) The term "Transfer Agreement" means a written contract with other facilities providing for transfer of patients between the facilities and for interchange of medical and other information when the facility cannot provide the level of care needed by the patient;

(k) "Physician" shall mean a doctor of medicine and/or a doctor of osteopathy duly licensed to practice in this State by the Composite State Board of Medical Examiners, under the provision of the Georgia Medical Practice Act, O.C.G.A. § 43-34-20*et seq.*;

(l) "Dentist" means any person who is licensed to practice in this State under the provisions of the Dentists and Dental Hygienists Act;

(m) "Pharmacist" shall mean an individual licensed to practice pharmacy in accordance with the provisions of O.C.G.A. § 26-4-1*et seq.*;

(n) "Physical Therapist" shall mean an individual who practices physical therapy, and who is registered with the Board of Physical Therapy of the State of Georgia, O.C.G.A. § 43-33-1*et seq.*;

(o) A "Registered Nurse" is a person who holds a current and valid license as a registered nurse issued by the State of Georgia;

(p) A "Licensed Undergraduate Nurse" is a person who holds a current and valid license as a licensed undergraduate nurse issued by the State of Georgia;

(q) A "Licensed Practical Nurse" is a person who holds a current and valid license as a licensed practical nurse by the State of Georgia;

(r) The term "Full-time Employee" means any person employed who normally works forty (40) hours per week in the home;

(s) The term "Governing Body" means the Board of Trustees, the partnership, the corporation, the association, the person or group of persons who maintain and control the home and who is legally responsible for the operation;

(t) The term "Administrator" means an individual who is licensed by the Georgia State Board of Nursing Home Administrators and who has the necessary authority and responsibility for management of the home;

(u) "Permit" means authorization by the Department to the Governing Body to operate a home and signifies satisfactory compliance with these rules and regulations;

(v) "Provisional Permit" means authorization by the Department to the Governing Body to operate a home on a conditional basis for a period not to exceed six months to allow a newly established home a reasonable but limited period of time to demonstrate operational procedures in satisfactory compliance with these rules and regulations; or to allow an existing home a reasonable length of time to comply with these rules and regulations, provided said home shall first present a plan of improvement acceptable to the Department. Successive Provisional Permits may be granted to any home having deficiencies only in exceptional cases, in which cases the Governing Body must present a plan of improvement acceptable to the Department;

(w) The term "Plan of Improvement" means a written plan submitted by the Governing Body and acceptable to the Department. The plan shall identify the existing noncompliance of the institution, the proposed procedures, methods, means and period of time to correct the noncompliance;

(x) The term "Board" means the Board of Community Health of the State of Georgia;

(y) The term "Department" means the Department of Community Health of the State of Georgia;

(z) The term "Commissioner" means the chief executive of the Department.

(aa) The term "Dining Assistant" means an individual employed or compensated by the nursing home, or who is used under an arrangement with another agency or organization, to provide assistance with feeding and hydration to residents in need of such assistance. Such individual shall not provide other personal care or nursing services unless certified as a nurse aide or licensed as a registered nurse or practical nurse.

(bb) "Certified Medication Aide" is a person who is a Georgia certified nurse aide and in good standing with the Department who has successfully completed a state-approved medication aide training program, successfully passed a written competency examination and has demonstrated the requisite clinical skills to serve as a medication aide and who is registered on the Georgia Certified Medication Aide Registry.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.01
Authority: O.C.G.A. § 31-7-1*et seq*.
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Dec. 29, 2021; eff. Jan. 18, 2022.

Rule 111-8-56-.02. Governing Body.

(1) There shall be a governing body which assumes full legal responsibility for the overall conduct of the home.

(2) The ownership of the home shall be fully disclosed to the Department. In the case of corporations, partnerships and other bodies created by statute the corporate officers and all others owning ten percent or more of the corporate stock or ownership shall be made known to the Department.

(3) The governing body shall be responsible for compliance with all applicable laws and regulations pertaining to the home.

(4) The governing body shall certify to the Commissioner, the name of the person to whom is delegated the responsibility for the management of the home, including the carrying out of rules and policies adopted by the governing body. This person shall be known as the administrator.

(5) The word hospital, sanitorium or sanitarium shall not be used in the official title of any home permitted under the provisions of these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.02
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Governing Body" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.03. Administration.

(1) Each nursing home shall be under the supervision of a licensed nursing home administrator. An administrator may serve as the administrator of not more than one facility, except that two facilities having common ownership or management located on the same premises may be served by a single administrator. Distinct part facilities sharing a common roof shall be considered one facility. In exceptional circumstances, a waiver may be granted by the Department for a period of six months. Existing facilities not currently meeting this requirement would be exempt for a period of two years from the effective date of this regulation. If an existing facility should undergo a change of administrators during this two-year period, such facility would be required to comply with the regulations.

(2) Each home shall be operated in accordance with policies approved by the Department. These policies shall include but not be limited to those governing admissions, transfers, discharges, physicians' services, nursing services, dietary services, restorative services, pharmaceutical services, diagnostic services, social services, environmental sanitation services, recreational services and clinical records.

(3) Each home shall have a written transfer agreement in effect with one or more hospitals. Nursing homes that are a Distinct Part of a hospital will be considered to meet this requirement if acceptable provisions for the transfer of patients are included in the facility's policies.

(4) There shall be a separate personnel folder maintained for each employee. This folder shall contain all personal information concerning the employee, including the application and qualifications for employment, physical examination and job title assigned. A current job description shall be available for each classification of employee, but may be maintained separately from the personnel folder. The nursing home shall also maintain all documentation of successful completion of the entire certified medication aide training program for each certified medication aide it employs. In addition to all other documents required by state or federal regulations, the nursing home shall maintain documentation of successful completion of the dining assistant training program for each dining assistant.

(5) The home and its premises shall be used only for the purposes for which the home is operated and permitted.

(6) Each home shall, as a condition precedent to obtaining or maintaining a permit to operate a nursing home, carry or be covered by liability insurance coverages or establish or have established for its benefit a self-insurance trust for a nursing home claim. If a home fails to carry or be covered by liability insurance coverages or establish or have established for its benefit a self-insurance trust for a nursing home claim, the Department shall provide notice to such home of its noncompliance and allow such home 60 days in which to comply. A home's failure to maintain such coverage or establish such trust shall result in the Department:

(a) Revoking such home's permit issued to operate the nursing home;

(b) Denying any application to renew such permit; and

(c) Denying any application for a change of ownership of the nursing home.

(7) In response to a reasonable request by a patient or visitor, privacy shall be afforded for conversation and/or consultations.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.03
Authority: O.C.G.A. § 31-7-1 et seq.
History. Original Rule entitled "Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Jan. 27, 2017; eff. Feb. 16, 2017.
Amended: F. Dec. 29, 2021; eff. Jan. 18, 2022.

Rule 111-8-56-.04. Nursing Services.

(1) A registered nurse shall be employed full time as director of nursing services. She shall not also be the administrator.

(2) The director of nursing services shall normally be employed on the daytime shift and shall devote full time to the administration of the nursing service which includes a reasonable amount of time with all nursing shifts.

(3) The director of nursing services may also serve as the director of nursing services in another facility in close proximity to the home provided she has a registered nurse assistant who is assigned to each facility full time as supervisor of nursing care. The director's assistant shall devote full time to the supervision of nursing care.

(4) There shall be at least one nurse, registered, licensed undergraduate, licensed on duty and in charge of all nursing activities during each eight-hour shift.

(5) A nursing home may employ certified medication aides for the purpose of performing the technical aspects of the administration of certain medications in accordance with O.C.G.A. § 31-7-12.7. A nursing home shall not employ an individual as a certified medication aide unless such individual is listed in the medication aide registry established and maintained by the Department pursuant to paragraph (2) of subsection (g) of O.C.G.A § 31-7-12.2, and is in good standing with the Department, and has met all of the qualifications in paragraph (3) of subsection (g) of O.C.G.A § 31-7-12.2.

(a) A certified medication aide who meets the criteria established in O.C.G.A. § 31-7-12.7 shall be permitted to perform the following tasks in a nursing home in accordance with the written instructions of a physician:

i. Administer physician ordered oral, ophthalmic, topical, otic, nasal, vaginal, and rectal medications;

ii. Administer insulin, epinephrine, and B12 pursuant to physician direction and protocol;

iii. Administer medications via a metered dose inhaler;

iv. Conduct finger stick blood glucose testing following established protocol;

v. Administer a commercially prepared disposable enema as ordered by a physician; and

vi. Assist residents in the supervision of self-administration of medications.

(b) A certified medication aide shall record in the medication administration record all medications that such certified medication aide has personally administered to a resident of a nursing home and any refusal of a resident to take a medication. A certified medication aide shall observe a resident to whom a medication has been

administered and shall report any changes in the condition of such resident to a charge nurse.

(c) All medications administered by a certified medication aide in accordance with O.C.G.A. § 31-7-12.7 shall be in unit or multidose packaging.

(d) Nothing in this rule or O.C.G.A. § 31-7-12.7 shall authorize certified medication aides employed by a nursing home to administer any Schedule II controlled substance that is a narcotic.

(e) A nursing home that employs one or more certified medication aides to administer medications in accordance with O.C.G.A. § 31-7-12.7 shall secure the services of a licensed pharmacist to perform the following duties as part of the nursing home's peer review, medical review, and quality assurance functions:

(i) Perform a quarterly review of the drug regimen of each resident of the nursing home and report any irregularities to the nursing home administrator;

(ii) Remove for proper disposal any drugs that are expired, discontinued, in a deteriorated condition, or when the resident for whom such drugs were ordered is no longer a resident;

(iii) Establish or review policies and procedures for safe and effective drug therapy, distribution, use, and control; and

(iv) Monitor compliance with established policies and procedures for medication handling and storage.

(f) A nursing home that employs one or more certified medication aides to administer medications in accordance with this Code section shall ensure that each certified medication aide receives ongoing medication training as prescribed by the Department. A registered professional nurse or pharmacist shall conduct quarterly unannounced medication administration observations and report any issues to the nursing home administrator.

(g) A nursing home that employs certified medication aides the nursing home shall annually conduct a comprehensive clinical skills competency review of each certified medication aide employed by such nursing home.

(6) There shall be sufficient nursing staff on duty at all times to provide care for each patient according to his needs. A minimum of 2.0 hours of direct nursing care per patient in a 24-hour period must be provided. For every seven (7) total nursing personnel required, there shall be not less than one registered nurse or licensed practical nurse employed. Dining assistants are to be used to supplement, not replace, existing nursing staff requirements

and as such are not considered nursing staff and are not to be included in computing the required minimum hours of direct nursing care.

(7) The nursing staff shall be employed for nursing duties only.

(8) There shall be sufficient qualified personnel in attendance at all times to ensure properly supervised nursing services to the patients, including direct supervision of dining assistants in accordance with these rules. This includes staff members dressed, awake and on duty all night.

(9) All nursing care and related services shall be carried out in accordance with the facility's patient care policies. The lines of administrative authority and supervisory responsibility shall be clearly stated. Duties assigned to staff members shall be clearly defined and consistent with their training and experience. Policies and procedures governing nursing care shall be assembled, available and understood by the staff members and shall be the basis for staff education and practice.

(10) An active in-service nursing education program shall be in effect for all nursing personnel. This program shall be developed and conducted by a registered nurse who may be employed part-time and under the direction of the director of nursing services.

(11) The in-service nursing educational program shall be in writing and shall show the frequency of training. Attendance and progress records shall be kept for each person receiving instruction.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.04
Authority: O.C.G.A. § 31-7-1*et seq*.
History. Original Rule entitled "Nursing Service" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Dec. 29, 2021; eff. Jan. 18, 2022.

Rule 111-8-56-.05. Professional Service.

(1) There shall be an organized professional staff, with one physician designated as chief of staff. The professional staff shall consist of at least one physician, one dentist and one registered nurse. Other professional personnel such as the dietitian, social worker, physical therapist, pharmacist, etc. may be included on the professional staff. This organization shall function under appropriate bylaws and shall meet at regularly scheduled intervals not less than semiannually. It shall be the responsibility of this staff to develop and review care policies and to advise administration on matters pertaining to patient care. The minutes of the meetings of this staff shall be available for inspection by the Department.

(2) Patients shall be admitted only on referral of a physician.

(3) Each patient shall be under the continuing care of a physician who sees the patient at least once every thirty (30) days following admission. The patient's total program of care (including medications and treatment) is reviewed during a visit by the attending physician at least once every thirty (30) days for the first ninety (90) days, and revised as necessary. A progress note is written and signed by the physician at the time of each visit and he signs all his orders. Subsequent to the ninetieth day following admission, an alternate schedule for physician visits may be adopted where the attending physician determines and so justifies in the patient's medical record that the patient's condition does not necessitate visits at thirty-day intervals.

(4) A home shall admit only those patients for which it can provide needed care and only if the home has a permit covering that type of care. When a patient develops a condition requiring care of a level or type not provided at that home, the administration shall arrange for transfer of the patient to another home, hospital or home health agency which has a permit or is certified to provide such care or shall make satisfactory arrangements for the needed care if the condition is to be of short duration.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.05
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Professional Service" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.06. Dietary Service.

(1) Each home shall employ the services of a qualified dietitian (American Dietetic Association or equivalent qualifications). The services of the dietitian shall not be less than eight (8) hours per month.

(2) Meals, adequate as to quantity and quality, shall be served in sufficient numbers with a maximum of five (5) hours apart with no longer than fourteen (14) hours between the evening meal and breakfast. Between meal and bedtime snacks shall be offered each patient.

(3) A nutritionally adequate diet shall be provided all patients and adjusted to patient's age, sex, activity, and physical condition. Nutrient concentrates and supplements shall be given only on written order of a physician.

(4) Menus shall be planned or approved by a qualified dietitian and dated. Used menus shall be kept on file for a period of thirty days for reference by the patient's physician and personnel of the home.

(5) Modified diets shall be provided in accordance with written orders of a physician or dentist. An approved diet manual shall be readily available to food service personnel.

(6) Sufficient perishable foods for a twenty-four hour period and nonperishable foods for a three-day period shall be on the premises for use in an emergency.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.06
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Dietary Service" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.07. Social Service.

(1) Each home shall provide services to assist all patients in dealing with social and related problems through one or more case-workers on the staff of the facility or through arrangements with an appropriate outside agency.

(2) Social service information concerning each patient shall be obtained and kept. This information shall cover social and emotional factors related to the patient's condition and information concerning his home situation, financial resources and relationships with other people.

(3) All nursing personnel and employees having contact with patients shall receive social service orientation and in-service training toward understanding emotional problems and social needs of patients.

(4) One person in each home shall be designated as being responsible for the social services aspects of care in the home.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.07
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Social Service" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.08. Pharmacy Management and Administration.

Each home shall provide pharmaceutical services in full compliance with State and Federal laws and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.08
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Pharmacy Management and Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.09. Physical Therapy Service.

(1) When a home has a physical therapy program, the services must be provided or directly supervised by a physical therapist.

(2) A therapy record will be kept as a part of the medical record on each patient receiving physical therapy. Information in the medical record shall include referral, diagnosis,

precautions, initial physical therapy evaluation treatment plan and objectives, frequency and dates of medical reevaluations.

(3) The physical therapist shall keep progress notes on each patient including progress or lack of progress, symptoms noted, and changes in treatment plans.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.09
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Physical Therapy Service" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.10. Medical, Dental and Nursing Care.

(1) Each patient shall have a physician's written statement of his or her condition at time of admission or within forty-eight (48) hours thereafter and it shall be kept on file with the patient's medical record.

(2) Each patient shall have a physician's orders for treatment and/or care upon admission to the facility.

(3) Each home shall have an adequate arrangement for medical and dental emergencies.

(4) Reports of all evaluations and examinations shall be kept with the patient's medical records.

(5) The home shall have a microbial and infection control program. Policies and procedures for infection control shall be written, assembled and available to all staff members. Procedures shall be specific for practice in the home and shall be included in the training of every staff member. As a minimum, procedures shall include the following control measures:

(a) Prevention of spread of infection from personnel to patient: Any person whose duties include direct patient care, handling food, or handling clean linen, and who has an acute illness such as "strep" throat, or an open sore or boil, shall not be allowed to work until he is fully recovered;

(b) Prevention of spread of infection from visitors to patients;

(c) Prevention of spread of infection from patient to personnel or other patients: Isolation techniques to be observed according to the source of infection and the method of spread;

(d) Reporting of communicable diseases as required by the rules and regulations for notification of diseases which have been promulgated by the Department.

(6) All medications, administered to patients must be ordered in writing by the patient's physician or oral orders may be given to a licensed nurse, immediately reduced to writing, signed by the nurse and countersigned by the physician as soon as practical.

(a) Medications not specifically limited as to time or number of doses, when ordered, must be automatically stopped in accordance with written policy approved by the organized professional staff.

(b) The patient's attending physician shall be notified of stop order policies and contacted promptly for renewal of such orders so that continuity of the patient's therapeutic regimen is not interrupted.

(7) All medications must be administered by medical or nursing personnel in accordance with the Medical and Nurse Practice Acts of the State of Georgia. Each dose administered shall be properly recorded in the clinical records:

(a) The nurses' station shall have readily available items necessary for the proper administration of medication;

(b) In administering medications, medication cards or other State approved systems must be used and checked against the physician's orders;

(c) Legend drugs prescribed for one patient shall not be administered to any other patient unless ordered by a physician;

(d) Self-administration of medications by patients should be discouraged except for emergency drugs on special order of the patient's physician or in a predischarge program under the supervision of a licensed nurse;

(e) Medication errors and drug reactions shall be immediately reported to the patient's physician and an entry thereof made in the patient's clinical records as well as on an incident report;

(f) Up-to-date medication reference texts and sources of information shall be available.

(8) Nursing care shall be provided each patient according to his needs and in accordance with his patient care plan.

(9) Restraint and/or forcible seclusion of a patient will be used only on a signed order of a physician, except in emergency and then only until the advice of a physician can be obtained.

(10) Provisions shall be made for proper sterilization of supplies, utensils, instruments, and other materials as needed for the patients.

(11) When a patient dies in the facility, a physician assistant, a nurse practitioner, or a registered professional nurse licensed in this state and employed by the facility at the time of the patient's apparent death, may make the determination and pronouncement of death in the absence of a physician. When it appears that a patient died from other than natural causes, only a physician may make the determination or pronouncement of death. The determination or pronouncement shall be made in writing on a form approved by the department.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.10
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-7-1 *et seq.*
History. Original Rule entitled "Medical, Dental and Nursing Care" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Mar. 19, 2018; eff. Apr. 8, 2018.

Rule 111-8-56-.11. Records.

(1) Each home shall maintain a complete medical record on each patient containing sufficient information to validate the diagnosis and to establish the basis upon which treatment is given. All active medical records shall be maintained at the nurses' station. The completed record shall normally contain the following:

(a) Name, address, birth date, sex, marital status of the patient and religion; the name, address and telephone number of physician; the name, address and telephone number of the responsible party to contact in emergency;

(b) Date and time of admission;

(c) Date and time of discharge or death;

(d) Admitting diagnosis;

(e) Final diagnosis;

(f) Condition on discharge;

(g) History and physical examination;

(h) Treatment and medication orders;

(i) Physicians' progress notes (at least monthly);

(j) Nurses' notes;

(k) Special examination and reports.

(2) Each home shall keep patient statistics, including admissions, discharges, deaths, patient days, and percent of occupancy. Statistical records shall be open for inspection and upon request, data shall be submitted to the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.11
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Records" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.12. Equipment.

(1) Patient beds shall be single, at least thirty-six inches wide, with firm even springs covered by a mattress not less than four inches thick.

(2) The home shall provide all linens and blankets essential to the treatment and comfort of patients.

(3) Wheelchairs, walkers, and mechanical lifters shall be provided by the home when needed.

(4) Each patient shall have necessary furniture which shall include a bedside table, a reading lamp, a chair, drawer space for clothes, enclosed space for hanging clothing, and individual towel rack, soap dish, drinking glass, and access to a mirror. Each patient shall have a suitable signaling device.

(5) Individual equipment shall be cleaned after each use and disinfected at least once each week. Equipment such as bedpans, urinals and wash basins, if not individual, should be disinfected after each use.

(6) Each patient shall be provided adequate supplies and equipment for proper oral hygiene including a toothbrush or a denture brush and denture receptacle when needed.

(7) Bedrails shall be available for use as required by the patient's condition.

(8) There shall be an electric clock with a bold face that can be read from a distance of twenty (20) feet installed in the lobby of each home.

(9) Disposable equipment and supplies shall be used only once and disposed of in an approved manner.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.12
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Equipment" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.13. Safety.

(1) All buildings and equipment shall be maintained in such condition that no hazards to the life and safety of the patients exist.

(2) Adequate parking shall be available nearby. Parking areas and service entrances shall be so designated that fire fighting equipment will have unobstructed access to all parts of the building.

(3) Handrails shall be provided on all stairways and ramps. Stairways shall be made of or covered with safe nonslip material. Doors opening onto stairways shall not open directly onto risers, but shall open onto a landing not less than the width of the door.

(4) Safety barriers at the head of stairways, and handrails in hallways shall be provided. There shall be no low windows, open porches, changes in floor levels or similar hazards.

(5) Doors to rooms used by patients shall be equipped with locks or other devices which will not allow the room to be locked from the inside.

(6) Floor surfaces shall be smooth and level; scatter rugs and highly polished floors in patient areas are prohibited.

(7) Showers, tubs and toilets shall have grab bars firmly installed convenient to patient use; the floor in bathing areas shall be provided with a nonslip surface. No patient shall be permitted to bathe without an available attendant to regulate water temperature and to provide generally for the safety of the patient, unless the patient's physician has provided a written statement to the effect that the patient is sufficiently responsible to bathe himself. Shower heads shall not be installed above bathtubs.

(8) Warning signs shall be posted prohibiting smoking or open flames of any kind in areas where oxygen is in use or stored.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.13
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Safety" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.14. Environmental Sanitation and Housekeeping.

(1) Equipment and supplies for proper sanitation will be maintained on the premises.

(2) Laundry shall be handled, stored, and processed so that spread of infection will be minimized. A sufficient clean linen supply shall be insured at all times. Soiled linen shall not be permitted to accumulate.

(3) The premises and all areas within the home shall be kept clean and free from debris. Ventilation openings, such as ports for exhaust fans, shall be equipped with covers that

close automatically when the fan is not in operation. Doors and other openings shall be equipped and maintained to minimize ingress of flies, insects and rodents.

(4) Sanitary containers, sputum cups, and other satisfactory individual containers must be provided when needed.

(5) Each home shall have an infection control program which provides for policies, procedures and training programs. Great care should be exercised to prevent spread of infection by fomites or by infected person to person.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.14
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Environmental Sanitation and Housekeeping" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.15. Health of Employees.

Each home shall require that each employee receive a physical examination upon employment. The examination shall be in sufficient detail, with pertinent laboratory and X-ray data to insure that the employee is physically and mentally qualified to perform the job to which he is assigned. An annual physical examination thereafter is recommended. However, as a minimum, on an annual basis each employee will have a physical inspection to help insure freedom from communicable disease. As part of the annual examination or inspection a tuberculin skin test will be given to all previous negative reactors. If the skin test is positive, a chest X-ray will be required and the individual referred to his physician or appropriate health authority for possible prophylaxis treatment. Copies or certificates of physical examinations shall be kept in the employee's personnel folder.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.15
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Health of Employees" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.16. Recreation.

(1) An individual shall be designated as being in charge of patient activities. This individual shall have experience and/or training in group activities, or shall have consultation made available from a qualified recreational therapist or group activity leader.

(2) Provisions shall be made for suitable recreational and entertainment activities for patients according to their needs and interests. These activities are an important adjunct to daily living and are to encourage restoration to self-care and resumption of normal activities. Variety in planning shall include some outdoor activities in suitable weather.

(3) Patients shall be encouraged but not forced to participate in patient activities.

(4) The facility shall make available a variety of supplies and equipment adequate to satisfy the individual interests of residents. Examples are: books, magazines, daily newspapers, games, stationery, radio, television and the like.

(5) An active patient activities program shall be carried out that will meet the needs of all patients.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.16
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Recreation" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.17. Patient Capacity.

(1) The number of beds provided shall be indicated on each permit and provisional permit.

(2) The number of patients receiving care within the home shall not exceed the number of beds shown on the permit. In exceptional cases, temporary waivers, not to exceed thirty (30) days, may be granted by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.17
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Patient Capacity" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.18. Physical Plant Standards.

(1) Requirements under this rule "Physical Plant Standards" will be enforced with the effective date of these regulations EXCEPT that homes holding a valid permit prior to the effective date of these regulations, shall comply with the regulations in effect at the time the home was issued a permit or the plans were approved. Provided however, that any such homes which hold a valid permit prior to the effective date of these regulations must comply with these regulations when improvements or modifications are made within any twelve (12) month period and the cost of such improvements or modifications exceeds a total of twenty percent (20%) of the fair market value of the home. If no such improvements are made, the homes holding a valid permit prior to the effective date of these regulations must then comply with these regulations within fifteen (15) years of the effective date of these regulations. In exceptional cases and upon application to the Department by the governing body of the home, variances may be granted at the discretion of the Department (if it determines that these requirements will place an undue burden or extreme hardship on the home or its occupants), provided that the health and safety of the patients is not jeopardized.

(2) At least two rooms per fifty (50) beds shall be designed for single occupancy (one bed). At least one room designed for single occupancy shall have an adjoining private

bathroom, containing a lavatory, water closet and a bathtub or shower equipped with grab bars.

(3) All patient rooms shall open into corridors leading to the exterior of the building. No patient room will be so located as to make it necessary for a patient to pass through another room to gain entrance to a corridor leading to the exterior.

(4) Each patient room shall be an outside room with window space equal to at least one-eighth of the floor area with opening in area large enough to remove patient by mattress.

(5) Patient bedrooms shall contain not less than one hundred (100) square feet of usable floor space in private or single rooms and no less than eighty (80) square feet per bed of usable floor space in multibed rooms. Usable floor space is in addition to area provided for closets, toilet rooms and entry ways.

(6) Not less than three (3) feet of space shall be provided between beds and between the foot of the bed and wall or other obstruction. There shall be sufficient space so beds may be made accessible from both sides for nursing care when needed.

(7) An individual clothes closet or wardrobe with door shall be provided per bed in every patient room. Clothes closets or wardrobes shall be at least twenty-two (22) inches deep and twenty (20) inches wide with at least one shelf above a hanging space equipped with a device for clothes hangers.

(8) Each patient room having more than one bed shall have permanently installed curtain tracks to permit closing each bed with curtains to allow for the privacy of each patient without obstructing the passage of other patients either to the corridor or to the toilet or lavatory adjacent to the patient room. Curtains used for enclosing patient beds shall be rendered and maintained flame resistant.

(9) Employees, staff and visitors shall not use water closets provided for patients. Toilets, including a water closet, lavatory, soap, paper towels and dispensers shall be provided near or adjacent to the following locations:

(a) Nurses' station or medication area;

(b) Kitchen;

(c) Lobby area or waiting room.

(10) Patient bathing and toilet facilities:

(a) There shall be a general bathing area in each nursing unit. This area shall contain at least one bathtub accessible from three sides, one stall shower equipped with grab bars with adjacent drying space, one lavatory and one water closet. This unit shall be of sufficient size to provide space for dressing, a wheelchair, and an attendant. Unless the bathing fixtures are located in separate rooms,

compartments must be provided to permit independent use to afford privacy for each sex. Special institutional tubs or showers may be approved for use if the program of service indicates;

(b) At least one enclosed water closet and one lavatory shall be provided for each eight beds or major fraction thereof;

(c) At least one bathing facility (bathtub or shower) shall be provided for each fifteen (15) beds, or major fraction thereof, located in patient bedrooms that do not adjoin a toilet room in which a bathing facility is located;

(d) Unless bathtubs in bathrooms adjoining patient rooms are located so as to be accessible from three sides, handrails or grab bars on the tub or on the wall by the tub shall be provided;

(e) All shower stalls shall be at least four feet by four feet square and must have handrails on three sides, be equipped with curtains and be designed for wheelchair use. Thresholds to showers must be flush with the floor. The floor of the shower shall be designed to drain properly;

(f) Grab bars, securely attached to walls and conveniently located, adjacent to all bathtubs, showers and water closets intended for patient use shall be provided.

(11) A nurses' station shall be provided in each nursing unit. It shall contain a nurses' call system, charting desk and supplies, medicine storage, lavatory with soap, towels and towel dispenser, preparation area and a refrigerator. The nurses' station shall not be more than 120 feet from the entrance of the most remote room served.

(12) There shall be separate clean and soiled utility rooms in each nursing unit located near the nurses' station. The clean utility room shall contain wall and base cabinets and stain resistant counter top, a small sink set into the counter or with drain boards. The soiled utility room shall contain a counter with a stain resistant top and storage cabinets underneath. In addition, it shall contain a deep service sink with stopper for chemical sterilization of bedpans, urinals and commode pails. The deep service sink with stopper may be omitted if a steam autoclave for sterilizing is available to the home.

(13) At least one bedpan cleansing device shall be provided in each nursing unit. It may be located in the soiled utility room or in a special bedpan closet conveniently located in each nursing unit. The bedpan cleansing device may be omitted if water closets in patient toilets are equipped with bedpan lugs, spray hose and elevated vacuum breaker.

(14) Sufficient space shall be provided in each nursing unit for stretcher and wheelchair parking. Such space shall be out of corridor traffic.

(15) There shall be a floor pantry in each nursing unit located near or adjacent to the nurses' station. The floor pantry shall contain a hot plate, sink, counter, cabinets and a refrigerator that shall not be used to store drugs, biologicals or laboratory specimens.

(16) A drinking fountain which shall not impair any passageway shall be provided in each nursing unit.

(17) There shall be a treatment room convenient to patient rooms containing a treatment table, lavatory equipped with soap, paper towels and dispenser, instrument table and storage cabinet and providing adequate room for transfer of patients. A treatment room may be used for consultation if appropriately enlarged.

(18) There shall be a patient dining and recreation area provided in each home. The minimum total area shall be twenty (20) square feet of floor space per bed. One-half the required space shall be for dining.

(19) A room with sufficient space for patients' active exercise regimens including such equipment as a full-length mirror, parallel bars, a wall-mounted wheel, and an exercise table shall be provided. The room shall also contain a lavatory with gooseneck spout and wrist controls. Soap, paper towels and towel dispenser shall also be provided.

(20) There shall be a lobby and/or waiting room in each home. The size of this area shall be determined in relation to the size of the home and the program of service.

(21) There shall be at least one building exit at ground level and at least one building exit shall be provided with a suitable ramp designed for a stretcher and a wheelchair. There shall be one such exit leading to the outdoor recreation area.

(22) A public telephone shall be located near the lobby. At least one telephone shall be arranged to be convenient for a wheelchair user.

(23) The central kitchen area shall be located to permit efficient service to the dining rooms and the nursing units. It must be arranged and equipped for adequate food storage; preparation and serving of foods in proper sequence; dish and utensil cleaning and storage, and refuse storage and removal. Homes that are a distinct part of another home may utilize the service of a central kitchen provided it is of adequate size and adequately equipped to serve the total patient population. Storage space shall be sufficient to store a 24-hour supply of perishable foods and a 3-day supply of nonperishable foods.

(24) Separate and adequate clean laundry storage and separate and adequate soiled laundry storage rooms shall be provided appropriate to the frequency of deliveries and linen needs.

(25) Janitor's closets shall be provided on the basis of at least one closet for the dietary area and one for the remainder of the home. This room shall be of sufficient size to include racks for equipment, storage space and a service sink.

(26) General storage space for the storage of supplies, furniture, equipment and patients' possessions shall be provided. Such space may be provided in one or more rooms and shall be commensurate with the needs of the home, but not less than five (5) square feet per bed.

(27) Maintenance area or areas commensurate with the needs of the home, including storage space for building and grounds maintenance equipment, tools, supplies and materials and shop space for mechanical, painting and carpentry work shall be provided.

(28) Floor, wall and ceiling finishes shall be smooth, easily cleaned and be wear-resistant appropriate to location. In addition, the floors of the following spaces shall be waterproof: toilets, baths, bedpan rooms, floor of pantries, kitchens, utility rooms, janitors' closets and treatment rooms. Areas subject to wetting shall have nonslip flooring. Carpeting, wall and ceiling finishes shall be approved by the State Fire Marshal.

(29) Stairways, doors and corridors:

(a) Stairways serving patient areas shall not be less than forty-four (44) inches in clean width;

(b) Stairs shall be individually enclosed and be separated from any public hall;

(c) A landing shall be provided at the top and bottom of every stair run. Doors shall swing with exit travel to provide safe exit;

(d) The minimum dimension of landing shall be as wide as the required width of the stairway it serves. A door swinging into a landing, when open, shall not overlap the required width of the landing;

(e) The width of stair to risers shall not be less than ten (10) inches plus a one (1) inch nosing;

(f) Winders and single risers are not acceptable;

(g) Stairs and landings shall have a non slippery finish;

(h) Patients' room corridor entrances and all required exits shall be not less than forty-four (44) inches in clean width. All other doors through which patients must pass shall be not less than thirty-six (36) inches in clean width except that doors to toilets in patient bedrooms may not be less than thirty-two (32) inches wide. Doors through which patients or equipment do not pass shall be not less than thirty (30) inches wide, except that doors to patient closets may not be less than twenty (20) inches wide;

(i) When a door swings out on any platform, balcony, or porch or terrace, the minimum width of the platform, balcony, porch or terrace shall be thirty (30)

inches plus the width of the door, measured at right angles to the wall containing the door. Exit doors, other than for living units shall swing in the direction of exit from the structure;

(j) Corridors in areas used by patients shall not be less than eight (8) feet in clean width. Handrails may project into corridors, but drinking fountains, desk or other projections or obstructions may not reduce the eight (8) foot minimum dimension;

(k) Ramps shall be not less than forty-four (44) inches wide. Where ramps provide a change of corridor level, the minimum width shall be not less than that of the corridor;

(l) The maximum slope of ramps shall be not greater than ten (10) percent. Changes in direction, if any, shall be on level landings with a minimum width the same as the ramp width;

(m) Ramps shall have a nonslip finish. Ramps serving as a required means of egress shall be enclosed or protected as indicated for required stairways;

(n) Handrails shall be provided on each side of all patient corridors and on each side of stairways and ramps.

(30) Light and Ventilation:

(a) The total glass area in patient bedrooms shall be not less than one-eighth of the floor area of the room. The ventilating area shall be not less than four (4) percent of the floor area;

(b) Openings providing required natural light, which open on a covered porch whose depth exceeds four (4) feet, shall be increased in area ten (10) percent per foot of depth over four (4) feet;

(c) The heads of windows (sash opening) shall not be more than one foot below the finished ceiling unless they are at least six (6) feet eight (8) inches above the finished floor. The lower level of the window glass shall be not more than forty-eight (48) inches above the floor level;

(d) Ceiling lights shall be not less than eight (8) feet except that seven (7) feet six (6) inches may be used in corridors, halls, toilet rooms and bathrooms;

(e) The lower edge of patient bedroom windows shall in every instance be above grade.

(31) Mechanical:

(a) All bathrooms and toilet rooms shall be provided with mechanical ventilation capable of producing a minimum of ten (10) air changes per hour. Utility rooms, community rooms and corridors shall be provided with not less than four (4) changes per hour with at least two (2) of the air changes being outside air. Ducts ventilating bathrooms or toilet rooms shall not be interconnected with other duct systems but shall be discharged to the outside. Patient rooms shall be provided with at least two (2) air changes per hour of outside air. Corridors and exit halls shall not be used as a plenum for supply or return air to heating or air-conditioning system;

(b) Kitchens, laundries, non-refrigerated garbage storage rooms, and rooms used to store combustible materials, shall be provided with an independent system of mechanical ventilation discharging above the roof and remote from any window. A minimum of ten (10) air changes per hour shall be provided. Exhaust hoods shall be installed over cooking ranges;

(c) All buildings shall be provided with a heating system designed to maintain a temperature of 75 degrees Fahrenheit in all habitable rooms and corridors when the outside temperature is at design level. The heating system should provide warm floors;

(d) All steam-operated equipment such as sterilizers, laundry and kitchen units, shall be provided with steam at temperatures and pressures as recommended by the equipment manufacturers;

(e) The quality and quantity of the water supply and the method of sewage disposal shall have the approval of the Department;

(f) The method employed to heat water shall provide an adequate supply of hot water at necessary temperatures for all purposes, in a safe manner;

(g) Temperature controls shall be provided so that hot water for personal uses shall not exceed 110 degrees Fahrenheit;

(h) Hot water temperatures for other uses shall be as required by the equipment served;

(i) The quantity of hot water for kitchens and laundries shall be adequate to serve the equipment installed;

(j) Wrist control handles shall be provided for sinks or lavatories in floor pantries, medicine preparation rooms, clean utility rooms, soiled utility rooms, treatment or examination rooms, rehabilitation or physical therapy rooms and at handwashing fixtures in the kitchen area;

(k) Gooseneck spouts shall be provided for sinks or lavatories in treatment or examination rooms, physical therapy or rehabilitation rooms and at handwashing fixtures in the kitchen area;

(l) Vacuum breakers shall be provided for any plumbing fixture having a hose or hoses attached or to any plumbing fixture having trim to which a hose may be attached, including shampoo sinks, service sinks, combination hot and cold water outlets at can wash areas. Hose bibs shall be provided for clean-up purposes in the dishwash area of kitchens;

(m) Aerators shall not be included as part of trim for plumbing fixtures;

(n) With relationship to adjacent areas, a positive air pressure shall be provided for clean utility rooms, floor pantries and medicine preparation rooms;

(o) With relationship to adjacent areas, a negative air pressure shall be provided for soiled utility rooms, physical therapy or rehabilitation rooms, janitor's closets, soiled laundry rooms and bathrooms or toilets. Air from these rooms shall not be recirculated; air shall be exhausted;

(p) Floor grilles shall not be used for supply or return air openings in heating, air-conditioning or ventilating systems;

(q) Ventilation openings, such as ports for exhaust fans, etc., shall be equipped with covers that close automatically when the fan is not in operation;

(r) Intake air ducts shall be designed and maintained so as to prevent the entrance of dust and insects;

(s) Hot air ducts from the heating system shall not emit temperatures in excess of 150 degrees Fahrenheit.

(32) Electrical:

(a) All areas shall be adequately lighted as required for duties performed in each space. Bedrooms and combination living-bedrooms shall have a night light, a light for general illumination and a reading light at the head of each bed. The outlets for general illumination and night lights shall be switched at the door. The reading light shall be controlled at the bedside. Each stairway, hall, corridor or general passage shall have five (5) foot candles of illumination, doubled at building and stair entrance, or change of floor level, or at ramps;

(b) Receptacles appropriate for the designed space use shall be located where plug-in service is required. There shall be not less than one duplex receptacle at the head or near the head of each bed. All other spaces shall have general and special purpose outlets suited to the need of the space; including an outlet in the lobby

for an electric clock and receptacles for cleaning and maintenance equipment spaced not more than fifty (50) feet apart in corridors;

(c) Emergency lighting supplied by an emergency generator or a battery with automatic switch, shall be provided for exits, stairs and corridors;

(d) Each toilet room and bathroom and each bed location shall be furnished with an electrical or mechanical nurses' call audible or visible at the nurses' station. A duplex unit may be used for two beds.

(33) Elevators and Dumbwaiters:

(a) Where patients' rooms are located on more than one floor at least one elevator shall be provided. Other elevators shall be provided, depending upon the needs and size of the home;

(b) At least one elevator in multistory buildings shall be arranged of sufficient size to admit a stretcher and an attendant;

(c) Elevator doors shall be automatic slide type with safety interlock. Elevators shall be equipped with hand rails and automatic self-leveling control which will automatically bring car platforms level with the landing;

(d) Dumbwaiter cabs shall be not less than twenty-four (24) by thirty-six (36) inches of steel with one shelf.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.18
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Physical Plant Standards" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.19. Application for Permit.

(1) The governing body shall submit to the Department an application for a permit.

(2) The application for a permit shall be made on forms provided by the Department and shall be filed at least thirty (30) days prior to the anticipated date of opening and commencement of operation of a new home.

(3) Each application shall be accompanied by a copy of the bylaws of the professional staff, a copy of the policies for operating the home and a certification from each member appointed to the professional staff that he has accepted the appointment including the name and license number of the administrator and the name and license number of the director of nursing. In homes with a professional staff of ten (10) or more physician

members, only the physician members elected as officers need submit a certification as to their appointment.

(4) A plan for progressive employment of personnel to match increase bed occupancy and to assure compliance with these rules and regulations shall be submitted at the time established for the preopening inspection.

(5) Proof of ownership shall accompany the application.

(a) Corporations shall submit a copy of their charter and the name and address of all owners with ten (10) percent or more of the stock and shall identify each corporate officer;

(b) Nonprofit associations and hospital authorities shall submit legal proof of the organization, the name and address of each trustee and the office held, if any;

(c) All others shall submit the name and address of each person owning any part of the facility.

(6) Proof of an active liability insurance policy or a self-insurance trust for the home's benefit for a nursing home claim.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.19
Authority: O.C.G.A. §§ 31-2-4 et seq. and 31-7-1 et seq.
History. Original Rule entitled "Application for Permit" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-56-.20. Permits.

(1) To be eligible for a permit the home must be in satisfactory compliance with these rules and regulations and the provisions at law which apply to the locations, construction and maintenance of homes and the safety of the patients therein.

(2) Prior to the issuance of a permit and at the request of the Commissioner, the governing body shall furnish to the Department evidence of satisfactory compliance with any laws or regulations thereunder applicable to homes but the enforcement of which is the responsibility of a department or agency of government other than the Department.

(3) The permit shall be framed and publicly displayed at all times.

(4) Permits are not transferable from one governing body to another, nor valid when the home is moved from one location to another.

(5) The permit shall be returned to the Department when the home ceases to operate, or is moved to another location, or the ownership changes, or the governing body is significantly changed, or the permit is suspended or revoked.

(6) A permit shall be required for each home located on different premises where more than one home is operated under the same governing body. When a home operates as distinct parts, then a permit shall be required for each distinct part.

(7) Each home shall be in compliance with O.C.G.A. § 26-2-370*et seq.*, entitled "Food Service Establishments" and the Rules and Regulations as adopted and promulgated thereunder entitled "Rules and Regulations for Food Service" and with any amendment to the law or rules promulgated thereunder.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.20
Authority: O.C.G.A. §§ 26-2-370*et seq.*, 31-2-4 *et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Permits" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.21. Provisional Permits.

(1) Provisional permits may be granted to the governing body of a newly established home to demonstrate operational procedures in satisfactory compliance.

(2) A provisional permit may be granted to the governing body of an existing home to demonstrate operational procedures in satisfactory compliance.

(3) Provisional permits granted to allow a reasonable time to demonstrate satisfactory compliance of operational procedure shall be limited to a period of not more than six (6) months.

(4) A provisional permit may be granted to the governing body of an existing home to give reasonable time to comply with violations of regulations and standards which relate to the structural or physical condition of the home. Provisional permits granted to allow time for correction of structural or physical conditions shall not exceed twelve (12) months.

(5) No provisional permits shall be granted to the governing body of a newly established home which is in substantial noncompliance with rules, regulations and standards relating to the structural or physical condition of the home.

(6) A provisional permit shall not be issued when there are noncompliances of any type which present an immediate hazard to the life, health or safety of the patients.

(7) No provisional permit shall be granted to an existing home unless the governing body shall first present to the Commissioner a plan of improvement which shall list each noncompliance to be corrected, the time required to demonstrate acceptable operational procedures or to correct noncompliances which relate to the structural or physical

condition of the home and the means, methods and procedures to be used in the correction of the noncompliances.

(8) The governing body of a home operating under a provisional permit may petition the Department for an extension of time if needed to correct noncompliances where the failure to make such corrections within the time allotted is an extenuating circumstance beyond the control of the governing body. Such petitions shall be submitted to the Department at least thirty (30) days prior to expiration date of the provisional permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.21
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Provisional Permits" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.22. Inspections.

(1) The home shall be available at reasonable hours for observation and examination by properly identified representatives of the Department.

(2) The administrator or authorized representative shall notify the Department of the anticipated opening date of a newly constructed home in order that a pre-opening licensure survey of the home may be conducted to determine compliance with these rules and regulations.

(3) The administrator or his representative shall accompany the Department representative on tours of inspection.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.22
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "Inspections" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.23. New Construction.

(1) General Requirements:

(a) A program narrative and all plans and specifications for construction, including additions, alterations and renovations, shall be approved by the Department prior to commencing work on the building;

(b) The program narrative shall be submitted prior to or along with the schematic or initial plans for construction. The program narrative should include the following:

1. The names and addresses of each owner. If the owner is a public stock corporation, the names and addresses of each officer shall be included;

2. The geographical area to be served;

3. Admission policies;

4. Cooperative programs of service with local agencies, including hospitals;

5. Arrangements for medical and dental care, e.g., physicians on contract and agreements with hospital for patient referral;

6. List of personnel by types of employees and proposed salaries;

7. Plans for securing the services of professional personnel including registered nurses, licensed practical nurses, social workers, dietitians, pharmacists, physicians and therapists;

8. A description of the service to be provided the community, i.e., the level of care to be provided and the economic segments of the population to be served;

9. Source and amount of financing;

10. Anticipated first two-year cost of operation, income and source of operating funds;

11. Exact location of proposed site;

12. Utilities available, i.e., electricity, gas, water, sewage and waste disposal and transportation;

13. The name, address and telephone number of the person selected to represent the owner during the period of planning construction.

(c) Any individual or group planning construction shall submit complete architectural, structural, mechanical and electrical plans and specifications to the Department for review and approval prior to any new construction, addition, alteration or renovation. Final plans submitted shall be in sufficient detail to show the building site, driveways and parking areas, type of construction, mechanical and electrical systems, the type and location of major items of equipment, the intended use of each room, the proposed location of beds, the type and source of utilities, food service system, and the proposed system of garbage and refuse disposal;

(d) Plans for addition and/or remodeling of an existing building will be submitted in sufficient detail to include type of construction and layout of the existing building to show overall relationship. Any changes in the approved final plans shall also be submitted to the Department for approval.

(2) Location and Site:

(a) The site shall be approved by the Department;

(b) The site shall have proper drainage. Sewage disposal, water, electrical, telephone and other necessary facilities shall be available to the site.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.23
Authority: O.C.G.A. §§ 31-2-4*et seq.* and 31-7-1 *et seq.*
History. Original Rule entitled "New Construction" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.24. Enforcement.

The administration and enforcement of these rules and regulations shall be as prescribed in O.C.G.A. §§ 31-2-8 and 50-13-13*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.24
Authority: O.C.G.A. §§ 31-2-4*et seq.*, 31-7-1 *et seq.* and 50-13-13 *et seq.*
History. Original Rule entitled "Enforcement" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.25. Dining Assistants.

(1) Dining assistants shall work under the direct supervision of a registered nurse or a licensed practical nurse. Direct supervision means that the registered nurse or licensed practical nurse is present in the same room and available to respond to the need for assistance.

(2) Dining assistants are to be used to supplement, not replace, existing nursing staff requirements and as such are not considered nursing staff and are not to be included in computing the required minimum hours of direct nursing care.

(3) Dining assistants shall:

(a) Be at least 16 years of age; and

(b) Have successfully completed the dining assistant training program in accordance with these rules.

(4) Dining assistants shall provide feeding and hydration assistance only to those residents who have been determined to meet the following criteria:

(a) A nursing home's registered professional nursing staff shall determine which residents a dining assistant may safely assist with feeding and hydration. The determination shall be based on the resident's latest nursing assessment and plan of

care, which is performed in accordance with generally accepted standards of practice and applicable laws and regulations;

(b) The resident's plan of care shall clearly reflect the nurse's determination that the resident may be safely assisted with feeding and hydration by a dining assistant; and

(c) Dining assistants shall not provide feeding and hydration assistance to residents who have complicated feeding problems, including, but not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.

(5) The nursing home's dining assistant training program shall be conducted under the direction of a registered nurse and shall require participants to perform return demonstrations, as applicable, to demonstrate competencies on program components.

(6) The minimum requirements of the dining assistant training program shall include a minimum of 16 hours of training. The training shall include practical application of feeding and hydration skills and shall include at least the following components:

(a) Feeding techniques;

(b) Assistance with feeding and hydration;

(c) Communication and interpersonal skills;

(d) Appropriate responses to resident behavior;

(e) Safety and emergency procedures, including the Heimlich Maneuver;

(f) Infection control;

(g) Recognizing changes in residents that are inconsistent with their normal behavior and the importance of reporting such changes to the supervisory nurse;

(h) Reporting requirements as specified by Article 4 of Chapter 8 of Title 31 of the Official Code of Georgia Annotated, the "Long-term Care Facility Resident Abuse Reporting Act"; and

(i) Resident rights, including abuse and neglect prevention.

(7) The nursing home shall maintain a written record of all individuals who have successfully completed the dining assistant training program. At a minimum, such written record maintained by the nursing home must include the dining assistant's complete name and address, the name and address of the nursing home, the name and signature of the registered nurse directing the training program, and the date the training program was successfully completed. The nursing home shall provide a copy of such written record in

a timely manner to any dining assistant who has successfully completed the training program upon the dining assistant's written request.

(8) A copy of the written record of the satisfactory completion of the dining assistant training program may be used by a subsequent nursing home hiring the dining assistant in lieu of repeating the training, provided that the dining assistant satisfactorily performs return demonstrations of the minimum skills required of dining assistants as specified in these rules for the hiring nursing home. Such satisfactory demonstrations of skills shall be documented by a registered nurse and retained by the nursing home in the dining assistant's record along with a copy of the initial documentation of successful completion of the training program as specified in these rules.

(9) In addition to all other documents required by state or federal regulations, the nursing home shall maintain the following records:

(a) A copy of the nursing home's dining assistant training program; and

(b) Documentation of successful completion of the training program for each dining assistant.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.25
Authority: O.C.G.A. § 31-7-1*et seq.*
History. Original Rule entitled "Dining Assistants" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.26. Background Screening and Employees.

(1) Prior to hiring an employment applicant, each nursing home shall first screen the potential employee for a history of abuse, neglect, or exploitation. This includes attempting to obtain information from previous employers and current employers and checking with the applicable licensing boards and registries. The background screenings shall include, but not be limited to:

(a) The nursing home shall request a criminal records check from the Georgia Crime Information Center (GCIC) to determine whether the applicant has a criminal record. In accordance with the provisions of Section 31-7-350, *et seq.*, of the Official Code of Georgia Annotated, the nursing home shall make a written determination for each applicant for whom a criminal records check is performed. A nursing home shall not employ a person with an unsatisfactory determination as such term is defined by Section 31-7-350 of the Official Code of Georgia Annotated;

(b) Before allowing an individual to serve as a nurse aide or a dining assistant, the nursing home shall contact the state's Nurse Aide Registry to determine whether a finding has been entered concerning abuse, neglect, exploitation, or misappropriation of resident property. The nursing home shall also seek

information from other state nurse aide registries that the nursing home believes may contain information on the individual, based on the applicants prior work history; and

(c) The nursing home shall not employ individuals who have been:

1. Found guilty of abusing, neglecting, or mistreating residents by a court of law; or

2. Have had a finding entered into the state Nurse Aide Registry concerning abuse, neglect, exploitation, or misappropriation of resident property.

(2) Documentation of the nursing home's background screening shall be maintained for each employee.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.26
Authority: O.C.G.A. §§ 31-7-1*et seq.* and 31-7-350*, et seq.*
History. Original Rule entitled "Background Screening of Employees" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-56-.27. Vaccines.

(1) Unless contraindicated, all nursing homes shall annually offer an influenza virus vaccine, contingent on availability, to all Medicare and Medicaid eligible residents and private pay residents in their facilities and a pneumococcal bacteria vaccine, contingent on availability, to all Medicare eligible residents and all private pay residents, 65 years of age or older, in their facilities.

(2) Vaccines and other medications shall only be administered by the nursing home's licensed personnel in accordance with applicable state laws and regulations.

(3) Vaccines and other medications shall be stored safely and appropriately monitored to prevent unauthorized use or access.

(4) Vaccines and other medications shall be properly labeled and handled in accordance with current accepted standards of practice and applicable laws and regulations. Outdated, mislabeled, or otherwise unusable vaccines and other medications shall not be available for resident use.

(5) Vaccines and other medications shall be kept in original containers with original labels intact.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.27
Authority: O.C.G.A. § 31-7-1*et seq.*

History. Original Rule entitled "Vaccines" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-62. PERSONAL CARE HOMES.

Rule 111-8-62-.01. Authority.

The legal authority for this Chapter is the Official Code of Georgia Annotated, Chapters 2 and 7 of Title 31.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.01
Authority: O.C.G.A. §§ 31-2-4, 31-2-7, 31-2-8, and 31-7-1*et seq.*
O.C.G.A. Secs. 31-2-4, 31-2-7, 31-2-8, 31-2-9, 31-2-11, 31-7-1*et seq.*
History. . Original Rule entitled "Authority" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.02. Purposes.

The purposes of these rules and regulations are to establish the minimum standards for the operation of personal care homes which provide residential and personal services to adults who require varying degrees of supervision and care and to assure safe, humane and comfortable, supportive residential settings.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.02
Authority: O.C.G.A. Secs. 31-2-7, 31-2-8, 31-2-9, 31-2-11, 31-7-1, 31-7-2.1, 31-7-12.
History. . Original Rule entitled "Purposes" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.03. Definitions.

In these rules, unless the context otherwise requires, the words, phrases and symbols shall mean the following:

(a) "Abuse" means any intentional or grossly negligent act or series of acts or intentional or grossly negligent omission to act which causes injury to a resident, including but not limited to, assault or battery, failure to provide treatment or care, or sexual harassment of the resident.

(b) "Activities of daily living" means bathing, shaving, brushing teeth, combing hair, toileting, dressing, eating, laundering, cleaning private living space, managing money, writing letters, shopping, using public transportation, making telephone calls, grooming, obtaining appointments, engaging in leisure and recreational activities, or other similar activities.

(c) "Administrator" means the manager designated by the governing body as responsible for the day-to-day management, administration and supervision of the personal care home, who may also serve as the on-site manager and responsible staff person except during periods of his or her own absence.

(d) "Ambulatory Resident" means a resident who has the ability to move from place to place by walking, either unaided or aided by prosthesis, brace, cane, crutches, walker or hand rails, or by propelling a wheelchair or scooter; who can respond to an emergency condition, whether caused by fire or otherwise, and escape with minimal human assistance such as guiding a resident to an exit, using the normal means of egress.

(e) "Applicant" means any of the following:

1. When the personal care home is owned by a sole proprietorship, the individual proprietor shall be the applicant for the license, complete the statement of responsibility and serve as the licensee.

2. When the personal care home is owned by a partnership, the general partners shall be the applicant for the license, complete the statement of responsibility and serve as the licensee.

3. When the personal care home is owned by an association or limited liability company (LLC), the governing body of the association or LLC shall authorize the application for the license and complete the statement of responsibility and the association shall serve as the licensee.

4. When the personal care home is owned by a corporation, the governing body of the corporation shall authorize the application for the license and complete the statement of responsibility and the corporation shall serve as the licensee.

(f) "Assisted living care" means the specialized care and services provided by an assisted living community which includes the provision of personal services, the administration of medications by a certified medication aide, the provision of assisted self-preservation, and the provision of limited nursing services.

(g) "Certificate" means a certificate issued by the Department to operate a memory care center in a licensed assisted living community or personal care home.

(h) "Chemical Restraint" means a psychopharmacologic drug that is used for discipline or convenience and is not required to treat medical symptoms.

(i) "Department" means the Georgia Department of Community Health operating through the Division of Healthcare Facility Regulation.

(j) "Direct care staff person" means any employee, facility volunteer or contract staff who provides to residents any personal services, including but not limited to, medication

administration or assistance, assistance with ambulation and transfer, and essential activities of daily living such as eating, bathing, grooming, dressing, and toileting.

(k) "Disabled individual" means an individual that has a physical or mental impairment that substantially limits one or more major life activities and who meets the criteria for a disability under state or federal law.

(l) "Employee" means any person, other than a director, utilized by a personal care home to provide personal services to any resident on behalf of the personal care home or to perform at any facilities of the personal care home any duties which involve personal contact between that person and any paying resident of the personal care home.

(m) "Exploitation" means an unjust or improper use of another person or the person's property through undue influence, coercion, harassment, duress, deception, false representation, false pretense, or other similar means for one's own personal advantage.

(n) "Governing Body" means the person or group of persons as defined in Georgia law who maintain and control the home and who are legally responsible for the operation of the home.

(o) "Health services" means the specialized assistance that may be provided by or at the direction of either licensed healthcare professionals, such as doctors, nurses, physical therapists or through licensed healthcare programs, such as home health agencies, hospices and private home care providers to address health needs that the home is not authorized by law or regulations to provide.

(p) "Injury" as used in the definition of abuse means a wrong or harm caused by an individual to a resident which is manifested by a physical or behavioral reaction or change in the appearance or actions of the resident, such as, but not limited to, reddened or bruised skin not related to routine care, crying, startling or cowering reaction by the resident and malnutrition or pressure ulcers, such as skin breakdowns, for which the home has not provided proper care.

(q) "Legal Surrogate" means a duly appointed person who is authorized to act, within the scope of the authority granted under the legal surrogate's appointment, on behalf of a resident who is adjudicated or certified incapacitated. The legal surrogate may act on a resident's behalf where a resident has not been adjudicated as incapacitated provided that the action is consistent with the resident's wishes and intent and is within the scope of the authority granted. Where such authority is exercised pursuant to a Power of Attorney executed by a resident, the facility must maintain a copy of this document in the resident's files. The resident's duly appointed legal surrogate(s) shall have the authority to act on the resident's behalf as established by written applicable federal and state of Georgia law, and shall be entitled to receive information relevant to the exercise of his or her authority. No member of the governing body, administration, or staff of the personal care home or affiliated personal care homes or their family members may serve as the legal surrogate for a resident.

(r) "Limited nursing services" means the assessment of the physical, mental, and emotional status to determine the appropriate level of care for an individual; the performance of health maintenance activities, as defined in division (a)(9)(C)(ii) of Code Section 43-26-12; and the provision of any nursing care within the direct care staff person's scope of practice that can be completed within seven days or intermittently.

(s) "Medical services" means services which may be provided by a person licensed pursuant to Article II of Chapter 34 of Title 43 of the Official Code of Georgia Annotated. or appropriately licensed and supervised nurse practitioners and physicians assistants.

(t) "Memory care services" means the additional watchful oversight systems, program, activities and devices that are required for residents who have cognitive deficits which may impact memory, language, thinking, reasoning, or impulse control, and which place the residents at risk of eloping, i.e., engaging in unsafe wandering activities outside the home.

(u) "Memory care center" means the freestanding or incorporated specialized unit within a personal care home or assisted living community that either:

(i) holds itself out as providing additional or specialized care to persons with diagnoses of probably Alzheimer's or other dementias or with cognitive deficits that may place the resident at risk; or

(ii) charges higher rates for care for residents with Alzheimer's or other dementias than for care to other residents.

(v) "Non-Family Adult" means a resident 18 years of age or older who is not related by blood within the third degree of consanguinity or by marriage to the person responsible for the management of the personal care home or to a member of the governing body.

(w) "Nursing services" means those services which may be rendered by a person licensed pursuant to Articles I and 2 of Chapter 26 of Title 43 of the Official Code of Georgia Annotated.

(x) "On-site manager" means the administrator or person designated by the administrator as responsible for carrying on the day-to-day management, supervision, and operation of the personal care home, who may also serve as the responsible staff person except during periods of his or her own absence.

(y) "Owner" means any individual or any person affiliated with a corporation, partnership, or association with 10 percent or greater ownership interest in the facility providing care to persons under the license of the facility in this state and who:

1. purports to or exercises authority of the owner in a facility;

2. applies to operate or operates a facility;

3. maintains an office on the premises of a facility;

4. resides at a facility;

5. has direct access to persons receiving care at a facility;

6. provides direct personal supervision of facility personnel by being immediately available to provide assistance and direction during the time such facility services are being provided; or

7. enters into a contract to acquire ownership of a facility.

(z) "Permit" or "Regular Permit" means the authorization granted by the Department to the governing body to operate a Personal Care Home.

(aa) "Personal Care Home", "home" or "facility" means any dwelling, whether operated for profit or not, which undertakes through its ownership or management to provide or arrange for the provision of housing, food service, and one or more personal services for two or more adults who are not related to the owner or administrator by blood or marriage.

(bb) "Personal Services" includes, but is not limited to, individual assistance with or supervision of self-administered medication, assistance with ambulation and transfer, and essential activities of daily living such as eating, bathing, grooming, dressing, and toileting.

(cc) "Physician" means an individual who is currently licensed to practice medicine in the State of Georgia. For purposes of these rules, it shall be acceptable for any services required to be performed by a physician to be performed by any other licensed medical professional (i.e., Nurse Practitioner, Physician Assistant, etc.) who is permitted to provide such services under applicable state scope of practice rules and regulations.

(dd) "Proxy caregiver" means an unlicensed person or a licensed health care facility that has been selected by a disabled individual or a person legally authorized to act on behalf of such individual to serve as such individual's proxy caregiver and meets the requirements contained in the Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, Chapter 111-8-100.

(ee) "Physical Restraints" are any manual or physical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom or normal access to one's body. Physical restraints include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, and wheelchair safety bars. Also included as restraints are practices employed by the home which function as a restraint, such as tucking in a sheet so tightly that a bedbound resident cannot move, bedrails, or chairs that prevent rising, or placing a wheelchair-bound resident so close to a wall that the wall prevents the resident from rising. Wrist bands or devices on clothing

that trigger electronic alarms to warn staff that a resident is leaving a room do not, in and of themselves, restrict freedom of movement and should not be considered as restraints.

(ff) "Plan of Correction" means the written plan prepared in response to cited rule violations which identify by date certain the specific actions that will be taken by the personal care home to come into compliance with applicable rules.

(gg) "Representative" means a person who voluntarily, with the resident's written authorization, may act upon resident's direction with regard to matters concerning the health and welfare of the resident, including being able to access personal records contained in the resident's file and receive information and notices pertaining to the resident's overall care and condition. This written authorization may take the form of an advance directive.

(hh) "Resident" means any non-family adult receiving or requiring personal assistance and residing in a personal care home.

(ii) "Responsible Staff Person" means the employee designated by the administrator or on-site manager as responsible for supervising the operation of the home during periods of temporary absence of the administrator or on-site manager.

(jj) "Self-administration of medications" or "self-administered medications" means those prescription or over-the-counter drugs that the resident personally chooses to ingest or apply where the resident has been assessed and determined to have the cognitive skills necessary to articulate the need for the medications and generally knows the times the medications are to be taken, and physical characteristics of medications to be taken.

(kk) "Self-preservation" means the ability to respond to an emergency condition, whether caused by fire or otherwise, and escape the emergency without physical, hands-on assistance from staff. The resident may move from place to place by walking, either unaided or aided by prosthesis, brace, cane, crutches, walker or hand rails, or by propelling a wheelchair or scooter.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.03
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-2-9, 31-7-2.1, 31-7-1 et seq., 31-8-80 et seq.
History. Original Rule entitled "Definitions" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Apr. 16, 2018; eff. May 6, 2018.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.04. Applicability of Rules and Exemptions.

(1) These rules apply to all personal care homes unless the facility is specifically exempted as provided in paragraph (2) of this rule.

(2) These regulations do not apply to the following facilities:

(a) Boarding homes or rooming houses which provide no personal services other than lodging and meals.

(b) Facilities offering temporary emergency shelter, such as those for the homeless and victims of family violence.

(c) Other facilities, homes or residences licensed by the Department which have not been classified as personal care homes, e.g. assisted living communities, hospices, traumatic brain injury facilities, drug abuse treatment facilities.

(d) Facilities providing residential services for federal, state or local correctional institutions under the jurisdiction of the criminal justice system.

(e) Facilities regulated by the Department of Behavioral Health and Developmental Disabilities.

(f) Host homes as defined in O.C.G.A. § 37-1-20(18).

(g) Group residences organized by or for persons who choose to live independently or who manage their own care and share the cost of services including but not limited to attendant care, transportation, rent, utilities and food preparation.

(h) Charitable organizations providing shelter and other services without charging any fee to the resident.

(i) Any separate and distinct dwelling which is classified by the Department as a community living arrangement subject to the Rules and Regulations for Community Living Arrangements, Chapter 290-9-37. A facility classified as a Community Living Arrangement cannot be operated on the same premises as a personal care home.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.04
Authority: O.C.G.A. §§ 26-5-1, 31-2-4, 31-2-7, 31-7-1 et seq., 37-1-20(18).
History. Original Rule entitled "Exemptions" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New title of "Applicability of Rules and Exemptions". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.05. Application for Permit.

(1) The governing body of each home must submit to the Department an application for a permit in the required format in order to be eligible to operate if the application is approved.

(2) No application for licensure will be acted upon by the Department unless it has been determined to be complete and include all required attachments and fees due the Department as specified in the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

(3) The application must truthfully and accurately disclose required information.

(4) Each application for a permit must be accompanied by a sketch, plat, photos or simple drawing of the home, and grounds with identification of all structures on the premises by the applicant. The visual depiction must show the property, windows, doors, room measurements, and bed placement for residents, family and/or staff and be accompanied by documentation of ownership or lease agreement for the property on which the home will be operated.

(5) The name of the administrator or on-site manager, who will be working in the home, if known, must be included with the application for a permit. If such information is not known at the time of application, it must be provided to the Department before a permit will be issued.

(6) The ownership of the home shall be fully disclosed in its application for a permit. In the case of corporations, partnerships, and other bodies created by statute, the corporate officers and all other individuals or family groups owning ten percent or more of the corporate stock or ownership must be disclosed in the application for a permit as well as the registered agent for service of process.

(7) Local zoning and other local requirements regarding the proper location and establishment of homes must be addressed by the applicant with the responsible local officials.

(8) The filing of an application for licensure constitutes a representation that the applicant is or will be in complete control of the home as of a specified date.

(9) For initial application for licensure of a home with twenty-five (25) beds or more, the applicant shall include a financial stability affidavit from a certified public accountant affirming the applicant's ability to operate as a going concern for the next two years.

(10) No personal care home shall be operated and no residents admitted without such a permit which is current under these rules and regulations.

(11) No memory care center shall be operated and no residents admitted without a certificate which is current under these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.05
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-2-14, 31-7-1 et. seq.
History. Original Rule entitled "Application for Permit" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.06. Permits.

(1) The governing body of each personal care home must obtain a valid permit from the Department prior to operating as a personal care home.

(2) The permit must be displayed in a conspicuous place on the premises that is visible to residents and visitors.

(3) A licensed personal care home must not serve more residents than its approved licensed capacity

(4) A permit is no longer valid and must be returned to the Department when the home ceases to operate, is moved to another location, the ownership changes, the governing body is significantly changed, or the permit is suspended or revoked.

(5) A permit is required for each home located on different premises where more than one home is operated under the same governing body.

(6) No personal care home is permitted to provide personal services to individuals living in spaces which are not located within the authorized space assigned to the licensed personal care home.

(7) A home licensed as a personal care home, but not specifically licensed as an assisted living community, must not provide assisted living care.

(8) A personal care home must not operate or allow another business to operate on the premises of the licensed home where the business intrudes on the residents' quiet enjoyment and use of the licensed home.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.06
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-2-11, 31-7-1, 31-7-2.1, 31-7-12.
History. Original Rule entitled "Permits" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.07. Governing Body.

(1) The governing body is responsible for providing the oversight necessary to ensure that the home operates in compliance with applicable requirements: Chapter 7 of Title 31 of the Official Code of Georgia Annotated, administrative rules and regulations of the Department of Community Health, Chapters 111-8-25, 111-8-62 and 111-8-100, and all other statutes, rules and regulations.

(2) The governing body must ensure that the Department has current contact information consisting of name, e-mail address for departmental notifications to the home, physical addresses, and phone numbers for the governing body and the administrator or on-site

manager of the home. The governing body must ensure that staff is held accountable for delivering any notices provided to the governing body at the listed addresses to the governing body.

(3) The governing body is responsible for implementing policies, procedures and practices in the home that support the core values of dignity, respect, choice, independence and privacy of the residents in a safe environment and in accordance with these rules. At a minimum, the policies and procedures that are developed must provide direction for the staff and residents on the following:

(a) The services available in the home, including, personal services, memory care services/centers and any other specialized services such as designated proxy caregivers.

(b) Admissions, discharges and immediate transfers which ensure that the home does not admit or retain residents who need more care than the home is authorized or capable of providing.

(c) Refunds when a resident is transferred or discharged.

(d) Training and ongoing evaluation of staff, including specialized training if designated proxy caregivers are provided or memory care is offered.

(e) House rules and their enforcement.

(f) Protecting the rights of the residents as set forth in these rules;

(g) Medication management, procurement and the professional oversight provided for such services.

(h) Health and hygiene issues for residents and staff relating to infection control, work policies and return to work policies, food borne illnesses and reportable diseases.

(i) The investigation and reporting of abuse, neglect, exploitation of residents, residents' wandering away from the community, accidents, injuries and changes in residents' conditions to required parties.

(j) Discipline procedures for handling conduct which is inconsistent with the policies of the home committed by staff.

(k) Emergency preparedness, drills and evacuation requirements.

(l) Quality assurance and peer review mechanisms to determine opportunities for improving care utilizing information acquired from reports and investigations of serious incidents, including resident and family feedback.

(m) The use of volunteers, who have unsupervised access to the residents and their orientation regarding resident's rights and basic safety precautions.

(n) The specific use of proxy caregivers allowed within the home and the oversight of proxy caregivers the home requires or provides in accordance with Georgia law, these rules and the rules for proxy caregivers, Chapter 111-8-100.

(o) The safety and security precautions that will be employed by the home to protect residents from harm by other residents, designated proxy caregivers and other individuals, not employed by the home who routinely come into the home.

(p) The staffing plan which takes into account the specific needs of the residents and also includes arrangements for staffing in the absence of regularly scheduled staff.

(4) The governing body must not permit any person who is a member of the governing body, administration or staff to serve as the representative of a resident of the home.

(5) Where a member of the governing body, administration or staff serves as the representative payee of the resident, the home must use the funds received for the exclusive use and benefit and in the best interest of the resident and maintain necessary records to support such use.

(6) The governing body must ensure that staff accepts certified mail from the Department when sent to the licensed home.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.07
Authority: O.C.G.A. §§ 31-2-7, 31-7-1, 31-7-2.1, 31-7-3, 31-7-12.
History. Original Rule entitled "Provisional Permits" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New title "Governing Body." F. Dec. 19, 2012; eff. Jan. 8, 2013.
Note: Correction of non-substantive typographical error in Rule History, "**Amended:** Dec. 19, 2012; eff. Jan. 8, 2013." corrected to "Amended: New title "Governing Body." F. Dec. 19, 2012; eff. Jan. 8, 2013." to cite title change omitted in 2012. Effective Sep. 13, 2021.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.08. Administration.

(1) The home must have an administrator, who is at least 21 years of age and meets the following requirements, as applicable:

(a) Administrators of homes licensed for fewer than twenty-five (25) beds must have either (i) an Associate's Degree or, (ii) a G.E.D. or a high school diploma and 2 years of experience working in a licensed personal care home or other healthcare-related setting.

(b) Administrators of homes licensed for twenty-five (25) or more beds must hold a valid license from the State Board of Long-Term Care Facility Administrators with an effective date no greater than sixty (60) days from the date of hire or July 1, 2021, whichever is later.

(2) The administrator or on-site manager of each personal care home must do the following:

(a) Ensure that the policies and procedures are effective and enforced to support the health and safety of the residents.

(b) Designate qualified staff as responsible staff to act on his or her behalf and to carry out his or her duties in the administrator or on-site manager's absence. No resident shall be designated as staff.

(c) Investigate serious incidents involving residents which result in injuries or death in order to identify and implement opportunities for improvement in care.

(d) Monitor and document staff performance to ensure that care and services are being delivered safely and in accordance with these rules.

(3) Personnel must be assigned duties consistent with their positions, training, experience, and the requirements of Rule 111-8-62-.09.

(4) The facility must comply with the requirements of Chapter 111-8-16, Rules and Regulations for Disaster Preparedness Plans.

(5) Each home must have a telephone which is maintained in working order at all times and is accessible to the residents.

(6) **Notification of Emergency Relocation**. The home must provide timely notification of the relocation address to the residents, their family contacts and representatives, if any, and the Department whenever the home must relocate the residents as a result of an emergency situation which disrupts the provision of room and board for the residents at the licensed location.

(7) **Notification of Bankruptcy, Eviction or Change of Ownership**. The home must provide:

(a) a minimum of sixty (60) days written notice to the department and all residents of any impending bankruptcy or property eviction that may force discharge or relocation of residents or otherwise adversely impact the provision of safe care and oversight; and

(b) a minimum of thirty (30) days written notice to the department and all residents of any impending change of ownership. The notice to the department shall be in the

form of an application which must be approved before the permit is issued to the new owner(s).

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.08
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-7-1 et seq., 43-27-1 et seq.
History. Original Rule entitled "Governing Body" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Administration." F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Apr. 16, 2018; eff. May 6, 2018.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.09. Workforce Qualifications and Training.

(1) Age Requirements. The on-site manager and all other direct-care supervisory staff working in a personal care home must be at least 21 years of age. Non-supervisory staff providing hands-on care to the residents must be at least 18 years of age.

(2) The administrator or on-site manager must be responsible for ensuring that any person working in the home as an employee, under contract or otherwise, receives work-related training within the first sixty days of employment. Such training must include, at a minimum, the following:

(a) Evidence of current certification in emergency first aid except where the staff person is a currently licensed health care professional;

(b) Evidence of current certification in cardiopulmonary resuscitation where the training course required return demonstration of competency;

(c) Emergency evacuation procedures;

(d) Medical and social needs and characteristics of the resident population;

(e) Residents' rights;

(f) Identification of conduct constituting abuse, neglect or exploitation of a resident and reporting requirements to include the employee's receipt of a copy of the Long-Term Care Facility Resident Abuse Reporting Act as outlined in O.C.G.A. § 31-8-81 et seq.; and

(g) General infection control principles including the importance of hand hygiene in all settings and attendance policies when ill.

(3) At least one staff person having completed the minimum training requirements of Rule 111-8-62-.09(2)(a) through (g) above must be present in the home at all times resident(s) are present in the home.

(4) All direct care staff, including the administrator or on-site manager, must satisfactorily complete continuing education each year, in courses, relevant to their job duties, including, but not limited to, appropriate medication assistance, working with the elderly, working with residents with Alzheimer's or other cognitive impairments, working with the mentally ill and developmentally disabled, social and recreational activities, legal issues, physical maintenance and fire safety, housekeeping, or other topics as needed or as determined by the Department.

(5) All direct care staff, including the administrator or on-site manager, must have at least sixteen (16) hours of training per year.

(6) The administrator, on-site manager, and each employee must have received a tuberculosis screening and a physical examination by a licensed physician, nurse practitioner or physician assistant within twelve months prior to their employment with the home which examination was sufficiently comprehensive to assure that the employee is free of diseases communicable within the scope of employment and physically qualified to work. Follow-up examinations must be conducted by a licensed physician, nurse practitioner or physician assistant of each administrator or staff person to determine readiness to return to work following a significant illness or injury. Copies of information regarding staff member health must be kept in the staff person's file accessible at the licensed home or within one hour of the request.

(7) **Criminal History Background Checks for Owners Required**. Prior to the issuance of any new license, the owner of the business or agency applying for the license must comply with the requirements of the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(8) **Criminal History Background Checks for Directors, Administrators and Onsite Managers Required**. The home must obtain a satisfactory fingerprint records check determination for the person being considered for employment as a director, administrator or onsite manager. The records check determination must be done in compliance with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(9) **Criminal History Background Checks for Direct Access Employees Required**. Prior to serving as a direct access employee, the home must obtain a satisfactory fingerprint records check determination for the person to be hired in compliance with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(10) The administrator or on-site manager must obtain and verify a five year employment history when possible for each employee and maintain documentation in the employee's file. If the potential employee has no prior employment history, then the home must retain documentation of a satisfactory personal reference check.

(11) Personnel file(s) for each employee must be maintained either in the home or available for inspection by departmental staff within one hour of request or prior to the end of the on-site survey and for three years following the employee's departure or discharge. These files must include all of the following:

(a) Evidence of a satisfactory fingerprint record check determination, if applicable.

(b) Report of a physical examination completed by a licensed physician, nurse practitioner or physician assistant.

(c) Evidence of trainings, skills competency determinations and recertifications as required by these rules and, if applicable, the Rules for Proxy Caregivers, Chapter 111-8-100.

(d) Employment history, if previously employed, including places of work, employers and telephone contacts with previous employers.

(e) Supporting documentation reflecting that the employee has the basic qualifications as represented, e.g. personal references, documentation of good standing by nursing board, no findings of abuse, neglect or exploitation entered against the individual in the nurse aide registry, satisfactory report of motor vehicle driving record where the employee may be transporting residents.

(f) Written evidence of satisfactory initial and annual work performance reviews, which can take the form of skills competency checklists, for unlicensed staff providing hands-on personal care. Where the unlicensed staff performs specialized tasks, such as health maintenance activities, such performance reviews must include the satisfactory completion of skills competency checklists as specified in applicable rules. Such reviews must be conducted by staff or contractors qualified by education, training and experience to assess that the assigned duties are being performed in accordance with applicable rules and accepted health and safety standards.

(12) Where the home permits a resident to hire his or her own companion-sitter, proxy caregiver to perform health maintenance activities or aide of any sort, the home must require assurance that the companion-sitter, proxy caregiver or aide so hired is familiar with emergency evacuation routes and has documentation reflecting compliance with the provisions of the Rules for Proxy Caregivers, Chapter 111-8-100, as applicable.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.09
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-7-2.1, 31-7-12, 31-7-350.
History. Original Rule entitled "Administration" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Workforce Qualifications and Training". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.10. Staffing.

(1) Homes licensed for less than 25 beds must maintain a minimum on-site staff to resident ratio of one awake direct care staff person per 15 residents during waking hours and one awake direct care staff person per 25 residents during non-waking hours where the residents have minimal care needs. Homes licensed for 25 or more beds must maintain an average monthly minimum on-site staff to resident ratio of one awake direct care staff person per 15 residents during waking hours and one awake direct care staff person per 20 residents during non-waking hours. Average monthly minimum staffing levels shall be calculated and documented by the home using methods and forms specified by the department. Notwithstanding the above requirements, all homes must staff above these minimum on-site staff ratios to meet the specific residents' ongoing health, safety and care needs.

   (a) Staff, such as cooks and maintenance staff, who do not receive on-going direct care training and whose job duties do not routinely involve the oversight or delivery of direct personal care to the residents, must not be counted towards these minimum staffing ratios. Personnel who work for another entity, such as a private home care provider, hospice, or private sitters cannot be counted in the staff ratios for the home.

   (b) At least one administrator, on-site manager, or a responsible staff person must be on the premises 24 hours per day and available to respond to resident needs, with a minimum of one staff person per occupied floor.

   (c) Residents must be supervised consistent with their needs.

(2) All staff, including the administrator or on-site manager, who offer direct care to the residents on behalf of the home, must maintain an awareness of each resident's normal appearance and must intervene, as appropriate, if a resident's state of health appears to be in jeopardy.

(3) For purposes of these regulations, a resident must not be considered a staff person.

(4) All homes must develop and maintain accurate staffing plans that take into account the specific needs of the residents and monthly work schedules for all employees, including relief workers, showing planned and actual coverage for each day and night.

(5) The home must retain the completed staff schedules for a minimum of one year.

(6) Sufficient staff time must be provided by the home such that each resident:

   (a) Receives treatments, medications and diet as prescribed.

   (b) Receives proper care to prevent pressure ulcers and contractures.

   (c) Is kept comfortable and clean.

   (d) Is treated with dignity, kindness, and consideration and respect.

(e) Is protected from avoidable injury and infection.

(f) Is given prompt, unhurried assistance if she or he requires help with eating.

(g) Is given assistance, if needed, with daily hygiene, including baths, oral care.

(h) Is given assistance with transferring when needed.

(7) The administrator, on-site manager, or staff person must not be under the influence of alcohol or other controlled substances while engaged in any work-related activity on behalf of the home.

(8) A home licensed to serve more than 24 residents must ensure that staff wear employee identification badges which are readily visible.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.10
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-2-14, 31-7-1 et seq., 31-7-250 et seq.
History. Original Rule entitled "Personnel" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Staffing". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.11. Home Accountability and Inspections.

(1) The home and its records must be available for review and examination by properly identified representatives of the Department. Inspections may be conducted both on an announced and unannounced basis. Unannounced inspections shall be conducted as needed.

(2) Where the Department identifies rule violations, the home will receive a written report of inspection. Within 10 days of receipt of the written report of inspection, the home must develop a written plan for correcting any rule violations identified. The plan of correction must identify the specific actions the home will take promptly to come into compliance with each rule for which a deficient practice was identified and file the plan with the Department as directed.

(3) If the home disagrees with the facts and conclusions stated in the inspection report, the home may include with its plan of correction a written statement explaining its disagreement and any evidence supporting the disagreement to the Department. Where the Department concurs with the written statement of disagreement, the Department will issue a revised inspection report to the home.

(4) A copy of the most recent inspection report and plan of correction must be displayed in the home in a location that is routinely used by the home to communicate information to residents and visitors. Additionally, if the home maintains a website, it shall post a web

link in a prominent location on the main page of the website that provides access to copies of all inspection reports and plans of correction from the previous 18 months. When the Department develops a web site for receiving plans of correction electronically and notifies the home of the appropriate internet address, the home also must file its plan of correction electronically on the Department's web site within 10 days of receipt of the report of inspection.

(5) The home must assess the effectiveness of its plan of correction in correcting the deficient practice and modify the plan of correction as necessary to ensure compliance with the rules.

(6) The home must complete and maintain an accurate and current licensed residential care profile on file with the Department when the Department makes available a system for the submission and collection of such information electronically.

(7) The home must provide services that are consistent with the information reported on its licensed residential care profile, its license and these rules.

(8) A personal care home which is not licensed as an assisted living community must not use the term "assisted living" in its name or marketing materials.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.11
Authority: O.C.G.A. §§ 31-2-7, 31-7-1, 31-7-3, 31-7-2.1, 31-7-12, 31-7-12.2, 31-7-12.3.
History. Original Rule entitled "Staffing" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Home Accountability and Inspections". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.

Rule 111-8-62-.12. Home Design Requirements.

(1) A home must be constructed, arranged, and maintained to provide adequately for all of the following:

(a) Health, safety, and well-being of the residents.

(b) Independence, privacy and dignity of the residents.

(c) Safe access of all residents with varying degrees of functional impairments to living, dining and activity areas within the home.

(2) A currently licensed home which undergoes major structural renovation or one that is first licensed after the effective date of these rules must be designed and constructed in compliance with applicable state and local building and fire codes.

(3) Where the home intends to make changes to the home which would result in a change to the floor sketch from the one that was submitted at the time of initial licensing or

certificate of need review, the home must have such proposed changes approved by the Department.

(4) Any renovations to the home which put the home out of compliance with these rules may subject the home to revocation of its license.

(5) **Common Areas.** The home must provide common living areas for the use of the residents.

(a) Separate and distinct sleeping and living areas must be provided which allow for necessary supervision and assistance by staff and are conveniently located within easy walking distance of each resident's private living space (room), available for the residents' informal use at any time and do not require any resident to leave the building to use.

(b) Living rooms must be provided which are large enough to accommodate the residents without crowding. The rooms must be comfortably and attractively furnished, well heated, well lighted, ventilated and clean.

(c) The home must have handrails, grab bars, doorways and corridors which accommodate permitted mobility devices, such as walkers, motorized scooters, wheel chairs and crutches or canes as the residents require for their safety and allow the residents to move about the home freely.

(d) The home must provide an area for use by residents and visitors which affords privacy.

(e) The home must place at least one current calendar and working clock in the common living area.

(f) The home must provide a comfortable dining area which is properly equipped and adequate in size for the number of residents being served.

(g) The home must provide a means of locked storage for any resident's valuables or personal belongings, upon request.

(h) No living room, dining room, hallway, and any other room not ordinarily used for sleeping is permitted to be used for sleeping by residents, family, staff or renters.

(i) A home must provide laundering facilities on the premises for the residents' personal laundry that prevents the cross-contamination of clean and dirty laundry.

(6) **Bedrooms or Private Living Spaces.** The following minimum standards for resident bedrooms or private living spaces must be met:

(a) Bedrooms or private living spaces must have at least 80 square feet of usable floor space per resident. Usable floor space is defined as that floor space under a ceiling

at least seven feet in height. However, licensed personal care homes approved prior to or on February 6, 1981 to operate with bedrooms or private living spaces with a minimum of 70 square feet of usable floor space per resident which have continuously operated since that date may continue to use the minimum 70 square feet standard. Where a home operating under this exception has its permit revoked, changes ownership, changes location, or undergoes extensive renovations, or for any other reason surrenders its permit, this exception regarding the minimum square footage is no longer available.

(b) There shall be no more than four residents per bedroom or private living space unless the home is presently permitted to serve more than four residents per bedroom or private living space and no change in the ownership, location or licensure status of the home occurs.

(c) Each bedroom or private living space must have at least one window opening through an exterior wall of the home. Bedrooms or private living spaces must be well ventilated and maintained at a comfortable temperature.

(d) If the residents specifically choose in writing to share a private bedroom or living space with another resident of the home, then the residents must be permitted to share the room, subject to the usable square feet requirement and the limitation that no more than four residents may share any bedroom or private living space.

(e) Bedrooms or private living spaces for residents must be separated from halls, corridors and other rooms by floor to ceiling walls.

(f) The floor plan of the home must be such that no person other than the residents assigned to a bedroom or private living space should pass through that residents' bedroom or private living space in order to reach another room.

(g) Doorways of bedrooms or private living spaces occupied by residents must be equipped with side-hinged permanently mounted doors equipped with positively latching hardware which will insure opening of the door by a single motion, such as turning a knob or by pressing with normal strength on a latch. For bedrooms or private living spaces which have locks on doors, both the occupant and administrator or on-site manager must be provided with keys to assure easy entry and exit.

(h) A room must not be used as a bedroom or private living space where more than one-half the room height is below ground level. Bedrooms or private living spaces which are partially below ground level must have adequate natural light and ventilation and be provided with two useful means of egress. Control of dampness must be assured.

(i) When a resident is discharged, the room and its contents must be thoroughly cleaned.

(7) **Bathroom Facilities**. The following minimum standards apply to bathroom facilities:

(a) At least one functional toilet and lavatory must be provided for each four residents and at least one bathing or showering facility must be provided for each eight residents living in a home.

(b) At least one toilet and lavatory must be provided on each floor having residents' bedrooms.

(c) Grab bars and nonskid surfacing or strips must be installed in all showers and bath areas.

(d) Bathrooms and toilet facilities without windows must have forced ventilation to the outside. Bathroom windows used for ventilation must open easily.

(e) Toilets, bathtubs and showers must provide for individual privacy.

(f) All plumbing and bathroom fixtures must be maintained in good working order at all times and must present a clean and sanitary appearance.

(g) A home serving a person dependent upon a wheelchair or scooter for mobility must have at least one bathroom that permits the resident to use all bathroom fixtures easily and independently where able.

(8) **Interior Design and Construction.** The home must be designed and built to provide for the following:

(a) All stairways and ramps must have sturdy and securely fastened handrails, not less than 30 inches nor more than 34 inches above the center of the tread. Exterior stairways, decks and porches must have handrails on the open sides.

(b) Floor covering must be intact and securely fastened to the floor. Any hazard that may cause tripping must be removed.

(c) All areas of the home, including hallways and stairs must provide sufficient ambient lighting such that the residents may move about safely and objects may be easily observed by the residents. In addition, appropriate task lighting necessary for more visually demanding activities such as reading, knitting or preparing food must also be provided for resident use.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.12
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-1, 31-7-2.1, 31-7-3, 31-7-12.
History. Original Rule entitled "Inspections" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Home Design Requirements". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.13. Physical Plant Health and Safety Standards.

(1) Each home must be in compliance with fire and safety rules promulgated by the Office of the Safety Fire Commissioner for the personal care homes it regulates.

(2) Each home must be in compliance with applicable local ordinances that specifically address fire safety in homes of that size and function. Private quarters must be maintained in such a manner as to comply with fire safety codes and not threaten the health or safety of residents. In the absence of or in addition to any such local ordinances, the following requirements must be met:

(a) Wall type electric outlets and lamps or light fixtures must be maintained in a safe and operating condition. The home must provide functioning light bulbs for light fixtures.

(b) Cooking appliances must be suitably installed in accordance with approved safety practices. Where metal hoods or canopies are provided, they must be equipped with filters which must be maintained in an efficient condition and kept clean at all times.

(c) Space heaters must not be used, except during an emergency situation after obtaining specific written approval of the fire safety authority having jurisdiction over the home.

(d) Fire screens and protective devices must be used with fireplaces, stoves and heaters, including space heaters.

(e) Each home must be protected with sufficient smoke detectors, powered by house electrical service with battery back-up which, when activated, must initiate an alarm which is audible in the sleeping rooms.

(f) Each home must have at least one charged 5 lb. multipurpose ABC fire extinguisher on each occupied floor and in the basement. These extinguishers must be checked annually to assure they remain in operable condition.

(g) Each home must have a working doorbell or doorknocker which is audible to staff inside at all times.

(h) Exterior doors must be equipped with locks which do not require keys to open them from the inside.

(3) The electrical service of the home must be inspected by a licensed electrician or local code enforcement official and declared free of hazards within no more than six months prior to the date of filing the application for a permit. A signed copy of this inspection report must be submitted to the Department as a part of the application. Electrical service must be maintained in a safe condition at all times. The Department may require a re-inspection of the electrical service at any time renovation or repair work is done in the home or there is a request for a change in capacity or there is reason to believe that a risk to residents exists.

(4) Where the Department has reason to believe, based on the number of residents requiring assistance with ambulation and staffing patterns that the home may not be able to evacuate all of the residents to a designated point of safety within an established period of time as determined by the fire safety officials, the Department may either require the home to conduct an immediate fire safety drill or make a referral for a new compliance determination to responsible fire safety officials. The Department may also require a repeat fire safety inspection where substantial renovations or repairs have been made to the home.

(5) Water and sewage systems must meet applicable federal, state, and local standards and/or regulations.

(6) Floors, walls, and ceilings must be kept clean and in good repair.

(7) Kitchen and bathroom areas must be kept clean and sanitized, at least once daily with disinfectant and more often as needed to insure cleanliness and sanitation.

(8) The storage and disposal of bio-medical and hazardous wastes must comply with applicable federal, state, and local rules and/or standards.

(9) Solid waste which is not disposed of by mechanical means must be stored in vermin-proof, leak-proof, nonabsorbent containers with closefitting covers until removed. Waste must be removed from the kitchen at least daily and from the premises at least weekly.

(10) An insect, rodent or pest control program must be maintained and conducted in a manner which continually protects the health of residents.

(11) Poisons, caustics, and other dangerous materials must be stored and safeguarded in areas away from residents, food preparation and food storage areas, and medication storage areas.

(12) The home must have an adequate hot water system that supplies heated water, comfortable to the touch but not exceeding 120 degrees Fahrenheit (F.) to the residents for their usage.

(13) Entrances and exits, sidewalks, yards and escape routes must be maintained free of any hazards such as refuse, equipment, unsafe furniture, debris or any other impediments. Ice and snow must be cleared from the home's entrances, exits and walkways.

(14) The home must have its house number and name displayed so as to be easily visible from the street.

(15) The exterior of the home must be properly maintained to remain safe and in good repair.

(16) The following evacuation requirements must be met:

(a) Residents who need assistance with ambulation must be assigned bedrooms which have a ground-level exit to the outside or to rooms above ground level which have exits with easily negotiable ramps or easily accessible elevators.

(b) There must be an established procedure and mechanism for alerting and caring for residents in case of emergencies and evacuating them to safety. This procedure must include instructions and evacuation plans posted on each floor of a home. Each sleeping room must have a secondary exit. This secondary exit may be a door or a window usable for escape. A plan showing these routes of escape must be posted in the home on each floor.

(c) A home serving person(s) dependent upon wheelchairs or scooters for mobility must provide at least two exits from the home, remote from each other, that are accessible to these persons.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.13
Authority: O.C.G.A. §§ 31-2-9, 31-7-1, 31-7-2.1, 31-7-12.
History. Original Rule entitled "Minimum Floor Plan Requirements" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Physical Plant Health and Safety Standards". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.14. Furnishings and Fixtures.

(1) Furnishings of the home in the living room, bedrooms and dining room must be maintained in good condition, intact, and functional.

(2) Furnishings and housekeeping standards must be such that a home presents a clean and orderly appearance.

(3) Resident bedroom furnishings must include all of the following:

(a) An adequate closet or wardrobe.

(b) Working lighting fixtures sufficient for reading and other resident activities.

(c) A bureau or dresser or the equivalent and at least one chair with arms per resident in each bedroom or private living space.

(d) A mirror appropriate for grooming unless the resident or resident's representative specifically requests to have it removed;

(e) An individual bed at least 36-inches wide and 72-inches long with comfortable springs and mattress, clean and in good condition. Where a particular resident is very tall, the home must provide an extra long mattress upon request. The mattress shall be not less than five-inches thick, or four-inches, if of a synthetic

construction. Couples may request a double bed when available. Roll-a-ways, cots, double-decks, stacked bunks, hide-a-beds and studio couches are not to be used in lieu of standard beds.

(f) Bedding for each resident which includes two sheets, a pillow, a pillow case, a minimum of one blanket and bedspread. A home must maintain a linen supply for not less than twice the bed capacity where the residents do not choose to provide their own linens. Where the residents choose to provide their own linens, the home must maintain an adequate supply of spare linens on hand to accommodate the needs of the residents. A home must change and launder bed linens for each resident at least weekly or more often if soiled.

(4) Provision must be made for assisting a resident to personalize the bedroom by allowing the use of his or her own furniture if so desired and mounting or hanging pictures on bedroom walls.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.14
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-1, 31-7-2.1, 31-7-12.
History. Original Rule entitled "Physical Plant Health and Safety Standards" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Furnishings and Fixtures". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.15. Admission.

(1) Criteria for admission and retention of residents in a home are as follows:

(a) Persons admitted to a personal care home must be at least 18 years of age.

(b) Except for aging in place exceptions, the home is permitted to admit and retain only ambulatory residents who are capable of self-preservation with minimal assistance, i.e. staff may assist the resident in transferring from a sitting or reclining position and provide verbal directions to residents who are able to self-propel to the nearest exit.

(c) Aging in Place Exceptions. The home may allow up to three (3) non-ambulatory residents to remain in the home to support an aging in place strategy that is in the best interests of the resident, subject to the requirements herein. These aging in place exceptions may be revoked by the Department at any time, as part of the survey process, if the facility fails to meet any of the following criteria:

(i) The resident has not experienced any significant change in a physical or medical condition which would make continued placement in the facility inappropriate;

(ii) The facility maintains responsibility for meeting resident needs for continuing care provided within the scope of services the personal care home is licensed to deliver;

(iii) The resident remains under hospice services (if the resident was under such services at the time of the aging in place decision);

(iv) The facility monitors its performance of fire drills to ensure that it can safely evacuate all of the residents at any time in 13 minutes or less;

(v) The facility increases the number of documented fire drills to a minimum of one fire drill per month, covering all shifts, as long as one or more residents in the facility are non-ambulatory;

(vi) The facility notifies the local fire department in writing within two (2) weeks of the change in the resident's status to aging in place so that there is local awareness of the presence of a non-ambulatory resident at the home;

(vii) The facility ensures sufficient staff on all shifts to support the safe and timely evacuation of all residents in the event of an emergency; and

(viii) The facility is in substantial compliance with the department's rules and is not subject to any pending enforcement action by the department.

(d) The home must not admit, or retain persons who require the use of physical or chemical restraints, isolation, or confinement for behavioral control.

(e) No home is permitted to admit residents who either require continuous medical services or continuous nursing care and treatment.

(f) Medical, nursing, health or therapeutic services required on a periodic basis, or for short-term illness, must not be provided as services of the home. When such services are required, they must be purchased by the resident or the resident's representative or legal surrogate, if any, from appropriately licensed providers managed independently from the home. The home may assist in arrangement for such services, but not provision of those services.

(2) No home is permitted to admit or retain a resident who needs care beyond which the home is permitted to provide.

(3) The administrator or on-site manager of a home must conduct an interview with the applicant and/or representative or legal surrogate, if any, of the applicant to ascertain that the home can meet the applicant's needs. The administrator or on-site manager must obtain a report of physical examination conducted by a by a licensed physician, nurse

practitioner or physician's assistant dated within 30 days prior to the date of admission using the specific report of physical examination form made available by the Department on its website to assess whether the home can meet the applicant's needs. Where a home admits a resident without the required physical examination pursuant to a specific request for an emergency placement made by a governmental agency responsible for adult protective service, local law enforcement or a case manager, the home must retain documentation of the need for the emergency placement and obtain a copy of a physical examination within 14 days following the emergency admission. The required report of physical examination form must be completed in its entirety.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.15
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-7-1 et seq.
History. Original Rule entitled "Furnishings and Fixtures" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Admission". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.16. Admission Agreement.

(1) A written admission agreement must be entered into between the governing body and the resident. Such agreement must contain the following:

(a) A current statement of all fees and daily, weekly or monthly charges; any other services which are available on an additional fee basis, for which the resident must sign; a request acknowledging the additional cost; and the services provided in the home for that charge.

(b) A statement that residents and their representatives or legal surrogates must be informed, in writing, at least 30 days prior to any increase in established charges related to the provision of personal services and at least 60 days prior to any increase in charges for room and board.

(c) The resident's authorization and consent to release medical information to the home as needed.

(d) Provisions for the administrator or on-site manager's continuous assessment of the resident's needs, referral for appropriate services as may be required if the resident's condition changes and referral for transfer or discharge if required due to a change in the resident's condition.

(e) Provision for transportation of residents for shopping, recreation, rehabilitation and medical services, which must be available either as a basic service or on a reimbursement basis. Provision must also be made for access to emergency transportation at all times.

(f) A statement of the home's refund policy including but not limited to when a resident decides not to move into the home, dies, is transferred or discharged.

(g) A statement that a resident may not perform services for the home.

(h) A copy of the house rules, which must be in writing and also posted in the home. House rules must be consistent with residents' rights. House rules must include, but not be limited to, policies regarding the use of tobacco and alcohol, the times and frequency of use of the telephone, visitors, hours and volume for viewing and listening to television, radio and other audiovisual equipment, whether residents' personal pets or household pets are permitted and the use of personal property.

(i) For residents first admitted after the effective date of these rules, a statement disclosing whether the home permits the resident to hire independent proxy caregivers, sitters, or requires the purchase of such services from the home or approved providers.

(j) For residents first admitted after the effective date of these rules, the admission agreement must disclose how and by what level of staff medications are handled in the home. The agreement must also specify who is responsible for initial acquisition, refilling of prescribed medications and whether unit or multi-dose packaging of medications is required.

(k) An explanation of how and when residents must be discharged or transferred from the home.

(1) For residents first admitted after the effective date of these rules, an explanation of how social media, photos of residents and other media involving residents are handled.

(2) Each resident, and representative, where applicable, prior to the execution of the admissions agreement, must have an opportunity to read the agreement. In the event that a resident is unable to read the agreement, the administrator or on-site manager must take special steps to assure communication of its contents to the resident.

(3) The resident and representative or legal surrogate, if any, must each be given a signed copy of the agreement and a copy signed by both parties (resident and administrator or on-site manager) must be retained in the resident's file and maintained by the administrator or on-site manager of the home.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.16
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-7-1, 31-7-2.1, 31-7-12.
History. Original Rule entitled "Admission" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Admission Agreement." F. Dec. 19, 2012; eff. Jan. 8, 2013.

Amended: F. Apr. 16, 2018; eff. May 6, 2018.

Rule 111-8-62-.17. Services.

(1) Personal assistance must be given to those residents who are unable to keep themselves neat and clean.

(2) Each home must provide sufficient activities to promote the physical, mental and social well-being of each resident.

(3) Each home must provide books, newspapers, and games for leisure time activities. Each home must encourage and offer assistance to residents who wish to participate in hobbies, music, arts and crafts, religion, games, sports, social, recreational and cultural activities available in the home and in the community.

(4) Each home must have at least one operable, non-pay telephone which is accessible at all times for emergency use by staff. Residents must have access to an operable, non-pay telephone in a private location, both to make and receive personal calls. The same telephone may meet all the requirements of this section.

(5) The daily living routine of the home must be such that a resident may spend the majority of his or her non-sleeping hours out of the resident's bedroom, if he or she so chooses.

(6) A home must not restrict a resident's free access to the common areas of the home unless the resident is living in a specialized memory care center. If the resident is residing in a specialized memory care center, unrestricted access to the common areas contained within the memory care center must be provided to the resident.

(7) A home must not lock the resident into or out of the resident's bedroom or private living space.

(8) **Resident Needs Assessment**. The home must complete an assessment of the resident at the time of admission and update as changes occur that addresses the resident's care needs taking into account the resident's family supports, the resident's functional capacity relative to the activities of daily living, physical care needs, medical information provided, cognitive and behavioral impairments, if any, and personal preferences relative to care needs.

(9) **Written Care Plan**. Utilizing the information acquired during the admission process and the move-in adjustment period, a home which provides proxy caregivers or memory care must develop the resident's individual written care plan within 14 days of admission and require staff to use the care plan as a guide for the delivery of care and services to the resident. The care plan must include the following:

   (a) A description of the resident's care and social needs and the services to be provided, including frequency to address care and social needs.

(b) Resident's particular preferences regarding care, activities and interests.

(c) Specific behaviors to be addressed with interventions to be used.

(d) Any physician order or order of a nurse practitioner or physician assistant working under protocol or job description, respectively for assistive devices.

(e) Staff primarily responsible for implementing the care plan.

(f) Evidence of resident and family involvement in the development of the plan when appropriate.

(g) Evidence of the care plan being updated at least annually and more frequently where the needs of the resident change substantially.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.17
Authority: O.C.G.A. §§ 31-2-7, 31-2-9 and 31-7-1 et seq.
History. Original Rule entitled "Admission Agreement" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Services". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.18. Precautions for Residents at Risk of Elopement.

(1) A home which serves residents with cognitive deficits which place the residents at risk of eloping, i.e. engaging in unsafe wandering activities outside the home must do the following:

(a) Develop, train and enforce policies and procedures for staff to deal with residents who may elope from the home including what actions, as specified in rule 111-8-62-.30 are to be taken if a resident wanders away (elopes) from the home.

(b) Utilize appropriate effective safety devices, which do not impede the residents' rights to mobility and activity choice or violate fire safety standards, to protect the residents who are at risk of eloping from the premises.

1. If the safety devices include locks used on exit doors, as approved by the fire marshal having jurisdiction over the home, then the locking device shall be electronic and release whenever the following occurs: activation of the fire alarm or sprinkler system, power failure to the home or by-pass for routine use by the public and staff for service using a key button/key pad located at the exit or continuous pressure for thirty (30) seconds or less.

2. If the safety devices include the use of keypads to lock and unlock exits, then directions for operation must be posted on the outside of the door to allow individuals' access to the memory care center. However, if the center

is a whole home, then directions for the operation of the locks need not be posted on the outside of the door. The center must not have entrance and exit doors that are closed with non-electronic keyed locks nor shall a door with a keyed lock be placed between a resident and the exit.

(2) A home serving residents who are at risk of eloping from the premises must retain on file at the home current pictures of residents who are at risk of eloping.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.18
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-7-1 et seq.
History. Original Rule entitled "Services" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Requirements for Memory Care Services". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: New Title "Precautions for Residents at Risk of Elopement." F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.19. Additional Requirements for Certified Memory Care Centers.

(1) A home must meet the additional requirements contained in rule 111-8-62-.19 where the home serves persons with probable diagnoses of Alzheimer's Disease or other dementia and does any of the following:

(a) Holds itself out as providing additional or specialized care to such residents; or

(b) Charges rates in excess of that charged other residents for the provision of additional or specialized care.

(2) **Written Description**. The home must develop an accurate written description of the memory care center that includes the following:

(a) A statement of philosophy and mission.

(b) How the services of the memory care center are different from services provided in the rest of the personal care home.

(c) Staffing, including job titles of staff who work in the center, staff training and continuing education requirements.

(d) Admission procedures, including screening criteria.

(e) Assessment and service planning protocol, including criteria to be used that would trigger a reassessment of the resident's status before the customary quarterly review.

(f) Staffing patterns, maintained within the center, including the ratio of direct care staff to resident for a 24-hour cycle.

(g) A description of the physical environment including safety and security features.

(h) A description of activities, including frequency and type, how the activities meet the needs of residents with dementia.

(i) The program's fee or fee structure for all services provided by the center.

(j) Discharge criteria and procedures;

(k) The procedures that will be utilized for handling emergency situations.

(l) The involvement of the center with families and family support programs.

(3) **Disclosure of Description**. A personal care home with a memory care center must disclose the written description of the center to:

(a) Any person upon request.

(b) The family or resident's representative before admission of the resident to the center.

(4) **Physical Design, Environment, and Safety**. The memory care center must be designed to accommodate residents with severe dementia or Alzheimer's Disease in a home-like environment which includes the following:

(a) Multipurpose room(s) for dining, group and individual activities which are appropriately furnished to accommodate the activities taking place.

(b) Secured outdoor spaces and walkways which are wheel chair accessible and allow residents to ambulate safely but prevent undetected egress.

(c) High visual contrasts between floors and walls and doorways and walls in resident use areas except for fire exits, door and access ways which may be designed to minimize contrast to conceal areas where the residents should not enter.

(d) Adequate and even lighting which minimizes glare and shadows.

(e) The free movement of the resident, as the resident chooses, between the common space and the resident's own personal space in a bedroom that accommodates no more than four residents.

(f) Individually identified entrances to residents' rooms to assist residents in readily identifying their own personal spaces.

(g) An effective automated device or system to alert staff to individuals entering or leaving the building in an unauthorized manner. A home need not use an automated alert for an exit door when the particular exit is always staffed by a receptionist or other staff member who views and maintains a log of individuals entering and leaving the home. If the exit door is not always staffed, then the home must have a system that activates an automated alert when the door is not attended;

(h) A communication system(s) which permit staff in the center to communicate with other staff outside the center and with emergency services personnel as needed; and

(i) A center or home which undergoes major renovation or is first constructed after December 9, 2009 must be designed and constructed in compliance with applicable state and local building and fire codes relevant to the center and the home.

(5) **Staffing Requirements**. The home must ensure that the center is staffed at all times with sufficient specially trained staff to meet the unique needs of the residents in the center. At a minimum, the home must provide the following staffing:

(a) One dementia trained direct care staff person for every 12 residents on-site during all waking hours and for every 15 residents on-site during all nonwaking hours based on a monthly average; provided, however, that such ratio is adequate to meet the needs of the residents;

(b) One registered professional nurse, licensed practical nurse, or certified medication aide on-site at all times;

(c) Two direct care staff persons on-site at all times, with at least one on each occupied floor; and

(d) One registered professional nurse or licensed practical nurse on-site or available in the building at all times as follows:

(i) For memory care centers with one to 12 residents, a minimum of eight hours per week;

(ii) For memory care centers with 13 to 30 residents, a minimum of 16 hours per week;

(iii) For memory care centers with 31 to 40 residents, a minimum of 24 hours per week; or

(iv) For memory care centers with more than 40 residents, a minimum of 40 hours per week.

(6) **Staff Training Requirements**. The home shall ensure that all staff are properly trained initially and on an annual basis to provide safe, quality care to residents in the memory care center. Effective July 1, 2021, the memory care center shall meet the following training requirements:

(a) General Orientation. All staff, regardless of role, shall receive at least four (4) hours of dementia-specific orientation within the first thirty (30) days of working in the center. Such orientation shall include:

(i) Basic information about the nature, progression, and management of Alzheimer's and other dementias;

(ii) Techniques for creating an environment that minimizes challenging behavior from residents with Alzheimer's and other dementias;

(iii) Methods of identifying and minimizing safety risks to residents with Alzheimer's and other dementias; and

(iv) Techniques for successful communication with individuals with Alzheimer's and other dementias.

(b) Direct Care Orientation. All direct care staff shall receive initial orientation training within the first thirty (30) days of caring for residents independently that, at a minimum, includes:

(i) General training, to include:

(A) Development, updating, and implementation of comprehensive and individual service plans;

(B) Skills for recognizing physical or cognitive changes in the resident that warrant seeking medical attention;

(C) Residents' rights and identification of conduct constituting abuse, neglect, or exploitation;

(D) General infection control principles;

(E) Emergency preparedness training;

(F) Emergency first aid; and

(G) Cardiopulmonary resuscitation.

(iii) A minimum of sixteen (16) hours of specialized, competency-based training using forms specified by the department, to include, at a minimum:

(A) The nature of Alzheimer's and other dementias;

(B) The center's philosophy related to the care of residents with Alzheimer's and other dementias;

(C) The center's policies and procedures related to care of residents with Alzheimer's and other dementias;

(D) Common behavior problems characteristic of residents with Alzheimer's and other dementias;

(E) Positive therapeutic interventions and activities;

(F) Skills for maintaining the safety of the resident; and

(G) The role of the family in caring for residents with Alzheimer's and other dementias.

(c) Ongoing Training. Direct care staff shall complete a minimum of eight (8) hours of specialized competency-based training in dementia care on an annual basis using forms specified by the department.

(d) Hospice Training for Certified Medication Aides Administering Morphine. The memory care center shall ensure that any medication aide(s) who will be administering liquid morphine to any hospice patient(s) residing in the center receive adequate training from a licensed hospice on the safe and proper administration of liquid morphine prior to such administration and on an annual basis thereafter. The memory care center shall maintain documentation of all training provided.

(e) Training Documentation. The memory care center shall maintain documentation reflecting course content, instructor qualifications, agenda, and attendance rosters for all training sessions provided.

(7) **Special Admission Requirements for Memory Care Center Placement**. Residents must have a Report of Physical Examination completed by a licensed physician, nurse practitioner or physician's assistant within 30 days prior to admission to the center on forms provided by Department. The physical examination must clearly reflect that the resident has a diagnosis of probable Alzheimer's Disease or other dementia and has symptoms which demonstrate a need for placement in the center. However, the center may also care for a resident who does not have a probable diagnosis of Alzheimer's Disease or other dementia, but desires to live in the center as a companion to a resident with a probable diagnosis of Alzheimer's Disease or other dementia with which the resident has a close personal relationship. In addition, the physical examination report

must establish that each potential resident of the center does not require 24-hour skilled nursing care.

(8) **Post-Admission Assessment**. The home must assess each resident's care needs to include the following components: resident's family supports, level of activities of daily living functioning, physical care needs and level of behavior impairment.

(9) **Individual Service Plans**. The post-admission assessment must be used to develop the resident's individual service plan within 14 days of admission. The service plan must be developed by a team with at least one member of the direct care staff participating and input from each shift of direct care staff that provides care to the resident. All team members participating must sign the service plan and the service plan must be shared with the direct care staff providing care to the resident and serve as a guide for the delivery of services to the resident. The service plan must include the following:

(a) A description of the resident's care and social needs and the services to be provided, including frequency to address care and social needs.

(b) Resident's expressed preferences regarding care, activities and interests.

(c) Specific behaviors to be addressed with interventions to be used.

(d) Names of staff primarily responsible for implementing the service plan.

(e) Evidence of family involvement in the development of the plan, if possible, with incorporation of family and personal history to support a person-centered approach to care.

(f) Evidence of the service plan being updated at least quarterly or more frequently if the needs of resident change substantially.

(10) **Therapeutic Activities**. The center must provide therapeutic activities appropriate to the needs of the individual residents and adapt the activities, as necessary, to encourage the participation of the residents. The following kinds of therapeutic activities must be provided at least weekly with at least some therapeutic activities occurring daily:

(a) Gross motor activities; e.g. exercise, dancing, gardening, cooking, other outdoor activities.

(b) Self-care activities; e.g. dressing, personal hygiene/grooming;

(c) Social activities; e.g. games, music, crafts.

(d) Sensory enhancement activities, e.g. distinguishing pictures and picture books, reminiscing and scent and tactile stimulation.

(11) No licensed personal care home may provide or hold itself out as providing specialized care for residents with probable Alzheimer's disease or other dementia or charge a differential rate for care of residents with cognitive deficits that place the residents at risk of engaging in unsafe wandering activities (eloping) unless it meets the additional requirements specified in Rule 111-8-62-.19.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.19
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-7-1 et seq., 43-26-32.
History. Original Rule entitled "Requirements for Memory Care Services" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Additional Requirements for Specialized Memory Care Units or Homes". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: New Title "Additional Requirements for Certified Memory Care Centers." F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.20. Medications.

(1) **Self-Administration of Medications**. Residents who have the capacity to self-administer medications safely and independently without staff assistance or supervision must be allowed to store their own medications securely and self-administer medications if they so desire.

(2) **Assistance with Self-Administration**. A resident who is not capable of independent self-administration of medication may be assisted and supervised in self-administration by staff to the following extent;

(a) Staff providing such assistance or supervision may perform the following:

1. Take the medication, in its previously dispensed, properly labeled container, from where it is stored, and bring the medication to the resident.

2. Read the label, open the container, remove a prescribed amount of medication from the container, and close the container, in the presence of the resident.

3. Place an oral dosage in the resident's hand or in another container where the resident requests assistance.

4. Apply topical medications.

5. Assist with self-administration of drops, inhalers, nasal sprays and patches.

6. Return the medication container to proper secured storage.

7. Assist the resident's use of an EPI pen where the resident has known severe allergies for which an EPI pen has been prescribed on condition that there is

an established written protocol detailing how it is to be used and when. The protocol must include immediately calling Emergency Services, 911, after any use of the EPI pen.

(b) Staff assisting with or supervising self-administration of medications must be proficient in English and able to read, write and follow written instructions in English.

(3) **Basic Medication Training for Staff Assisting with Self-Administration**. The home must provide and document medication training for the unlicensed staff that are providing assistance with or supervision of self-administration of medications to capable residents. The medication training must be conducted with an appropriate curriculum for providing medication assistance and include at least the following topics:

(a) The home's medication policy and procedures, including actions to take if concerns regarding resident's capacity to self-administer medications are identified.

(b) How to read prescription labels including common abbreviations.

(c) Providing the right medication to the right resident at the right time in the right amount and the right way including how to measure various medications.

(d) Actions to take when concerns regarding medications are identified.

(e) Infection control procedures relative to providing assistance with medications.

(f) Proper medication storage and disposal.

(g) Recognition of side effects and adverse reactions for the specific medications.

(h) Understanding the common classifications of medications, typical side effects and adverse reactions and medications for which unlicensed staff may never provide assistance with or supervision of self-administration.

(i) Proper documentation and record keeping using the Medication Assistance Record.

(4) **Medication Skills Competency Determinations**. Unlicensed staff in homes providing assistance with or supervision of self-administered medications must demonstrate to a qualified supervisor when hired and at least, annually thereafter, the necessary skills to perform the medication tasks assigned competently.

(5) **Memory Care Medication Administration.** Medications for residents living in the memory care center must be provided to the residents by a proxy caregiver trained in accordance with the requirements of Chapter 111-8-100; a licensed registered nurse; a

licensed practical nurse working under the supervision of a physician or registered nurse; or a certified medication aide subject to the requirements set forth below.

(6) **Certified Medication Aide Requirements.** A home using certified medication aides must meet the requirements below. CMAs working in the memory care center may also assist non-memory care residents in the same building.

(a) Check the Registry. The home must check to ensure that the medication aides employed in the home are listed in good standing on the Georgia Certified Medication Aide Registry and have no record of being terminated for cause relating to the performance of medication aide tasks before permitting the aides to administer medications.

(b) Administer Skills Competency Checks. The home must administer skills competency checks to determine and document that the medication aides who have been certified for more than one year upon hiring continue to have the knowledge and skills necessary to administer medications properly for the residents in care. The home must use a skills competency checklist which meets the requirements contained in the standardized clinical skills competency checklist used to certify medication aides.

(c) Quarterly Observations. The home must use a licensed registered professional nurse or a pharmacist to conduct quarterly random medication administration observations to determine that the aides are administering medications correctly and in compliance with these rules and report any issues to the home's administration for resolution.

(d) Quarterly Drug Regimen Reviews. The home must secure the services of a licensed pharmacist to perform all of the following duties:

(i) conduct quarterly reviews of the drug regimen for each resident of the assisted living community and report any irregularities to the assisted living community administration;

(ii) remove for proper disposal any drugs that are expired, discontinued or in a deteriorated condition or where the resident for whom such drugs were ordered is no longer a resident;

(iii) establish or review policies and procedures for safe and effective drug therapy, distribution, use and control; and

(iv) monitor compliance with established policies and procedures for medication handling and storage.

(e) Authorized Tasks for Certified Medication Aides. A home may allow a certified medication aide to do only the following tasks related the administration of medications utilizing only unit or multidose packaging of medications:

(i) Administer physician ordered oral, via a feeding tube, ophthalmic, topical, otic, nasal, vaginal and rectal medications;

(ii) Administer insulin, epinephrine, and B12 pursuant to physician direction and protocol;

(iii) Administer medications via a metered dose inhaler;

(iv) Conduct finger stick blood glucose testing following established protocol;

(v) Administer a commercially prepared disposable enema ordered by a physician;

(vi) Assist residents in the supervision of self-administration of medications; and

(vii) Administer liquid morphine to a resident of the community who is the patient of a licensed hospice, pursuant to a hospice physician's written order that contains specific instructions for indication, dosage, frequency and route of administration.

(f) Annual Competency Reviews. Complete comprehensive clinical skills competency reviews for each certified medication aide utilizing the skills competency checklist at least, annually after hiring to determine that the aides continue to have the necessary skills to perform the medication tasks assigned competently. Such skills competency checklists must be administered by Georgia-licensed registered nurses, pharmacists or physicians, who indicate in writing that the tasks observed are being performed competently.

(g) Proper Notice of Separation for Cause. Ensure that where a medication aide is terminated for cause relating to the performance of medication aide tasks, the aide is provided with the following:

(i) a separation notice that clearly describes the facts that support the termination for cause;

(ii) written notice that being terminated for cause related to the administration of medications, if not successfully appealed through a hearing on right to unemployment benefits will result in the loss of good standing on the Georgia Certified Medication Aide Registry; and

(iii) the loss of good standing on the Certified Medication Aide Registry will make the aide ineligible for hiring as a certified medication aide by another assisted living community.

(h) Registry Notification. Submit to the Georgia Certified Medication Aide Registry a copy of the Separation Notice for the certified medication aide only if the separation related specifically to the performance of medication aide tasks and the termination for cause has either been finally upheld by the Department of Labor or the time for appealing the Separation Notice has expired.

(7) Homes Conducting Certified Medication Aide Training. A home choosing to provide a certified medication aide training program must do all of the following:

(a) Utilize the state-approved medication aide training program ensuring that the training is administered by a Georgia licensed registered nurse, pharmacist, or physician;

(b) Require the aide to demonstrate the requisite clinical skills to serve as a medication aide before a Georgia-licensed registered nurse, pharmacist or physician utilizing the standardized medication administration checklist developed by the Department;

(c) Prepare the aide to take the written competency examination to become a certified medication aide;

(d) Verify that the aide is in good standing on the Georgia certified nurse aide registry;

(e) Provide information to the aide on the registration and locations for taking the written competency examination;

(f) Provide the documentation to the Georgia Certified Medication Aide Registry that is necessary to complete the application for placement of the aide's name on the Georgia Certified Medication Aide Registry; and

(g) Not permit the aide to administer medications independently unless the aide is listed on the Georgia certified medication aide registry in good standing.

(8) **Maintaining Records on Medication Assistance and Administration**. Where the home either provides assistance with, or supervision of self-administered medications, or administers medications to residents, the home must maintain a daily Medication Assistance Record (MAR) for each resident receiving such service.

(a) The MAR must include the name of the specific resident, any known allergies, the name and telephone number of the resident's health care provider, the name, strength and specific directions including a summary of severe side effects and adverse reactions for use of each medication and a chart for staff who provide assistance or administration to record initials, time and date when medications are taken, refused or a medication error is identified (e.g. missed dosage).

(b) The staff providing the assistance or administration of medications must update the MAR each time the medication is offered or taken.

(c) The home must make medication information concerning the descriptions of medication, dosing, side effects, adverse reactions and contraindications for each medication being administered to the residents immediately available for reference by staff providing medication assistance or administration.

(d) Staff providing assistance with or administration of medications must document in the resident's record any unusual reactions to the medications and provide such information to the resident, the resident's representative and the health care provider as appropriate.

(e) Refills of prescribed medications must be obtained timely so that there is no interruption in the routine dosing. Where the home is provided with a new medication for the resident, the MAR must be modified to reflect the addition of the new medication within 48 hours or sooner if the prescribing physician, advance practice registered nurse or physician assistant indicates that the medication change must be made immediately. In homes, where unit or multi-dose packaging is not available for immediate changes in medications, unit or multi-dose packaging of the medication must be obtained when the prescription is refilled.

(f) For any administration of liquid morphine by a certified medication aide, staff shall observe and document the following in the resident's record:

(i) the resident's need for PRN liquid morphine, including but not limited to verbalizations of pain, groaning, grimacing or restlessness;

(ii) the date, time and location of the initial dose administered by a licensed hospice health care professional;

(iii) the dosage, time and route of administration for the morphine administered in the community;

(iv) the training provided by the licensed hospice; and

(v) information regarding the special circumstances under which the hospice was unavailable to administer the medication.

(9) **Orders Required for All Medications**. A home must not allow its staff to assist with, provide supervision of self-administered medications, including over-the-counter medications, unless there is a physician, advance practice registered nurse or physician assistant's order or individualized prescription bottle, specifying clear instructions for its use on file for the resident.

(10) **Timely Management of Medication Procurement**. The home must obtain new prescriptions within 48 hours of receipt of notice of the prescription or sooner if the prescribing physician indicates that a medication change must be made immediately. If the pharmacy does not have the medication needed for the immediate change, available and has not obtained further directions from the physician, the home must notify the physician of the unavailability of the prescription and request direction.

(11) **Storage of Medications**.

(a) The home is accountable for having an effective system to manage the medications it receives including storing medications under lock and key, or other secure system to prevent unauthorized access, at all times, whether kept by a resident or kept by the home for the resident, except when required to be kept by a resident on his or her person due to need for frequent or emergency use, as determined by the resident's physician, advance practice registered nurse or physician assistant, or when closely attended by a staff member. Additionally, for controlled substances, the secure storage must be a locked cabinet or box of substantial construction and a log must be maintained and updated daily by the home to account for all inventory.

(b) Medication kept by a resident may be stored in the resident's bedroom, in a locked cabinet or other locked storage container. Single occupancy bedrooms which are kept locked at all times are acceptable. Duplicate keys for the resident's locked storage container and room must be available to the resident and the administrator, on-site manager or designated staff.

(c) Medications must be kept in original containers with original labels intact.

(d) A home may stock over-the-counter medications such as aspirin or acetaminophen for the convenience of residents who have PRN (as needed) orders for the specific medication and dosage. However, where the resident takes an over-the-counter medication daily as prescribed in a written order by a licensed physician, nurse practitioner or physicians assistant, such as vitamins or low-dose aspirins, the resident must have an individual bottle of the prescribed medication that is kept for the resident's individual usage.

(e) Unused or expired medications must be properly disposed of using the current U.S. Food and Drug Administration or U.S. Environmental Protection Agency guidelines for the specific medications.

(f) The supply of liquid morphine on site shall be limited to 50 ml for each hospice patient in the home for which there is a physician's order for such medication.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.20
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-7-1, 31-7-2, 31-7-2.1, 31-7-12, 31-8-180 et seq., 43-26-32.
History. Original Rule entitled "Additional Requirements for Specialized Memory Care Units or Homes" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.

Amended: New Title "Medications". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.21. Nutrition.

(1) A minimum of three regularly scheduled, well-balanced, meals must be provided seven days a week. There must be no more than 14 hours elapsing between the scheduled evening and morning meals. Meals must meet the general requirements for nutrition currently found in the Recommended Daily Diet Allowances, Food and Nutrition Board, National Academy of Sciences Meals must be of sufficient quantity, proper form, consistency and temperature. Food for at least one nutritious snack shall be available and offered each mid-afternoon and evening.

(2) Food received or used in a personal care home must be from satisfactory sources and must be clean, wholesome, free from spoilage, adulteration, and misbranding, and safe for human consumption.

(3) **Properly Furnished Food Areas.** A home must have a properly equipped kitchen with appropriate cabinets, drawers, holders and shelves or racks for storage of necessary equipment and utensils to prepare meals safely unless the home has arranged for meals to be obtained from a permitted food service establishment. The kitchen must be kept clean and disinfected at least daily unless more frequent sanitization is required to prevent the spread of infection or food borne illnesses.

(4) **Handling of Food.** All foods while being stored, prepared and served must be protected from spoilage and contamination and be safe for human consumption. The home must ensure that staff does the following:

(a) Store perishable foods properly, such as but not limited to meat, fish, eggs, dairy products, juices at temperatures that will minimize spoilage, i.e. at or below 41 degrees F.

(b) Thaw frozen foods properly, i.e. in the refrigerator or under cold running water with an unplugged sink.

(c) Provide hot and cold running water and sanitizing agents and ensure that they are used appropriately in the kitchen to clean and sanitize food, hands and utensils as required for safe food preparation.

(d) Prevent cross-contamination of foods via hands, cutting boards or utensils during preparation.

(e) Ensure that hot foods leave the kitchen (e.g. pot, steam table) for serving at or above 140 degrees F. and that cold foods leave the kitchen for serving at or below 41 degrees F.

(5) A home serving 25 or more residents must possess a valid food service permit issued through the authority of the Department of Public Health or a copy of the valid food service permit of the caterer who provides meals to the residents.

(6) **Catered Food Service.** When the a home uses a catered food service (food service establishment), the home must ensure that the service is properly licensed, provides meals in accordance with these rules, has a satisfactory record of compliance with food safety requirements and properly transports and stores food at time of delivery to maintain food safety.

(7) A home must maintain a three day supply of non-perishable food and water for emergency needs. The quantity of food required to be stored must be based on the usual resident census. The food must be kept in sealed containers which are labeled and dated. The food must be rotated in accordance with shelf life to ensure safety and palatability. Water sufficient for drinking and food preparation must also be stored.

(8) Menus must be written and posted 24 hours prior to serving the meal. Any change or substitution must be noted and considered as a part of the original menu. Alternatives to the food offered on the menu must be available to accommodate individual resident preferences.

(9) Homes must maintain records of all menus as served for 30 days after use.

(10) The person designated by the home as being responsible for managing the preparation of meals for the residents must enforce safe food handling practices which address basic food safety, hygiene, cross contamination, time and temperature requirements and sanitation with staff and residents.

(11) A home must arrange for special therapeutic diets as prescribed by the resident's physician, advance practice registered nurse of physicians assistant.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.21
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-1, 31-7-2.1, 31-7-12, 31-12-3.
History. Original Rule entitled "Medications" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Nutrition". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.22. Temperature Conditions.

(1) The temperature throughout the home must be maintained by an adequate heating and cooling systems or its equivalent at ranges which are consistent with individual health needs of residents and provides a comfortable environment for the residents.

(2) Temperatures in the home must not fall below 68 degrees during waking hours and 62 degrees F during sleeping hours. Mechanical cooling devices must be made available for

use in those areas of the building used by residents when inside temperatures exceed 80 degrees F. No resident must be in any residence area that exceeds 85 degrees F.

(3) Where a power outage or mechanical failure impacting the ability of the home to maintain appropriate temperature ranges occurs, the home must take immediate action to provide for the health and safety of the residents, including but not limited to, arranging immediately for a service call, providing additional blankets or fans or utilizing an emergency power generator in accordance with the home's emergency preparedness plan.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.22
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-2.1.
History. Original Rule entitled "Nutrition" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Temperature Conditions". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.23. Infection Control, Sanitation and Supplies.

(1) The home must have a supply of first-aid materials available for use. This supply must include, at a minimum, gloves, band aids, thermometer, tape, gauze, and an antiseptic.

(2) A home must provide hand-sanitizing agents or soap and water at the sinks, clean towels and toilet tissue at each commode.

(3) Hand washing facilities provided in both kitchen and bathroom areas must include hot and cold running water, soap, and clean towels.

(4) The home must have an effective infection control program which includes, at least the following:

(a) Training provided to staff on effective measures for minimizing the spread of infections and food borne illnesses.

(b) Responding to disease outbreaks appropriately and participating in infection control investigations.

(c) Staff demonstrating their understanding and use of proper infection control practices in their delivery of care to the residents.

(d) Enforcing work and return to work policies to minimize the spread of infection and illnesses.

(f) Providing notices as recommended by public health regarding outbreaks and infestation issues to residents, staff and any visitors. Homes licensed for twenty-five (25) or more beds must meet the notification requirements of the Rules and Regulations for Disaster Preparedness Plans, Chapter 111-8-16.

(5) The home must have an adequate supply of sanitizing and cleaning agents, e.g. effective hand hygiene products, hand soap, laundry soap, household disinfectants and other cleaning materials, properly stored to prevent accidental ingestion but available for and properly used in the home to minimize the spread of infections.

(6) Residents' private living spaces or bedrooms must be thoroughly cleaned and sanitized after residents move out of the rooms.

(7) The home must clean the residents' private living spaces periodically and as needed to ensure that the space does not pose a health hazard.

(8) Homes licensed for twenty-five (25) or more beds must follow the additional infection control requirements set forth in the Rules and Regulations for Disaster Preparedness Plans, Chapter 111-8-16, regarding pandemic plans, supplies and policies and procedures.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.23
Authority: O.C.G.A. §§ 31-2-7, 31-2-9, 31-7-2.1, 31-7-12.3, 31-7-12.5.
History. Original Rule entitled "Temperature Conditions" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Infection Control, Sanitation and Supplies". F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-62-.24. Resident Files.

(1) An individual resident file must be maintained by the administrator or on-site manager for each resident in the home. Personal information must be treated as confidential and must not be disclosed except to the resident and his or her representative or legal surrogate, if any, an authorized agent of the Department, and others to whom written authorization is given by the resident or his representative or legal surrogate, if any. The resident file must be made available for inspection and/or copy to the Department, the resident or the resident's representative or legal surrogate, if any, upon request.

(2) Each resident file must include the following information:

(a) Identifying information including name, social security number, veteran status and number, age, sex, and previous address.

(b) Name, address and telephone number of next of kin, legal guardian and/ or representative or legal surrogate, if any, or representative payee and any court order or written document designating the resident's representative or legal surrogate, if any.

(c) Name, address and telephone number of any person or agency providing additional services to the resident. This information must include the name of the agency personnel primarily responsible, (i.e. the caseworker, case manager, or therapist).

(d) An admission and discharge log to include the date of admission, prior residence of resident, referral source, agency-contact and telephone number of referral source.

(e) Date of discharge, facility or residence discharged to and telephone number.

(f) The name, address and telephone number of a physician, hospital and pharmacy of the resident's choice.

(g) A record of all monetary transactions conducted on behalf of the resident with itemized receipts of all disbursements and deposits.

(h) A record of all monies and other valuables entrusted to the home for safekeeping; a receipt for same shall be provided to the resident or representative or legal surrogate, if any, at the time of admission and at anytime thereafter when the resident acquires additional property and wishes to entrust such property to the home for safekeeping.

(i) Health information including all health appraisals, diagnoses, prescribed diets, medications, and physician's instructions.

(j) An inventory of all personal items brought to the home by the resident to be updated at anytime after admission if a resident or representative or legal surrogate, if any, submits to the home a new inventory of the resident's personal items.

(k) A signed copy of the Resident's Rights form.

(l) A signed copy of the admission agreement.

(m) Any power of attorney or document issued by a court or by the Social Security Administration or any other governmental authority which designates another person as responsible for management of the resident's finances.

(n) A copy of a living will and/or durable power of attorney for health care if executed prior to 2007 or a copy of the Georgia advance directive for health care and a physician's order for life-sustaining treatment, if any. At least the advance directive for health care form must be made available at the time of admission and shall remain available to the resident.

(o) A copy of the resident's written waiver of the personal needs allowance charge pursuant to the provisions of Rule 111-8-62-.26(p)1.

(p) Any signed medical orders impacting end of life care, e.g. do not resuscitate, physician's orders for life sustaining treatment.

(q) All individual written care plans required by these rules and the rules for proxy caregivers, Chapter 111-8-100 if applicable.

(r) Any informed written consents signed by the resident or resident's representative, designating and delegating to any trained proxy caregiver, whether employed by the home or not, the performance of identified health maintenance activities.

(s) A copy of the search results obtained from the National Sex Offender Registry website maintained through the Department of Justice and any resulting safety plan for residents, staff and visitors.

(3) The following information may be requested to be given voluntarily by the resident, guardian, or representative or legal surrogate, if any, but may not be required of the resident:

(a) Spiritual preference e.g., church membership, name and telephone number of minister, priest, rabbi, or imam.

(b) Information about insurance policies and prearranged funeral and burial provisions, if any.

(4) Resident files must be maintained by the home for a period of three years after a resident's discharge.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.24
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-2.1, 31-7-12.3, 31-8-131, 32-32-1.
History. Original Rule entitled "Supplies" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Resident Files". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.25. Supporting Residents' Rights.

(1) The home must operate in a manner that respects the personal dignity of the residents and the human rights of the residents, which rights cannot be waived, except as provided in these rules by the resident or the resident's representative or legal surrogate.

(a) Each resident must receive care, and services which must be adequate, appropriate, and in compliance with applicable federal and state law and regulations.

(b) The home, its agents or employees, must not punish or harass the resident, because of the resident's efforts to enforce his or her rights.

(c) Each resident must have the right to:

1. Exercise the constitutional rights guaranteed to citizens of this state and this country including, but not limited to, the right to vote.

2. Choose activities and schedules consistent with the resident's interests and assessments.

3. Interact with members of the community both inside and outside the home and to participate fully in the life of the community.

4. Make choices about aspects of his or her life in the home that are significant to the resident.

(d) Each resident must have the right to enjoy privacy in his or her room; home personnel and others must respect this right by knocking on the door before entering the resident's room.

(e) Each resident must have the right to associate and communicate freely and privately with persons and groups of the resident's choice without being censored by staff.

(f) Each resident must be treated with dignity, kindness, consideration and respect and be given privacy in the provision of personal care. Each resident must be accorded privacy and freedom for the use of bathrooms at all hours.

(g) No religious or spiritual belief or practice may be imposed upon any resident. Residents must be free to practice their religious beliefs as they choose. Each resident must have the right to participate in social, religious, and community activities that do not interfere with the rights of other residents.

(h) Each resident has the right to be free from mental, verbal, sexual and physical abuse, neglect and exploitation. Each resident has the right to be free from actual or threatened physical or chemical restraints and the right to be free from isolation, corporal or unusual punishment and interference with the daily functions of living, such as eating or sleeping.

(i) Each resident has the right to use, keep and control his or her own personal property and possessions in the immediate living quarters, except to the extent a resident's use of his or her property would interfere with the safety or health of other residents. Each resident has the right to reasonable safeguards for the protection and security of his or her personal property and possessions brought into the home.

(j) Each resident's mail must be delivered unopened to the resident on the day it is delivered to the home. Each resident's outgoing correspondence may not be opened or tampered with prior to being mailed or otherwise delivered.

(k) Each resident must have access to a telephone and the right to have a private telephone, at the resident's own expense. Telephones must be placed in areas to insure privacy without denying accessibility.

(l) Each home must permit immediate access to residents by others who are visiting with the consent of the resident. Residents have the right to have visitors at mutually agreed upon hours. Once the hours are agreed upon, no prior notice is necessary. Each resident has the right to refuse to see visitors or terminate any visit.

(m) Each resident has the right to manage his or her own financial affairs, including the right to keep and spend his or her own money unless that resident has been adjudicated incompetent by a court of competent jurisdiction. Each resident has the right to be free from coercion to assign or transfer to the home money, valuables, benefits, property or anything of value other than payment for services rendered by the home.

(n) Each resident has the right to a personal needs allowance for the free use of the resident in the amount of twenty dollars per week to be distributed by the administrator, on-site manager, or a responsible staff person in the home unless waived by the resident. The following conditions must be met regarding the personal needs allowance:

1. The personal needs allowance must be included as a charge for services to each resident's account which a resident or a resident's representative or legal surrogate, if any, may waive by signing a written waiver upon admission or anytime thereafter. No allowance charge may be assessed where a resident or a resident's representative or legal surrogate, if any, has signed a written waiver of the personal needs allowance. Such a waiver must be kept in a resident's file.

2. Where no waiver has been signed, the personal needs allowance must be tendered to each resident, in cash, on the same day each week.

3. The personal needs allowance must not be intended or needed for purchasing necessary goods such as toilet paper and light bulbs which the home ordinarily supplies, and must in no way relieve the home of the obligation to insure that such necessary goods are available to the resident.

(o) Each resident has the right to receive or reject medical care, dental care, or other services except as required by law or regulations.

(p) Each resident has the right to choose and retain the services of a personal physician and any other health care professional or service. No home is permitted to interfere with the resident's right to receive from the resident's attending physician complete and current information concerning the resident's diagnosis,

treatment and prognosis. Each resident and his or her representative or legal surrogate, if any, has the right to be fully informed about care and of any changes in that care and the right of access to all information in medical records retained in the home.

(q) Each resident has the right to fully participate in the planning of his or her care. Case discussion, consultation and examination shall be confidential and conducted discreetly. A person who is not directly involved in the resident's care may be present when care is being rendered only if he or she has the resident's permission.

(r) Each resident has the right to inspect his or her records on request. Each resident has the right to make a copy of all records pertaining to the resident. Each resident has the right to confidential treatment of personal information in the resident file.

(s) Each resident who has not been committed to the home by court order or who does not have a representative or legal surrogate with specific written authority to admit, transfer or discharge, may discharge or transfer himself or herself upon notification to the home in conformance with the home's policies and procedures.

(t) Each resident has the right to access to the State Long-Term Care Ombudsman Program O.C.G.A. § 31-8-50*et seq.* and the name, address, and telephone number of the ombudsman must be posted in a common area of the home.

(u) Residents have the right to form a Resident Council and have meetings in the home outside the presence of owners, management or staff members of the home.

(v) Each resident has the right to file a complaint with the Department concerning care being provided in the home that violates these rules. The home must post the name of the Department and the address and telephone number where licensing complaints are received in the common area of the home.

(2) Each resident must be provided, at the time of admission to the home, with a copy of the Resident's Bill of Rights, as provided in Rule 111-8-62-.25 which must include provisions for protecting the personal and civil rights of each resident. In the event that a resident is unable to read the Resident's Bill of Rights the manager must take special steps to assure communication of its contents to the resident.

(3) A personal care home must comply with the provisions of the "Remedies for Residents of Personal Care Homes Act" as outlined in O.C.G.A. § 31-8-131*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.25
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-2.1, 31-8-131*et seq.*, 31-32-1 *et seq.*
History. Original Rule entitled "Resident Files" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Supporting Residents' Rights". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.26. Procedures for Change in Resident Condition.

(1) In case of an accident or sudden adverse change in a resident's physical condition or emotional adjustment, a home must take the actions appropriate to the specific circumstances to address the needs of the resident, including notifying the representative or legal surrogate, if any. The home must retain a record of all such accidents or sudden adverse changes and the home's response in the resident's files.

(2) Where the sudden change in the resident's condition causes the resident to experience cardiac or respiratory arrest, the home must immediately take one of the following actions:

(a) If the resident is enrolled in a licensed hospice and has a specific hospice plan of care, the home must contact the hospice for directions regarding the care to be provided. If the hospice staff is not available to provide direction, then home must immediately contact the duly-appointed health care agent for direction. If no health care agent has been appointed or is not available and if no Do Not Resuscitate (DNR) order has been written, then the home must initiate cardiopulmonary resuscitation immediately and must contact emergency medical services immediately to arrange for emergency transport.

(b) If the resident has a valid DNR order, the caregiver may effectuate the DNR order if done in good faith.

(c) If the resident has appointed a health care agent in a living will, durable power of attorney for health care or an advance directive for health care which complies with the requirements of O.C.G.A. § 31-32-1*et seq.* then the home must immediately contact the health care agent for directions regarding the care to be provided. Where the health care agent is not immediately available and there is no valid DNR order for the resident, the home must initiate cardiopulmonary resuscitation immediately and contact emergency medical services to arrange for emergency transport.

(d) If the resident is not enrolled in hospice, and does not have either a DNR or an advance directive, then the staff of the home must immediately initiate cardiopulmonary resuscitation where it is not obvious from physical observation of the resident's body (e.g. body is stiff, cool to the touch, blue or grayish in color) that such efforts would be futile and there is not a physician, or authorized registered nurse or physician assistant on site to assess and provide other direction and contact emergency medical services immediately to arrange for emergency transport.

(3) The staff must have ready access to phone numbers for emergency medical personnel and the resident's file or appropriate emergency medical and contact information for each resident, both at the home and when residents are being transported by the home for any reason.

(4) An immediate investigation of the circumstances associated with an accident or injury involving a resident must be initiated by the administrator or on-site manager of the home. Additionally, a report of the occurrence of the accident or injury must be made to the representative or legal surrogate, if any, with a copy of the notification report maintained in the resident's file. The complete investigative review concerning the circumstances, cause of the incident and opportunities identified to improve care, must be retained in a central file for quality assurance/peer review.

(5) In the event a resident develops a significant change in physical or mental condition, the governing body must provide to the Department, upon request, a current physical examination report from a physician, nurse practitioner or physician assistant, indicating the resident's continued ability to meet the resident retention requirements in these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.26
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-2.1, 31-7-12.3, 31-8-50*et seq.*, 31-8-131 *et seq.*
History. Original Rule entitled "Residents' Rights" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Procedures for Change in Resident Condition". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.27. Death of a Resident.

(1) Should a resident die while in the home, the administrator, on-site manager or responsible staff person must immediately notify the resident's physician, the next of kin, and the representative or legal surrogate, as applicable. Statutes applicable to the reporting of sudden or unexpected death and reports which must accompany the deceased must be followed.

(2) Upon death of the resident, the home must refund to the representative or legal surrogate, as applicable, any security deposit made to the home by or on behalf of the resident in compliance with O.C.G.A. § 44-7-30*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.27
Authority: O.C.G.A. Secs. 31-2-7, 31-7-2.1, 31-2-9, 31-7-2.1, 44-7-30.
History. Original Rule entitled "Procedures for Change in Resident Condition" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Death of a Resident". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.28. Immediate Transfer of Residents.

(1) The administrator or on-site manager of the home must initiate immediate transfer if the resident develops a physical or mental condition requiring continuous medical care or nursing care or if a resident's continuing behavior or condition directly and substantially threatens the health, safety and welfare of the resident or any other resident.

(2) In the event such immediate transfer is required, the administrator or on-site manager of the home must advise both the resident and the resident's representative or legal surrogate and case manager, if any, and immediate arrangements must be made based on the written admission agreement to transfer such resident to an appropriate facility. The administrator or on-site manager must document in the resident's file the reasons for the transfer.

(3) Where immediate transfer is to be made pursuant to paragraphs (1) and (2), the administrator or on-site manager must make arrangements for transfer in accordance with the admission agreement and shall transfer the resident to an appropriate facility where the resident's needs can be met. Prior to making such transfer, the administrator or on-site manager must:

(a) Inform the resident and representative or legal surrogate and case manager, if any, of the reason for the immediate transfer.

(b) Inquire as to any preference of the resident and representative or legal surrogate, if any, regarding the facility to which the resident is to be transferred.

(c) Inform the representative or legal surrogate, if any, of the resident's choice regarding such transfer.

(d) Inform the resident and the representative or legal surrogate, if any, of the place to which the resident is to be transferred.

(e) Provide a copy of the resident file to the receiving facility within 24 hours of transfer.

(f) Document in the resident's file the following:

1. The reason for the immediate transfer.

2. The manner in which the resident and the representative or legal surrogate, if any, were informed pursuant to this paragraph.

3. The name, address, and telephone number of the place to which the resident is to be transferred or discharged.

(4) Upon immediate transfer of the resident, the home must refund to the resident or representative or legal surrogate, if applicable, any security deposit made to the home by or on behalf of the resident in compliance with O.C.G.A. § 44-7-30*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.28
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-2.1, 44-7-30*et seq.*
History. Original Rule entitled "Death of a Resident" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Immediate Transfer of Residents". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.29. Discharge or Transfer of Residents.

(1) The administrator or on-site manager must contact the representative or legal surrogate, if any, when there is need for discharge or transfer of a resident. The home must provide 30 days' written notice of its intent to discharge or transfer the resident unless an immediate transfer is required. The written notice must be issued to both the resident and the representative or legal surrogate, if any.

(2) In all cases, except those requiring immediate transfer pursuant to Rule 111-8-62-.28, residents whose needs cannot be met by the home or who no longer choose to live in the home must be discharged or transferred to an appropriate facility based on discharge and transfer procedures entered into at the time of admission. Where the resident is incapable of making informed decisions and there is no representative or legal surrogate or the representative or legal surrogate is unwilling to act, the administrator or on-site manager must petition the probate court in the county where the home is located for an order authorizing the discharge or transfer. The transferring home must provide a copy of the resident's file to the receiving facility prior to or at the time of transfer.

(3) Where the Department has reason to believe that a resident is receiving or requires continuous medical or nursing care, the Department may require the home to discharge the resident. However, the provision of medical, nursing or health services required by the resident on a periodic basis or for a short-term illness, where such services are not provided by the home is permissible.

(4) Upon discharge or transfer of the resident, the home must refund to the resident or representative or legal surrogate, if any, any security deposit made to the home by or on behalf of the resident in compliance with O.C.G.A. § 44-7-30*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.29
Authority: O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-2.1, 44-7-30*et seq.*
History. Original Rule entitled "Immediate Transfer of Residents" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Discharge or Transfer of Residents". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.30. Reporting.

(1) The staff of the personal care home must call the local police department to report the elopement of any resident from the home within 30 minutes of the staff receiving actual knowledge that such person is missing from the home in accordance with the Mattie's Call Act and the requirements set forth in O.C.G.A. § 35-3-170*et seq.* The home must also report the initiation and discontinuation of a Mattie's call to the Department utilizing the complaint intake system within 30 minutes of communications with local law enforcement authorities having occurred.

(2) The personal care home must report a serious incident using the complaint intake system and location designated by the Department within 24 hours following the occurrence of a serious incident or the home's learning that a serious incident involving a resident may have occurred. The serious incidents that must be reported to the Department include the following:

(a) Any accidental or unanticipated death of a resident not directly related to the natural course of the resident's underlying medical condition.

(b) Any serious injury to a resident that requires medical treatment.

(c) Any rape, assault, any battery on a resident, or any abuse, neglect, or exploitation of a resident in accordance with the Long Term Care Resident Abuse Reporting Act O.C.G.A. § 31-8-80*et seq.*

(d) An external disaster or other emergency situation that affects the continued safe operation of the residence.

(e) Any circumstances where a member of the governing body, administration, staff associated with or affiliated with the personal care home, or family member of staff becomes associated with an account at a financial institution, will, trust, benefit of substantial value or life insurance policy of a resident or former resident to verify that such gift is knowingly and voluntarily made and not the result of any coercion.

(f) When an owner, director or employee acquires a criminal record as defined in these rules.

(3) The incident report, submitted through the home's peer review process will be received by the Department in confidence and must include at least:

(a) The name of the personal care home and the name of the administrator or site manager.

(b) The date of the incident and the date the personal care home became aware of the incident.

(c) The type of incident suspected, with a brief description of the incident.

(d) Any subsequent remedial and quality measures determined through peer review to be taken by the personal care home to make such injury or harm arising from the particular incident less likely to recur.

(4) Where the Department determines that a rule violation related to the reported incident has occurred, the Department will initiate a separate complaint investigation of the incident. The complaint investigation report and the report of any rule violation compiled by the

Department arising either from the initial report received from the personal care home or an independent source is subject to disclosure in accordance with applicable laws.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.30
Authority: O.C.G.A. §§ 31-2-7, 31-7-2.1, 31-7-12, 31-8-80*et seq.* and 35-3-170 *et seq.*
O.C.G.A. Secs. 31-2-7, 31-2-9, 31-7-2.1, 31-7-12, 31-8-80*et seq.*, 35-3-170 *et seq.*, 44-7-30 *et seq.*
History. Original Rule entitled "Discharge or Transfer of Residents" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Reporting". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.31. Deemed Status.

The Department may accept the certification or accreditation of a home by an accreditation body or certifying authority recognized and approved by the Department provided that certification or accreditation constitutes compliance with standards that are substantially equivalent to these rules. Nothing herein shall prohibit any departmental inspection to determine compliance with licensure rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.31
Authority: O.C.G.A. Secs. 31-7-1, 31-2-9, 31-7-2.1, 31-7-3, 31-7-12, 31-8-80*et seq.*, 35-3-170 *et seq.*
History. Original Rule entitled "Reporting" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Deemed Status". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.32. Variance and Waiver.

(1) The Department may, in its discretion, grant variances and waivers of specific rules upon application or petition filed on forms provided by the Department. The Department may establish conditions which must be met by the home in order to operate under the variance or waiver granted.

(a) **Variance**. A variance may be granted by the Department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety, and care of the residents exist and will be met in lieu of the exact requirements of the rule or regulations in question. The Department may require additional documentation by the home to support its application for a variance or waiver.

(b) **Waiver.** The Department, in its discretion, may dispense entirely with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, care, and rights of the residents.

(c) **Experimental Variance or Waiver**. The Department may grant variances and waivers to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant or petitioner that the intended protections afforded by the rule or regulation which is the subject of the request are met and that the innovative approach has the potential to improve service delivery without compromising health, safety, residents' rights, or other relevant standards.

(2) The home may request a final review of the initial waiver or variance decision made by program staff to the chief of the division by filing a written request for review of the initial decision and providing any additional written information which supports the request for review. The chief of the division will issue a final decision on behalf of the Department. Where the governing body believes that the Department has abused its discretion in acting upon the waiver or variance request, it may seek appropriate relief.

(3) Where the Department has denied the application for a waiver or variance in writing, the Department will not consider a subsequent application for the same waiver or variance as a new application unless the applicant includes new evidence of a substantial change in the circumstances which formed the basis for the initial request.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.32
Authority: O.C.G.A. §§ 31-2-7, 31-7-2.1 and 31-7-12.
O.C.G.A. Secs. 31-2-7, 31-7-1, 31-7-2.1, 31-7-3, 31-7-12.
History. Original Rule entitled "Deemed Status" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Variance and Waiver". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.33. Enforcement and Penalties.

A home that fails to comply with licensing requirements contained in these rules, the Rules and Regulations for the Use of Proxy Caregivers, Chapter 111-8-100 as applicable and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25, is subject to civil and administrative actions brought by the Department to enforce licensing requirements as provided by law and rules. Such actions will be initiated in compliance with the Georgia Administrative Procedures Act, O.C.G.A. § 50-13-1*et seq.*, O.C.G.A. § 31-2-11 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.33
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*, 43-26-12 and 50-13-1 *et seq.*
O.C.G.A. Secs. 31-2-7, 31-2-8, 31-2-9, 31-7-1, 31-7-2.1, 31-7-12, 43-26-12 and 50-13-1*et seq.*
History. Original Rule entitled "Variance and Waivers" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Enforcement and Penalties". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Rule 111-8-62-.34. Severability.

In the event that any rule, sentence, clause or phrase of any of the rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions thereof shall remain in full force and effect as if such rule or portions thereof so determined, declared or adjudicated invalid or unconstitutional were not originally part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-62-.34
Authority: O.C.G.A. Secs. 31-2-7, 31-2-8, 31-2-11, 31-7-2.1, 31-7-1*et seq.*, 31-7-4.
History. Original Rule entitled "Enforcement and Penalties" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: New Title "Severability". F. Dec. 19, 2012; eff. Jan. 8, 2013.

Subject 111-8-63. RULES AND REGULATIONS FOR ASSISTED LIVING COMMUNITIES.

Rule 111-8-63-.01. Authority.

The legal authority for this Chapter is found in O.C.G.A. §§ 31-2-7 and Chapter 7 of Title 31.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.01
Authority: O.C.G.A. §§ 31-2-4, 31-2-7, 31-2-8, 31-2-9 and 31-7-1, *et seq.*
History. Original Rule entitled "Authority" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.02. Purpose.

The purpose of these rules and regulations is to establish the minimum standards for the operation of personal care homes to be licensed as assisted living communities. Such communities provide assisted living care to adults who require varying degrees of assistance with the activities of daily living but who do not require continuous medical or nursing care.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.02
Authority: O.C.G.A. §§ 31-2-7 and 31-7-1*et seq.*
History. Original Rule entitled "Purpose" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.03. Definitions.

In these rules, unless the context otherwise requires, the words, phrases and symbols set forth herein shall mean the following:

(a) "Abuse" means any intentional or grossly negligent act or series of acts or intentional or grossly negligent omission to act which causes injury to a resident, including but not limited to, assault or battery, failure to provide treatment or care, or sexual harassment of the resident.

(b) "Activities of daily living" means bathing, shaving, brushing teeth, combing hair, toileting, dressing, eating, walking, transferring from place to place, laundering, cleaning room, managing money, writing letters, shopping, using public transportation, making telephone calls, grooming, obtaining appointments, engaging in leisure and recreational activities, or other similar activities.

(c) "Administrator" means the manager designated by the Governing Body as responsible for the day-to-day management, administration and supervision of the assisted living community, who may also serve as the on-site manager and responsible staff person except during periods of his or her own absence.

(d) "Applicant" means an individual or entity that submits an application for licensure pursuant to these rules as described below:

1. When the assisted living community is owned by a sole proprietorship, the individual proprietor must be the applicant for the license, complete the statement of responsibility and serve as the licensee;

2. When the assisted living community is owned by a partnership, the general partners must be the applicant for the license, complete the statement of responsibility and serve as the licensee;

3. When the assisted living community is owned by an association, limited liability company (LLC) the governing body of the association or LLC must authorize the application for the license, complete the statement of responsibility and serve as the licensee; and

4. When the assisted living community is owned by a corporation, the governing body of the corporation must authorize the application for the license, complete the statement of responsibility and serve as the licensee.

(e) "Assistive device" means a device that may restrain movement which has been determined to be required by a licensed physician, nurse practitioner or physician's assistant working under a protocol or job description respectively and is applied for protection from injury or to support or correct the body alignment of the person, for the treatment of a person's physical condition, and may only be used as a treatment intervention where a specific written plan of care has been developed and the resident consents to such use.

(f) "Assisted living care" means the specialized care and services provided by an assisted living community which includes the provision of personal services, the administration of medications by a certified medication aide, the provision of assisted self-preservation, and the provision of limited nursing services.

(g) "Assisted living community" or "community" means a personal care home serving 25 residents or more that is licensed by the department to provide assisted living care.

(h) "Assisted self-preservation" means the capacity of a resident to be evacuated from an assisted living community to a designated point of safety and within an established period of time as determined by the Office of Fire Safety Commissioner. Assisted self-preservation is a function of all of the following:

1. the condition of the individual,

2. the assistance that is available to be provided to the individual by the staff of the assisted living community; and

3. the construction of the building in which the assisted living community is housed, including whether such building meets the state fire safety requirements applicable to an existing health care occupancy.

(i) "Certificate" means a certificate issued by the department to operate a memory care center in a licensed assisted living community or personal care home.

(j) "Chemical Restraint" means a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.

(k) "Department" means the Department of Community Health of the State of Georgia operating through the Division of Healthcare Facility Regulation.

(l) "Direct care staff person" means any employee, facility volunteer, or contract staff who provides to residents:

(i) any personal services, including but not limited to, medication administration or assistance, assistance with ambulation and transfer, and essential activities of daily living such as eating, bathing, grooming, dressing, and toileting; or

(ii) any other limited nursing services.

(m) "Director" means the chief administrator, executive officer or manager.

(n) "Disabled individual" means an individual that has a physical or mental impairment that substantially limits one or more major life activities and who meets the criteria for a disability under state or federal law.

(o) "Employee" means any person, other than a director, utilized by an assisted living community to provide personal services to any resident on behalf of the assisted living community or to perform at any facilities of the assisted living community any duties which involve personal contact between that person and any paying resident of the assisted living community.

(p) "Exploitation" means an unjust or improper use of another person or the person's property through undue influence, coercion, harassment, duress, deception, false representation, false pretense, or other similar means for one's own personal advantage.

(q) "Governing Body" means the owner, the board of trustees or directors, the partnership, the corporation, the association, the sole proprietorship or the person or group of persons who maintains and controls the assisted living community and who is legally responsible for the operation of the community.

(r) "Health maintenance activities" means those limited activities that, but for a disability, a person could reasonably be expected to do for himself or herself. Such activities are typically taught by a registered professional nurse, but may be taught by an attending physician, advanced practice registered nurse, physician assistant, or directly to a patient and are part of ongoing care. Health maintenance activities are those activities that do not include complex care such as administration of intravenous medications, central line maintenance, and complex wound care; do not require complex observations or critical decisions; can be safely performed and have reasonably precise, unchanging directions; and have outcomes or results that are reasonably predictable. Health maintenance activities conducted pursuant to this paragraph shall not be considered the practice of nursing.

(s) "Health services" means the specialized assistance that may be provided by or at the direction of either licensed healthcare professionals, such as doctors, nurses, physical therapists or through licensed healthcare programs, such as home health agencies, hospices and private home care providers to address health needs that the assisted living community is not staffed to provide or is not authorized by law or regulations to provide.

(t) "Injury" as used in the definition of "abuse" means a wrong or harm caused by an individual to a resident which is manifested by a physical or behavioral reaction or change in the appearance or actions of the resident, such as, but not limited to, reddened or bruised skin not related to routine care, crying, startling or cowering reaction by the resident and malnutrition or pressure ulcers for which the facility has not provided proper care.

(u) "Legal Surrogate" means a duly appointed person who is authorized to act, within the scope of the authority granted under the legal surrogate's appointment, on behalf of a resident who is adjudicated incapacitated.

(v) "Limited nursing services" means the assessment of the physical, mental, and emotional status to determine the appropriate level of care for an individual; the performance of health maintenance activities, as defined in division (a)(9)(C)(ii) of Code Section 43-26-12; and the provision of any nursing care within the direct care staff person's scope of practice that can be completed within seven days or intermittently.

(w) "Medical services" means services which may be provided by a person licensed pursuant to Article II of Chapter 34 of Title 43 of the Official Code of Georgia Annotated.

(x) "Memory care services" means the additional watchful oversight systems and devices that are required for residents who have cognitive deficits which may impact memory, language, thinking, reasoning, or impulse control, and which place the residents at risk of

eloping, i.e. engaging in unsafe wandering activities outside the assisted living community.

(y) "Memory care center" means the freestanding or incorporated specialized unit that either:

(i) holds itself out as providing additional or specialized care to persons with diagnoses of probable Alzheimer's or other dementias or with cognitive deficits that may place the resident at risk; or

(ii) charges higher rates for care for residents with Alzheimer's or other dementias than for care to other residents.

(z) "Non-Family Adult" means a resident 18 years of age or older who is not related by blood within the third degree of consanguinity or by marriage to the person responsible for the management of the assisted living community or to a member of the governing body.

(aa) "Nursing services" means those services which may be rendered by a person licensed pursuant to Articles I and 2 of Chapter 26 of Title 43 of the Official Code of Georgia Annotated.

(bb) "On-site manager" means the administrator or person designated by the administrator as responsible for carrying out the day-to-day management, supervision, and operation of the assisted living community, who may also serve as responsible staff person except during periods of his or her own absence.

(cc) "Owner" means any individual or any person affiliated with a corporation, partnership, or association with 10 percent or greater ownership interest in the business or agency licensed as an assisted living community and who:

1. purports to or exercises authority of an owner in the business or agency;

2. applies to operate or operates the business or agency;

3. maintains an office on the premises of the assisted living community;

4. resides at the assisted living community;

5. has direct access to persons receiving care at the assisted living community;

6. provides direct personal supervision of assisted living community personnel by being immediately available to provide assistance and direction during the time such assisted living community services are being provided; or

7. enters into a contract to acquire ownership of such a business or agency.

(dd) "Permit" or "license" means the authorization granted by the Department to the governing body to operate an assisted living community.

(ee) "Personal care home" means any dwelling, whether operated for profit or not, which undertakes through its ownership or management to provide or arrange for the provision of housing, food service, and one or more personal services for two or more adults who are not related to the owner or administrator by blood or marriage.

(ff) "Personal Services" includes, but is not limited to, individual assistance with or supervision of self-administered medication, assistance, essential activities of daily living such as eating, bathing, grooming, dressing, toileting, ambulation and transfer.

(gg) "Physical Restraints" are any manual or physical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom or normal access to one's body. Physical restraints include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, and wheelchair safety bars. Also included as restraints are assisted living community practices which function as a restraint, such as tucking in a sheet so tightly that a bedbound resident cannot move, bedrails, or chairs that prevent rising, or placing a wheelchair-bound resident so close to a wall that the wall prevents the resident from rising. Wrist bands or devices on clothing that trigger electronic alarms to warn staff that a resident is leaving a room do not, in and of themselves, restrict freedom of movement and should not be considered as restraints.

(hh) "Physician" means an individual who is currently licensed to practice medicine in the State of Georgia. For purposes of these rules, it shall be acceptable for any activities required to be performed by a physician to be performed by any other licensed medical professional (i.e., Nurse Practitioner, Physician Assistant, etc.) who is permitted to perform such activities under applicable state scope of practice rules and regulations.

(ii) "Plan of Correction" means the written plan prepared in response to cited rule violations that identifies by date certain the specific actions that will be taken by the assisted living community to come into compliance with these rules.

(jj) "Proxy caregiver" means an unlicensed person or a licensed health care facility that has been selected by a disabled individual or a person legally authorized to act on behalf of such individual to serve as such individual's proxy caregiver and meets the requirements contained in the Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, Chapter 111-8-100.

(kk) "Representative" means a person who voluntarily, with the resident's written authorization, acts upon resident's direction with regard to matters concerning the health and welfare of the resident, including being able to access personal and medical records contained in the resident's file and receive information and notices pertaining to the resident's overall care and condition. This written authorization may take the form of an advance directive.

(ll) "Resident" means any non-family adult who receives or requires assisted living care and resides in the assisted living community.

(mm) "Responsible Staff Person" means the employee designated by the administrator or on-site manager as responsible for supervising the operation of the assisted living community during periods of temporary absence of the administrator or on-site manager.

(nn) "Self-administration of medications" or "self-administered medications" means those prescription or over-the-counter drugs that the resident personally chooses to ingest or apply where the resident has been assessed and determined to have the cognitive skills necessary to articulate the need for the medication and generally knows the times, and physical characteristics of medications to be taken.

(oo) "Self-preservation" means the ability to respond to an emergency condition, whether caused by fire or otherwise, and escape the emergency without physical, hands-on assistance from staff. The resident may move from place to place by walking, either unaided or aided by prosthesis, brace, cane, crutches, walker or hand rails, or by propelling a wheelchair.

(pp) "Staff" means any person who performs duties in the assisted living community on behalf of the assisted living community.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.03
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-2-9, 31-7-1, 31-7-12.2, 43-26-12.
History. Original Rule entitled "Definitions" adopted. F. Nov. 19, 2009; eff. Dec. 9, 2009.
Amended: F. Dec. 19, 2012; eff. Jan. 8, 2013.
Amended: F. Apr. 16, 2018; eff. May 6, 2018.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.04. Exemptions.

These regulations do not apply to the following facilities:

(a) boarding homes or rooming houses which provide no services other than lodging and meals;

(b) facilities offering temporary emergency shelter, such as those for the homeless and victims of family violence;

(c) other facilities, homes or residences licensed by the department which have not been classified as assisted living communities, e.g. community living arrangements, personal care homes, hospices, traumatic brain injury facilities;

(d) facilities providing residential services for federal, state or local correctional institutions under the jurisdiction of the criminal justice system;

(e) charitable organizations providing shelter and other services without charging any fee to the resident or billing any fee on behalf of the residents;

(f) group residences organized by or for persons who choose to live independently or who manage their own care and share the cost of services including but not limited to attendant care, transportation, rent, utilities and food preparation;

(g) facilities licensed by the Department of Behavioral Health, Developmental Disabilities and Addictive Diseases; or

(h) host homes as defined in O.C.G.A. § 37-1-20(18).

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.04
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*, 37-1-20 and 37-1-29.
History. Original Rule entitled "Exemptions" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.05. Application for Permit.

(1) The governing body of each assisted living community must submit to the Department an application for a permit in order to operate.

(2) The application for a permit must be made on forms made available by the Department or in a format acceptable to the Department.

(3) No application for licensure will be acted upon by the Department unless it has been determined to be complete and include all required attachments and fees due the Department as specified in the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

(4) Each application for a permit must be accompanied by an accurate floor plan showing windows, doors, common areas, and resident room measurements and digital copies in .jpg format of pictures of the assisted living community's exterior, common areas and typical resident room.

(5) The name of the administrator or on-site manager, who will be working in the assisted living community, if known, must be included with the application for a permit. If such information is not known at the time of application, it must be provided to the Department before a permit will be issued.

(6) The ownership of the assisted living community must be fully disclosed in the application for a permit. In the case of corporations, partnerships, and other entities recognized by statute, the corporate officers and all other individuals or family groups owning ten percent or more of the corporate stock or ownership must be disclosed in the application, as well as the registered agent for service of process.

(7) Each application must include documentation of ownership or lease agreement for the property on which the assisted living community will be operated.

(8) The filing of an application for licensure constitutes a representation that the applicant is or will be in complete control of the community as of a specified date.

(9) Local zoning and other local requirements regarding the proper location and establishment of the assisted living community must be addressed by the applicant with the responsible local officials.

(10) The initial application for licensure shall include a financial stability affidavit from a certified public accountant affirming the applicant's ability to operate as a going concern for the next two years.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.05
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-2-9, 31-7-1 et seq.
History. Original Rule entitled "Application for Permit" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.06. Permits.

(1) The governing body of each assisted living community must obtain a valid permit from the Department to provide assisted living care prior to admitting any residents.

(2) The permit must be displayed on the premises in a conspicuous place that is visible to residents and visitors.

(3) Permits are not transferable from one assisted living community or location to another.

(4) A permit must be returned to the Department and is no longer valid when any of the following events occurs:

(a) The assisted living community is moved to another location which has not been licensed.

(b) The ownership of the community changes.

(c) The permit is suspended or revoked.

(5) A separate permit is required for each assisted living community located on different premises.

(6) An assisted living community must not serve more residents than its approved licensed capacity, which is listed on the face of the permit issued by the Department.

(7) An assisted living community must provide assisted living care as authorized by law and these rules.

(8) An assisted living community must disclose its licensure classification as an assisted living community in its marketing materials.

(9) An assisted living community must not operate or allow another business to operate on the premises of the assisted living community where the business intrudes on the residents' quiet enjoyment and exclusive use of the premises, in any way.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.06
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-2-9 and 31-7-1*et seq.*
History. Original Rule entitled "Permits" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.07. Owner Governance.

(1) The assisted living community must have a functioning governing body which is responsible for providing the oversight necessary to ensure that the community operates in compliance with these rules, the Rules for General Licensing and Enforcement, Chapter 111-8-25, the Rules for Proxy Caregivers, Chapter 111-8-100, as applicable and other applicable state laws and regulations.

(2) The governing body is responsible for implementing policies, procedures and practices in the community that support the core values of dignity, respect, choice, independence and privacy of the residents in a safe environment and in accordance with these rules. At a minimum, the policies and procedures that are developed must provide direction for the staff and residents on the following:

(a) the services available in the assisted living community, including, personal services, assisted living care, memory care services and any other specialized services such as memory care centers and designated proxy caregivers;

(b) the staffing plan that the community utilizes to ensure that staffing ratios increase proportionally as the number of residents who require assisted self-preservation increases;

(c) admissions, discharges and immediate transfers which ensure that the community does not admit or retain residents who need more care that the assisted living community is authorized or capable of providing;

(d) refunds when a resident is transferred or discharged;

(e) training and ongoing evaluation of staff, including specialized training if designated proxy caregivers are provided or memory care is offered;

(f) house rules and their enforcement;

(g) protecting the rights of the residents as set forth in these rules;

(h) medication management, procurement, the use of certified medication aides and professional oversight provided for such services;

(i) health and hygiene issues for residents and staff relating to infection control, work policies and return to work policies, food borne illnesses and reportable diseases;

(j) the investigation and reporting of abuse, neglect, exploitation of residents, residents' wandering away from the community, accidents, injuries and changes in residents' conditions to required parties;

(k) discipline procedures for handling acts committed by staff which are inconsistent with the policies of the assisted living community;

(l) emergency preparedness, drills and evacuation requirements;

(m) quality assurance review mechanisms, including resident and family feedback to determine opportunities for improving care;

(n) the use of volunteers and their orientation regarding resident's rights and basic safety precautions;

(o) the specific use of proxy caregivers allowed within the community and the oversight of proxy caregivers the community requires or provides in accordance with Georgia law, these rules and the rules for proxy caregivers, Chapter 111-8-100; and

(p) the safety and security precautions that will be employed by the assisted living community to protect residents from harm by other residents, designated proxy caregivers, and other individuals, not employed by the community who routinely come into the community.

(3) The governing body must designate an administrator or on-site manager as responsible for the overall management of the assisted living community and for carrying out the rules and policies adopted by the governing body.

(4) The governing body must ensure that the Department has current emergency contact information consisting of name, e-mail contact for notifications to the licensed community, physical addresses, and phone numbers for the governing body and the administrator or on-site manager of the assisted living community.

(5) The governing body must take appropriate measures within its control, to protect the residents from criminal activity occurring in the assisted living community.

(6) The governing body must not allow persons who are not residents of the assisted living community to live on the premises if they are listed on the National Sex Offender Registry.

(7) No member of the governing body, administration, or staff of the assisted living community or an affiliated assisted living community or family members of the governing body or any staff may serve as the legal surrogate or representative of a resident.

(8) Where the governing body, a member of the governing body's family or a staff member of the assisted living community or an affiliated assisted living community serves as the representative payee of a resident, the individual or entity must be covered by a surety bond.

(9) Notification of Emergency Relocation**.** The community must provide timely notification of the relocation address to the residents, their family contacts and representatives, if any, and the department whenever the community must relocate the residents as a result of an emergency situation which disrupts the provision of room and board for the residents at the licensed location.

(10) Notification of Bankruptcy, Eviction or Change of Ownership. The community must provide:

(a) a minimum of sixty (60) days written notice to the department and all residents of any impending bankruptcy or property eviction that may force discharge or relocation of residents or otherwise adversely impact the provision of safe care and oversight; and

(b) a minimum of thirty (30) days written notice to the department and all residents of any impending change of ownership. The notice to the department shall be in the form of an application which must be approved before the permit is issued to the new owner(s).

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.07
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1 et seq.
History. Original Rule entitled "Owner Governance" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.08. Community Leadership.

(1) Each community must have a full-time administrator to provide day-to-day leadership to the community. The administrator must be 21 years of age or older and hold a valid license from the State Board of Long-Term Care Facility Administrators with an effective date no greater than sixty (60) days from the date of hire or July 1, 2021, whichever is later.

(2) The administrator is responsible for ensuring that the policies and procedures are effective and enforced to ensure compliance with these rules and community policies and procedures.

(3) Each assisted living community must have a separate administrator or on-site manager who works under the supervision of the administrator.

(4) The administrator or on-site manager must designate qualified staff as responsible staff to act on his or her behalf and to carry out his or her duties in the absence of the administrator or on-site manager.

(5) Residents must not be allowed to function or be counted as staff.

(6) Staff must be assigned duties consistent with their positions, training, experiences, and the requirements of Rule 111-8-63-.09.

(7) The administrator is responsible for ensuring that the assisted living community has an effective quality assurance program which includes at least the following:

(a) investigating resident incidents which result in injuries or death in order to identify and implement opportunities for improvement in care;

(b) implementing changes made to support improved care, such as those necessary to minimize illness outbreaks and eliminate identified rule violations;

(c) monitoring staff performance to ensure that care and services are being delivered safely and in accordance with these rules and community policies; and

(d) obtaining and using feedback from the residents and representatives, at least annually, on the quality of services provided by the community and opportunities for improvement of services.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.08
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1 et seq., 43-27-1 et seq.
History. Original Rule entitled "Community Leadership" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.09. Workforce Qualifications, Training and Staffing.

(1) **The on-site manager and responsible staff persons must be at least 21 years of age and responsible for supervising the provision of care by all other staff**. No staff person under the age of 18 is permitted to work in the assisted living community unless there is direct line-of-sight supervision being provided by the administrator, on-site manager or a responsible staff person or the staff member is at least 17 years of age and

has successfully completed a vocational technical training track as a nursing assistant through a Georgia high school.

(2) **Initial Training for All Staff**. The administrator or on-site manager must ensure that any person working in the assisted living community as staff, receives training within the first 60 days of employment on the following:

(a) residents' rights and identification of conduct constituting abuse, neglect or exploitation of a resident and reporting requirements to include the employee's receipt of a copy of the Long-Term Care Facility Resident Abuse Reporting Act as outlined in O.C.G.A. § 31-8-81 et seq.;

(b) general infection control principles including importance of hand hygiene in all settings and attendance policies when ill;

(c) training necessary to carry out assigned job duties; and

(d) emergency preparedness.

(3) **Initial Training for Staff Providing Hands-On Personal Services**. In addition to the initial training required of all staff in paragraph (2) above, the administrator must ensure that staff hired to provide hands-on personal services to residents receive training within the first 60 days of employment which includes the following:

(a) current certification in emergency first aid except where the staff person is a currently licensed health care professional;

(b) current certification in cardiopulmonary resuscitation where the training course required return demonstration of competency;

(c) medical and social needs and characteristics of the resident population, including special needs of residents with dementia;

(d) residents' rights and the provision of care to residents that is individualized and helpful; and

(e) training specific to assigned job duties, such as, but not limited to, permissible assistance with medications, contraindications for medications that must be brought to the attention of appropriate individuals, assisting residents in transferring, ambulation, proper food preparation, proper performance of health maintenance activities if serving as a designated proxy caregiver and responding appropriately to dementia-related behaviors.

(4) **Trained Staff Present**. At least two staff who have completed the minimum training requirements of Rule 111-8-63-.09(2)(a) through (d) and (3)(a) through (e) above must be present in the assisted living community at all times any residents are present, with at least one staff person on each occupied floor, to provide necessary oversight and

assistance to staff providing hands-on personal services who have not completed the training, to ensure that care and services are delivered safely and in accordance with these rules.

(5) **Training Hours Required During First Year of Employment**. All staff offering hands-on personal services to the residents, including the administrator or on-site manager, must satisfactorily complete a total of at least twenty-four (24) hours of continuing education within the first year of employment as a direct care worker. The courses offered must be relevant to assigned job duties and include such topics as cardiopulmonary resuscitation and first aid certifications, utilizing standard precautions in working with aging residents, working with residents with Alzheimer's or other cognitive impairments, working with persons who have developmental disabilities or persons who have mental illness, providing social and recreational activities, understanding legal issues, performing necessary physical maintenance, fire safety, housekeeping activities, recognizing and reporting abuse, neglect and exploitation, preparing and serving food safely, preserving the dignity and rights of residents receiving care to make meaningful choices, providing and documenting medication assistance, or other topics as determined necessary by the Department to support compliance.

(6) **Ongoing Staff Training**. Beginning with the second year of employment, staff providing hands-on personal services must have a minimum of sixteen (16) hours of job-related continuing education as referenced in paragraph 111-8-63-.09(5) above annually.

(7) **Training Records**. The community must maintain documentation reflecting course content, instructor qualifications, agenda and attendance rosters for all trainings provided.

(8) **Proxy Caregiver Training**. An assisted living community employing proxy caregivers must provide training to the proxy caregivers in accordance with the Rules and Regulations for Use of Proxy Caregivers, Chapter 111-8-100 subject to the limitation that only certified medication aides may administer medications on behalf of the community.

(9) **Hospice Training**. The assisted living community shall ensure that any medication aide(s) who will be administering liquid morphine to any hospice patient(s) residing in the community receive adequate training from a licensed hospice on the safe and proper administration of liquid morphine prior to such administration and on an annual basis thereafter. The community shall maintain documentation of all training provided.

(10) **Staff Health Examinations and Screenings**. The administrator, on-site manager, and each employee must have received a tuberculosis screening and a physical examination by a licensed physician, nurse practitioner or physician's assistant within twelve months prior to providing care to the residents. The physical examination must be sufficiently comprehensive to assure that the employee is physically qualified to work and free of diseases communicable within the scope of employment. Follow-up examinations must be conducted by a licensed physician, nurse practitioner or physician's assistant for each administrator or staff person to determine readiness to return to work following a significant illness or injury. Health information, screenings, assessments and medical

releases regarding each staff member must be retained in a readily retrievable format by the assisted living community and made available for review and/or copying by Department representatives upon request.

(11) **Criminal History Background Checks for Owners Required**. The owner of the business or agency applying for the license must comply with the requirements of the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(12) **Criminal History Background Checks for Director, Administrator and Onsite Manager Required**. Prior to serving as a director, administrator or onsite manager of an assisted living community, the community must obtain a satisfactory fingerprint records check determination for the person to be hired in compliance with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(13) **Criminal History Background Checks for Direct Access Employees Required**. Prior to serving as a direct access employee, the community must obtain a satisfactory fingerprint records check determination for the person to be hired in compliance with the Rules and Regulations for Criminal Background Checks, Chapter 111-8-12.

(14) The administrator or on-site manager must obtain an employment history for each employee and maintain documentation in the employee's file. If the potential employee has no prior employment history, then the assisted living community must retain documentation of a satisfactory personal reference check.

(15) Personnel files must be maintained in the assisted living community for each employee and for three years following the employee's departure or discharge. These files must be available for inspection by departmental staff but must be maintained to protect the confidentiality of the information contained in them from improper disclosure. The files must include the following:

(a) evidence of a satisfactory fingerprint record check determination, if applicable;

(b) report of physical examination completed by a licensed physician, nurse practitioner or physician's assistant, and a TB screening completed within the 12 months preceding the date of hire;

(c) evidence of trainings, skills competency determinations and recertifications as required by these rules and, if applicable, the Rules for Proxy Caregivers, Chapter 111-8-100;

(d) employment history, including previous places of work, employers and telephone contacts with previous employers;

(e) supporting documentation reflecting that the employee has the basic qualifications as represented, e.g. documentation of good standing by nursing board, no findings of abuse, neglect or exploitation entered against the individual

in the nurse aide registry, satisfactory report of motor vehicle driving record where the employee may be transporting residents; and

(f) written evidence of satisfactory initial and annual work performance reviews for unlicensed staff providing hands-on personal care. Where the unlicensed staff perform specialized tasks, such as health maintenance activities, assistance with medications or medication administration, such performance reviews must include the satisfactory completion of skills competency checklists as specified in applicable rules. Such reviews must be conducted by staff or contractors qualified by education, training and experience to assess that the assigned duties are being performed in accordance with these rules and accepted health and safety standards.

(16) Where the assisted living community permits a resident to hire his or her own companion-sitter, proxy caregiver to perform health maintenance activities or aide of any sort, the assisted living community must require assurance that the companion-sitter, proxy caregiver or aide so hired is familiar with emergency evacuation routes and has documentation reflecting compliance with the provisions of the Rules for Proxy Caregivers, Chapter 111-8-100, as applicable.

(17) The administrator, on-site manager, and staff persons must not be under the influence of alcohol or other controlled substances while engaged in any work-related activity on behalf of the assisted living community.

(18) The community must maintain an average monthly minimum on-site staff to resident ratio of one awake direct care staff person per 15 residents during waking hours and one awake direct care staff person per 20 residents during non-waking hours where the residents have minimal care needs. Average monthly minimum staffing levels shall be calculated and documented by the community using methods and forms specified by the department. However, the assisted living community must staff above these minimum on-site staff ratios to meet the specific residents' ongoing health, safety and care needs.

(a) Staff, such as cooks and maintenance staff, who do not receive on-going direct care training and whose job duties do not routinely involve the oversight or delivery of direct personal care to the residents, must not be counted towards these minimum staffing ratios. Personnel who work for another entity, such as a private home care provider, hospice, etc. or private sitters cannot be counted in the staff ratios for the assisted living community.

(b) At least two on-site direct care staff persons must be on the premises 24 hours per day providing supervision whenever residents are present, with at least one staff person on each occupied floor.

(c) A registered professional nurse or licensed practical nurse must be on-site to support care and oversight of the residents, as follows:

(i) For communities with one to 30 residents, a minimum of 8 hours per week;

(ii) For communities with 31 to 60 residents, a minimum of 16 hours per week;

(iii) For communities with 61 to 90 residents, a minimum of 24 hours per week;

(iv) For communities with more than 90 residents, a minimum of 40 hours per week;

(d) Residents must be supervised consistent with their needs.

(19) Sufficient staff time must be provided by the assisted living community such that each resident:

(a) receives services, treatments, medications and diet as prescribed;

(b) receives proper care to prevent decubitus ulcers and contractures;

(c) is kept comfortable and clean;

(d) is treated with dignity, kindness, and consideration and respect;

(e) is protected from avoidable injury and infection;

(f) is given prompt, unhurried assistance if she or he requires help with eating;

(g) is given assistance, if needed, with daily hygiene, including baths and oral care; and

(h) is given assistance in transferring and assisted self-preservation when needed.

(20) All persons, including the administrator or on-site manager, who offer direct care to the residents on behalf of the assisted living community, must maintain an awareness of each resident's normal appearance and must intervene, as appropriate, if a resident's state of health appears to be in jeopardy.

(21) All assisted living communities must develop and maintain accurate staffing plans that take into account the specific needs of the residents and monthly work schedules for all employees, including relief workers, showing planned and actual coverage for each day and night. The assisted living community must retain the completed staff schedules for a minimum of one year.

(22) Staff must wear employee identification badges which are readily visible with abbreviations for professional/special credentials displayed on the badges, if any.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.09
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-2-9, 31-7-1 et seq., 43-26-12.
History. Original Rule entitled "Workforce Qualifications, Training and Staffing" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.10. Community Accountability.

(1) The records required by these rules and other records maintained in the normal course of the business of the community must be available for inspection and review by properly identified representatives of the Department.

(2) Where the Department identifies rule violations, the assisted living community will receive a written report of inspection. If the assisted living community disagrees with the facts and conclusions stated in the inspection report, it must submit its written statement explaining its disagreement and any evidence supporting the disagreement to the Department within 10 days of the receipt of the written inspection report. Where the Department concurs with the written statement of the assisted living community, it will issue a revised inspection report to the assisted living community.

(3) Within 10 days of receipt of the written report of inspection, the assisted living community must develop a written plan for correcting any rule violations identified. The plan of correction must identify the specific actions that the assisted living community will take by date certain to come into compliance with each rule for which a deficient practice was identified.

(4) A copy of the most recent inspection report and plan of correction must be displayed in the assisted living community in a location that is routinely used by the community to communicate information to residents and visitors. Additionally, if the community maintains a website, it shall post a web link in a prominent location on the main page of the website that provides access to copies of all inspection reports and plans of correction from the previous 18 months. When the Department develops a website for receiving plans of correction electronically and notifies the community of the appropriate internet address, the community also must file its plan of correction electronically on the Department's website within 10 days of receipt of the report of inspection.

(5) The assisted living community must take the corrective actions necessary to achieve compliance with the rules.

(6) The assisted living community must complete and maintain an accurate and current licensed residential care profile on file with the Department when the Department makes available a system for the submission and collection of such information electronically.

(7) The assisted living community must provide services that are consistent with the information reported on its licensed residential care profile, its license and these rules.

(8) The assisted living community's marketing materials must be consistent with its licensure classification as an assisted living community, the information reported on its licensed residential care profile, and these rules.

(9) Only an assisted living community licensed pursuant to these rules may hold itself out as offering assisted living care.

(10) No memory care center shall be operated and no residents admitted without a certificate which is current under these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.10
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1 et seq.
History. Original Rule entitled "Community Accountability" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.11. Community Design and Use Requirements.

(1) An assisted living community shall be designed, constructed, arranged, and maintained so as to provide for all of the following:

(a) health, safety, and well-being of the residents;

(b) independence, privacy and dignity of the residents; and

(c) safe access of all residents with varying degrees of functional impairments to living, dining and activity areas within the assisted living community.

(2) An assisted living community which undergoes major structural renovation or is first constructed after the effective date of these rules must be designed and constructed in compliance with applicable state and local building and fire codes.

(3) The assisted living community must have handrails, doorways and corridors which accommodate mobility devices, such as walkers, wheel chairs and crutches or canes as the residents may require for their safety.

(4) Assisted living communities serving persons dependent upon wheelchairs for mobility must provide at least two (2) exits from the community which are remote from each other and wheelchair accessible.

(5) **Common Areas.** The assisted living community must have common areas which meet the following requirements:

(a) The assisted living community must have separate and distinct living room(s) which are conveniently located within easy walking distance of each resident's private living space, available for the residents' informal use at any time and not requiring any resident to leave the building to use.

(b) The assisted living community must have living rooms large enough to accommodate the residents without crowding. The rooms must be comfortably and attractively furnished.

(c) The assisted living community must have areas in the community for use by residents and visitors which afford them privacy.

(d) The assisted living community must have a kitchen and a comfortable dining area which are properly equipped and adequate in size for the number of residents being served.

(e) All stairways and ramps must have sturdy and securely fastened handrails, not less than 30 inches nor more than 34 inches above the center of the tread. Exterior stairways, decks and porches must have handrails on the open sides.

(f) Floor coverings must be intact and securely fastened to the floor and free of hazards that might cause tripping.

(g) All areas of the assisted living community, including hallways and stairs must provide sufficient ambient lighting such that the residents may move about safely and objects may be easily observed by the residents. In addition, appropriate task lighting necessary for more visually demanding activities such as reading, knitting or preparing food must also be provided for resident use.

(h) The assisted living community must provide laundering facilities on the premises for residents' personal laundry.

(i) An assisted living community which provides laundry services for the residents must have a storage area that is used for clean laundry that is separate from the dirty laundry.

(j) Common areas, such as living, dining, activity, laundry or other multi-purpose rooms, or hallways must not be used as sleeping accommodations for residents, family or staff.

(6) **Bedrooms or Private Living Spaces.** The assisted living community must have bedrooms or private living spaces for the residents which meet the following requirements:

(a) Bedrooms or private living spaces assigned to individual residents must have at least 80 square feet of usable floor space per resident with no more than two residents sharing the private living space. Usable floor space is defined as that floor space under a ceiling at least seven feet in height. However, licensed personal care homes approved prior to or on February 6, 1981 to operate with bedrooms with a minimum of 70 square feet of usable floor space per resident which have continuously operated since that date seeking licensure as assisted living communities, may continue to use the minimum 70 square feet standard. Where an assisted living community operating under this exception has its permit revoked, changes ownership, changes location, or undergoes extensive renovations, or for any other reason surrenders its permit, this exception regarding the minimum square footage is no longer available.

(b) The resident's private living space must be self-contained and separated from halls, corridors and other rooms by floor to ceiling walls and must not be used as a passageway or corridor by others to access other parts of the assisted living community.

(c) The resident's private living space must have at least one window opening through an exterior wall of the assisted living community.

(d) Each sleeping room must have a secondary exit. This secondary exit may be a door or a window usable for escape.

(e) A room must not be used as a bedroom or private living space where more than one-half the room height is below ground level. Bedrooms or private living spaces which are partially below ground level must have adequate natural light and ventilation and have two useful means of egress. Control of dampness must be assured.

(f) Doorways of bedrooms or private living spaces occupied by residents must be equipped with side-hinged permanently mounted doors equipped with positively latching hardware which will insure opening of the door by a single motion, such as turning a knob or by pressing with normal strength on a latch. For bedrooms or private living spaces which have locks on doors, both the occupant and staff must be provided with keys to assure easy entry and exit.

(7) **Bathing and Toileting Facilities.** The assisted living community must provide bathing and toileting facilities that meet the accessibility needs of the residents and the following requirements:

(a) At least one toilet and lavatory must be provided for each four residents' use based on the licensed capacity of the assisted living community.

(b) At least one bathing or showering facility must be provided for each eight residents based on the licensed capacity of the assisted living community. Assisted

living communities serving residents who are dependent on wheel chairs or walkers, for mobility must have fully accessible bathrooms available for these residents.

(c) There must be at least one toilet and lavatory provided on each floor where residents have bedrooms.

(d) There must be a separate toilet and lavatory for the staff's use that is not counted in the minimum ratio of toilets and lavatories required for residents.

(e) Grab bars and nonskid surfacing or strips must be properly installed in all showers and bath areas.

(f) Bathrooms and toilet facilities must have working exhaust fans vented to the outside or windows that are screened and open to the outside easily.

(g) Toilets, bathtubs and showers must provide for individual privacy.

(8) **Electrical Inspection.** An applicant to operate an assisted living community must submit evidence of a satisfactory inspection of the electrical service of the assisted living community by a qualified electrician within no more than six months prior to the date of filing the application for a permit However, where the applicant holds a personal care home permit for the premises at the time of the application to become an assisted living community, no new electrical inspection is required unless renovation or repair work has been done since the last electrical inspection. Electrical service must be maintained in a safe condition at all times. The Department may require a re-inspection of the electrical service at any time renovation or repair work is done in the assisted living community or there is a request for a change in capacity or there is reason to believe that a risk to residents exists.

(9) **Fire Safety.** The assisted living community must have an effective fire safety program for the benefit of the residents which takes into account the unique needs of the residents being served.

(a) The assisted living community must comply with applicable fire and safety rules published by the Office of the Safety Fire Commissioner.

(b) The assisted living community must comply with applicable local ordinances that specifically address fire safety.

(c) The assisted living community is required to obtain a repeat fire safety inspection if at any time the physical plant undergoes substantial repair, renovation or additions.

(d) Where the Department has reason to believe, based on the number of residents requiring assisted self-preservation and staffing patterns that an assisted living

community may not be able to evacuate all of the residents to a designated point of safety within an established period of time as determined by the Office of the Safety Fire Commissioner, the Department may either require the assisted living community to conduct an immediate fire safety drill or make a referral for a new compliance determination to the Office of the State Fire Commissioner.

(10) **Water and Sewage.** The assisted living community's water and sewage systems must meet applicable federal, state, and local regulations.

(11) **Outdoor Spaces.** Assisted living communities must provide or have conveniently located access to outdoor spaces for the use of the residents and access to parking spaces for the use of residents and visitors. Such outdoor spaces may include solaria, porches, balconies, roof decks, gardens or patios.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.11
Authority: Ga. O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1, *et seq.*
History. Original Rule entitled "Community Design and Use Requirements" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.12. Community Furnishings.

(1) The assisted living community must provide furnishings throughout the assisted living community for the use of the residents that are maintained in good condition, intact, and functional.

(2) The assisted living community must provide a name plate, or other identification, outside the resident's bedroom or personal living space that marks the area as the personal living space of the particular resident(s), unless the resident specifically requests no identification markers to be used.

(3) Each resident's bedroom or private living space must have an adequate closet or wardrobe.

(4) Each resident's bedroom or private living space must have working lighting fixtures sufficient for reading and other resident activities.

(5) If the community provides the furnishings, each resident's bedroom or private living space must have a bureau or dresser or the equivalent and at least one comfortable chair per resident in each bedroom or private living space.

(6) Each resident bedroom must have a mirror appropriate for grooming unless the resident or resident's representative explicitly requests to have the mirror removed.

(7) Each resident's bedroom or private living space must have a waste basket unless the resident or resident's representative specifically requests to have it removed.

(8) The assisted living community must allow the resident to personalize the bedroom or private living space as the resident chooses by permitting the resident to use personal furniture so long as such furnishings do not pose a threat to the health or safety of the other residents. The assisted living community must provide the resident with assistance in mounting or hanging pictures on bedroom walls.

(9) Each resident must have an individual bed which is at least 36-inches wide and 72-inches long with comfortable springs and mattress, clean and in good condition. Where a particular resident is very tall, the assisted living community must provide an extra-long mattress. The mattress must not be less than five-inches thick, or four-inches, if of a synthetic construction. Roll-a-ways, cots, double-decks, stacked bunks, hide-a-beds and studio couches are not to be provided by the assisted living community in lieu of standard beds. However, residents who prefer to furnish their own living units may choose to use different-sized beds in lieu of standard twin-size beds.

(10) The assisted living community must make available for each resident who requires linen service an adequate supply of clean linens which includes, at a minimum, two sheets, pillow, pillowcase, blanket, bedspread, towels and wash cloth. If the resident requires more blankets for comfort, the assisted living community must provide them.

(11) The assisted living community must change and launder linens for each resident at least weekly or more often unless the resident specifically declines the linen service. Whether or not the resident declines linen services, the assisted living community must maintain an adequate supply of spare linens on hand to accommodate the needs of the residents.

(12) At least one current calendar and working clock must be placed in the common living area of each assisted living community.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.12
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, and 31-7-1*et seq.*
History. Original Rule entitled "Community Furnishings" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.13. Community Safety Precautions.

(1) The interior and exterior of the assisted living community must be kept clean, in good repair and maintained free of unsanitary or unsafe conditions which might pose a health or safety risk to the residents and staff.

(2) Where the assisted living community includes private living space for persons who are not receiving services as residents of the assisted living community, the maintenance of the private living space must comply with fire safety codes and not threaten the health or safety of the residents.

(3) The assisted living community must maintain wall-type electric outlets and working lamps or light fixtures throughout the assisted living community in good working order and which are safe for the intended use. The assisted living community must provide necessary light bulbs.

(4) Refrigeration and cooking appliances must be properly installed, maintained in accordance with manufacturer's recommendations and kept clean. Where metal hoods or canopies are provided, they must be equipped with filters which are maintained in an efficient condition and kept clean at all times.

(5) Space heaters must not be used, except during an emergency situation after obtaining specific written approval of the fire safety authority having jurisdiction over the assisted living community.

(6) Fire screens and protective devices must be used with fireplaces, stoves and heaters.

(7) Each assisted living community must be protected with sufficient functioning smoke detectors, powered by house electrical service with battery back-up, which when activated, must initiate an alarm which is audible in the sleeping rooms.

(8) Each assisted living community must have charged 5 lb. or more multipurpose ABC fire extinguishers available for use throughout the community as required by state or local fire codes, whichever is more stringent. These fire extinguishers shall be checked and tagged annually by a licensed fire extinguisher company to assure the extinguishers remain in operable condition.

(9) Each assisted living community must have a working doorbell or doorknocker which is audible to staff inside at all times.

(10) Exterior doors must be equipped with locks which do not require keys to open them from the inside.

(11) Entrances and exits, sidewalks, and escape routes must be maintained free of any hazards such as refuse, equipment, furniture, ice, snow, debris or any other impediments to ensure complete and immediate entry and exit in the case of fire or other emergency.

(12) The assisted living community must have its name and house number displayed so as to be easily visible from the street.

(13) The assisted living community must store and safeguard poisons, caustics, and other dangerous materials in safe areas and separate from food preparation and storage areas, and medication storage areas.

(14) Heated water must be made available by the assisted living community to the residents for their usage and must be comfortable to the touch but must not exceed 120 degrees Fahrenheit (F.).

(15) Where the assisted living community provides transportation to the residents, the assisted living community must maintain on the vehicle: basic emergency contact information on the residents being transported.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.13
Authority: O.C.G.A. §§ 31-2-7, 31-2-8 and 31-7-1*et seq.*
History. Original Rule entitled "Community Safety Precautions" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.14. Emergency Preparedness.

(1) An assisted living community must comply with the requirements of Chapter 111-8-16, Rules and Regulations for Disaster Preparedness Plans.

(2) Building evacuation maps with routes of escape clearly marked must be posted conspicuously on each floor of the assisted living community. Assisted living communities must have a clearly accessible route for emergencies throughout the common areas of the assisted living community.

(3) The disaster preparedness plan must be readily accessible to staff, residents and their families at the assisted living community and identify the staff position(s) responsible for implementing the plan, obtaining necessary emergency medical attention or intervention for residents.

(4) The assisted living community must provide timely notification of the relocation address to the residents, their family contacts and representatives, if any, and the Department whenever the assisted living community must relocate the residents as a result of an emergency situation which disrupts the provision of room and board for the residents at the licensed location.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.14
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*, 38-3-51.
History. Original Rule entitled "Emergency Preparedness" adopted. F. Dec. 13, 2011; eff. Jan. 2, 2012.
Note: Correction of typographical error on SOS Rules and Regulations website. In accordance with Official Compilation Rules and Regulations of the State of Georgia, eff. Jan. 2, 2012, original filed date,"Dec. 13, 2012", corrected to "Dec. 13, 2011." Effective May 6, 2018.
Amended: F. Apr. 16, 2018; eff. May 6, 2018.

Rule 111-8-63-.15. Admission and Resident Retention.

(1) **Resident Profile for Admission.** The assisted living community must determine that the potential residentmustmeet all of the following criteria at the time of admission:

(a) The resident must be an adult who is at least 18 years of age.

(b) The resident must not have active tuberculosis, or require continuous medical or nursing care and treatment or require physical or chemical restraints, isolation or confinement for behavioral control.

(c) The resident's physical condition must be such that the resident is capable of actively participating in transferring from place to place.

(d) The resident must be able to participate in the social and leisure activities provided in the assisted living community.

(2) **Evaluation of Applicants for Admission.** In determining whether the assisted living community will be able to meet the needs of the applicant for admission to the assisted living community, the administrator or on-site manager of an assisted living community must consider and maintain documentation of the following:

(a) the information provided in an interview with the applicant and/or representative or legal surrogate, if any, regarding the applicant's care and social needs and behavioral issues that may require more watchful oversight;

(b) a physical examination conducted by a licensed physician, nurse practitioner or physician's assistant dated within 30 days prior to the date of admission which reflects that the resident does not require continuous medical or nursing care and services and is free of active tuberculosis. The report of the physical examination must be completed on forms made available by the Department;

(c) either the results of an inquiry of the National Sex Offender Registry website coordinated by the Federal Bureau of Investigation or a fingerprint records check;

(d) where the applicant for admission is a registered sex offender or has committed another violent crime, the assisted living community must document the additional safety measures that the assisted living community will employ to ensure the safety of all residents, such as additional monitoring, room and roommate selection and in-servicing of staff; and

(e) whether the applicant for admission has retained the services of a designated proxy caregiver which complies with the requirements of the Rules and Regulations for Proxy Caregivers Used In Licensed Healthcare Facilities, Chapter 111-8-100.

(3) **Emergency Placement.** Where the applicant for admission is being evaluated for admission pursuant to an emergency placement made at the request of the Adult Protective Services Section of the Division of Aging Services, Department of Human Services or another licensed facility that is requesting the placement pursuant to activation of its emergency preparedness plan for relocation of residents, the complete physical examination required by Rule 111-8-63-.16(2)(b) may be deferred for up to 14 days after the emergency admission if no record of a qualifying physical examination or a copy of a current clinical record is available at the time of admission.

(4) **Community Admission Decisions.** The assisted living community must not admit residents who either do not meet the admission profile or who meet the profile but whose care needs cannot be met by staff available to provide assistance. The assisted living community's decision to admit a resident must reflect that it has taken into account the condition of the resident to be admitted, the needs of currently admitted residents, the assistance with self-preservation current residents require, and the construction of the building including whether such building meets the state fire safety requirements applicable to an existing health care occupancy.

(5) **Community Retention Decisions.** The assisted living community must require a resident to move out when any one of the following occurs:

(a) The resident requires continuous medical or nursing care.

(b) The resident's specific care needs cannot be met by available staff in the community, e.g., the resident is not ambulatory and not capable of assisted self-preservation.

(c) The community is not able to evacuate all of the current residents to a point of safety within established fire safety standards.

(6) **Change in Condition Requiring Reevaluation.** In the event a resident develops a significant change in physical or mental condition, the assisted living community must obtain medical information necessary to determine that the resident continues to meet the retention requirements and the assisted living community is capable of meeting the resident's needs. Where the Department has reason to believe either that the assisted living community cannot meet needs of the resident or the resident no longer meets the retention criteria for living in the licensed assisted living community, the governing body must provide to the Department, upon request, a current physical examination for the resident from a physician, advanced practice registered nurse or physician's assistant as properly authorized.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.15
Authority: O.C.G.A. §§ 31-2-7, 31-2-8 and 31-7-1*et seq.*
History. Original Rule entitled "Admission and Resident Retention" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.16. Admission Agreements.

(1) **Contents of the Written Admission Agreement.** The assisted living community must ensure that the admission agreement is written in plain and understandable language and is consistent with the information contained on the licensed residential care profile.

(a) The admission agreement must include a current statement of all fees and daily, weekly or monthly charges; the services covered by those basic fees and any other services which the assisted living community provides on an additional fee basis.

(b) The admission agreement must contain a statement that residents and their representatives or legal surrogates shall be informed, in writing, at least 30 days prior to any increase in established charges related to the provision of personal services and at least 60 days prior to any increase in charges for room and board.

(c) The admission agreement must contain provisions for the administrator or on-site manager's continuous assessment of the resident's needs, referral for appropriate services as may be required if the resident's condition changes and referral for transfer or discharge if required due to a change in the resident's condition.

(d) The admission agreement must contain a description of how the community responds to formal complaints received from residents and their representatives and how to file a complaint within the community.

(e) The admission agreement must contain provisions for transportation of residents for shopping, recreation, rehabilitation, medical services. Such transportation service may be provided by the assisted living community as either a basic service or on a reimbursement basis; with transportation for emergency use available at all times.

(f) The admission agreement must include the assisted living community's refund policy when a resident dies, is transferred or discharged.

(g) The admission agreement must include a statement that a resident may not be required to perform services for the assisted living community.

(h) The admission agreement must include a copy of the house rules, which must be in writing and also posted in the assisted living community and explain how violations of the house rules will be addressed by the community. House rules must be consistent with residents' rights. House rules must include, but not be limited to policies regarding the use of tobacco and alcohol, the times and frequency of use of the telephone, visitors elopement from the community, hours and volume for viewing and listening to television, radio and other audiovisual equipment, whether residents' personal pets or household pets are permitted and the use of personal property.

(i) The admission agreement must disclose how and by what level of staff medications are handled in the community. The agreement must also specify who is responsible for initial acquisition and refilling of prescribed medications utilizing unit or multidose packaging for the resident. Either this responsibility will remain with the resident, representative or legal surrogate, if any, or be assigned to the assisted living community operating through the administrator or on-site manager.

(j) The admission agreement must disclose whether the community permits the resident to employ independent proxy caregivers, sitters, etc. or requires the purchase of such services from approved providers.

(2) The assisted living community must provide each resident, representative, legal surrogate with an opportunity to read the complete agreement prior to the execution of the admissions agreement. In the event that a resident, representative or legal surrogate is unable to read the agreement, the administrator or on-site manager must take steps to assure communication of the contents of the admission agreement to be signed.

(3) The assisted living community must provide the resident and representative or legal surrogate, if any, with a signed copy of the agreement. A copy signed by both parties (resident and administrator or on-site manager) must be retained in the resident's file and maintained by the administrator or on-site manager of the assisted living community.

(1) The assisted living community must not use a written admission agreement or any other written agreement signed by the resident or the resident's legal representative which waives or attempts to waive any of the resident's rights these rules protect.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.16
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*
History. Original Rule entitled "Admission Agreements" adopted. F. Dec. 13, 2011; eff. Jan. 2, 2012.
Note: Correction of typographical error on SOS Rules and Regulations website. In accordance with Official Compilation Rules and Regulations of the State of Georgia, eff. Jan. 2, 2012, original filed date,"Dec. 13, 2012", corrected to "Dec. 13, 2011." Effective May 6, 2018.
Amended: F. Apr. 16, 2018; eff. May 6, 2018.

Rule 111-8-63-.17. Services in the Community.

(1) The assisted living community must provide assisted living, including protective care and watchful oversight, which meets the needs of the residents it admits and retains.

(2) **Resident Needs Assessment**. The assisted living community must complete an assessment of the resident that addresses the resident's care needs taking into account the resident's family supports, the resident's functional capacity relative to the activities of daily living, physical care needs, medical information provided, cognitive and behavioral impairments, if any, and personal preferences relative to care needs.

(3) **Written Care Plan**. Utilizing the information acquired during the admission process and the move-in adjustment period, the assisted living community must develop the resident's individual written care plan within 14 days of admission and require staff to use the care plan as a guide for the delivery of care and services to the resident. The care plan must include the following:

(a) a description of the resident's care and social needs and the services to be provided, including frequency to address care and social needs;

(b) resident's particular preferences regarding care, activities and interests;

(c) specific behaviors to be addressed with interventions to be used;

(d) any physician order or order of a nurse practitioner or physician assistant working under protocol or job description, respectively for assistive devices;

(e) staff primarily responsible for implementing the care plan;

(f) evidence of family involvement in the development of the plan when appropriate; and

(g) evidence of the care plan being updated at least annually and more frequently where the needs of the resident change substantially or the resident is assigned to a memory care center.

(4) **Social Activities**. Each assisted living community must provide social activities on a daily basis that promote the physical, mental and social well-being of each resident and take into account the personal preferences of the residents.

(5) **Activity Resources**. The assisted living community must provide, books, current newspapers or magazines, and games for leisure time activities. The assisted living community must offer assistance to residents who wish to participate in hobbies, music, arts and crafts, religion, games, and sports, social, recreational and cultural activities available in the assisted living community and in the community.

(6) **Available Telephone**. The assisted living community must have at least one operable, non-pay telephone which is accessible at all times for emergency use by staff on the premises. Residents must also have access to an operable, non-pay telephone in a private location, both to make and receive personal calls. The same telephone may be used for staff and resident access.

(7) The assisted living community must not restrict a resident's free access to the common areas of the assisted living community or the memory care center or lock the resident into or out of the resident's bedroom.

(8) **Proxy Caregiver Services**. Where the assisted living community chooses to allow proxy caregivers to function in the community to perform certain health maintenance activities that are not covered in the basic assisted living care the community is required to provide, the assisted living community must do either of the following:

(a) Provide employees who are available for designation by a resident to serve as proxy caregivers to perform certain health maintenance activities; or

(b) Permit the resident or a person legally authorized to act on behalf of the resident to employ designated proxy caregivers to provide health maintenance activities.

(9) **Proxy Caregiver Records**. The community must maintain documentation on all proxy caregivers performing health maintenance activities which complies with the Rules and Regulations for Proxy Caregivers, Chapter 111-8-100.

(10) **Prohibited Proxy Caregiver Services**. Where the assisted living community employs proxy caregivers, the community must not permit proxy caregivers to provide assistance with or administer medications.

(11) Medical, nursing (other than developing and updating care plans, training, medication administration and skills competency determinations) health services required on a periodic basis, or for short-term illness, must not be provided as services of the assisted living community. When such services are required, they shall be purchased by the resident or the resident's representative or legal surrogate, if any, from appropriately licensed providers which are managed independently and not owned or operated by the assisted living community. The assisted living community may assist in arrangement for such services, but not in the provision of those services.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.17
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1 et seq., 43-26-12.
History. Original Rule entitled "Services in the Community" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.18. Precautions for Residents at Risk of Elopement.

(1) An assisted living community which serves residents with cognitive deficits which place the residents at risk of eloping, i.e. engaging in unsafe wandering activities outside the assisted living community must do the following:

(a) Develop, train and enforce policies and procedures for staff to deal with residents who may wander away from the assisted living community including what actions, are to be taken if a resident wanders away (elopes) from the assisted living community.

(b) Utilize appropriate effective safety devices, which do not impede the residents' rights to mobility and activity choice or violate fire safety standards, to protect the residents who are at risk of eloping from the premises.

1. If the safety devices include magnetic locks used on exit doors, as approved by the fire marshal having jurisdiction over the assisted living community, then the locking device shall be electronic and release whenever the following occurs: activation of the fire alarm or sprinkler system, power

failure to the assisted living community or by-pass for routine use by the public and staff for service using a key button/key pad located at the exit or continuous pressure for thirty (30) seconds or less.

2. If the safety devices include the use of keypads to lock and unlock exits, then directions for their operations shall be posted on the outside of the door to allow individuals' access to the unit. However, if the unit is a whole assisted living community, then directions for the operation of the locks need not be posted on the outside of the door. The units must not have entrance and exit doors that are closed with non-electronic keyed locks nor shall a door with a keyed lock be placed between a resident and the exit.

(2) An assisted living community serving residents who are at risk of eloping from the premises must retain on file at the assisted living community current pictures of any such residents.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.18
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1 et seq.
History. Original Rule entitled "Requirements for Memory Care Services" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: New title "Precautions for Residents at Risk of Elopement." F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.19. Additional Requirements for Certified Memory Care Centers.

(1) In addition to all other requirements contained in this Chapter, where an assisted living community holds itself out as providing additional or specialized care to persons with probable diagnoses of Alzheimer's Disease or other dementia, or charges rates in excess of that charged other residents for the provision of additional or specialized care, the assisted living community must meet the following requirements:

(a) **Written Description**. The assisted living community must include in its licensed residential care profile an accurate written description of the memory care center that includes the following:

1. a statement of philosophy and mission;

2. how the services and activities of the memory care center are different from those provided in the rest of the assisted living community;

3. staffing including job titles of staff who work in the center, staff training and continuing education requirements;

4. admission procedures, including screening criteria;

5. assessment and service planning protocol, including criteria to be used that would trigger a reassessment of the resident's status before the customary quarterly review;

6. staffing patterns, including the ratio of direct care staff to resident for a 24-hour cycle, and a description of how the staffing pattern differs from that of the rest of the program;

7. a description of the physical environment including safety and security features;

8. a description of activities, including frequency and type, and how the activities meet the needs of residents with dementia,

9. the program's fee or fee structure for all services provided by the center or assisted living community;

10. the discharge criteria and procedures;

11. the procedures that will be utilized for handling emergency situations; and

12. the involvement of the center with families and family support programs.

(b) **Physical Design, Environment, and Safety**. The memory care center must be designed to accommodate residents with severe dementia or Alzheimer's Disease in an assisted living community-like environment which includes the following:

1. multipurpose room(s) for dining, group and individual activities which are appropriately furnished to accommodate the activities taking place;

2. secured outdoor spaces and walkways which are wheel chair accessible and allow residents to ambulate safely but prevent undetected egress;

3. high visual contrast between floors and walls and doorways and walls in resident use areas-except for fire exits, door and access ways which may be designed to minimize contrast to conceal areas where the residents should not enter;

4. adequate and even lighting which minimizes glare and shadows;

5. the free movement of the resident, as the resident chooses, between the common space and the resident's own personal space in a bedroom that accommodates no more than two (2) residents;

6. individually identified entrances to residents' rooms to assist residents in readily identifying their own personal spaces;

7. an effective automated device or system to alert staff to individuals entering or leaving the center in an unauthorized manner. An assisted living community need not use an automated alert for an exit door when the particular exit is always staffed by a receptionist or other staff member who views and maintains a log of individuals entering and leaving the assisted living community. If the exit door is not always staffed, then the assisted living community must activate an automated alert when the door is not attended;

8. communication system(s) which permit staff in the center to communicate with other staff outside the center and with emergency services personnel as needed; and

9. a center providing specialized memory care services which undergoes major renovation or is first constructed after December 9, 2009, must be designed and constructed in compliance with applicable state and local building and fire codes relevant to the center and the assisted living community.

(c) **Staffing Requirements**. The assisted living community must ensure that the memory care center is staffed with sufficient specially trained staff to meet the unique needs of the residents in the center. At a minimum, the memory care center must provide the following staffing:

(i) One dementia trained direct care staff person for every 12 residents on-site during all waking hours and for every 15 residents on-site during all nonwaking hours based on a monthly average; provided, however, that such ratio is adequate to meet the needs of the residents;

(ii) One registered professional nurse, licensed practical nurse, or certified medication aide on-site at all times;

(iii) Two direct care staff persons on-site at all times, with at least one on each occupied floor; and

(iv) One registered professional nurse or licensed practical nurse on-site or available in the building at all times as follows:

(A) For memory care centers with one to 12 residents, a minimum of 8 hours per week;

(B) For memory care centers with 13 to 30 residents, a minimum of 16 hours per week;

(C) For memory care centers with 31 to 40 residents, a minimum of 24 hours per week; or

(D) For memory care centers with more than 40 residents, a minimum of 40 hours per week.

(d) **Staff Training Requirements**. The community shall ensure that all staff are properly trained initially and on an annual basis to provide safe, quality care to residents in the memory care center. The memory care center shall meet the following training requirements:

(i) General Orientation. All staff, regardless of role, shall receive at least four (4) hours of dementia-specific orientation within the first thirty (30) days of working in the center. Such orientation shall include:

(A) Basic information about the nature, progression, and management of Alzheimer's and other dementias;

(B) Techniques for creating an environment that minimizes challenging behavior from residents with Alzheimer's and other dementias;

(C) Methods of identifying and minimizing safety risks to residents with Alzheimer's and other dementias; and

(D) Techniques for successful communication with individuals with Alzheimer's and other dementias.

(ii) Direct Care Orientation. All direct care staff shall receive initial orientation training within the first thirty (30) days of caring for residents independently that, at a minimum, includes:

(A) General training, to include:

(I) Development, updating, and implementation of comprehensive and individual service plans;

(II) Skills for recognizing physical or cognitive changes in the resident that warrant seeking medical attention;

(III) Residents' rights and identification of conduct constituting abuse, neglect, or exploitation;

(IV) General infection control principles;

(V) Emergency preparedness training;

(VI) Emergency first aid;

(VII) Cardiopulmonary resuscitation.

(B) A minimum of sixteen (16) hours of specialized, competency-based training using forms specified by the department, to include, at a minimum:

(I) The nature of Alzheimer's and other dementias;

(II) The center's philosophy related to the care of residents with Alzheimer's and other dementias;

(III) The center's policies and procedures related to care of residents with Alzheimer's and other dementias;

(IV) Common behavior problems characteristic of residents with Alzheimer's and other dementias;

(V) Positive therapeutic interventions and activities;

(VI) Skills for maintaining the safety of the resident; and

(VII) The role of the family in caring for residents with Alzheimer's and other dementias.

(iii) Ongoing Training. Direct care staff shall complete a minimum of eight (8) hours of specialized training in dementia care on an annual basis.

(iv) Training Documentation. The memory care center shall maintain documentation reflecting course content, instructor qualifications, agenda, and attendance rosters for all training sessions provided.

(e) **Special Admission Requirements for Memory Center Placement**. Residents must have a physician's report of physical examination completed within 30 days prior to admission to the center on forms made available by Department. The physical examination must clearly reflect that the resident has a diagnosis of probable Alzheimer's Disease or other dementia and has symptoms which demonstrate a need for placement in the center. However, the center may also care for a resident who does not have a probable diagnosis of Alzheimer's Disease or other dementia, but desires to live in this center and waives his or her right to live in a less restrictive environment. In addition, the physical examination report must establish that the potential resident of the center does not require 24-hour skilled nursing care.

(f) **Post-Admission Assessment**. If the resident is admitted directly into the specialized memory care center, the center must obtain an assessment of each resident's care needs to include the following components: resident's family supports, level of activities of daily living functioning, physical care needs and level of behavior impairment.

(g) **Individual Written Care Plan and Reviews**. The resident's written care plan will be developed or updated by staff with at least one member of the specialized memory care staff providing direct care participating. Input from each shift of direct care staff that provides care to the resident will be requested. All team members participating shall sign the written care plan and the plan will be shared with the direct care staff providing care to the resident and serve as a guide for the delivery of care to the resident. The resident's family shall participate in the development of the plan, if possible, with incorporation of family and personal history to support a person-centered approach to care. The written care plan must be reviewed at least quarterly and modified as changes in the resident's needs occur.

(h) **Therapeutic Activities**. The unit shall provide activities appropriate to the needs of the individual residents and adapt the activities, as necessary, to encourage participation of the residents in the following at least weekly with at least some therapeutic activities occurring daily:

1. gross motor activities; e.g. exercise, dancing, gardening, cooking, etc;

2. self-care activities; e.g. dressing, personal hygiene/grooming;

3. social activities; e.g. games, music;

4. sensory enhancement activities, e.g. distinguishing pictures and picture books, reminiscing and scent and tactile stimulation; and

5. outdoor activities; e.g. walking outdoors and field trips.

(2) No licensed assisted living community is permitted to hold itself out as providing specialized care for residents with probable Alzheimer's disease or other dementia or charge a differential rate for care of such residents unless it meets the additional requirements specified in Rule 111-8-63-.19(1) and its subparagraphs (a) through (h) above.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.19
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1 et seq., 43-26-32.
History. Original Rule entitled "Additional Requirements for Specialized Memory Care Units" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: New title "Additional Requirements for Certified Memory Care Centers." F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.20. Medications.

(1) **Self-Administration of Medications.** Residents who have the cognitive and functional capacities to engage in the self-administration of medications safely and independently without staff assistance or supervision must be allowed to store their own medications securely and self-administer medications if they so desire.

(2) **Assistance with Self-Administration.** An assisted living community must provide assistance with or supervision of self-administered medications to those residents who have the cognitive capacity to engage in the self-administration of medications, but require or request staff assistance with or supervision of the self-administration of medications for safety or convenience.

(a) Such staff assistance with or supervision of self-administered medications may only be provided for unit or multi-dose packaged medications prescribed for the particular resident and may include only the following tasks:

1. taking the medication, in its previously dispensed, properly labeled container, from where it is stored, and bringing the medication to the resident;

2. reading the label, opening the container, removing a prescribed amount of medication from the container, and closing the container, in the presence of the resident;

3. placing an oral dosage in the resident's hand or placing the dosage in another container where the resident requests assistance;

4. applying topical medications;

5. returning the medication container to proper secured storage; and

6. assisting the resident's use of an EPI pen where the resident has known severe allergies for which an EPI pen has been prescribed on condition that there is an established written protocol detailing how it is to be used and when. The protocol must include immediately calling Emergency Services, 911, after any use of the EPI pen.

(b) Staff assisting with or supervising self-administration of medications must be proficient in English and able to read, write and follow written instructions in English.

(3) **Community Administration of Medications.** Where the residents either are not capable of self-administration of medications or choose not to self-administer medications with assistance or supervision, the assisted living community must provide medication administration services to the residents in accordance with physicians' orders, the needs of the residents and these rules.

(4) **Specialized Staffing for Medication Administration.** The assisted living community offering medication administration services must employ certified medication aides, at a minimum, to administer medications.

(5) **Certified Medication Aide Requirements.** An assisted living community using certified medication aides to administer specific medications must do all of the following:

(a) **Check the Registry.** Ensure that the medication aides employed in the community are listed in good standing on the Georgia Certified Medication Aide Registry and have no record of being terminated for cause relating to the performance of medication aide tasks before permitting the aides to administer medications.

(b) **Administer Skills Competency Checks.** Determine and document that the medication aides who have been certified for more than one year upon hiring, continue to have the knowledge and skills necessary to administer medications properly for the particular community. The community must use a skills competency checklist which meets the requirements contained in the standardized clinical skills competency checklist used to certify medication aides.

(c) **Quarterly Observations.** Use a licensed registered professional nurse or a pharmacist to conduct quarterly random medication administration observations to determine that the aides are administering medications correctly and in compliance with these rules and report any issues to the assisted living community administration for resolution.

(d) **Quarterly Drug Regimen Reviews.** Secure the services of a licensed pharmacist to perform all of the following duties:

1. Conduct quarterly reviews of the drug regimen for each resident of the assisted living community and report any irregularities to the assisted living community administration.

2. Remove for proper disposal any drugs that are expired, discontinued or in a deteriorated condition or where the resident for whom such drugs were ordered is no longer a resident.

3. Establish or review policies and procedures for safe and effective drug therapy, distribution, use and control.

4. Monitor compliance with established policies and procedures for medication handling and storage.

(e) **Authorized Tasks for Certified Medication Aides.** An assisted living community may allow a certified medication aide to do only the following tasks related the administration of medications utilizing only unit or multidose packaging of medications:

1. Administer physician ordered oral, via a feeding tube, ophthalmic, topical, otic, nasal, vaginal and rectal medications.

2. Administer insulin, epinephrine, and B12 pursuant to physician direction and protocol.

3. Administer medications via a metered dose inhaler.

4. Conduct finger stick blood glucose testing following established protocol.

5. Administer a commercially prepared disposable enema ordered by a physician.

6. Assist residents in the supervision of self-administration of medications.

7. Administer liquid morphine to a resident of the community who is the patient of a licensed hospice, pursuant to a hospice physician's written order that contains specific instructions for indication, dosage, frequency and route of administration.

(f) **Annual Competency Reviews.** Complete comprehensive clinical skills competency reviews for each certified medication aide utilizing the skills competency checklist at least, annually after hiring to determine that the aides continue to have the necessary skills to perform the medication tasks assigned competently. Such skills competency checklists must be administered by Georgia-licensed registered nurses, pharmacists or physicians, who indicate in writing that the tasks observed are being performed competently.

(g) **Proper Notice of Separation for Cause.** Ensure that where a medication aide is terminated for cause relating to the performance of medication aide tasks, the aide is provided with the following:

1. a separation notice that clearly describes the facts that support the termination for cause;

2. written notice that being terminated for cause related to the administration of medications, if not successfully appealed through a hearing on right to unemployment benefits will result in the loss of good standing on the Georgia Certified Medication Aide Registry; and

3. the loss of good standing on the Certified Medication Aide Registry will make the aide ineligible for hiring as a certified medication aide by another assisted living community.

(h) **Registry Notification.** Submit to the Georgia Certified Medication Aide Registry a copy of the Separation Notice for the certified medication aide only if the separation related specifically to the performance of medication aide tasks and the termination for cause has either been finally upheld by the Department of Labor or the time for appealing the Separation Notice has expired.

(6) **Communities Conducting Certified Medication Aide Training.** A community choosing to provide a certified medication aide training program must do all of the following:

(a) Utilize the state-approved medication aide training program ensuring that the training is administered by a Georgia-licensed registered nurse, pharmacist, or physician.

(b) Require the aide to demonstrate the requisite clinical skills to serve as a medication aide before a Georgia-licensed registered nurse, pharmacist or physician utilizing the standardized medication administration checklist developed by the Department.

(c) Prepare the aide to take the written competency examination to become a certified medication aide.

(d) Verify that the aide is in good standing on the Georgia certified nurse aide registry.

(e) Provide information to the aide on the registration and locations for taking the written competency examination.

(f) Provide the documentation to the Georgia Certified Medication Aide Registry that is necessary to complete the application for placement of the aide's name on the Georgia Certified Medication Aide Registry.

(g) Not permit the aide to administer medications independently unless the aide is listed on the Georgia certified medication aide registry in good standing.

(7) **Basic Medication Training for Staff Assisting with Self-Administration.** The assisted living community must provide and document medication training for the unlicensed staff who are not certified medication aides but who are providing assistance with or supervision of self-administration of medications to capable residents. The medication training must be conducted with an appropriate curriculum for providing medication assistance and include at least the following topics:

(a) the assisted living community's medication policy and procedures, including actions to take if concerns regarding resident's capacity to self-administer medications are identified;

(b) how to read prescription labels including common abbreviations;

(c) providing the right medication to the right resident at the right time in the right amount and the right way including how to measure various medications;

(d) actions to take when concerns regarding medications are identified;

(e) infection control procedures relative to providing assistance with medications;

(f) proper medication storage and disposal;

(g) recognition of side effects and adverse reactions for the specific medications;

(h) understanding the common classifications of medications, typical side effects and adverse reactions and medications for which unlicensed staff may never provide assistance with or supervision of self-administration; and

(i) proper documentation and record keeping using the Medication Assistance Record.

(8) **Medication Skills Competency Determinations.** Unlicensed staff who are not certified as medication aides providing assistance with or supervision of self-administered medications must demonstrate when hired and at least, annually thereafter, the necessary skills to perform the medication tasks assigned competently by completing skills competency checklists before appropriately trained community staff.

(9) **Maintaining Records on Medication Assistance and Administration.** Where the assisted living community either provides assistance with, or supervision of self-administered medications or administers medications to residents, the community must maintain a daily Medication Assistance Record (MAR) for each resident who receives assistance or administration. The MAR must include the name of the specific resident, any known allergies, the name and telephone number of the resident's health care provider, the name, strength and specific directions including key side effects and adverse reactions for use of each medication and a chart for staff who provide assistance or administration to record initials, time and date when medications are taken, refused or a medication error is identified (e.g. missed dosage). The staff providing the assistance or administration of medications must update the MAR each time the medication is offered or taken.

(a) The assisted living community must make medication information concerning the descriptions of medication, dosing, side effects, adverse reactions and contraindications for each medication being administered to the residents immediately available for reference by staff providing medication assistance or administration.

(b) Staff of the assisted living community providing assistance with or administration of medications must document in the resident's record any unusual reactions to the

medications and provide such information to the resident, the resident's representative and the health care provider as appropriate.

(c) For any administration of liquid morphine by a certified medication aide, staff shall observe and document the following in the resident's record:

1. the resident's need for PRN liquid morphine, including but not limited to verbalizations of pain, groaning, grimacing or restlessness;

2. the date, time and location of the initial dose administered by a licensed hospice health care professional;

3. the dosage, time and route of administration for the morphine administered in the community;

4. the training provided by the licensed hospice; and

5. information regarding the special circumstances under which the hospice was unavailable to administer the medication.

(10) **Orders Required for All Medications.** An assisted living community must not allow its staff to assist with, provide supervision of self-administered medications or administer any medications, including over-the-counter medications, unless there is a physician's order specifying clear instructions for its use on file for the resident.

(11) **Timely Management of Medication Procurement.** Where the assisted living community procures medications on behalf of the residents, the community must obtain new prescriptions within 48 hours of receipt of notice of the prescription or sooner if the prescribing physician indicates that a medication change must be made immediately. If the pharmacy does not have the medication needed for the immediate change, available and has not obtained further directions from the physician, the community must notify the physician of the unavailability of the prescription and request direction. Refills of prescribed medications must be obtained timely so that there is no interruption in the routine dosing. Where the assisted living community is provided with a new medication for the resident, the MAR must be modified to reflect the addition of the new medication within 48 hours or sooner if the prescribing physician indicates that the medication change must be made immediately.

(12) **Storage and Disposal of Medications.** Medications must be stored securely and inventoried appropriately to prevent loss and unauthorized use. Medications must be stored under lock and key at all times whether kept by a resident or kept by the assisted living community for the resident, unless the medication is required to be kept by the resident on his or her person or staff member in close attendance due to the need for physician-prescribed frequent or emergency use. Additionally, for controlled substances, the secure storage must be a locked cabinet or box of substantial construction and a log must be maintained and updated daily by the community to account for all inventory.

(a) Duplicate keys for all medication storage containers must be available on site for appropriate use.

(b) Medications must be kept in original containers with original labels intact.

(c) Medications must be properly labeled in separate unit or multi-unit dose packaging and handled in accordance with physician's instructions, and laws and regulations applicable to the medications.

(d) The assisted living community must ensure that it properly disposes of unused medications using the current U.S. Food and Drug Administration or U.S. Environmental Protection Agency guidelines for the specific medications.

(e) The supply of liquid morphine on site shall be limited to 50 ml for each hospice patient in the community for which there is a physician's order for such medication.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.20
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1 et seq.
History. Original Rule entitled "Medications" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Feb. 28, 2020; eff. Mar. 19, 2020.

Rule 111-8-63-.21. Nutrition and Food Preparation.

(1) **Regularly Scheduled Meals.** The assisted living community must provide a minimum of three regularly scheduled well-balanced meals per day seven days a week which meet the nutritional needs of residents, and must provide therapeutic diets as ordered by the residents' healthcare providers for residents that require special diets. There must be no more than fourteen hours elapsing between the scheduled evening and morning meals.

(2) **Nutritious Meals.** Meals must meet the general requirements for nutrition adjusted for age, sex and activity, currently found in the Recommended Daily Diet Allowances, Food and Nutrition Board, National Academy of Sciences.

(3) **Snacks.** Food for at least one nutritious snack must be available and offered each day in addition to the regularly scheduled meals. Snacks are not considered to be meals for the purposes of calculating the time between meals.

(4) **Wholesome Food.** Food received or used in an assisted living community must be clean, wholesome, free from spoilage, adulteration, and misbranding, and safe for human consumption.

(5) **Proper Handling of Food.** All foods while being stored, prepared and served must be protected from spoilage and contamination and be safe for human consumption. At a

minimum to protect from spoilage and contamination, the assisted living community must do all of the following:

(a) Store perishable foods, such as but not limited to meat, fish, eggs, dairy products, juices at temperatures that will minimize spoilage, i.e. at or below 41 degrees F.

(b) Thaw frozen foods properly, i.e. in the refrigerator or under cold running water with an unplugged sink.

(c) Provide hot and cold running water and sanitizing agents and ensure that they are used appropriately in the kitchen to clean and sanitize food, hands and utensils as required for safe food preparation.

(d) Prevent cross-contamination of foods via hands, cutting boards or utensils during preparation.

(e) Ensure that hot foods leave the kitchen (pot, steam table, etc.) for serving at or above 140 degrees F. and that cold foods leave the kitchen for serving at or below 41 degrees F.

(6) **Duties of Food Service Manager.** The person designated by the assisted living community as being responsible for managing the preparation of meals for the residents must enforce safe food handling practices which address basic food safety, hygiene, cross contamination, time and temperature requirements and sanitation with staff and residents.

(7) **Emergency Food Supply.** A 3-day supply of non-perishable dry or canned foods and water, must be on hand at all times in the assisted living community for emergency use. The quantity of food required to be stored must be based on the usual resident census. The food must be kept in sealed containers which are labeled and dated. The food must be rotated in accordance with shelf life to ensure safety and palatability. Water sufficient for drinking and food preparation must also be stored.

(8) **Properly Furnished Food Areas.** Kitchen and dining areas must be properly equipped with appropriate cabinets, drawers, holders and shelves or racks for storage of necessary equipment and utensils. These rooms must be kept clean and disinfected at least daily unless more frequent sanitization is required to prevent the spread of infection or food borne illnesses.

(9) **Food Service Permit Required.** An assisted living community must either possess a valid food service permit issued through the authority of the Department of Public Health pursuant to Chapter 290-5-14 or a copy of the valid food service permit of the caterer' who provides meals to the community.

(10) **Menu Requirements.** Menus to be served in assisted living residences must be dated and planned at least one week in advance for both regular and therapeutic diets. Residents must be encouraged to participate in menu planning. Planned menus must be conspicuously posted or easily available to residents. Regular and therapeutic menus as

served, with substitutions noted before the meal is served, must be kept on file in the assisted living community for 30 days.

(11) **Food Safety Reports**. The assisted living community must retain copies of food safety inspection reports required by law which were issued during the year preceding the most recent inspection. The most recent food service inspection report must be posted in the assisted living community.

(12) **Catered Food Service.** When the assisted living community uses a catered food service (food service establishment), the assisted living community must ensure that the service is properly licensed, provides meals in accordance with these rules, has a satisfactory record of compliance with food safety requirements and properly transports and stores food at time of delivery to maintain food safety.

(13) **Catering Records.** An assisted living community utilizing a catered food service must maintain copies of the current contract between the assisted living community and the food service establishment agreeing to provide food service in the assisted living community, the certificate or license authorizing the operation of the food service establishment issued by the county health agency and the most recent food safety inspection reports.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.21
Authority: O.C.G.A. §§ 31-2-7, 31-2-8 and 31-7-1*et seq.*
History. Original Rule entitled "Nutrition and Food Preperation" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.22. Temperature Control.

(1) The temperature throughout the assisted living community must be maintained by an adequate central heating and cooling system or its equivalent at ranges which are consistent with individual health needs of residents and provides a comfortable environment for the residents.

(2) Temperatures in the assisted living community must not fall below 62 degrees F during sleeping hours or above 85 degrees F during the day. Mechanical cooling devices shall be made available for use in those areas of the building used by residents when inside temperatures exceed 80 degrees F.

(3) Where a power outage or mechanical failure impacting the ability of the assisted living community to maintain these temperature ranges occurs, the assisted living community must take immediate action to provide for the health and safety of the residents, including but not limited to, arranging immediately for a service call, providing additional blankets or fans or utilizing an emergency power generator in accordance with the assisted living community's emergency preparedness plan.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.22
Authority: O.C.G.A. §§ 31-2-7, 31-2-8 and 31-7-1*et seq.*
History. Original Rule entitled "Temperature Control" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.23. Infection Control, Sanitation and Supplies.

(1) The assisted living community must have an effective infection control program which includes, at a minimum, the following:

(a) training provided to staff on effective measures for minimizing the spread of infections and food borne illnesses;

(b) responding to disease outbreaks appropriately and participating in infection control investigations;

(c) staff demonstrating their understanding and use of proper infection control practices in their delivery of care to the residents;

(d) enforcing work and return to work policies to minimize the spread of infection and illnesses; and

(e) implementing the additional infection control requirements set forth in the Rules and Regulations for Disaster Preparedness Plans, Chapter 111-8-16, regarding pandemic plans, supplies and policies and procedures.

(2) The assisted living community must have an adequate supply of sanitizing and cleaning agents, e.g.. effective hand hygiene products, hand soap, laundry soap, household disinfectants and other cleaning materials, available and used in the assisted living community to minimize the spread of infections.

(3) Toilet tissue, soap, hot and cold running water and clean towels must be available for use wherever commodes are located.

(4) The assisted living community must have a supply of first-aid materials available for use. This supply must include, at a minimum, gloves, band aids, thermometer, tape, gauze, and an antiseptic.

(5) The storage and disposal of bio-medical and hazardous wastes must comply with applicable federal, state, and local rules and/or standards.

(6) Solid waste which is not disposed of by mechanical means must be stored in vermin-proof, leak-proof, nonabsorbent containers with close-fitting covers until removed. Waste must be removed from the kitchen at least daily and from the premises at least weekly.

(7) An insect, rodent or pest control program must be maintained and conducted in a manner which continually protects the health of residents.

(8) Residents' private living spaces or bedrooms must be thoroughly cleaned and sanitized after residents move out of the rooms.

(9) The assisted living community must clean the residents' private living spaces periodically and as needed to ensure that the space does not pose a health hazard.

(10) The assisted living community must notify residents of infectious disease outbreaks or incidents as specified in the Rules and Regulations for Disaster Preparedness Plans, Chapter 111-8-16.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.23
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1 et seq.
History. Original Rule entitled "Infection Control, Sanitation and Supplies" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Aug. 24, 2021; eff. Sept. 13, 2021.

Rule 111-8-63-.24. Residents' Files.

(1) An individual resident file must be maintained by the administrator or on-site manager for each resident in the assisted living community. Personal information must be treated as confidential and must not be disclosed except to the resident and his or her representative or legal surrogate, if any, an authorized agent of the Department, and others to whom written authorization is given by the resident or his representative or legal surrogate, if any. The resident file must be made available for inspection and/or copying to the resident or the resident's representative or legal surrogate, if any, and Department representatives, upon request.

(2) Each resident's file must include the following information:

(a) identifying information including name, social security number, veteran status, age, sex and previous address;

(b) name, address and telephone number of next of kin, legal guardian and/ or representative or legal surrogate, if any, or representative payee and any court order or written document designating the resident's representative or legal surrogate, if any;

(c) name, address and telephone number of any person or agency providing additional services to the resident. This information must include the name of the agency personnel primarily responsible where provided to the community by the person or agency, (i.e., the caseworker, case manager, or therapist);

(d) an admission and discharge log to include the date of admission, prior residence of resident, referral source, agency contact and telephone number of referral source date of discharge, facility or residence discharged to and telephone number;

(e) all individual written care plans required by the serules and the rules for proxy caregivers, Chapter 111-8-100 if applicable;

(f) the name, address and telephone number of a physician, hospital and pharmacy of the resident's choice;

(g) a record of all monetary transactions conducted on behalf of the resident with itemized receipts of all disbursements and deposits;

(h) a record of all monies and other valuable sentrusted to the assisted living community for safe keeping; a receipt for same shall be provided to the resident or representative or legal surrogate, if any, at the time of admission and at any time there after when the resident acquires additional property and wishes to entrust such property to the assisted living community for safe keeping;

(i) health information including all health appraisals, diagnoses, prescribed diets, medications, and physician's instructions;

(j) an inventory of valuable personal items brought to the assisted living community for use by the resident to be updated at anytime after admission if a resident or representative or legal surrogate, if any, submits to the assisted living community a new inventory of the resident's personal items;

(k) a signed copy of the Resident's Rights form;

(l) a signed copy of the admission agreement;

(m) any power of attorney or document issued by a court or by the Social Security Administration or any other governmental authority which designates another person as responsible for management of the resident's finances;

(n) a copy of a living will and/or durable power of attorney for healthcare if executed prior to 2007 or a copy of an executed Georgia advance directive for healthcare, if any, the forms for which must be made available at the time of admission and remain available to the resident upon request;

(o) any signed medical or ders impacting end of life care, e.g. do not resuscitate, physician's orders for life sustaining treatment, etc.

(p) a copy of the resident's written waiver, if any, of the personal needs allowance charge pursuant to the provisions of Rule 111-8-63-.25(p)1;

(q) a copy of any findings from a search of the National Sex Offender Registry maintained through the Department of Justice, etc.; and

(r) any informed written consents signed by the resident or resident's representative, designating and delegating to any trained proxy caregiver, whether employed by the assisted living community or not, the performance of identified health maintenance activities.

(s) evidence the resident has received educational information on influenza disease no later than September 1 of each year. Such information shall include, but is not limited to, the risks associated with influenza disease; the availability, effectiveness, and known contraindications of the influenza immunization; causes and symptoms of influenza; and the means in which it is spread. Provision of the appropriate and current Vaccine Information Statement as provided by the Centers for Disease Control and Prevention shall be deemed to comply with this regulation.

(3) The following information may be given voluntarily by the resident, guardian, or representative or legal surrogate, if any, but may not be required of the resident:

(a) religious preference, church membership, name and telephone number of minister, priest or rabbi, if applicable; and

(b) information about insurance policies and prearranged funeral and burial provisions, if any.

(4) Resident files must be maintained by the assisted living community for a period of three years after a resident's discharge.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.24
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-2-9, 31-7-1, 31-8-131, 31-32-1 et seq.
History. Original Rule entitled "Residents' Files" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.
Amended: F. Jan. 27, 2017; eff. Feb. 16, 2017.

Rule 111-8-63-.25. Supporting Residents Rights and Obtaining Feedback.

(1) The assisted living community must operate in a manner that respects the personal dignity of the residents and the human rights of the residents which rights cannot be waived, except as provided in these rules by the resident or the resident's representative or legal surrogate.

(a) The assisted living community must provide to each resident care and services which are adequate, appropriate, and in compliance with state law and regulations.

(b) The assisted living community, its agents or employees must not punish or harass a resident because of the resident's efforts to enforce his or her rights.

(c) The assisted living community must operate in a manner that protects each resident's rights to do all of the following:

1. exercise the constitutional rights guaranteed to citizens of this state and this country including, but not limited to, the right to vote;

2. choose activities and schedules consistent with the resident's interests, and assessments;

3. interact with members of the community both inside and outside the assisted living community and to participate fully in the life of the community; and

4. make choices about aspects of his or her life in the assisted living community that are significant to the resident.

(d) Each resident must have the right to enjoy privacy in his or her room. Assisted living community staff and others must respect this right by knocking on the door before entering the resident's room.

(e) Each resident must have the right to associate and communicate freely and privately with persons and groups of the resident's choice without being censored by staff.

(f) If a resident is married and the spouse is also a resident in the assisted living community, the residents must be permitted to share a room unless they request otherwise, subject to the limitation that no more than two residents may share a bedroom or private living space.

(g) Each resident must be treated with dignity, kindness, consideration and respect and be given privacy in the provision of assisted living care. Each resident must be accorded privacy and freedom to use the bathroom(s) at all hours.

(h) No religious belief or practice must be imposed upon any resident. Residents must be free to practice their religious beliefs as they choose. Each resident must have the right to participate in social, religious, and community activities that do not interfere with the rights of other residents.

(i) Each resident must have the right to be free from mental, verbal, sexual and physical abuse, neglect and exploitation.

(j) Each resident has the right to be free from actual or threatened physical or chemical restraints and the right to be free from isolation, corporal, or unusual punishment including interference with the daily functions of living, such as eating or sleeping.

(k) Each resident must have the right to use, keep and control his or her own personal property and possessions in the immediate living quarters, except to the extent a resident's use of his or her property would interfere with the safety or health of other residents. Each resident must have the right to reasonable safeguards for the protection and security of his personal property and possessions brought into the assisted living community.

(l) Each resident's mail must be delivered unopened to the resident on the day it is delivered to the assisted living community. The assisted living community must not permit any resident's outgoing correspondence to be opened or tampered with prior to being mailed or otherwise delivered.

(m) Each resident must have access to a telephone made available by the assisted living community and the right to have a private telephone, at the resident's own expense. Telephones must be placed in areas to insure privacy without denying accessibility.

(n) Each assisted living community must permit immediate access to residents by others who are visiting with the consent of the resident. Residents have the right to have visitors at mutually agreed upon hours. Once the hours are agreed upon, no prior notice is necessary. Each resident also has the right to refuse to see visitors or terminate any visit.

(o) Each resident must have the right to manage his own financial affairs, including the right to keep and spend his own money unless that resident has been adjudicated incompetent by a court of competent jurisdiction. Each resident must have the right to be free from coercion to assign or transfer to the assisted living community money, valuables, benefits, property or anything of value other than payment for services rendered by the assisted living community.

(p) Each resident must have the right to a personal needs allowance for the free use of the resident in the amount of twenty dollars per week to be distributed by the administrator, on-site manager, or a responsible staff person in the assisted living community. The following conditions must be met regarding the personal needs allowance:

1. The personal needs allowance must be included as a charge for services to each resident's account which a resident or a resident's representative or legal surrogate, if any, may waive by signing a written waiver upon admission or anytime thereafter. No allowance charge may be assessed where a resident or a resident's representative or legal surrogate, if any, has signed a written waiver of the personal needs allowance. Such a waiver must be kept in a resident's file.

2. Where no waiver has been signed, the personal needs allowance must be tendered to each resident, in cash, on the same day each week.

3. The personal needs allowance must not be intended or needed for purchasing necessary goods such as toilet paper and light bulbs which the assisted living community ordinarily supplies, and shall in no way relieve the assisted living community of the obligation to insure that such necessary goods are available to the resident.

(q) Each resident must have the right to receive or reject medical care, dental care, or other services by those authorized and/or licensed to provide such medical care except as required by law or regulations.

(r) Each resident must have the right to choose and retain the services of a personal physician and any other health care professional or service. No assisted living community is permitted to interfere with the resident's right to receive from the resident's attending physician complete and current information concerning the resident's diagnosis, treatment and prognosis. Each resident and his or her representative or legal surrogate, if any, must have the right to be fully informed about care provided in the community and of any changes in that care and the right of access to all information in medical records retained by the community.

(s) Each resident must have the right to fully participate in the planning of his or her care and to question the need for changes in the plan of care. Case discussion, consultation and examination must be confidential and conducted discreetly. A person who is not directly involved in the resident's care may be present when care is being rendered only if he or she has the resident's permission. The resident's duly appointed legal surrogate(s) shall have the authority to act on the resident's behalf as established by written applicable federal and state of Georgia law, and shall be entitled to receive information relevant to the exercise of his or her authority.

(t) Each resident, representative or legal surrogate must have the right to inspect his or her records on request. Each resident must have the right to make a copy of all records pertaining to the resident on the premises or obtain a copy from the community. The community may charge a fee for providing photocopies of the records, but such charge may not exceed what is charged by the local library for photocopies. Each resident has the right to confidential treatment of personal information in the resident file.

(u) Each resident who has not been committed to the assisted living community by court order or who does not have a representative or legal surrogate with specific written authority to admit, transfer or discharge, may discharge or transfer himself or herself upon 30 days written notification to the assisted living community in conformance with the assisted living community's policies and procedures.

(v) Each resident must have the right to access to the State Long-Term Care Ombudsman Program O.C.G.A. § 31-8-50*et seq.* and the name, address, and

telephone number of the ombudsman assigned to the assisted living community must be posted in a common area of the assisted living community.

(w) Residents must have the right to form a Resident Council and have meetings in the assisted living community outside the presence of owners, management or staff members of the assisted living community and the assisted living community must provide assistance in coordinating the meetings of the Resident Council.

(2) Each resident must be provided, at the time of admission to the assisted living community, with a copy of the Resident's Bill of Rights, as provided in Rule 111-8-63.25. The Bill of Rights must include provisions for protecting the personal and civil rights of each resident. In the event that a resident is unable to read the Resident's Bill of Rights the manager must take steps to assure communication of its contents to the resident.

(3) An assisted living community must comply with the provisions of the "Remedies for Residents of Personal Care Homes Act" as outlined in O.C.G.A. § 31-8-131*et seq.*

(4) The assisted living community must ensure that residents and their representatives, where applicable, are given opportunities to provide feedback in writing and otherwise on their satisfaction with the services being provided by the assisted living community with respect to at least the following areas: quality of care, food, activities, cleanliness of the assisted living community and helpfulness of the staff.

(5) The assisted living community must retain a copy of the resident's record for two years following the date of discharge.

(6) The assisted living community must maintain documentation of the feedback it receives and its response to the feedback.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.25
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*, 31-8-50 *et seq.* and 31-8-131 *et seq.*
History. Original Rule entitled "Supporting Resident's Rights and Obtaining Feedback" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.26. Procedures for Change in Resident's Condition.

(1) In case of an accident or sudden adverse change in a resident's condition or adjustment, an assisted living community must immediately take the actions appropriate to the specific circumstances to address the needs of the resident, including notifying the representative or legal surrogate, if any. The assisted living community must retain a record of all such adverse changes and the assisted living community's response in the resident's files.

(2) Where the sudden change in the resident's condition causes the resident to become unresponsive, the assisted living community must immediately take one of the following actions:

(a) If the resident is enrolled in a licensed hospice and has a specific hospice plan of care, the assisted living community must contact the hospice for directions regarding the care to be provided. If the hospice staff is not available to provide direction, then the assisted living community must immediately contact the duly-appointed health care agent for direction. If no health care agent has been appointed or is not available, then the assisted living community must immediately contact emergency medical services to arrange for emergency transport and must initiate cardiopulmonary resuscitation if no DNR order has been written.

(b) If the resident has a valid Do Not Resuscitate (DNR) order readily available, the caregiver may effectuate the DNR order if done in good faith.

(c) If the resident has appointed a health care agent in a living will, durable power of attorney for health care or an advance directive for health care which complies with the requirements of O.C.G.A. § 31-32-1*et seq.*,then the assisted living community must immediately contact the health care agent for directions regarding the care to be provided. Where the health care agent is not immediately available and there is no valid DNR order for the resident, the assisted living community must immediately contact emergency medical services to arrange for emergency transport and must initiate cardiopulmonary resuscitation.

(d) If the resident is not enrolled in hospice, and does not have either a DNR or an advance directive, then the staff of the assisted living community must immediately contact emergency medical services to arrange for emergency transport and must initiate cardiopulmonary resuscitation where it is not obvious from physical observation of the resident's body (e.g. body is stiff, cool to the touch, blue or grayish in color, etc.) that such efforts would be futile and there is not a physician, or authorized registered nurse or physician's assistant on site to assess and provide other direction.

(2) The staff must have ready access to phone numbers for emergency medical personnel and the resident's file or appropriate emergency medical and contact information for each resident, both at the assisted living community and when residents are being transported by the assisted living community for any reason.

(3) Immediate investigation of the cause of an accident, injury or death involving a resident must be initiated by the administrator or on-site manager of the assisted living community and a report made to the representative or legal surrogate, if any, with a copy of the report maintained in the resident's file and in a central file for quality assurance review.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.26
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.* and 31-32-1 *et seq.*
History. Original Rule entitled "Procedures for Change in Resident's Condition" adopted. F. Dec. 13, 2012; eff. Jan.

2, 2012.

Rule 111-8-63-.27. Death of a Resident.

(1) Should a resident die while in the assisted living community, the administrator, on-site manager or designated staff must immediately notify the resident's physician, the next of kin, and the representative or legal surrogate, if any, and appropriate law enforcement authorities where the law so requires, such as in the case of a sudden or unexpected death.

(2) Upon death of the resident, the assisted living community must refund to the representative or legal surrogate, if any, any security deposit made to the assisted living community by or on behalf of the resident in compliance with O.C.G.A. § 44-7-30*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.27
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.* and 44-7-30 *et seq.*
History. Original Rule entitled "Death of a Resident" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.28. Immediate Transfers of Residents.

(1) The administrator or on-site manager of the assisted living community must initiate an immediate transfer to an appropriate setting if the resident develops a physical or mental condition requiring continuous medical care or nursing care.

(2) Where immediate transfer is required to be made, the administrator or on-site manager shall make arrangements for transfer in accordance with the admission agreement and must transfer the resident to an appropriate setting where the resident's needs can be met. Prior to making such transfer, the administrator or on-site manager shall:

(a) inform the resident and representative or legal surrogate, if any, of the reason for the immediate transfer;

(b) inquire as to any preference of the resident and representative or legal surrogate, if any, regarding the appropriate setting to which the resident is to be transferred;

(c) inform the representative or legal surrogate, if any, of the resident's choice regarding such transfer;

(d) inform the resident and the representative or legal surrogate, if any, of the place to which the resident is to be discharged;

(e) provide a copy of the resident file to the receiving setting within 24 hours of transfer; and

(f) document in the resident's file the following:

1. the reason for the immediate transfer;

2. the fact that the resident and the representative or legal surrogate, if anywhere informed pursuant to this paragraph; and

3. appropriate location and contact information regarding the place to which the resident is to be transferred or discharged.

(3) Upon immediate transfer of the resident, the assisted living community must refund to the resident or representative or legal surrogate, if any, any security deposit made to the assisted living community by or on behalf of the resident in compliance with O.C.G.A. § 44-7-30*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.28
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.* and 44-7-30 *et seq.*
History. Original Rule entitled "Immediate Transfers of Residents" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.29. Discharge or Transfer of Residents.

(1) Each admission agreement shall include a written procedure for handling the discharge and transfer of the resident. The administrator or on-site manager must contact the representative or legal surrogate, if any, when there is need to discharge or transfer of a resident. The community must provide 30 days' written notice of its intent to discharge or transfer the resident unless an immediate transfer is required. The written notice must be issued to both the resident and the representative or legal surrogate, if any.

(2) In all cases except those requiring immediate transfer pursuant to Rule 111-8-63-.28, residents whose needs cannot be met by the assisted living community or who no longer choose to live in the assisted living community must be discharged or transferred to an appropriate facility or other appropriate setting in accordance with the resident's, representative or legal surrogate's wishes based on discharge and transfer procedures entered into at the time of admission. Where there is no representative or legal surrogate or the representative or legal surrogate is unwilling to act to consent to the discharge or transfer, the administrator or on-site manager must petition the probate court in the county where the assisted living community is located for an order authorizing the discharge or transfer. The transferring assisted living community must provide a copy of the resident file to the receiving facility prior to or at the time of transfer.

(3) Where the Department has reason to believe that a resident is receiving or requires continuous medical or nursing care, other than as permitted by a certified medication aide, the Department may require the assisted living community to discharge the resident. However, the provision of medical, nursing or health services required by the resident on

a periodic basis or for a short-term illness, where such services are not provided by the assisted living community is permissible.

(4) Upon discharge or transfer of the resident, the assisted living community must refund to the resident or representative or legal surrogate, if any, any security deposit made to the assisted living community by or on behalf of the resident in compliance with O.C.G.A. § 44-7-30*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.29
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*, 31-36A-7 and 44-7-30 *et seq.*
History. Original Rule entitled "Discharge or Transfer of Residents" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.30. Reports to the Department.

(1) The staff of the assisted living community must call the local police department to report the elopement of any resident from the assisted living community within 30 minutes of the staff receiving actual knowledge that such person is missing from the assisted living community in accordance with the Mattie's Call Act and the requirements set forth in O.C.G.A. § 35-3-170*et seq.* The assisted living community shall also report the initiation and discontinuation of a Mattie's call to the Department within thirty (30) minutes of communications with local law enforcement authorities having occurred.

(2) Whenever a serious incident involving a resident occurs, the assisted living community must report in a format acceptable to the Department either within 24 hours after the incident has occurred, or the assisted living community has reasonable cause to believe that a reportable incident involving a resident has occurred. The serious incidents that must be reported to the Department include the following:

(a) any accidental or unanticipated death not directly related to the natural course of the resident's underlying medical condition;

(b) any serious injury to a resident that requires medical attention;

(c) any rape, assault, any battery on a resident, or any abuse, neglect, or exploitation of a Resident in accordance with the Long Term Care Resident Abuse Reporting Act O.C.G.A. § 31-8-80*et seq.;*

(d) an external disaster or other emergency situation that affects the continued safe operation of the residence; and

(e) when an owner, director or employee acquires a criminal record as defined in these rules.

(3) The incident report required by these rules must be filed with the Department, in confidence and must include at least:

(a) the name of the assisted living community and the name of the administrator or site manager;

(b) the date of the incident and the date the assisted living community became aware of the incident;

(c) the type of incident suspected, with a brief description of the incident; and

(d) any immediate corrective or preventative action taken by the assisted living community to ensure against the replication of the incident.

(4) Where the Department determines that a rule violation related to the incident has occurred, the Department will initiate a separate complaint investigation of the incident. The complaint investigation report and the report of any rule violation compiled by the Department arising either from the initial report received from the assisted living community or an independent source is subject to disclosure in accordance with applicable laws.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.30
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*, 31-8-80 *et seq.* and 35-3-170 *et seq.*
History. Original Rule entitled "Reports to the Department" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.31. Deemed Status.

The Department may accept the certification or accreditation of an assisted living community by an accreditation body or certifying authority recognized and approved by the Department provided that certification or accreditation constitutes compliance with standards that are substantially equivalent to these rules. Nothing herein shall prohibit any departmental inspection to determine compliance with licensure rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.31
Authority: O.C.G.A. §§ 31-7-1 and 31-7-3(b).
History. Original Rule entitled "Deemed Status" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.32. Variances and Waivers.

(1) The Department may, in its discretion, grant variances and waivers of specific rules upon application or petition filed on forms made available by the Department. The Department may establish conditions which must be met by the assisted living community in order to operate under the variance or waiver granted.

(a) **Variance.** A variance may be granted by the Department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the

variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety, and care of the residents exist and will be met in lieu of the exact requirements of the rule or regulations in question. The Department may require additional documentation by the assisted living community to support its application for a variance or waiver.

(b) **Waiver.** The Department may dispense entirely with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, care, and rights of the residents.

(c) **Experimental Variance or Waiver.** The Department may grant variances and waivers to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant or petitioner that the intended protections afforded by the rule or regulation which is the subject of the request are met and that the innovative approach has the potential to improve service delivery without compromising health, safety, residents' rights, or other relevant standards.

(2) The decision of the Department regarding either granting or denying the application of the governing body of the assisted living community for a waiver or variance is not subject to further administrative review. The governing body may file a petition for judicial review in the appropriate superior court.

(3) Where the Department has denied the application for a waiver or variance in writing, the Department will not consider a subsequent application for the same waiver or variance as a new application unless the applicant includes new evidence of a substantial change in the circumstances which formed the basis for the initial request.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.32
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*, 50-13-9.1 and 50-13-19.
History. Original Rule entitled "Variance and Waivers" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.33. Enforcement of Licensing Requirements.

An assisted living community that fails to comply with licensing requirements contained in these rules, the Rules and Regulations for the Use of Proxy Caregivers, Chapter 111-8-100 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25, is subject to civil and administrative actions brought by the Department to enforce licensing requirements as provided by law and rules. Such actions will be initiated in compliance with the Georgia Administrative Procedures Act, O.C.G.A. § 50-13-1*et seq.*, O.C.G.A. § 31-2-11 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.33
Authority: O.C.G.A. §§ 31-2-7, 31-2-8, 31-7-1*et seq.*, 43-26-12 and 50-13-1 *et seq.*
History. Original Rule entitled "Enforcement of Licensing Requirements" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Rule 111-8-63-.34. Severability.

In the event that any rule, sentence, clause or phrase of any of the rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions thereof shall remain in full force and effect as if such rule or portions thereof so determined, declared or adjudicated invalid or unconstitutional were not originally part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-63-.34
Authority: O.C.G.A. § 31-2-7, 31-2-8 and 31-7-1*et seq.*
History. Original Rule entitled "Severability" adopted. F. Dec. 13, 2012; eff. Jan. 2, 2012.

Subject 111-8-65. RULES AND REGULATIONS FOR PRIVATE HOME CARE PROVIDERS.

Rule 111-8-65-.01. Legal Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated (O.C.G.A.) § 31-7-300*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.01
Authority: O.C.G.A. §§ 31-2-4, 31-2-5, 31-2-7 and 31-7-300*et seq.*
History. Original Rule entitled "Legal Authority" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.02. Title and Purposes.

These rules shall be known as the Rules and Regulations for Private Home Care Providers. The purposes of these rules are to provide for the licensing and inspection of private home care providers.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.02
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-7-300*et seq.*
History. Original Rule entitled "Title and Purposes" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.03. Definitions.

In these rules, unless the context otherwise requires, the words and phrases set forth herein shall mean the following:

(a) "Ambulation and transfer" means the act of moving or walking about or walking or being moved from place to place with or without assistance.

In these rules, unless the context otherwise requires, the words and phrases set forth herein shall mean the following.

(b) "Applicant" means:

1. When the private home care provider is owned by a sole proprietorship, the individual proprietor shall be the applicant for the license, complete the statement of responsibility and serve as the licensee;

2. When the private home care provider is owned by a partnership, the general partners shall be the applicant for the license, complete the statement of responsibility and serve as the licensee;

3. When the private home care provider is owned by an association limited liability company (LLC), the governing body of the association or LLC shall authorize the application for the license and complete the statement of responsibility and the association shall serve as the licensee; and

4. When the private home care provider is owned by a corporation, the governing body of the corporation shall authorize the application for the license and complete the statement of responsibility and the corporation shall serve as the licensee.

(c) "Companion or sitter tasks" means the following tasks which are provided to elderly, handicapped, or convalescing individuals: transport and escort services; meal preparation and serving; and household tasks essential to cleanliness and safety.

(d) "Criminal history background check" means a search as required by law of the criminal records maintained by law enforcement authorities to determine whether the applicant has a criminal record as defined in these rules.

(e) "Criminal record" means:

1. Conviction of a crime; or

2. Arrest, charge, and sentencing for a crime where:

(i) A plea of nolo contendere was entered to the charge; or

(ii) First offender treatment without adjudication of guilt pursuant to the charge was granted; or

(iii) Adjudication or sentence was otherwise withheld or not entered on the charge; or

3. Arrest and being charged for a crime if the charge is pending, unless the time for prosecuting such crime has expired pursuant to Chapter 3 of Title 17, O.C.G.A.

(f) "Department" means the Department of Community Health.

(g) "Director" means the chief administrative or executive officer or manager.

(h) "Home health agency" means a facility licensed as a home health agency in accordance with the applicable licensing statutes and associated rules.

(i) "Home management" means those activities normally performed by a homemaker for the maintenance of a home's essential services, including but not limited to activities such as meal planning, shopping, and bill paying; any employee that is authorized unlimited access to a client's personal funds for home management shall be bonded through the provider.

(j) "Housekeeping or housekeeping tasks" means those activities performed for the upkeep and cleanliness of the home, including but not limited to such activities as laundry, changing linens, trash disposal, and cleaning.

(k) "Inspection" means any examination by the department or its representatives of a provider, including but not necessarily limited to the premises, and staff, persons in care, and documents pertinent to initial and continued licensing so that the department may determine whether a provider is operating in compliance with licensing requirements or has violated any licensing requirements. The term inspection includes any survey, monitoring visit, complaint investigation, or other inquiry conducted for the purposes of making a compliance determination with respect to licensing requirements.

(l) "Medically frail or medically compromised client" means a client whose health status, as determined by appropriate provider staff in accordance with accepted standards of practice, is likely to change or has changed because of a disease process, injury, disability or advanced age and underlying disease process(es).

(m) "Medically related activities" means activities such as but not limited to observing and reporting changes in a client's condition, arranging trips to the doctor, picking up prescription drugs, accompanying clients on medical appointments, documenting client's food and/or liquid intake or output, reminding clients to take medication, and assisting with self-administration of medication; such activities shall not include professional services that are subject to regulation under professional practice and licensing statutes and associated rules.

(n) "Owner" means any individual or any person affiliated with the corporation, partnership, or association with 10 percent or greater ownership interest in a business or agency licensed as a private home care provider and who:

1. Purports to or exercises authority of an owner in the business or agency;

2. Applies to operate or operates the business or agency; or

3. Enters into a contract to acquire ownership of such a business or agency.

(o) "Personal care home" means a facility licensed as a personal care home in accordance with the applicable licensing statutes and associated rules.

(p) "Personal care tasks" means assistance with bathing, toileting, grooming, shaving, dental care, dressing, and eating; and may include but are not limited to proper nutrition, home management, housekeeping tasks, ambulation and transfer, and medically related activities, including the taking of vital signs only in conjunction with the above tasks.

(q) "Private home care provider" means any person, business entity, corporation, or association, whether operated for profit or not for profit, that directly provides or makes provision for private home care services through:

1. its own employees who provide nursing services, personal care tasks or companion or sitter tasks;

2. contractual arrangements with independent contractors who are health care professionals licensed pursuant to the applicable chapter of Title 43; or

3. referral of other persons to render home care services, when the individual making the referral has ownership or financial interest in the delivery of those services by those other persons who would deliver those services.

(r) "Private home care services" means those items and services provided at a patient's residence that involve direct care to that patient and includes, without limitation, any or all of the following:

1. nursing services, provided that such services can only be provided by a person licensed as a Registered Professional Nurse or Licensed Practical Nurse in accordance with applicable professional licensing statutes and associated rules;

2. personal care tasks; and

3. companion or sitter tasks.

4. Private home care services shall not include physical, speech or occupational therapy; medical nutrition therapy; medical social services; home health aide

services provided by a home health agency; or proxy caregiver services provided by a proxy caregiver hired by the patient.

(s) "Records check application" means two sets of classifiable fingerprints, a records search fee to be established by the department by rule and regulation, payable in such form as the department may direct to cover the cost of a fingerprint records check, and an affidavit by the applicant disclosing the nature and date of any arrest, charge, or conviction of the applicant for the violation of any law, except for motor vehicle parking violations, whether or not the violation occurred in this state, and such additional information as the department may require.

(t) "Residence" means the place where an individual makes that person's permanent or temporary home, whether that person's own apartment or house, a friend or relative's home, or a personal care home, but shall not include a hospital, nursing home, hospice, or other health care facility licensed under O.C.G.A. § 31-7-1*et seq*.

(u) "Responsible Party" means any person authorized in writing by the client or appointed by an appropriate court to act upon the client's behalf; the term shall include a family member of a physically or mentally impaired client unable to grant the above authorization.

(v) "Satisfactory criminal history background check determination" means a written determination that a person for whom a records check was performed was found to have no criminal record which includes one of the covered crimes outlined in O.C.G.A. § 31-2-9, if applicable.

(w) "Transport and escort services" means accompanying clients or providing or arranging transportation for clients to places outside of their residences for purposes such as appointments, entertainment, exercise, recreation, shopping, or social activities. If the mode of transportation is not owned by the client and is operated by an employee of the provider, the provider shall either obtain a signed waiver by the client of any claims for damages arising out of the operation of the vehicle or make reasonable efforts to insure that there is current motor vehicle insurance that will provide medical coverage for the client, in the event that the vehicle is involved in an accident causing injuries to the client.

(x) "Unsatisfactory criminal history background check determination" means a written determination that a person for whom a records check was performed has a criminal record which includes one of the covered crimes outlined in O.C.G.A. § 31-2-9, if applicable.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.03
Authority: O.C.G.A. §§ 31-2-5, 31-2-7, 31-7-300*et seq.*
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.
Amended: F. Mar. 17, 2016; eff. Apr. 6, 2016.

Rule 111-8-65-.04. Governing Body.

Each private home care provider shall have a governing body empowered and responsible to determine all policies and procedures and to ensure compliance with these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.04
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-7-300*et seq.*
History. Original Rule entitled "Governing Body" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.05. Licenses.

(1) No private home care provider shall operate without a license or provisional license issued by the department.

(a) A license shall be issued and renewed periodically by the department upon a providers' compliance with these rules and shall remain in force and effect until the license expires or is suspended, revoked or limited.

(b) Prior to the issuance of any new license, the owner of the business or agency applying for the license shall be required to submit a records check application so as to permit the department to obtain a criminal history background check.

1. An owner may not be required to submit a records check application if a determination is made by the Department that the owner does not do any of the following:

(i) Maintains an office at the location where services are provided to clients;

(ii) Resides at a location where services are provided to clients;

(iii) Has direct access to persons receiving care; nor

(iv) Provides direct personal supervision of personnel by being immediately available to provide assistance and direction during the time services are being provided.

2. In lieu of a records check application, the owner may submit evidence, satisfactory to the department, that within the immediately preceding 12 months the owner has received a satisfactory criminal records check determination.

(c) A private home care provider license shall not be issued, and any issued license shall be revoked, where it has been determined that the owner has received an unsatisfactory criminal records check determination involving any of the following covered crimes, as outlined in O.C.G.A. 49-2-14.1*et seq.*:

1. A violation of Code Section 16-5-1, relating to murder and felony murder;

2. A violation of Code Section 16-5-21, relating to aggravated assault;

3. A violation of Code Section 16-5-70, relating to aggravated battery;

4. A violation of Code Section 16-5-70 relating to cruelty to children;

5. A violation of Code Section 16-5-100, relating to cruelty to a person 65 year of age or older;

6. A violation of Code Section 16-6-1, relating to rape;

7. A violation of Code Section 16-6-2, relating to aggravated sodomy;

8. A violation of Code Section 16-6-4, relating to child molestation;

9. A violation of Code Section 16-6-5, relating to enticing a child for indecent purposes;

10. A violation of Code Section 16-6-5.1, relating to sexual assault against persons in custody, detained persons, or patients in hospitals or other institutions;

11. A violation of Code Section 16-6-22.2, relating to aggravated sexual battery;

12. A violation of Code Section 16-8-41, relating to armed robbery;

13. A violation of Code Section 30-5-8, relating to abuse, neglect, or exploitation of a disabled adult or elder person; or

14. Any other offense committed in another jurisdiction that, if committed in this state, would be deemed to be a crime listed in this paragraph without regard to its designation elsewhere;

(d) An owner holding a valid private home care provider license issued on or before June 30, 2007 shall be required to obtain a fingerprint records check determination no later than December 31, 2008.

1. An owner holding a valid private home care provider license issued on or before June 30, 2007 who has received an unsatisfactory criminal records determination which includes any one of the covered crimes listed in Rule .05(c)(1)-(14) above, shall not have the license revoked prior to a hearing being held before a hearing officer pursuant to Chapter 13 of Title 50, the 'Georgia Administrative Procedures Act'.

2. An owner with a valid private home care provider license who acquires a criminal record for any of the crimes listed in Rule .14(7)(c)(1)-(14) above subsequent to the effective date of these rules shall disclose the criminal record to the department.

(e) If at any time the department has reason to believe an owner holding a valid license has been arrested, charged, or convicted of any of the covered crimes listed in Rule .14(7)(c)(1)-(14) above, the department shall require the owner to submit a records check application immediately for determination of whether a revocation action is necessary.

(f) A provisional license may be issued by the department on a conditional basis for one of the following reasons:

1. To allow a newly established provider a reasonable, but limited, time to demonstrate that its operational procedures comply with these rules; or

2. To allow an existing provider a reasonable length of time to comply with these rules and regulations, provided that the provider shall present a plan of improvement acceptable to the department.

(2) Qualifications Requirement. In order to obtain or retain a license or provisional license, the provider's administrator and its employees must be qualified, as defined in these rules, to direct or work in a program. However, the department may require additional reasonable verification of the qualifications of the administrator and employees either at the time of application for a license or provisional license or at any time during the license period whenever the department has reason to believe that an administrator or employee is not qualified under these rules to direct or work in a program.

(a) If a governing body maintains offices as a private home care provider in more than one location, then each location shall be separately licensed.

(b) The license shall be prominently and appropriately displayed at the private home care providers licensed location.

(c) No license issued under these rules is assignable or transferable. Each license or provisional license shall be returned to the department in cases of changes in name, location, ownership or governing body or if suspended, revoked, or limited. The department shall be provided 15 days notice in advance of any providers change in location.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.05
Authority: O.C.G.A. §§ 31-2-5, 31-2-7, 31-2-9 and 31-7-300*et seq.*
History. Original Rule entitled "Licenses" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.06. Applications.

(1) Initial applications for a license as a private home care provider must be submitted to the department on forms provided by the department, and shall include the submission of an application fee and a license fee established by the Board of Community Health, and a records check application for the owner. Such application shall include a description of the private home care provider services to be offered by the applicant and the geographic area that will be served.

(2) Renewal of Licenses. Licenses shall be renewed by the department periodically from the date of initial issuance upon submission of a renewal application, and a license renewal fee established by the Board of Community Health. Such renewal application shall include a description of the private home care provider services offered by the licensee and the geographic area served.

(3) Fees. Fees shall be reasonable and shall be set so that the total of the fees approximates the total of the direct and indirect costs to the state of the licensing program. Fees may be refunded for good cause as determined by the department.

(4) False or Misleading Information. The application for any license or renewal must be truthfully and fully completed. In the event that the department has reason to believe that any application has not been completed truthfully, the department may require additional reasonable verification for the facts alleged. The department may refuse to issue or renew any license where false statements have been made in connection with the application or any other documents required by the department.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.06
Authority: O.C.G.A. §§ 31-2-4, 31-2-5, 31-2-8 and 31-7-300*et seq.*
History. Original Rule entitled "Applications" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.07. Exemptions.

(1) These rules shall not apply to private home care services which are provided under the following conditions:

(a) When those services are provided directly by an individual, either with or without compensation, and not by agents or employees of the individual and not through independent contractors or referral arrangements made by an individual who has ownership or financial interest in the delivery of those services by others who would deliver those services.

(b) When those services are home infusion therapy services and the intermittent skilled nursing care is provided only as an integral part of the delivery and infusion of pharmaceuticals; however, such skilled nursing care, whether hourly or

intermittent, which provides care licensed by these rules beyond the basic delivery and infusion of pharmaceuticals is not exempt;

(c) When those services are provided through the temporary placement of professionals and paraprofessionals to perform those services in places other than a person's residence;

(d) When those services are provided by home health agencies which are licensed under state law;

(e) When those services are provided in a personal care home by the staff of the personal care home; and

(f) When those services are services within the scope of practice of pharmacy and provided by persons licensed to practice pharmacy.

(g) RESERVED.

(2) A certificate of need issued pursuant to O.C.G.A. § 31-6-1*et seq.* is not required for licensure so long as the provider does not operate as a licensed home health agency or personal care home.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.07
Authority: O.C.G.A. §§ 31-7-305 and 31-7-307.
History. Original Rule entitled "Exemptions" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.08. Inspections and Plans of Correction.

(1) Providers shall be inspected by the department periodically; provided, however, the department may exempt a provider from such periodic inspections if it is certified or accredited by a certification or accreditation entity recognized and approved by the department.

(a) A provider seeking exemption from on-site inspection shall be required to submit to the department documentation of certification or accreditation, including a copy of its most recent certification or accreditation report.

(b) Nothing contained herein shall be construed to prohibit the department from conducting inspections of any provider as the department determines necessary.

(2) Consent to Entry and Access. An application for a license or the issuance and renewal of any license by the department constitutes consent by the applicant or licensee and the owner of the premises for the department's representatives to enter the premises for the purpose of conducting any inspection during regular business hours.

(a) Department representatives shall be allowed reasonable and meaningful access to the provider's premises, all records relevant to licensure and all provider staff. Providers shall assist and cooperate in arranging for department representatives to have meaningful access to provider's clients who consent to be interviewed by department representatives in connection with any licensure activity.

(3) Cooperation with Inspection. All provider staff shall cooperate with any inspection conducted by the department and shall provide, without unreasonable delay, any documents to which the department is entitled hereunder.

(4) If as a result of the inspection, violations of these licensure regulations are identified, the provider will be given a written report of the inspection which identifies the licensure regulations violated. The provider must submit a written plan of correction (improvement) in response to the inspection report which states what the provider will do when to correct each of the violations identified. The provider may offer any explanation or dispute the findings of violations in the written plan of correction so long as an acceptable plan of correction is submitted within ten days of the receipt of the written report of licensure inspection.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.08
Authority: O.C.G.A. §§ 31-2-5, 31-2-7, 31-2-8 and 31-7-300*et seq.*
History. Original Rule entitled "Inspections and Plans of Correction" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.09. Administration and Organization.

(1) Services Description. A provider shall establish and implement written policies and procedures that define the scope of private home care services it offers and the types of clients it serves. No provider shall provide services that are prohibited by these rules, the applicable legal authority, or other laws.

(2) Service Agreements. No provider shall offer to provide a client any private home care services that it cannot reasonably expect to deliver in accordance with these rules.

(a) A provider shall establish and implement policies and procedures for service agreements. All services provided to a client shall be based on a written service agreement entered into with the client or the client's responsible party, if applicable. The service agreement must include the following:

1. Date that provider makes initial contact with client for services;

2. Date of referral, i.e. the date on which the provider received a specific request to deliver private home care services to a particular client;

3. Description of services needed as stated by client or responsible party, if applicable;

4. Description of services to be provided and expected frequency and duration of services;

5. Charges for such services, and mechanisms for billing and payment of such charges;

6. Acknowledgment of receipt of a copy of client's rights and responsibilities as outlined at rule .12;

7. A telephone number of the provider that a client can call for information, questions, or complaints about services supplied by the provider;

8. The telephone number of the state licensing authority, i.e. the department, to call for information or questions about the provider concerning a violation of licensing requirements that was not resolved to the client's satisfaction by complaining to the provider;

9. Authorization from client or responsible party, if applicable, for access to client's personal funds when home management services are to be provided and when those services include assistance with bill paying or any activities, such as shopping, that involve access to or use of such funds; similarly approved authorization for use of client's motor vehicle when services to be provided include transport and escort services and when the client's personal vehicle will be used;

10. Signatures for the provider's representative and the client or responsible party, if applicable, and date signed; if a client or responsible party refuses to sign the agreement, such refusal shall be noted on the agreement with an explanation from the provider's representative.

(b) For new clients, such initial service agreements shall be completed not later than the second visit to the client's residence to provide services if the second visit occurs on a different day from the first visit or not later than seven calendar days after services are initially provided in the residence, whichever is earlier.

1. If the provider is unable to complete the service agreement for good cause, the provider will document such reason(s) in the client's file.

2. Subsequent revisions to the initial service agreement may be handled by the provider noting in the client's record the specific changes in service (e.g. addition or deletion of service, changes in frequency, or duration, or charge for services, etc.) that will occur and that the change was discussed with and

agreed to by the client and/or responsible party, as appropriate, who signed the initial agreement prior to the change in services occurring.

(c) A client has the right to cancel any service agreement at any time and shall only be charged for services actually rendered prior to the time that the provider is notified of the cancellation. The provider may assess a reasonable charge for travel and staff time if notice of the cancellation of the service agreement is not provided in time to cancel the service prior to the provider's staff member arriving at the client's house to perform the service.

(3) Administrator. The governing body shall appoint an administrator who shall have full authority and responsibility for the operation of the private home care provider.

(a) Any administrator employed after the effective date of these rules must meet the following minimum qualifications:

1. Never have been shown by credible evidence (e.g. a court or jury, a department investigation, or other reliable evidence) to have abused, neglected, sexually assaulted, exploited, or deprived any person or to have subjected any person to serious injury as a result of intentional or grossly negligent misconduct as evidenced by an oral or written statement to this effect obtained at the time of application;

2. Participate in the orientation and training required by these rules;

3. Not have made any material false statements concerning qualifications requirements either to the department or the provider.

(4) Record keeping.

(a) Client Records. A provider shall maintain a separate file containing all written records pertaining to the services provided for each client that it serves and the file shall contain the following:

1. Identifying information including name, address, telephone number, and responsible party, if any;

2. Current service agreement as described at rule .09(2);

3. Current service plan as described at rule .11;

4. Clinical and/or progress notes if the client is receiving nursing services that have been signed and dated by the staff providing the direct care;

5. Documentation of personal care tasks and companion or sitter tasks actually performed for the client;

6. Documentation of findings of home supervisory visits by the supervisor unless entered in service plan;

7. Any material reports from or about the client that relate to the care being provided to the client including items such as progress notes and problems reported by employees of the provider, communications with personal physicians or other health care providers, communications with family members or responsible parties, or similar items;

8. The names, addresses, and telephone numbers of the client's personal physicians, if any; and

9. Date and source of referral.

(b) Retention and Confidentiality of Client Records. Written policies and procedures shall be established and implemented for the maintenance and security of client records specifying who shall supervise the maintenance of records, who shall have custody of records, to whom records may be released and for what purposes and how long the records will be retained.

1. At a minimum, all client records shall be retained for five years from the date of last service provided. The provider shall maintain the confidentiality of client records.

2. Employees of the provider shall not disclose or knowingly permit the disclosure of any information in a client record except to appropriate provider staff, the client, responsible party (if applicable), the client's physician or other health care provider, the department, other individuals authorized by the client in writing or by subpoena.

(c) Personnel Records. A provider shall maintain separate written records for each employee and the records shall include the following:

1. Identifying information such as name, address, telephone number, and emergency contact person(s);

2. A five year employment history or a complete employment history if the person has not been employed five years;

3. Records of qualifications;

4. Documentation of a satisfactory TB screening test upon employment and annually thereafter;

5. Date of employment;

6. The person's job description or statements of the person's duties and responsibilities;

7. Documentation of orientation and training required by these rules;

8. Documentation of at least an annual performance evaluation;

9. Documentation of bonding if the employee performs home management services which permit unlimited access to the client's personal funds. (If bonding is provided through a universal coverage bond, evidence of bonding need not be maintained separately in each personnel folder.)

(d) Reports of Complaints and Incidents. The provider shall maintain files of all documentation of complaints submitted pursuant to rule .12(2). A provider shall also maintain on file for a minimum of five years all incident reports or reports of unusual occurrences (e.g. falls, accidents, significant medication errors, etc.) that affect the health, safety, and welfare of its clients. Documentation required to be maintained shall include what actions, if any, the provider took to resolve clients' complaints and to address any incident reports or unusual occurrences required to be retained.

(5) Staffing. The provider shall have sufficient numbers of qualified staff as required by these rules to provide the services specified in the service agreements with its clients. In the event that the provider becomes aware that it is unable to deliver the specified services to the client because of an unexpected staff shortage, the provider shall advise the client and refer the client to another provider if the client so desires.

(a) All staff employed by a provider shall have included in their personnel records or files maintained by the particular provider a written evaluation that was performed within one year before or after the effective date of these rules. The written evaluation must reflect that the employee's performance of required job tasks was observed personally by a supervisor either by demonstration or observation and such performance was determined to be competent for all job tasks required to be performed. All staff hired after the effective date of these rules must meet the following minimum qualifications:

1. Never have been shown by credible evidence (e.g. a court or jury, a department investigation, or other reliable evidence) to have abused, neglected, sexually assaulted, exploited, or deprived any person or to have subjected any person to serious injury as a result of intentional or grossly negligent misconduct as evidenced by an oral or written statement to this effect obtained at the time of application;

2. Participate in the orientation and training required by these rules;

3. Not have made any material false statements concerning qualifications requirements either to the department or the provider.

(b) Nursing Personnel. Any persons employed by the provider to provide nursing services shall be licensed in Georgia in accordance with professional licensing laws and associated rules. Such persons may also provide any other types of private home care services offered by the provider.

(c) Personal Care Assistant (PCA). The provider may have PCAs perform personal care tasks for clients. Such persons may also perform companion or sitter tasks for clients, but shall not provide nursing services unless qualified as stated in rule .09(5)(b) above.

1. Any PCA hired after the effective date of these rules shall have the following training and/or experience:

(i) successful completion of a nurse aide training and competency evaluation program pursuant to the requirements of 42 CFR Part 483, Subpart D, as revised or recodified, if applicable; or

(ii) successful completion of a competency examination for nurse aides recognized by the department; or

(iii) successful completion of a health care or personal care credentialing program recognized and approved by the department; or

(iv) successful completion or progress in the completion of a 40 hour training program provided by a private home care provider, which addresses at least the following areas:

(I) Ambulation and transfer of clients, including positioning;

(II) Assistance with bathing, toileting, grooming, shaving, dental care, dressing, and eating;

(III) Basic first aide and CPR;

(IV) Caring for clients with special conditions and needs so long as the services are within the scope of the tasks authorized to be performed by demonstration;

(V) Home management;

(VI) Home safety and sanitation;

(VII) Infection control in the home;

(VIII) Medically related activities to include the taking of vital signs; and

(IX) Proper nutrition.

2. A training program described in rule .09(5)(c)1. (iv) must be conducted under the direction of a licensed registered professional nurse, or a health care professional with commensurate education and experience. Twenty hours of the program must be completed by the employee prior to serving clients and the additional twenty hours must be completed within six months of the date the training initially began. No PCA shall be assigned to perform a task for which training has not been completed and competency has not been determined. No PCA shall be assigned to care for a client with special conditions unless the PCA has received training and has demonstrated competency in performing such services related to such special conditions.

(d) Companions or Sitters. The provider may have companions or sitters perform companion or sitter tasks for clients.

1. Such persons may not provide other private home care services to clients unless qualified as stated in rules .09(5)(b)and(c).

2. Any companion or sitter hired after the effective date of these rules must meet the following minimal requirements:

(i) Be able to read and write, follow verbal and written instructions, and complete written reports and documents;

(ii) Successfully complete training or demonstrate understanding and practical competency in the following areas: understanding the needs and characteristics of elderly, handicapped, or convalescing individuals; meal preparation and serving; transportation and escort services; housekeeping to include sanitation; home safety; handling medical emergencies in the home; and infection control.

(6) Staff Training. Prior to working with clients, all employees hired or used on or after the effective date of these rules and who provide services to clients shall be oriented in accordance with these rules and shall thereafter receive additional training in accordance with these rules.

(a) Orientation shall include instruction in:

1. The provider's written policies and procedures regarding its scope of services and the types of clients it serves (rule .09(1) and clients rights and responsibilities and complaints (rule .12), as well as other policies that are relevant to the employee's range of duties and responsibilities;

2. The employee's assigned duties and responsibilities;

3. Reporting client progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of services in accordance with the client's services plan;

4. The employee's obligation to report known exposure to tuberculosis and hepatitis to the employer.

(b) Additional training consisting of a minimum of eight clock hours of training or instruction shall be provided annually for each employee after the first year of employment. Employees hired prior to the effective date of these rules are also required to receive eight clock hours of training or instruction annually beginning with the effective date of these rules. Such training or instruction shall be in subjects that relate to the employee's assigned duties and responsibilities.

(7) Contracted Services. If a provider arranges with independent contractors, individuals, or agents for them to provide any authorized private home care services on behalf of the provider in any way, such arrangements shall be set forth in writing detailing the services to be provided. The provider must assure that the independent contractor, individual, or agent supplying the services follow the provisions of these rules and are qualified to provide the services. The services must be supervised, as outlined in rule .10(2) (Supervision of Services), by a supervisor of the licensed provider.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.09
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-7-300*et seq.*
History. Original Rule entitled "Administration and Organization" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.10. Private Home Care Provider Services.

(1) A provider may provide three categories of home care services as defined in these rules.

(a) Nursing Services. If a provider provides nursing services, such services shall be provided by a licensed registered professional nurse or a licensed practical nurse under the direction of a supervisor as required by these rules. Such services shall be provided in accordance with the scope of nursing practice laws and associated rules, and the client's service plan.

1. Nursing services shall include the following: ...

   (i) Regularly assess the nursing needs of the client;

   (ii) Participate in the establishment and implementation of the client's service plan;

   (iii) Provide nursing services as needed and in accordance with the client's service plan;

   (iv) Report problems and progress of client to supervisory personnel or the client's personal physician.

(b) Personal Care Tasks. If a provider provides personal care tasks, such tasks, at a minimum, shall be performed by a qualified PCA under the direction of a supervisor as required by these rules, and in accordance with the client's service plan. In addition to following the service plan, a PCA must report on the personal care needs of the client, on changes in the client's condition, and on any observed problems that affect the client. Licensed nurses are also authorized to perform personal care tasks.

(c) Companion or Sitter Tasks. If a provider provides companion or sitter tasks, such tasks, at a minimum, shall be performed by a qualified companion or sitter under the direction of a qualified supervisor as required by these rules, and in accordance with the client's service plan. In addition to following the service plan, a companion or sitter must report on the needs of the client, on changes in the client's condition, and on any observed problems that affect the client.

(2) Supervision of Services. Services shall be supervised by qualified staff of the provider. Each staff member providing services to a client shall be evaluated in writing by his or her supervisor, at least annually, either through direct observation or demonstration, on the job tasks the staff member is required to perform. No supervisor shall knowingly permit an employee who has been exposed to tuberculosis or hepatitis or diagnosed with the same to provide services to clients until it is determined that the employee is not contagious.

(a) Supervision of Nursing Services. If a provider provides nursing services, it shall employ fully licensed Georgia registered professional nurse to supervise the provision of such services and the employees who provide the services. Such supervisor may perform other duties provided he or she is able to fulfill the supervisory responsibilities described in these rules. A supervisor shall complete the client's service plan in accordance with rule .11 and in coordination with the appropriate staff who will be providing the client's services.

(b) Supervision of Personal Care Tasks. If a provider offers personal care task services, the provider shall employ supervisor(s) that have been determined to be qualified by education, training and experience to supervise the provision of such tasks in accordance with accepted standards of care. A licensed registered professional or practical nurse shall supervise the provision of personal care tasks for clients determined to be medically frail or medically compromised. If such supervision is provided by a licensed practical nurse, the licensed practical nurse shall report to a licensed registered professional nurse who will continue to be responsible for the development and management of the service plan. Such supervisor may perform other duties provided he or she is able to fulfill the supervisory responsibilities described in these rules.

1. The appropriate supervisor as specified in these rules shall complete the client's service plan in accordance with rule .11 and in coordination with the appropriate staff who will be providing the client's services. For clients who are determined to be medically frail or compromised, a licensed registered professional nurse shall complete the initial service plan. Subsequent revisions to the service plan may be made by a licensed practical nurse who is supervising the provision of personal care tasks services to the client. Revisions made by the licensed practical nurse will be reviewed in a timely manner by the provider's licensed registered professional nurse ultimately responsible for the management of the client's care.

2. The appropriate supervisor shall make a supervisory home visit to each client's residence at least every 92 days, starting from date of initial service in a residence or as the level of care requires to ensure that the client's needs are met. The visit shall include an assessment of the client's general condition, vital signs, a review of the progress being made, the problems encountered by the client and the client's satisfaction with the services being delivered by the provider's staff. Such supervision shall also include observations about the appropriateness of the level of services being offered. Routine quarterly supervisory visits shall be made in the client's residence and shall be documented in the client's file or service plan.

(c) Supervision of Companion or Sitter Tasks. If a provider provides companion or sitter tasks, supervision of such tasks shall be provided by a qualified supervisor (e.g. registered professional nurse, licensed practical nurse, the administrator, or any other staff member assigned responsibility for supervision of the delivery of care.)

1. The appropriate supervisor, as specified in these rules, shall complete the client's service plan in accordance with rule .11 and in coordination with the appropriate staff who will be providing the client's services.

2. The appropriate supervisor shall make a supervisory home visit to each client's residence at least every 122 days starting from date of initial service in the residence or when the provider receives a complaint concerning services and the complaint raises a serious question concerning the services being delivered. The visit shall include an assessment of the client's general condition, a review of the progress being made, the problems encountered by the client and the client's satisfaction with the services being delivered by the provider's staff. Such supervision shall also include observations about the appropriateness of the level of services being offered. Routine supervisory visits shall be made in the client's residence. All supervisory visits shall be documented in the client's file or service plan.

(d) When employees or subcontractors are performing personal care tasks for clients who are medically frail or medically compromised in the clients' residences, the provider shall have a representative on call and accessible who shall be able to contact a nurse supervisor by telephone or other means to provide appropriate consultation to the employees or subcontractors concerning responding to the clients' medical needs.

(3) Documentation of Home Care Services Provided. A provider shall establish and implement written policies and procedures for documenting the services actually performed for its clients each day. Such documentation shall be incorporated into the client's file in accordance with rule .09(4)(a).

(4) Quality Improvement Program. The provider must have and maintain documentation reflecting that there is an effective quality improvement program that continuously monitors the performance of the program itself and client outcomes to ensure that the care provided to the clients meets acceptable standards of care and complies with the minimum requirements set forth in these rules. At a minimum, the quality improvement program must document the receipt and resolution (if possible) of client complaints, problems with care identified and corrective actions taken.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.10
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-7-300*et seq.*
History. Original Rule entitled "Private Home Care Provider Services" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.11. Service Plans.

(1) Service Plan Content. A provider shall establish and implement written policies and procedures for service planning. A written plan of service shall be established in collaboration with the client and the responsible party, if applicable, and the client's

personal physician if the services to be provided are nursing services and the client has a personal physician.

(a) The service plan shall include the functional limitations of the client, types of service required, the expected times and frequency of service delivery in the client's residence, the expected duration of services that will be provided, the stated goals and objectives of the services, and discharge plans.

(b) When applicable to the condition of the client and the services to be provided, the [service] plan shall also include pertinent diagnoses, medications and treatments, equipment needs, and diet and nutritional needs.

(2) Service plans shall be completed by the service supervisor within seven working days after services are initially provided in the residence. Service plans for nursing services shall be reviewed and updated at least every sixty-two days. Other service plans shall be reviewed and updated at the time of each supervisory visit. Parts of the plans must be revised whenever there are changes in the items listed in rules .11(l)(a)and(b), above.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.11
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-7-300*et seq.*
History. Original Rule entitled "Service Plans" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.12. Client Rights, Responsibilities, and Complaints.

(1) A provider shall establish and implement written policies and procedures regarding the rights and responsibilities of clients, and the handling and resolution of complaints.

(2) Such policies and procedures shall include a written notice of rights and responsibilities which shall be provided to each client or responsible party, if applicable, when the service agreement described in rule .09(2) is completed. The required notice shall include the following items:

(a) Right to be informed about plan of service and to participate in the planning;

(b) Right to be promptly and fully informed of any changes in the plan of service;

(c) Right to accept or refuse services;

(d) Right to be fully informed of the charges for services;

(e) Right to be informed of the name, business telephone number and business address of the person supervising the services and how to contact that person;

(f) Right to be informed of the complaint procedures and the right to submit complaints without fear of discrimination or retaliation and to have them

investigated by the provider within a reasonable period of time. The complaint procedure provided shall include the name, business address and telephone number of the person designated by the provider to handle complaints and questions;

(g) Right of confidentiality of client record;

(h) Right to have property and residence treated with respect;

(i) Right to receive a written notice of the address and telephone number of the state licensing authority, i.e. the department, which further explains that the department is charged with the responsibility of licensing the provider and investigating client complaints which appear to violate licensing regulations;

(j) Right to obtain a copy of the provider's most recent completed report of licensure inspection from the provider upon written request. The provider is not required to release the report of licensure inspection until the provider has had an opportunity to file a written plan of correction for the violations, if any, identified. The facility may charge the client reasonable photocopying charges;

(k) Right to be advised that the client and the responsible party, if applicable, must advise the provider of any changes in the client's condition or any events that affect the client's service needs.

(3) Such policies shall also include procedures for clients and others to present complaints, either orally or in writing, about services and to have their complaints addressed and resolved as appropriate by the provider in a timely manner.

(4) A provider shall supply all clients and responsible parties, if applicable, with the specific telephone number of the provider for information, questions or complaints about services being delivered by the provider.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.12
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-7-300*et seq.*
History. Original Rule entitled "Client Rights, Responsibilities and Complaints" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.13. Enforcement and Penalties.

(1) Enforcement of these rules and regulations shall be conducted in accordance with Rules and Regulations for Enforcement of Licensing Requirements,

(2) If the department finds that an applicant for a license has violated any provisions of these rules or other laws, rules, regulations, or formal orders related to initial or continued

licensing, it may, subject to notice and an opportunity for hearing, refuse to grant any license or limit or restrict any license.

(3) If the department finds that a provider has violated any provision of these rules or other laws, rules, regulations, or formal orders related to initial or continued registration, it may, subject to notice and an opportunity for hearing, take any of the following actions: administer a public reprimand; limit or restrict a license; suspend a license; impose a fine; refuse to renew a license; or revoke a license.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.13
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-2-8.
History. Original Rule entitled "Enforcement and Penalties" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.14. Waivers and Variances.

(1) The department may, in its discretion, grant waivers and variances of specific rules upon application or petition being filed on forms provided by the department. The department may establish conditions which must be met by the provider in order to operate under the waiver or variance granted. Waivers and variances may be granted in accordance with the following conditions:

(2) Variance. A variance may be granted by the department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety and care of persons in care exist and will be met in lieu of the exact requirements of the rule or regulation in question.

(3) Waiver. The department may dispense entirely with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety and care of persons in care.

(4) Experimental Variance or Waiver. The department may grant waivers and variances to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant or petitioner that the intended protections afforded by the rule or regulation which is the subject of the request are met and that the innovative approach has the potential to improve service delivery.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.14
Authority: O.C.G.A. §§ 31-2-5 and 31-2-7.
History. Original Rule entitled "Waivers and Variances" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Rule 111-8-65-.15. Severability.

(1) In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof.

(2) The remaining rules or portions thereof shall remain in full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-65-.15
Authority: O.C.G.A. §§ 31-2-5, 31-2-7 and 31-7-300*et seq.*
History. Original Rule entitled "Severability" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Subject 111-8-68. RULES AND REGULATIONS FOR RESIDENTIAL MENTAL HEALTH FACILITIES FOR CHILDREN AND YOUTH.

Rule 111-8-68-.01. Legal Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated § 31-7-1*et seq.*

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.01
Authority: O.C.G.A. Secs. 31-7-1, 31-7-2, 31-7-2.1, 31-7-3.
History. Original Rule entitled "Legal Authority" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.02. Title and Purposes.

These rules shall be known as the Rules and Regulations for Residential Mental Health Facilities for Children and Youth. The purposes of these rules are to emphasize the programmatic requirements necessary to meet the needs of patients in a safe, therapeutic environment, and to set forth the minimum requirements that Residential Mental Health Facilities for Children and Youth shall meet.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.02
Authority: O.C.G.A. Secs. 31-7-1, 31-7-2, 31-7-2.1.
History. Original Rule entitled "Title and Purpose" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.03. Definitions.

(1) "Abuse" means any unjustifiable intentional or grossly negligent act, exploitation or series of acts, or omission of acts which causes injury to a person, including but not

limited to verbal abuse, assault or battery, failure to provide treatment or care, or sexual harassment.

(2) "Administrator" means the person, by whatever title used, whom the governing body has delegated the responsibility for the management and operation of the facility including the implementation of the rules and policies adopted by the governing body.

(3) "Behavior management" means those principles and techniques used by a facility to assist a patient in facilitating self-control, addressing inappropriate behavior, and achieving positive outcomes in a constructive and safe manner. Behavior management principles and techniques shall be used in accordance with the patient's treatment plan, written policies and procedures governing service expectations, treatment goals, safety, security, and these rules and regulations.

(4) "Board" means the Board of the Department of Community Health.

(5) "Board certified child psychiatrist" means a child psychiatrist who has successfully met the training and experience requirements and passed the examination in child psychiatry by the American Board of Psychiatry and Neurology.

(6) "Board eligible child psychiatrist" means a child psychiatrist who has successfully met the training and experience requirements sufficient to be eligible for the examinations of the board.

(7) "Child care staff" means those staff members who provide direct care to patients twenty-four (24) hours a day under professional supervision.

(8) "Child psychiatrist" means a physician who successfully completed an accredited training program in child psychiatry consisting of two (2) years general psychiatry and two (2) years child psychiatry.

(9) "Department" means the Department of Community Health of the State of Georgia.

(10) "Emergency safety interventions" means those behavioral intervention techniques that are authorized under an emergency safety intervention plan and are utilized by properly trained staff in an urgent situation to prevent a patient from doing immediate harm to self or others.

(11) "Emergency safety intervention plan" means the plan developed by the facility utilizing a nationally recognized, evidence-based, training program for emergency safety intervention. The plan shall clearly identify the emergency safety interventions staff may utilize and those that may never be used.

(12) "Exploitation" means the illegal or improper use of a person or that person's resources through undue influence, coercion, harassment, duress, deception, false representation, false pretense, or other similar means for another person's profit or advantage.

(13) "Governing body" means the treatment facility authority created by the Georgia Hospital Act, O.C.G.A. § 31-7-72, the board of trustees, the partnership, the corporation, the association, the person or the group of persons who maintain and control the facility. The governing body may or may not be the owner of the properties in which the facility services are provided.

(14) "Hospital" means any institution designed, equipped and staffed to receive two (2) or more persons for diagnosis, treatment and other health services under the supervision of a practitioner for periods continuing twenty-four (24) hours or longer, and in which professional policies are adopted by the governing body after consultation with the active professional staff.

(15) "Manual hold" means the application of physical force, without the use of any device, for the purpose of restricting the free movement of a patient's body and is considered a form of restraint. A manual hold does not include briefly holding the patient without undue force to calm or comfort the patient, holding the patient by the hand or by the shoulders or back to walk the patient safely from one area to another where the patient is not forcefully resisting the assistance, or assisting the patient in voluntarily participating in activities of daily living or other functional activities.

(16) "Mechanical restraint" means a device attached or adjacent to the patient's body that is not a prescribed and approved medical protection device, and that he or she cannot easily remove, that restricts freedom of movement or normal access to his or her body. A mechanical restraint does not include devices used to assist patients with appropriate positioning or posture secondary to physical impairments or disabilities.

(17) "Multidisciplinary staff" means staff of various disciplinary backgrounds who can address the physical, social, mental, educational, recreational and other needs of the patient.

(18) "Neglect" means the absence or omission of essential services to the degree that it harms or threatens with harm the physical or emotional health of a person.

(19) "Patient" means any person residing in a treatment facility for the express purpose of receiving diagnostic, treatment or other health services for physical or mental conditions.

(20) "Patient safety interventions" means the safety observations, supervision, and methods developed and implemented by the facility to ensure the safety of patients.

(21) "Patient safety plan" means the plan developed by the facility that outlines the requirements for patient monitoring to ensure the continuous provision of sufficient regular, special, and emergency observation and supervision of all patients twenty-four (24) hours a day.

(22) "Permit" means authorization granted by the department to the governing body to operate a treatment facility and signifies substantial compliance with these rules and regulations.

(23) "Plan of correction" means a written plan submitted by the governing body and acceptable to the Department. The plan shall identify the existing noncompliance of the treatment facility, the proposed procedures, methods, means and period of time to correct the noncompliance.

(24) "Practitioner" means physician, dentist or osteopathic physician authorized to provide care in Georgia.

(25) "Provisional permit" means authorization granted by the department to the governing body to operate a treatment facility on a conditional basis to allow a newly established treatment facility a reasonable but limited period of time to demonstrate operational procedures in substantial compliance with these rules and regulations; or to allow an existing treatment facility a reasonable length of time to comply with these rules and regulations, provided said treatment facility shall first present a plan of improvement acceptable to the department.

(26) "Pharmacist" means any person who is licensed to practice in this State under the provisions of the Georgia Pharmacy Practice Act, O.C.G.A. § 26-4-5.

(27) "Physician" means any person who is authorized to practice medicine in this State under the provisions of the Composite State Board of Medical Examiners, O.C.G.A. § 43-34-20*et seq.*

(28) "Psychiatrist" means a physician who has successfully completed an accredited training program in psychiatry.

(29) "Qualified psychiatric nurse" means a nurse who holds a masters degree in psychiatric nursing from an accredited school of nursing.

(30) "Qualified psychologist" means any person who is licensed to practice in this State under the provisions of the Georgia Board of Examiners of Psychologists, O.C.G.A. § 43-39-1 and who has training and experience in child and adolescent psychology.

(31) "Qualified social worker" means a social worker who has a masters degree in social work from an accredited school of social work.

(32) "Registered Nurse" (R.N.) means any person who holds a current license as a registered nurse issued by the State of Georgia.

(33) "Record(s)" means the individual files established and maintained by a facility which include data concerning a patient.

(34) "Residential mental health facility for children and youth" or "facility" is a sub-classification of a "Specialized Hospital" and is defined as a facility providing twenty-four (24) hour care and having the primary functions of diagnosing and treating patients to age twenty-one (21) with psychiatric disorders to restore them to an optimal level of functioning.

(35) "Seclusion" means the involuntary confinement of a patient away from other patients, due to imminent risk of harm to self or others, in a room or an area from which the patient is physically prevented from leaving.

(36) "Shall" means a mandatory requirement.

(37) "Specialized hospital" means any hospital which limits its admissions to persons whose physical or mental disability is of a specific class or type. The department shall use a sub classification which adequately describes the proposed service. This service shall be under the supervision of physicians.

(38) "Supervision" means the continued responsibility of the facility to take reasonable action to provide for the health, safety, and well-being of a patient while under the supervision of the facility or the agent or employee of the facility, including protection from physical, emotional, social, moral, financial harm, and personal exploitation while in care. The facility is responsible for providing the degree of supervision indicated by the patient's age, developmental level, physical, emotional, and social needs.

(39) "Time out" means a behavior management technique that restricts a patient for a brief period of time to a designated area from which the patient is not physically prevented from leaving, for the purpose of permitting the patient to de-escalate and for providing an opportunity for the patient to regain self-control.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.03
Authority: O.C.G.A. Sec. 31-7-2.1.
History. Original Rule entitled "Definitions" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.04. General Policies.

(1) **Application**. An application to operate a licensed facility must comply with the following:

(a) The governing body of the facility shall submit to the department an application for a permit. Such application shall be signed by the executive officer of the governing body.

(b) The application for a permit shall be prepared in duplicate on forms provided by the department. The original copy shall be forwarded to the department and the copy retained by the governing body.

(c) The application for an original permit shall be accompanied by a program narrative of the service or services provided, a copy of the bylaws of the governing body and a copy of the policies and procedures adopted by the professional staff and approved by the governing body.

(d) The application for an original permit shall be submitted to the department not later than thirty (30) days prior to the anticipated date of the opening and commencement of operation of the facility.

(e) Application for change in status of a facility shall be submitted to the department not later than thirty (30) days prior to the effective date proposed.

(f) Proof of ownership and a notarized personal identification form shall accompany the application.

1. Corporations shall submit a copy of their charter and the name and address of all owners with ten (10) percent or more of the stock and shall identify each corporate officer;

2. Non-profit associations and facility authorities shall submit legal proof of the organization, the name and address of each trustee and the office held, if any; and

3. All other types of facilities shall submit the name and address of each person with ownership interests in the facility.

(2) **Permits**. The following requirements pertain to the permit to operate the licensed facility:

(a) The facility must be in substantial compliance with these rules and regulations and the provisions of law which apply to the location, construction and maintenance of treatment facilities and the safety of the patients therein. A permit shall remain in force and effect unless suspended or revoked or otherwise removed as hereinafter provided.

(b) Prior to the issuance of a permit and at the request of the department, the governing body shall furnish the department evidence of compliance with any laws or regulations thereunder applicable to facilities but the enforcement of which is the responsibility of a department or agency of government other than the department.

(c) The permit shall show the classification of the facility, and shall specify the number of beds designated for such treatment facility.

(d) The permit shall be framed and publicly displayed at all times.

(e) Permits are not transferable from one governing body to another, nor valid when the facility is moved from one location to another.

(f) The permit shall be returned to the department when the facility ceases to operate, or is moved to another location, or the ownership changes, or the governing body is significantly changed, or the permit is suspended or revoked.

(g) A permit shall be required for each facility. At the request of the governing body of multi-building facilities, a single permit may be issued to include all buildings provided that each building is in substantial compliance with these rules and regulations.

(3) **Provisional Permits.** The following requirements pertain to the issuance of a provisional permit to operate the licensed facility:

(a) Provisional permits may be granted to the governing body of a new or established facility to demonstrate operational procedures in substantial compliance with these rules and regulations.

(b) A provisional permit may be granted to the governing body of an existing facility to give reasonable time to comply with regulations and standards, which relate to the structural or physical condition of the treatment facility.

(c) Provisional permits granted to allow reasonable time to demonstrate satisfactory compliance with operational procedures shall be limited to periods of not more than six(6) months.

(d) Provisional permits granted to allow reasonable time to correct noncompliances relating to the structural or physical condition of the facility shall be limited to a period of not more than twelve (12) months; provided, however, that the department may extend such period for a period not to exceed another twelve (12) months.

(e) No provisional permits shall be granted to the governing body of a newly established facility which is not in substantial compliance with these rules and regulations, and standards relating to the structural or physical condition of the facility.

(f) A provisional permit shall not be issued when there is noncompliance of any type which present an immediate hazard to the life, health or safety of patients.

(g) No provisional permit shall be granted unless the governing body first presents to the department a plan of correction which shall list each noncompliance to be corrected, the time required to correct noncompliance which relates to the structural or physical condition of the facility and the means, methods and procedures to be used in the correction of the noncompliance.

(h) The governing body shall make periodic reports to the department regarding the progress being made in correcting noncompliance as agreed to by the terms of the plan of correction.

(i) The governing body of a facility operating under a provisional permit may petition the department for an extension of time, if needed, to correct noncompliance where the failure to make such corrections within the time allotted is due to an extenuating circumstance beyond the control of the governing body. Such petition shall be submitted to the department as agreed to by the terms of the plan of correction.

(4) **Patient Capacity**. The number of patients receiving care within the facility shall not exceed the number of residential mental health beds shown on the permit.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.04
Authority: O.C.G.A. Secs. 19-7-5, 31-7-2.1, 31-7-3.
History. Original Rule entitled "General Policies" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.05. Organization and Administration.

(1) **Incorporation**. All facilities shall be incorporated unless operated by a local or state governmental authority. The purpose or function of the facility shall be stated in the charter of incorporation.

(2) **Governing Body**. The governing body must ensure that the following requirements are met:

(a) Every facility shall have a governing body which has responsibility for the overall operation of the facility. Each governing body shall establish and be operated by a set of bylaws and guidelines.

(b) Bylaws or rules and regulations shall be in accordance with legal requirements and shall assure the quality of patient care. They shall also include:

1. a definition of powers and duties of the governing body, its officers and committees;

2. a statement of the qualifications of members, method of selection, numbers and terms of appointments, or election of officers and committees;

3. a determination of frequency of meetings, which shall be at least quarterly, attendance requirements and quorums at meetings;

4. provision for the appointment of a full-time administrator with a description of the qualifications, authority and responsibilities of such a person;

5. provision for the appointment of a clinical director with a description of the qualifications, authority and responsibilities of such a person;

6. a mechanism by which the administrative and clinical staff consult with and report to the governing body;

7. an effective, formal means by which the administrative and clinical staff may participate in the development of the facility's policies relative to both facility management and patient care; and

8. provision to establish rules and regulations that are not limited to, but shall include:

   (i) a statement of the regulations by which the clinical staff and administrative staff shall function;

   (ii) a requirement that controls are established for insuring that each professional member of the staff will observe all the ethical principles and standards of his profession, and will assume and carry out clinical and/or administrative functions consistent with local, state and federal laws and regulations; and

   (iii) a requirement that the evaluation and authentication of psychiatric and medical histories, the performance and recording of physical examinations, and the prescribing of medication be carried out by physicians with appropriate qualifications, licenses and clinical privileges within his/her sphere of authorization.

9. For a facility whose governing body does not solely function in support of the residential mental health facility, then an advisory board shall also be appointed to advise and advocate for the residential mental health program for children and youth. This board's members shall be selected with a broad community representation with specific expertise and/or interest in the mental health of children and youth. The advisory board shall meet at regular intervals, not less often than quarterly.

(3) **Finances**. The facility shall be operated in a fiscally responsible manner and addresses the following:

   (a) Each facility shall have a sound plan for financing, which assures sufficient funds to enable it to carry out its defined purposes.

(b) A new facility shall have sufficient funding assured to carry it through its first year of operation.

(c) An accounting system shall be maintained that produces information reflecting fiscal experience and the current financial position of the facility.

(d) The facility shall employ a system of accounting that clearly indicates the cost elements for assessment and therapeutic services for each program.

(e) All accounts shall be audited at least annually by a certified public accountant and the report made a part of the facility's records. A copy of this report shall be made available to the department upon request if the facility is subsidized by state or federal funds.

(4) **Goals, Policies and Procedures.** The facility shall develop and update as necessary, goals, policies and procedures which address the following:

(a) Each facility shall have a clear written statement of its purpose and objectives, with a formal, long-range plan adapted to guide and schedule steps leading to attainment of its projected objectives. This plan shall include a specifically delineated description of the services the facility offers. The plan shall also include:

1. the population to be served, age groups and other limitations;

2. an organizational chart with a description of each unit or department and its services, its relationship to other services and departments and how these are to contribute to the priorities and goals of the facility; and

3. plans for cooperation with other public and private agencies to assure that each patient will receive comprehensive treatment. Ongoing working arrangement contracts with agencies, such as schools and/or welfare agencies, shall be included as indicated, as well as regularly planned interagency conferences, which shall be documented.

(b) The facility shall develop and implement effectively policies and procedures for operations, including but not limited to:

1. the initial screening process;

2. the intake or admission process;

3. the development of treatment plans, including the involvement of the patient, parent(s), and/or legal guardian;

4. the appropriate use of behavior management techniques and emergency safety interventions;

5. the appropriate use of patient safety methods to ensure the continuous provision of sufficient regular, special, and emergency observation and supervision of all patients;

6. the provision of any community education consultation programs; and

7. the provision or arrangement for services required by the patient:

   (i) other medical, dental, special assessment and therapeutic services, which shall become a part of the clinical services plan;

   (ii) medical emergency services;

   (iii) educational services for all patients; and

   (iv) discharge and follow-up care and evaluation.

(5) **Personnel**. The facility shall meet the following personnel requirements:

(a) **Composition**. The composition of the staff shall be determined by the needs of the patients being served and the goals of the facility, and shall have available a sufficient number of mental health professionals, child care workers and administrative personnel to meet these goals.

1. The administrator of the facility shall have a master's degree in administration or a professional discipline related to child and adolescent mental health, and have at least three (3) years administrative experience. A person with a baccalaureate degree may also qualify for administrator with seven (7) years experience in child and adolescent mental health care with no less than three (3) year's administrative experience.

2. The clinical director shall be at least board eligible in psychiatry with experience in child and adolescent mental health.

3. If the clinical director is not full-time, then there shall also be a full-time service coordinator who is a professional person experienced in child and adolescent mental health and is responsible for the coordination of treatment aspects of the program.

4. Mental health professionals shall include, but are not limited to, child psychiatrists, qualified psychologists, qualified social workers and qualified psychiatric nurses. These persons, if not on a full-time basis, must be on a continuing consulting basis. The authority and participation of such mental

health professionals shall be such that they are able to assume professional responsibility for supervising and reviewing the needs of the patients and the services being provided. Such individuals shall participate in certain specific functions, e.g., assessment, treatment planning, treatment plan and individual case reviews, and program planning and policy and procedure development and review.

5. Other professional and paraprofessional staff shall include, but not be limited to, physicians, registered nurses, educators and twenty-four (24) hour child care staff. Also included on a regular basis, or as consultants on a continuing basis shall be activity therapists and vocational counselors.

6. Consultation shall be available as needed from dietitians, speech, hearing and language specialists, and other therapeutic professionals.

(b) **Organization**. The facility shall have an organizational plan which clearly explains the responsibilities of the staff. This plan shall also include:

1. lines of authority, accountability and communication;

2. committee structure and reporting or dissemination of material; and

3. established requirements regarding the frequency of attendance at general and departmental/service and/or team/unit meetings.

(c) **Policies and Records**. Personnel policies and practices shall be designed, established and maintained to promote the objectives of the facility and to ensure that there are sufficient qualified personnel to provide for the needs, care, safety, and supervision of patients.

1. Each facility shall have written personnel policies covering at least the following areas: job classifications; personnel selection; procedures and requirements for health evaluations; staff orientation and training programs; the maintenance and content of personnel records and, for all persons employed after effective date of these rules, the use of employment and criminal background checks to ensure that the employee has no history of violent or abusive behavior. Each new employee shall be given a copy of personnel practices when hired, including the policy to conduct employment and criminal background checks.

2. All prospective personnel must be checked against state sex offender registries where the applicant has lived since becoming an adult or have satisfactory criminal records check information on file prior to employment by the facility. The facility shall not hire or retain staff who have a history of violent or abusive behavior.

3. There shall be clear job descriptions for all personnel. Each description shall contain the position title, immediate supervisor, responsibilities and authority. These shall also be used as a basis for periodic evaluations by the supervisor.

4. Accurate and complete personnel records shall be maintained for each employee and include at least the following:

   (i) current background information, including the application, employment references, the results of employment and criminal background checks, and any accompanying documentation sufficient to justify the initial and continued employment of the individual and the position for which he was employed. Applicants for positions requiring a license shall be employed only after the facility has obtained verification of the license. Where certification is a requirement, this shall also be verified. Evidence of renewal of a license or certification shall be maintained in the employee's personnel record;

   (ii) current information relative to work performance evaluations, including any records of employee discipline arising from the inappropriate use of behavior management techniques and/or emergency safety interventions;

   (iii) records of initial, regular, and targeted health screenings, sufficient in scope to ensure that all facility personnel who are employed or under contract with the facility who may have patient contact or are providing patient care services do not have conditions that may place patients or other personnel at risk for infection, injury, or improper care; and

   (iv) records of orientation training and any continuing education or staff development programs completed.

(d) **Staff Development**. The facility shall provide and document completion of orientation programs and other staff training.

1. There shall be appropriate orientation and training programs provided for all new employees. Prior to working with patients, all employees, including administrative staff who work with the patients shall complete an orientation program which includes at a minimum instruction in:

   (i) the employee's assigned duties and responsibilities;

(ii) facility policies and procedures for receiving and handling family and patient grievances and complaints;

(iii) policies and procedures related to child abuse, neglect and exploitation including reporting requirements.

(iv) policies and procedures regarding appropriate behavior management and emergency safety interventions; and

(v) policies and procedures to protect the confidentiality of patient records.

2. The staff development program shall be facility-based with a designated person or committee who is responsible, on a continuing basis, for planning and insuring that training programs are implemented. The facility shall also make use of educational programs outside the facility.

(6) **Volunteer Program**. When volunteers are utilized in a program, a qualified staff member of the facility shall be designated to plan, supervise and coordinate the volunteer's functions as well as an appropriate training program.

(7) **Research and Human Rights Review**. Research practices involving human subjects shall comply with the State of Georgia agency policy on "Protection of Human Subjects."

(8) **Reporting**. Written summary reports shall be made to the department in a form acceptable to the department within twenty-four (24) hours (with a detailed investigative report to follow in five working days if not provided initially) regarding the following serious occurrences involving patients in care:

(a) Serious injury which causes any significant impairment of the physical condition of the resident as determined by qualified medical personnel. This includes, but is not limited to burns, lacerations, bone fractures, substantial hematoma, and injuries to internal organs, whether self-inflicted or inflicted by someone else;

(b) deaths;

(c) suicide attempts;

(d) emergency safety interventions resulting in any injury of a patient requiring medical treatment beyond first aid;

(e) elopements when the patient cannot be located within twenty-four (24) hours or where there are circumstances that place the health, safety, or welfare of the patient or others at risk; or

(f) any incident which results in any federal, state, or private legal action by or against the facility which affects any patient or the conduct of the facility. However, legal action involving the juvenile justice system is not required to be reported.

(9) **Child Abuse Reports**. Whenever the facility has reason to believe that a patient in care has been subjected to abuse, neglect or exploitation, the facility shall make a report of such abuse to the child welfare agency providing protective services as designated by the Department of Human Services (Division of Family and Children Services) or in the absence of such an agency to an appropriate police authority or district attorney in accordance with the requirements of O.C.G.A. § 19-7-5. A copy of the report shall also be filed with the Division of Healthcare Facility Regulation, Department of Community Health.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.05
Authority: O.C.G.A. Secs. 19-7-5, 31-7-2.1.
History. Original Rule entitled "Organization and Administration" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.06. Facilities.

(1) **General Requirements**. The facility shall provide an environment that is therapeutic to and supportive of all the patients, their healthy development and their changing needs. The therapeutic environment shall take into consideration the architecture of the facility, indoor and outdoor activity areas, furnishings, equipment, decorations and all other factors that involve the physical environment.

(a) Facilities shall be designed to meet the needs of the age group of the patients and the objectives of the program.

(b) Facilities shall be maintained in a safe and clean manner and must meet fire, safety, health and sanitation regulations.

(c) There shall be adequate and appropriate space and equipment for all facility programs and their various functions within the facility.

(d) Facilities shall provide sufficient space and equipment to ensure housekeeping and maintenance programs sufficient to keep the building and equipment clean, tidy and in a state of good repair.

(2) **Disaster Preparedness.** The facility shall prepare for potential emergency situations that may affect patient care by having an effective disaster preparedness plan that identifies emergency situations and outlines an appropriate course of action. The plan must be reviewed and revised at least annually, as appropriate, including any related written agreements.

(a) The disaster preparedness plan shall include at a minimum plans for the following emergency situations:

1. local and widespread weather emergencies or natural disasters, such as tornadoes, hurricanes, earthquakes, ice or snow storms, or floods;

2. man-made disasters such as acts of terrorism and hazardous materials spills;

3. unanticipated interruption of service of utilities, including water, gas, or electricity, either within the facility or within a local or widespread area;

4. loss of heat or air conditioning;

5. fire, explosion, or other physical damage to the facility; and

6. pandemics or other situations where the community's need for services exceeds the availability of beds and services regularly offered by the facility.

(b) There shall be plans to ensure sufficient staffing and supplies to maintain safe patient care during the emergency situation.

(c) There shall be plans for the emergency transport or relocation of all or a portion of the facility patients, should it be necessary, in vehicles appropriate to the patient's condition(s) when possible, including written agreements with any facilities which have agreed to receive patients in these situations.

(d) The facility shall document participation of all areas of the facility in quarterly fire drills.

(e) In addition to fire drills, the facility shall have its staff rehearse portions of the disaster preparedness plan, with a minimum of two (2) rehearsals each calendar year either in response to an emergency or through planned drills, with coordination of the drills with the local Emergency Management Agency (EMA) whenever possible.

(f) The facility shall provide a copy of the internal disaster preparedness plan to the local Emergency Management Agency (EMA) and shall include the local EMA in development of the facility's plan for the management of external disasters.

(g) The facility's disaster preparedness plan shall be made available to the department for inspection upon request. In addition, when provided with sixty (60) days notice in writing, the department may direct the facility to submit and periodically update the disaster preparedness plan electronically in a format acceptable to the department.

(h) The department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared a state of emergency.

(3) **Construction**. The plan, design and construction of the facility must meet the following requirements:

(a) All plans and specifications for the construction of new facilities shall be approved by the department prior to commencing work on the building. Such construction includes new buildings, additions, alterations, or renovations to existing buildings.

(b) A program narrative shall be submitted prior to or along with the submission of schematic plans for proposed new construction, additions or conversions. The program narrative shall contain information regarding:

1. sponsorship;
2. community needs;
3. program of service;
4. type of construction; and
5. financing for the construction and operation of the facility.

(c) Any individual or group planning construction of a facility shall submit schematic and/or preliminary plans to the department for review and counsel in the interpretation of these rules and regulations. Completed or final plans and specifications shall besubmitted for final review and approval; including site, driveways and parking areas, type of construction, mechanical and electrical systems, the type and location of major equipment, the intended use of each room, the proposed system of garbage and refuse disposal.

(d) Plans for additions and/or alterations to an existing building shall be submitted in sufficient detail to include type of construction and layout of the existing building to show overall relationship.

(e) Approved final plans shall not be materially changed without prior approval of such changes by the department.

(4) **Location and Site.**

(a) The site shall be approved by the department; and

(b) The site shall have proper drainage, sewage disposal, water, electrical, telephone and other necessary facilities available to the site.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.06
Authority: O.C.G.A. Sec. 31-7-2.1.
History. Original Rule entitled "Facilities" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.07. Services.

(1) **Intake and Admission.** Services shall be designed to meet the needs of the patient and must conform to the stated purposes and objectives of the facility.

(a) Acceptance of a child or adolescent for inpatient treatment shall be based on the initial assessment, arrived at by a multidisciplinary team of clinical staff, and clearly explained to the patient, parent(s), and/or legal guardian.

1. Whether the family voluntarily requests services or the patient is referred by the court, the facility shall involve the family's participation to the fullest extent possible.

2. Acceptance of the child or adolescent for treatment shall be based on the determination that the child or adolescent requires treatment of a comprehensive and intensive nature and is likely to benefit by the programs that the residential mental health facility has to offer.

3. Admission shall be in keeping with stated policies of the facility and shall be limited to those patients for whom the facility has qualified staff, program and equipment available to give adequate care.

4. Staff members who will be working with the patient, but who did not participate in the initial assessment, shall be oriented regarding the patient and the patient's anticipated admission prior to meeting the patient. When the patient is to be assigned to a group, the other patients in the group shall be prepared for the arrival of the new member. There shall be a specific staff member assigned to the new patient to observe the patient and help with the orientation period.

5. The admission procedure shall include communication with parent(s) and/or legal guardian, and documentation of such communication, concerning:

(i) responsibility for financial support including medical and dental care;

(ii) consent for medical and surgical care and treatment;

(iii) arrangements for appropriate family participation in the program, phone calls and visits when indicated;

(iv) arrangements for clothing, allowances and gifts;

(v) arrangements regarding the patient leaving the facility with or without medical consent;

(vi) description of the facility's services and the daily routines of patients;

(vii) the facility's policies and procedures for discipline and grievances;

(viii) patient rights; and

(ix) the facility's policy and procedures for the use of emergency safety interventions with written acknowledgment that the patient, parent(s), and/or legal guardian has been informed of these procedures and has been provided a copy of the procedures along with contact information for the Georgia protection and advocacy agency, currently designated as the Georgia Advocacy Office.

6. Decisions for admission shall be based on the initial assessment of the patient made by the appropriate multidisciplinary team of clinical staff. This assessment shall be in writing and recorded on admission. The initial assessment shall clearly indicate the patient's needs as related to the services offered by the facility.

7. The admission order must be written by a physician.

(2) **Assessment and Treatment Planning Including Discharge.** The facility shall provide to families at the time of initial assessment a description of the treatment services it provides, including content, methods, equipment and personnel involved. Each patient's treatment program must be individualized, and must describe which of the offered services are needed and are to be provided.

(a) **Assessment.** The facility is responsible for a complete assessment of the patient, some of which may be completed prior to admission, by reliable professionals acceptable to the facility's staff. The complete assessment shall include but is not limited to:

1. Physical examination, which includes at least a general physical examination and neurological assessment, performed within twenty-four (24) hours after admission by a licensed physician or a nurse practitioner or physician's assistant working under the direction of a licensed physician who is on staff at the facility. However, in lieu of performing the required physical examination; the staff physician, nurse practitioner or physician's assistant working under direction of the physician may examine and update the patient's physical condition within twenty-four (24) hours after

admission where an appropriate physical examination completed by any licensed physician or a nurse practitioner or physician's assistant working under the direction of the licensed physician was performed within forty-eight (48) hours prior to admission.

2. Assessment of motor development and functioning;

3. Dental assessment;

4. Speech, hearing and language assessment;

5. Vision assessment;

6. Review of immunization status and completion according to the U.S. Public Health Service Advisory Committee on Immunization Practices and the Committee on Control of Infectious Diseases of the American Academy of Pediatrics;

7. Laboratory workup including routine blood work and urinalysis;

8. Chest x-ray and/or tuberculin test;

9. Serology;

10. Follow-up testing and/or treatment by appropriately qualified and/or trained clinicians where any of the physical health assessments indicate the need for further testing or definitive treatment with any plans for treatments coordinated with the patient's overall treatment plan;

11. Psychiatric/psychological examination, including but not limited to:

    (i) Direct psychiatric evaluation and behavioral appraisal, evaluation of sensory, motor functioning, a mental status examination appropriate to the age of the patient and a psychodynamic appraisal. A psychiatric history, including history of any previous treatment for mental, emotional or behavioral disturbances shall be obtained, including the nature, duration and results of the treatment, and the reason for termination. An initial and ongoing assessment of the patient's potential risks of harm to self and others is also required;

    (ii) Appropriate psychological testing;

    (iii) An initial and ongoing assessment of the need for safety supervision and monitoring.

    (iv) Developmental/social assessment, including but not limited to:

(I) The developmental history of the patient including the prenatal period and from birth until present, the rate of progress, developmental milestones, developmental problems, and past experiences that may have affected the development. The assessment shall include an evaluation of the patient's strengths as well as problems. Consideration shall be given to the healthy developmental aspects of the patient, as well as to the pathological aspects, and the effects that each has on the other shall be assessed. There shall be an assessment of the patient's current age, appropriate developmental needs, which shall include a detailed appraisal of his peer and group relationships and activities.

(II) A social assessment including evaluation of the patient's relationships within the structure of the family and with the community at large, an evaluation of the characteristics of the social, peer group, and institutional settings from which the patient comes. Consideration shall be given to the patient's family circumstances, including the constellation of the family group, their current living situation, and all social, religious, ethnic, cultural, financial, emotional and health factors. Other factors that shall be considered are past events and current problems that have affected the patient and family; potentialities of the family's members meeting the patient's needs; and their accessibility to help in the treatment and rehabilitation of the patient. The expectations of the family regarding the patient's treatment, the degree to which they expect to be involved, and their expectations as to the length of time and type of treatment required shall also be assessed.

12. Nursing. The nursing assessment includes, but is not limited to the evaluation of:

(i) Self-care capabilities including bathing, sleeping, eating;

(ii) Hygienic practices such as routine dental and physical care and establishment of healthy toilet habits;

(iii) Dietary habits including a balanced diet and appropriate fluid and caloric intake;

(iv) Responses to physical diseases such as acceptance by the patient of a chronic illness as manifested by his compliance with prescribed treatment;

(v) Responses to physical handicaps such as the use of prostheses or coping patterns used by the visually handicapped; and

(vi) Responses to medications such as allergies or dependence.

13. Educational/Vocational. The patient's current educational/vocational needs in functioning, including deficits and strengths, shall be assessed. Potential educational impairment and current and future educational/vocational potential shall be evaluated using, as indicated, specific educational testing and special educators or others.

14. Recreational. The patient's work and play experiences, activities, interests and skills shall be evaluated in relation to planning appropriate recreational activities.

(b) **Treatment Planning**. An initial treatment plan shall be formulated, written, and interpreted to the staff and patient within forty-eight (48) hours of admission. The comprehensive treatment plan shall be formulated for each patient by a multidisciplinary staff, written, implemented, and placed in the patient's records within fourteen (14) days of admission. This plan must be reviewed at least monthly, or more frequently to meet the needs of the patients or if the objectives of the program indicate. Review shall be noted in the record. A psychiatrist as well as multidisciplinary professional staff must participate in the preparation of the plan and any major revisions.

1. The initial treatment plan shall be based on screening and initial assessments and shall reflect the reasons for admission, significant problems, and preliminary treatment and medication modalities to be used pending completion of the comprehensive treatment plan.

2. The comprehensive treatment plan shall outline an active treatment program and be based on the assessment of the physical; developmental; psychological; chronological and developmental age; family; educational; vocational; social; and recreational needs of the patient. The reason for admission should be specified as should specific treatment goals, stated in measurable terms, including a projected timeframe; treatment modalities to be used; staff who are responsible for coordinating and carrying out the treatment; and expected length of stay and designation of the person or agency to whom the patient will be discharged. The comprehensive

treatment plan shall be reviewed and revised at least monthly or more frequently to meet the needs of the patients.

3. The degree of the patient's family's involvement (parent or parent surrogates) shall be defined in the treatment plan.

4. Collaboration with resources and significant others shall be included in treatment planning, when appropriate.

(c) **Discharge.** Discharge planning begins at the time of admission. A discharge date shall be projected in the treatment plan. Discharge planning shall include a period of time for transition into the community, e.g., home visits gradually lengthened, schools, etc. for those patients who have been in the facility for an extended period of time. The facility shall provide clinical or other patient information as required for the receiving organization to provide appropriate follow-up care.

(3) **Staff Coverage**. There shall be a master clinical staffing plan which provides for the continuous provision of sufficient regular, special, and emergency supervision and observation of all patients twenty-four (24) hours a day to meet their physical, mental, social, and safety needs.

(a) There shall be a registered nurse on duty at all times. Services of a registered nurse shall be available for all patients at all times. An exception may be permitted in facilities having less than a daily average of twenty (20) patients or less than twenty-five (25) beds, in that a registered nurse will not be required to be on duty at all times. In such cases, a licensed practical nurse shall be on duty and shall be assigned responsibility for the care of the patient, and a physician or registered nurse shall be on call and available for emergencies.

(b) A physician shall be on call twenty-four (24) hours a day and accessible to the facility within sixty (60) minutes. The physician's name and contact information shall be clearly posted in accessible places for all staff.

(c) Assessments of staffing needs shall be made on an ongoing basis but minimally every twenty-four (24) hours. Staffing patterns shall be adjusted to meet the assessed needs of patients. Special attention shall be given to times which probably indicate the need for increased direct care, e.g., weekends, evenings, during meals, transition between activities, awaking hours, numbers of patients requiring special observations, etc.

(d) Staff interaction shall ensure that there is adequate communication of information regarding patients, e.g., between working shifts or change of personnel, with consulting professional staff at routine planning and patient review meetings, etc. These shall be documented in writing.

(4) **Program Activities**. Program goals of the facility shall include those activities designed to promote the "normal" growth and development of the patients, regardless of pathology or age level. There should be positive relationships with general community resources, and the facility staff shall enlist the support of these resources to provide opportunities for patients to participate in normal community activities as they are able.

All labeling of vehicles used for transportation of patients shall be such that it does not call unnecessary attention to the patients.

(a) **Group Size.** The size and composition of each living group shall be therapeutically planned and depend on the age, developmental level, sex and clinical conditions. It shall allow for appropriate staff-patient interaction, security, close observation and support.

(b) **Daily Routine.** A basic routine shall be delineated in a written plan which shall be available to all personnel. The daily program shall be planned to provide a consistent well structured yet flexible framework for daily living and shall be periodically reviewed and revised as the needs of individual patients or the living group change. A basic daily routine shall be coordinated with special requirements of the patient's treatment plan.

(c) **Social and Recreation Activities.** Programs of recreational, physical, and social activities shall be provided for all patients for daytime, evenings, and weekends, to meet the needs of the patients and goals of the program. Programs should be designed to assist patients to develop a sense of confidence, individuality, self-esteem, and establish appropriate skills for living within the community. There shall be documentation of these activities as well as schedules maintained of any planned activities.

(d) **Religious Activities.** Opportunity shall be provided for all patients to participate in religious services and other religious activities within the framework of their individual and family interests and clinical status. The option to celebrate holidays in the patient's traditional manner shall be provided and encouraged.

(e) **Education.** The facility shall arrange for or provide an educational program for all patients receiving services in that facility. The particular educational needs of each patient shall be considered in both placement and programming.

(f) **Vocational Programs**. The facility shall arrange for or provide some degree of vocational and/or prevocational training for patients in the facility for whom it is indicated.

1. If there are plans for work experience developed as part of the patient's overall treatment plan the work shall be in the patient's interest with

payment where appropriate, and never solely in the interest of the facility's goals or needs.

2. Patients shall not be responsible for any major phase of the facility's operation or maintenance, such as cooking, laundering, housekeeping, farming and repairing. Patients shall not be considered as substitutes for employed staff.

3. Adequate attention shall be paid to federal wage and hour laws.

(5) **Nutrition**. Food services must comply with the Rules and Regulations for Food Service, Chapter 290-5-14. There must be a provision for planning and preparation of special diets as needed. Menus shall be evaluated by a consultant dietitian relative to nutritional adequacy at least monthly, with observation of food intake and changes seen in the patient.

(6) **Physical Care**. The facility shall have available, either within its own organizational structure or by written arrangements with outside clinicians or facilities, a full range of services for the treatment of illnesses and the maintenance of general health. The facility's written plan for clinical services shall delineate the ways the facility obtains or provides all general and specialized medical, surgical, nursing and dental services. Definite arrangements shall be made for a licensed physician to provide medical care for the patients. This shall include arrangements for necessary visits to the facility as well as office visits. Each patient shall have a primary physician who maintains familiarity with the patient's physical health status.

(a) Patients who are physically ill shall be cared for in surroundings that are familiar to them as long as this is medically feasible. If medical isolation is necessary, there shall be sufficient and qualified staff available to give appropriate care and attention.

(b) Arrangements shall be made in writing for patients from the facility to receive care from outside clinicians and at appropriate hospital facilities in the event a patient requires services that the facility cannot properly handle.

(c) Every patient shall have a complete physical examination annually and more frequently if indicated. This examination shall be as inclusive as the initial examination. Efforts shall be made by the facility to have physical defects of the patients corrected through proper medical care. Immunizations shall be kept current (DPT, polio, measles, rubella), appropriate to the patient's age.

(d) Each member of the staff shall be able to recognize common symptoms of the illnesses of patients, and to note any marked defects of patients. Staff shall be able to provide nursing care under the supervision of a registered nurse.

(e) Staff shall have knowledge of basic health needs and health problems of patients, such as mental health, physical health and nutritional health. Staff shall teach attitudes and habits conducive to good health through daily routines, examples and discussion, and shall help the patients to understand the principles of health.

(f) Each facility shall have a definitely planned program of dental care and dental health which shall be consistently followed. Each patient shall receive a dental examination by a qualified dentist and prophylaxis at least twice a year. Reports of all examinations and treatment should be included in the patient's clinical record.

(7) **Emergency Services**. All clinical staff shall have training in matters related to handling emergency situations.

(a) Policies and procedures shall be written regarding handling and reporting of emergencies and these shall be reviewed at least quarterly by all staff.

(b) All patient care staff must have an up-to-date first-aid certificate and certification in basic cardiopulmonary resuscitation (CPR). The facility must maintain suction equipment and an automatic external defibrillator (AED). All patient care staff must have training in the use of oral suction and the use of an AED.

(c) There shall be an emergency kit made up under the supervision of a physician and inspected regularly with documentation of inspections. This kit shall include emergency drugs, equipment, etc. This kit shall be stored in a locked area, easily accessible to appropriate staff.

(d) There shall be an adequate number of appropriately equipped first aid kits stored with appropriate safeguards but accessible to staff in appropriate locations such as living units, recreation and special purpose areas, buses, vans, etc.

(8) **Pharmaceutical Services**. Policies and procedures related to pharmaceutical services shall include but are not limited to:

(a) The facility shall have a pharmacy or drug room onsite that shall be directed by a registered pharmacist.

1. The pharmacy or drug room shall be under competent supervision.

2. The pharmacist shall be responsible to the administration of the facility and for developing, supervising and coordinating all activities of the pharmacy.

(b) If there is a drug room with no pharmacist, prescription medication shall be dispensed by a qualified pharmacist elsewhere and only storage and distribution shall be done at the facility. A designated person shall have responsibility for the day-to-day operation of the drug room. A consulting pharmacist shall assist in

developing policies and procedures for the distribution of drugs, and shall visit the facility as needed.

(c) Special locked storage space shall be maintained at the facility to meet the legal requirements for storage of narcotics and other prescribed drugs.

(d) Written arrangements with outside pharmacies, clinicians or facilities shall be made for emergency pharmaceutical service.

(e) Establishment and maintenance of a satisfactory system of records and bookkeeping in accordance with the policies of the facility.

(f) An automatic stop order on all prescribed drugs not specifically prescribed as to time and number of doses. These stop orders shall be in accordance with federal and state laws. Individual drug plans shall be reviewed by a physician weekly or more frequently as needed.

(g) A drug formulary accepted for use in the facility which is developed and amended at regular intervals by medical staff in cooperation with the pharmacist.

(h) Drugs may be administered only by a licensed nurse, in accordance with the Nurse Practice Act, O.C.G.A. § 43-26-12*et seq.* relating to the practice of nursing in Georgia.

(i) Intravenous medications and fluids shall be administered in accordance with Georgia law. If administered by licensed nurses, they shall be administered only by those who have been trained and determined competent to perform this duty.

(j) Each facility shall provide pharmaceutical services in compliance with State and federal laws and regulations.

(9) **Medical orders** shall be in writing and signed by the physician. Telephone/verbal orders shall be used sparingly and given only to a licensed nurse or otherwise qualified individual as determined by the medical staff in accordance with State law. The individual receiving the telephone/verbal order shall immediately repeat the order and the prescribing physician shall verify that the repeated order is correct. The individual receiving the order shall document, in the patient's clinical record that the order was repeated and verified. Telephone/verbal orders must be signed by the physician within the timeframe designated in the facility's policies and procedures which ensure that it is done as soon as possible. Where telephone/verbal orders are routinely not being signed within the timeframe designated in the policy, the facility will take appropriate corrective action.

(10) **Laboratory and Pathology Services**. Provision shall be made for those services within the facility or with an outside facility to meet the needs of the patient. These services shall be provided by a CLIA certified facility. Laboratory and pathology tests to be performed require an order from a qualified physician and reports from such tests shall

be part of the patient's clinical records. Abnormal laboratory and pathology reports shall be followed up appropriately.

(11) **Patients' Rights**. Every effort shall be made to safeguard the legal and civil rights of patients and to make certain that they are kept informed of their rights, including the right to legal counsel and all other requirements of due process when necessary.

(a) **Treatment**. Each patient shall be provided treatment and care in the least restrictive environment as possible; each patient, parent(s), and/or legal guardian shall be encouraged to participate in the development of the patient's individualized treatment plan; and each patient shall be provided treatment and care in a manner that respects the patient's personal privacy and dignity.

(b) **Visitors.** Policies shall allow visitation of patient's family and significant others unless clinically contraindicated. Appropriate places for visits shall be provided.

(c) **Telephone and Mail**. Patients shall be allowed to conduct private telephone conversations with family and friends and to send and receive mail. When restrictions are necessary because of therapeutic or practical reasons, such as expense, these reasons shall be documented, explained to the patient and family and re-evaluated at least monthly.

(d) **Behavior Management.** Behavior management techniques shall be fair and consistent and must be applied based on the individual's needs and treatment plan, and following established and approved behavior management techniques in accordance with the Rule 111-8-68-.08.

(e) **Restraint and Seclusion**. Each patient has the right to be free from restraint or seclusion, in any form, used as a means of coercion, discipline, convenience, or retaliation.

(f) **Clothing.** Individual patients shall have their own appropriate amounts and types of clothing for the particular activities, climate, etc. There shall be an appropriate storage place for their clothing.

(g) **Grievances.** The patients shall have the opportunity to present opinions, recommendations and grievances to appropriate staff members. The facility shall have written policies and carry out appropriate procedures for receiving and responding to such patient communications in a way that will preserve and foster the therapeutic aspects of conflict-resolution and problem solving; e.g., patient-staff government meetings.

(12) **Records**. The form and detail of the clinical records may vary in accordance with these rules.

(a) **Content.** All clinical records shall contain all pertinent clinical information and each record shall contain at least:

1. Identification data, consent forms, acknowledgment of patient, parent(s), and/or legal guardian's receipt and explanation of facility's emergency safety intervention procedures and a copy of patients' rights; when these are not obtainable, reason shall be noted;

2. Source of referral;

3. Reason for referral, e.g. chief complaint, presenting problem;

4. Record of the complete assessment;

5. Initial formulation and diagnosis based upon the assessment;

6. Written treatment plan;

7. Medication history and record of all medications prescribed;

8. Record of all medication administered by facility staff, including type of medication, dosages, frequency of administration, and persons who administered each dose;

9. Documentation of course of treatment and all evaluations and examinations, including those from other facilities, example, emergency room or general hospital;

10. Documentation of the use and monitoring of emergency safety interventions;

11. Documentation of the use of patient safety observations/interventions;

12. Periodic progress report;

13. All consultation reports;

14. All other appropriate information contained from outside sources pertaining to the patient;

15. Discharge or termination summary report; and

16. Plans for follow-up and documentation of its implementation.

17. Identification data and consent form shall include the patient's name, address, home telephone number, date of birth, sex, next of kin, school name, grade, date of initial contact and/or admission to the service, legal status and legal document, and other identifying data as indicated.

18. **Progress Notes**. Progress notes shall include regular notations at least weekly by staff members, consultation reports and signed entries by authorized identified staff. Progress notes by the clinical staff shall:

    (a) Document a chronological picture of the patient's clinical course;

    (b) Document all treatment rendered to the patient;

    (c) Document the implementation of the treatment plan;

    (d) Describe each change in each of the patient's conditions;

    (e) Describe responses to and outcome of treatment including the use of any emergency safety interventions and medications; and

    (f) Describe the responses of the patient and the family or significant others to significant events.

19. **Discharge Summary.** The discharge summary shall include the initial formulation and diagnosis, clinical resume, final formulation, and final primary and secondary diagnoses, the psychiatric and physical categories. The final formulation shall reflect the general observations and understanding of the patient's condition initially, during appraisal of the fundamental needs of the patients. All relevant discharge diagnoses should be recorded and coded in the standard nomenclature of the current "Diagnostic and Statistical Manual of Mental Disorders," published by the American Psychiatric Association, and the latest edition of the "International Classification of Diseases," regardless of the use of other additional classification systems. Records of discharged patients shall be completed following discharge within a reasonable length of time, and not to exceed fifteen (15) days. In the event of death, a summation statement shall be added to the record either as a final progress note or as a separate resume. This final note shall take the form of a discharge summary and shall include circumstances leading to death. All discharge summaries must be signed by a physician.

20. **Recording.** Entries in the clinical records shall be made by all staff having pertinent information regarding the patient, consistent with the facility policies, and authors shall fully sign and date each entry. When mental health trainees are involved in, patient care, documented evidence shall be in the clinical records to substantiate the active participation of supervisory clinical staff. Symbols and abbreviations shall be used only when they have been approved by the clinical staff and when there is an explanatory legend. Final diagnosis, both psychiatric and physical, shall

be recorded in full, and without the use of either symbols or abbreviations.

(b) **Clinical Records Policies and Procedures**. The facility shall have written policies and procedures regarding clinical records which are enforced and provide that:

1. Clinical records shall be confidential, current and accurate;

2. The facility shall protect the confidentiality of clinical information and communication between staff members and patients;

3. All staff shall have training, as part of new staff orientation and with periodic updates, regarding the effective maintenance of confidentiality of clinical records. It shall be emphasized that confidentiality also refers to discussions regarding patients inside and outside the facility. Verbal confidentiality shall be discussed as part of all employee training.

4. Clinical records are the property of the facility and shall be maintained for the benefit of the patient, the staff and the facility;

5. The facility is responsible for safeguarding the information in the clinical record against loss, defacement, tampering or use by unauthorized persons;

6. Except as required by law, the written consent of the patient, or if the patient is a minor, the parent(s), and/or legal guardian, is required for the release of clinical record information;

7. Records may be removed from the facility's jurisdiction and safekeeping only according to the policies of the facility or as required by law; and

(c) **Maintenance of Records**. Each facility shall provide for a master filing system which shall include a comprehensive record of each patient's involvement in every program aspect.

1. Appropriate records shall be kept on the unit where the patient is being treated or be directly and readily accessible to the clinical staff caring for the patient;

2. The facility shall maintain a system of identification and filing to facilitate the prompt location of the patient's clinical records;

3. The facility shall retain patients' records at least until the fifth anniversary of the patients' discharge. If the patient is a minor, the records must be retained for at least five (5) years past the age of majority. Records may be

preserved in the facility's format of choice, including but not limited to paper or electronic format, so long as the records are readable, capable of being reproduced in paper format upon request, and stored and disposed of in a manner that protects the confidentiality of the record;

4. The clinical record services required by the facility shall be directed, staffed and equipped to facilitate the accurate processing, checking, indexing, filing, retrieval and review of all clinical records. The clinical records service shall be the responsibility of an individual who has demonstrated competence and training or experience in clinical record administrative work. Other personnel shall be employed as needed, in order to effect the functions assigned to the clinical record services; and

5. There shall be adequate space, equipment and supplies, compatible with the needs of the clinical record service, to enable the personnel to function effectively and to maintain clinical records so that they are readily accessible.

(13) **Program and Patient Evaluation**. The staff shall work towards enhancing the quality of patient care through specified, documented, implemented and ongoing processes of clinical care evaluation studies and utilization review mechanisms.

(a) **Individual Case Review.**

1. There shall be regular staff meetings and/or unit meetings to review and monitor the progress of the individual child or adolescent patient. Each patient's case shall be reviewed within a month after admission and at least monthly during residential treatment. Review of the use of emergency safety interventions shall be in accordance with Rule 111-8-68-.08(2)(l). The reviews shall be documented and the meeting may also be used for review and revision of treatment plans.

2. The facility shall provide for a follow-up review on each discharged patient to determine effectiveness of treatment and disposition.

(b) **Program Evaluation.**

1. **Clinical Care Evaluation Studies**. There shall be evidence of ongoing studies to define standards of care consistent with the goals of the facility, effectiveness of the program, the facility's progress in reducing the use of emergency safety interventions, and to identify gaps and inefficiencies in service. Evaluation shall include, but is not limited to, follow-up studies. Studies shall consist of the following elements:

(i) Selection of an appropriate design;

(ii) Specification of information to be included;

(iii) Collection of data;

(iv) Analysis of data with conclusions and recommendations;

(v) Transmissions of findings; and

(vi) Follow-up on recommendations.

2. **Utilization Review**. Each facility shall have a plan for and carry out utilization review. The review shall cover the appropriateness of admission to services, the provision of certain patterns of services, and duration of services. There shall be documentation of utilization review meetings either in minutes or in individual clinical records.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.07
Authority: O.C.G.A. Sec. 31-7-2.1.
History. Original Rule entitled "Services" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.08. Behavior Management and Emergency Safety Interventions.

(1) **Behavior Management.**

(a) The facility shall develop and implement policies and procedures on behavior management. Such policies and procedures shall set forth the types of patients served in accordance with its program purpose, the anticipated behavioral problems of the patients, and acceptable methods of managing such problems.

(b) Such behavior management policies and procedures shall incorporate the following minimum requirements:

1. Behavior management principles and techniques shall be used in accordance with the individual treatment plan, written policies and procedures, treatment goals, safety, security, and these rules and regulations.

2. Behavior management shall be limited to the least restrictive appropriate method, as described in the patient's treatment plan, and in accordance with the prohibitions as specified in these rules and regulations.

3. Behavior management principles and techniques shall be administered by facility staff members and shall be appropriate to the severity of the patient's behavior, chronological and developmental age, size, gender, physical, medical, psychiatric condition, and personal history (including any history of physical or sexual abuse).

(c) The following forms of behavior management shall not be used by staff members with patients receiving services from the facility:

1. assignment of excessive or unreasonable work tasks;

2. denial of meals and hydration;

3. denial of sleep;

4. denial of shelter, clothing, or essential personal needs;

5. denial of essential program services;

6. verbal abuse, ridicule, or humiliation;

7. restraint, manual holds, and seclusion used as a means of coercion, discipline, convenience, or retaliation;

8. denial of communication and visits unless restricted in accordance with Rule 111-8-68-.06(i)(2); and

9. corporal punishment.

(d) Patients shall not be permitted to participate in the behavior management of other patients or to discipline other patients, except as part of an organized therapeutic self-governing program in accordance with accepted standards of clinical practice that is conducted in accordance with written policy and is supervised directly by designated staff.

(2) **Emergency Safety Interventions**.

(a) Emergency safety interventions shall only be used when a patient exhibits a dangerous behavior reasonably expected to lead to immediate physical harm to the patient or others and less restrictive means of dealing with the injurious behavior have not proven successful or may subject the patient or others to greater risk of injury.

(b) Any emergency safety intervention involving use of mechanical restraints, manual holds, or seclusion must be ordered by a physician or other licensed professional

trained in emergency safety interventions and authorized by State law to order such use.

1. The order may not be a standing order or on an as-needed basis.

2. If the order is a verbal order, it must be received by a licensed nurse or otherwise qualified staff as determined by the medical staff in accordance with State law, prior to initiation of the emergency safety intervention, while the intervention is being initiated by staff, or immediately thereafter. The individual issuing the order must verify the verbal order in a signed written form in the patient's record within the timeframe designated by facility policy and procedure which ensures that it is done as soon as possible. The individual ordering the use of the intervention must be available to staff for consultation, at least by a two-way communication device, throughout the course of the emergency safety intervention.

3. Each order for use of restraint or seclusion must be limited to no longer than the duration of the emergency safety situation.

4. Each order for the use of mechanical restraint, manual hold, or seclusion, must include the name of the physician or other licensed professional, the date and time the order was obtained, the type of intervention ordered, and the length of time for which the use of the intervention was authorized. Restraint and seclusion orders shall not exceed:

   (i) four (4) hours for patients ages 18 to 21;

   (ii) two (2) hours for patients ages 9 to 17;

   (iii) one (1) hour for patients under age 9; and

   (iv) fifteen (15) minutes for manual holds with one order renewal for an additional fifteen(15) minutes for a total of thirty (30) minutes.

5. If the emergency safety situation continues beyond the time limit authorized in the order, a registered nurse or other licensed professional must immediately contact the ordering physician or the ordering licensed professional to receive further instructions.

(c) Emergency safety interventions shall not include the use of any restraint or manual hold that would potentially impair the patient's ability to breathe or has been determined to be inappropriate for use on a particular patient due to a documented medical or psychological condition.

(d) The facility shall have written policies and procedures for the use of emergency safety interventions, a copy of which shall be provided to and discussed with each

patient (as appropriate taking into account the patient's age and intellectual development) and the patient's parents and/or legal guardians prior to or at the time of admission. Emergency safety interventions policies and procedures shall include:

1. requirements for the documentation of an assessment at admission and at each annual exam by the patient's physician, a physician's assistant, or a registered nurse with advanced training working under the direction of a physician, which reflects that there are no medical issues that would be incompatible with the appropriate use of emergency safety interventions on that patient. Such assessment and documentation must be reevaluated following any significant change in the patient's medical condition;

2. requirements for prohibiting the use of mechanical restraints, manual holds, or seclusion use by any employee not trained in prevention and use of emergency safety interventions, as required by these rules; and

3. requirements that all actions taken that involve utilizing an emergency safety intervention shall be recorded in the patient's record, including at a minimum the following:

   (i) date and description of the precipitating incident;

   (ii) the order for use of any mechanical restraints, manual hold, or seclusion;

   (iii) description of the de-escalation techniques used prior to the emergency safety intervention, if applicable;

   (iv) environmental considerations;

   (v) names of staff participating in the emergency safety intervention;

   (vi) any witnesses to the precipitating incident and subsequent intervention;

   (vii) exact emergency safety intervention used;

   (viii) evidence of the continuous visual monitoring of a patient in mechanical restraint, manual hold, or seclusion, documented minimally at fifteen (15) minute intervals;

   (ix) the provision of fluids every hour, food at regular intervals, and bathroom breaks every two (2) hours;

   (x) beginning and ending time of the intervention;

(xi) outcome of the intervention;

(xii) detailed description of any injury arising from the incident or intervention; and

(xiii) summary of any medical care provided.

(e) Emergency safety interventions may be used to prevent runaways only when the patient presents an imminent threat of physical harm to self or others, or as specified in the individual treatment plan.

(f) Facility staff shall be aware of each patient's known or apparent medical and psychological conditions (e.g. obvious health issues, list of medications, history of physical abuse, etc.), as evidenced by written acknowledgement of such awareness, to ensure that the emergency safety intervention that is utilized does not pose any undue danger to the physical or mental health of the patient.

(g) Patients shall not be allowed to participate in the emergency safety intervention of another patient.

(h) Within one (1) hour of the initiation of an emergency safety intervention and immediately following the conclusion of the emergency safety intervention, a physician or other licensed independent practitioner; or a registered nurse or physician assistant; trained in the use of emergency safety interventions and permitted by the state and the facility to assess the physical and psychological well-being of patients must conduct a face-to-face assessment of the patient. The assessment at a minimum must include:

1. the patient's physical and psychological status;

2. the patient's behavior;

3. the appropriateness of the intervention measures; and

4. any complications and treatments resulting from the intervention.

(i) **Manual Holds.**

1. Emergency safety interventions utilizing manual holds require at least one (1) trained staff member to carry out the hold. Emergency safety interventions utilizing prone restraints require at least two trained staff members to carry out the hold.

2. When a manual hold is used upon any patient whose primary mode of communication is sign language, the patient shall be permitted to have his or

her hands free from restraint for brief periods during the intervention, except when such freedom may result in physical harm to the patient or others.

3. A manual hold requires physician authorization at fifteen (15) minute intervals and may not be used for more than thirty (30) minutes at any one time without the consultation of the ordering physician or other licensed professional authorized to order the use of manual holds. The ordering physician or other licensed professional authorized to order the use of the hold shall be contacted by a two-way communications device or in person to determine that the continuation of the manual hold is appropriate under the circumstances.

4. If the use of a manual hold on a patient reaches a total of one hour within a twenty-four (24) hour period, the staff shall reconsider alternative treatment strategies, and document same.

5. The patient's breathing, verbal responsiveness, and motor control shall be continuously monitored during any manual hold. Documentation of the monitoring by a trained staff member shall be recorded every fifteen (15) minutes during the duration of the restraint.

(j) **Seclusion**.

1. A room used for the purposes of seclusion must meet the following criteria:

   (i) The room shall be constructed and used in such ways that the risk of harm to the patient is minimized;

   (ii) The room shall be equipped with a viewing window so that staff can monitor the patient;

   (iii) The room shall be lighted and well-ventilated;

   (iv) The room shall be a minimum fifty (50) square feet in area; and

   (v) The room must be free of any item that may be used by the patient to cause physical harm to himself/herself or others.

2. No more than one (1) patient shall be placed in the seclusion room at a time.

3. A seclusion room monitoring log shall be maintained and used to record the following information:

   (i) name of the secluded patient;

   (ii) reason for the patient's seclusion;

(iii) time of patient's placement in the seclusion room;

(iv) name and signature of the staff member that conducted visual monitoring;

(v) signed observation notes; and

(vi) time of the patient's removal from the seclusion room.

(k) **Training, Evaluation, and Reporting.**

1. All facility staff members who may be involved in the use of emergency safety interventions, shall have evidence of having satisfactorily completed a nationally recognized training program for emergency safety interventions to protect patients and others from injury, which has been taught by an appropriately certified trainer in such program. Emergency safety interventions may only be used by those staff members who have received such training and successfully demonstrated the techniques learned for managing emergency safety situations.

2. At a minimum, the emergency safety intervention program that is utilized shall include the following:

   (i) techniques for de-escalating problem behavior including patient and staff debriefings;

   (ii) appropriate use of emergency safety interventions;

   (iii) recognizing aggressive behavior that may be related to a medical condition;

   (iv) awareness of physiological impact of a restraint on the patient;

   (v) recognizing signs and symptoms of positional and compression asphyxia and restraint associated cardiac arrest;

   (vi) instructions as to how to monitor the breathing, verbal responsiveness, and motor control of a patient who is the subject of an emergency safety intervention;

   (vii) appropriate self-protection techniques;

   (viii) policies and procedures relating to using manual holds, including the prohibition of any technique that would potentially impair a patient's ability to breathe;

(ix) facility policies and reporting requirements;

(x) alternatives to restraint;

(xi) avoiding power struggles;

(xii) escape and evasion techniques;

(xiii) time limits for the use of restraint and seclusion;

(xiv) process for obtaining approval for continual restraints and seclusion;

(xv) procedures to address problematic restraints;

(xvi) documentation;

(xvii) investigation of injuries and complaints;

(xviii) monitoring physical signs of distress and obtaining medical assistance; and

(xix) legal issues.

3. Emergency safety intervention training shall be in addition to the training required in Rule 111-8-68-.05(5)(d) and shall be documented in the staff member's personnel record.

4. The facility shall take and document appropriate corrective action when it becomes aware of or observes the inappropriate use of an emergency safety intervention technique as outlined in these rules and regulations and shall notify each patient's parents and/or legal guardians. Documentation of the incident and the corrective action taken by the facility shall be maintained.

(l) At least monthly, the facility, utilizing a master restraint/seclusion log and the patients' records, shall review the use of all emergency safety interventions for each patient and staff member, including the type of intervention used and the length of time of each use, to determine whether there was a clinical basis for the intervention, whether the use of the emergency safety intervention was warranted, whether any alternatives were considered or employed, the effectiveness of the intervention or alternative, and the need for additional training. Written documentation of all such reviews shall be maintained. Where the facility identifies opportunities for improvement as a result of such reviews or otherwise, the facility shall implement these changes through an effective quality improvement plan designed to reduce the use of emergency safety devices.

(m) Facilities shall submit to the department electronically or by facsimile a report, within twenty-four (24) hours, whenever the facility becomes aware of an incident which results in any injury of a patient requiring medical treatment beyond first aid that is received by a patient as a result of or in connection with any emergency safety intervention. In addition facilities must report the following:

1. For any thirty (30) day period, where three (3) or more incidents for the same patient occur where the facility has used mechanical restraint or seclusion lasting four (4) or more hours for patients ages 18-21; two (2) or more hours for patients ages 9 to 17; or one (1) or more hours for patients under nine (9) years of age and/or when three (3) or more incidents for the same patient occur where the facility has used manual holds lasting thirty (30) or more minutes. The reports shall include the type of emergency safety intervention, total amount of time in the intervention, and any actions taken to prevent further use of emergency safety interventions.

2. On a monthly basis, the total number of emergency safety interventions shall be reported by patient unit, including the total amount of time each intervention was used, and the monthly average daily census for each unit. The report shall include a summary of the facility's monthly evaluation of their use of emergency safety interventions, including actions taken.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.08
Authority: O.C.G.A. Secs. 31-2-9, 31-7-2.1.
History. Original Rule entitled "Behavior Management and Emergency Safety Interventions" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.09. Waivers and Variances.

(1) The department may, in its discretion, grant waivers and variances of specific rules upon application or petition being filed by a facility. The department may establish conditions which must be met by the facility in order to operate under the waiver or variance granted. Waivers and variances may be granted in accordance with the following considerations:

(a) Variance. A variance may be granted by the department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety and care of the patients exist and will be met in lieu of the exact requirements of the rule or regulations in question.

(b) Waiver. The department may dispense entirely with the enforcement of a rule or regulation upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety and care of patients.

(c) Experimental Variance or Waiver. The department may grant waivers and variances to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant or petitioner that the intended protections afforded by the rule or regulation which is the subject of the request are met and that the innovative approach has the potential to improve service delivery.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.09
Authority: O.C.G.A. Sec. 31-2-9.
History. Original Rule entitled "Waivers and Variances" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.10. Enforcement and Penalties.

(1) Enforcement of these rules and regulations shall be done in accordance with the Rules and Regulations for Enforcement of Licensing Requirements, Chapter 111-8-25.

(2) The facility shall notify each patient's parents and/or legal guardians of the department's actions to revoke the license or seek an emergency suspension of the facility's license to operate.

(3) The official notice of the revocation or emergency suspension action and any final resolution, together with the department's complaint intake phone number and website address, shall be provided by the facility to each current and prospective patient's parents and/or legal guardians.

(4) The facility shall ensure the posting of the official notice at the facility in an area that is visible to each patient's parents and/or legal guardians.

(5) The facility shall ensure that the official notice continues to be visible to each patient's parents and/or legal guardians throughout the pendency of the revocation and emergency suspension actions, including any appeals.

(6) The facility shall have posted in an area that is readily visible to each patient's parents and/or legal guardians any inspection reports that are prepared by the Department during the pendency of any revocation or emergency suspension action.

(7) It shall be a violation of these rules for the facility to permit the removal or obliteration of any posted notices of revocation, emergency suspension action, resolution, or inspection survey during the pendency of any revocation or emergency suspension action.

(8) The department may post an official notice of the revocation or emergency suspension action on its website or share the notice of the revocation or emergency suspension action and any information pertaining thereto with any other agencies that may have an interest in the welfare of the patients in care at the facility.

(9) The department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared a state of emergency.

(10) Inspections. The facility shall be available at reasonable hours for observation and examination by properly identified representatives of the department.

(a) At least annually, a report providing statistical data and brief program narrative shall be provided to the department, as requested.

(b) The governing body shall notify the department of the anticipated opening date of a newly constructed facility in order that a pre-opening licensure inspection of the treatment facility may be conducted to determine compliance with these rules and regulations.

(c) The administrator or his representative shall accompany the department representative on tours of inspection and shall sign the completed check-list.

(11) Plans of Correction. If violations of these licensing rules are identified, the facility will be given a written report of the violation that identifies the rules violated. The facility shall submit to the department a written plan of correction in response to the report of violation, which states what the facility will do, and when, to correct each of the violations identified. The facility may offer an explanation or dispute the findings or violations in the written plan of correction, so long as an acceptable plan of correction is submitted within ten (10) days of the facility's receipt of the written report of inspection. If the initial plan of correction is unacceptable to the department, the facility will be provided with at least one (1) opportunity to revise the unacceptable plan of correction. Failure to submit an acceptable plan of correction may result in the department commencing enforcement procedures. The facility shall comply with its plan of correction.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.10
Authority: O.C.G.A. Sec. 31-2-11.
History. Original Rule entitled "Enforcement and Penalties" adopted. F. July 14, 2010; eff. August 3, 2010.

Rule 111-8-68-.11. Severability.

In the event that any rule, sentence, clause, or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portion thereof. The remaining rules or portions of rules shall remain in full

force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-68-.11
Authority: O.C.G.A. Sec. 31-7-2.1.
History. Original Rule entitled "Severability" adopted. F. July 14, 2010; eff. August 3, 2010.

Subject 111-8-71. TRAUMATIC BRAIN INJURY FACILITIES.

Rule 111-8-71-.01. Legal Authority.

The legal authority for this chapter is Chapter 7 of Title 31 of the Official Code of Georgia annotated.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.01
Authority: O.C.G.A. § 31-7-1(4)(F).
History. Original Rule entitled "Legal Authority" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.02. Purpose.

The purpose of these rules is to implement the requirements of Chapter 7 of Title 31 of the Official Code of Georgia Annotated pertaining to the licensure of facilities that are devoted to the provision of treatment and rehabilitative care for periods continuing for 24 hours or longer for persons who have traumatic brain injury.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.02
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Purpose" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.03. Definitions.

(1) "Department" means the Georgia Department of Community Health.

(2) "Facility" means a place which is devoted to the provision of treatment and rehabilitative care for periods continuing for 24 hours or longer for persons who have traumatic brain injury. Such facility is not classified by the Department as a hospital, nursing home, intermediate care facility, or personal care home.

(3) "Traumatic Brain Injury" means a traumatic insult to the brain and its related parts resulting in organic damage thereto which may cause physical, intellectual, emotional, social, or vocational changes in a person. Persons having a traumatic brain injury may have organic damage or physical or social disorders, but for the purpose of these rules, traumatic brain injury shall not be considered mental illness.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.03
Authority: O.C.G.A. §§ 31-7-1(4)(F), 37-3-1(16.1).
History. Original Rule entitled "Purpose" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.04. Governing Body.

Each facility shall have a governing body empowered and responsible to determine all policies and procedures, and to ensure compliance with these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.04
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Governing Body" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.05. Permits.

No facility shall be operated without a permit or provisional permit issued by the Department.

(a) A permit shall be issued by the Department upon a facility's compliance with these rules and regulations.

(b) A provisional permit shall be issued by the Department on a conditional basis for one of the following reasons.

1. To allow a newly established facility a reasonable but limited period of time to demonstrate that its operational procedures equal standards specified by these rules and regulations.

2. To allow an existing facility a reasonable length of time to comply with these rules and regulations, provided that the facility shall present a plan of improvement acceptable to the Department.

(c) Any permit shall be displayed in a conspicuous place on the premises of the facility.

(d) Permits issued shall remain in force and effect until revoked or suspended.

Provisional permits shall remain in force and effect for such limited period of time as may be specified by the Department. Any permit is only valid at the location for which issued, and is not transferable between governing bodies.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.05
Authority: O.C.G.A. § 31-7-3.
History. Original Rule entitled "Permits" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.06. Applications.

Applications for a permit to operate a facility shall be submitted by the governing body on forms prescribed by the Department. An approved Certificate of Need shall accompany the application. Failure or refusal to file an application shall constitute a violation of Chapter 7 of Title 31 of the Official Code of Georgia Annotated.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.06
Authority: O.C.G.A. §§ 31-2-8, 31-7-3.
History. Original Rule entitled "Applications" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.07. Inspections.

(1) Upon submission of a completed application, the Department shall conduct an inspection of a facility to determine compliance with these rules and regulations. Following an inspection, the Department may issue or refuse to issue a permit or a provisional permit.

(2) The Department shall conduct such additional inspections as needed to determine if a facility continues to fulfill requirements. Failure to fulfill requirements may result in the revocation of a permit as provided in Chapter 111-8-71-.16.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.07
Authority: O.C.G.A. §§ 31-7-3, 31-7-4.
History. Original Rule entitled "Inspections" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.08. Admissions.

(1) Written policies and procedures shall be established and implemented for admission to the facility. Such policies shall include a description of the types of traumatic brain injured persons it serves, the continuum of treatment and rehabilitative care it provides, and the functional outcomes it intends to achieve for its clients in regard to degree of personal and living independence, level of work productivity, and psychosocial adjustment.

(2) Initial admissions shall be screened through review of a written application form, review of referral information and the client's most recent medical records, and personal interviews with the client. Factors to be considered in the screening include the client's medical history, functional status, and social circumstances.

(3) At admission the following information shall be explained to each client, and a responsible family member, guardian, or representative. Documentation of the explanation shall be maintained in the client's case record.

   (a) The types of treatment and rehabilitative care provided in the facility and an overview of the functional outcomes that the client may expect to achieve,

including details regarding the hours and specific times of specific therapies, services, and activities that are expected to be provided for the client.

(b) A fee schedule and required methods of payment, including information about payment options and costs of special therapies and services.

(c) The facility's rules, including any provisions for the maintenance of resident fund accounts if such accounts are made available.

(d) A description of the client's rights and responsibilities to at least include the right to be free of physical and psychological abuse and neglect, to participate in individual program planning and implementation, and to receive visitors at regular hours, and to manage one's own financial affairs.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.08
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Admissions" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.09. Client Assessment and Individual Program Planning.

(1) Written policies and procedures shall be established and implemented to provide for a complete, written assessment of the client within four weeks following admission. The purpose of the assessment shall be to determine client rehabilitation potential or need for ongoing lifetime support and the facility's ability to deliver appropriate treatment and rehabilitative care, or support to the client.

(2) The assessment shall be performed under the supervision of the program manager in collaboration with the rehabilitation professionals that provide therapies and services in the facility. The assessment must also include documentation of contact and input from the client's physician, previous rehabilitation providers and facilities, and rehabilitation professionals previously involved in the client's treatment and rehabilitative care. The assessment must identify the client's rehabilitation potential and behavioral, cognitive, educational, emotional, functional, medical, nursing, sociological, and vocational characteristics and needs. Whenever feasible, clients, families, and guardians or representatives should participate in assessments.

(3) An individual, written program plan shall be developed for each client, with his participation, by professional staff that participated in the assessment. The plan shall be based on the characteristics and needs identified in the assessment. The plan shall include specific goals oriented towards outcomes to achieve independence for the client.

(a) An individual case manager shall be assigned primary responsibility for managing the client's program plans.

(b) Program plans shall be reviewed by the case manager in collaboration with the client and other appropriate professional staff at least monthly and modified as needed.

(c) When transfer or discharge is planned, a discharge summary shall be included in the program plan. The summary must contain the reason for referral or discharge, the diagnosis, the client's functional limitations, the services that were provided, the outcomes of the services, and any recommendations of the case manager or professional staff. A facility shall provide every client at least ten days prior notification of transfer or discharge, provided, however, that an emergency transfer shall be done and notification given as soon as practical.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.09
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Client Assessment and Individual Program Planning" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.10. Recordkeeping.

An individual care record shall be maintained for each client admitted to the facility. Case records must be maintained in a central location, and contain the following materials:

(a) Case identification information;

(b) Names, addresses, and telephone numbers of responsible family members, guardians, or representatives;

(c) Names, addresses, and telephone numbers of emergency contacts to include the client's physicians;

(d) Admissions documentation;

(e) The client's complete written assessment;

(f) The client's written program plan, including the designation of a case manager; and

(g) Signed and dated progress reports, notes or similar documentation related to the mental and physical health, treatment, and rehabilitation of the client to include current drug regimens, treatment, and dietary needs.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.10
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Recordkeeping" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.11. Treatment and Rehabilitative Care.

A facility shall provide one or two levels of treatment and rehabilitative care. These are:

(a) Transitional Living. Such treatment and rehabilitative care shall be delivered to clients that require education and training for independent living with a focus on compensating for skills that cannot be restored. Such care prepares clients for maximum independence, teaches necessary skills for community interaction, works with clients on pre-vocational and vocational training, and stresses cognitive, speech, and behavioral therapies structured to the individual needs of clients.

1. Management of clients shall be provided by a program manager who shall be a rehabilitation professional with two years experience in the care or treatment of traumatic brain injured persons. The program manager shall be a full-time staff member with specialized education, training, and skill in rehabilitation.

2. Individual case management shall be provided by the program manager or other professional staff member such as occupational therapist, physical therapist, rehabilitation nurse, or social worker.

3. The following specialized services shall be provided, or arranged for by written agreements or contracts. Such services shall be delivered by professionals licensed by applicable existing Examining Boards of the Joint Secretary for Examining Boards of the Georgia Secretary of State.

   (i) Occupational Therapy;

   (ii) Psychology;

   (iii) Physical Therapy; and

   (iv) Speech-Language Therapy.

4. Based on the needs of the client's and the facility's stated continuum of treatment and rehabilitative care, the facility shall provide, arrange for, or assist clients to obtain the following services:

   (i) Audiology;

   (ii) Chaplaincy;

   (iii) Cognitive Rehabilitative Therapy;

   (iv) Dentistry;

   (v) Dietetics/Nutrition;

(vi) Driver Education;

(vii) Family Therapy;

(viii) Neuropsychology;

(ix) Nursing, including administration of medications if necessary;

(x) Orthotics;

(xi) Pharmaceuticals, including monitoring and safe storage of medications;

(xii) Physician;

(xiii) Prosthetics;

(xiv) Rehabilitation Engineer;

(xv) Respiratory Therapy;

(xvi) Social Work;

(xvii) Therapeutic Recreation; and

(xviii) Vocational Rehabilitation.

5. Coordinated services listed in subparagraph 3. and 4. above shall be provided to a client for at least five hours per weekday. Provision of such services shall be in accordance with the client's plan of care and cognitive and/or physical condition.

6. Twenty-four hour per day supervision for clients in the facility shall be provided by the program manager, professional rehabilitation staff, or other direct care rehabilitation staff at a ratio of 1 staff: 8 clients. Staff shall be available to respond to the needs of clients placed in an independent living arrangement, or outside the facility for employment or unsupervised activities.

(b) Lifelong Living. Such treatment and rehabilitative care shall be delivered to clients that have been discharged from rehabilitation, cannot live at home independently, and require ongoing lifetime support.

1. Management of clients shall be provided by a program manager who shall be a rehabilitation professional with two years of experience in the care or treatment of traumatic brain injured persons. The program manager shall be a full-time staff member with specialized education, training, and skill in rehabilitation. Individual case management may be provided by the program manager.

2. Twenty-four hour per day supervision for clients in the facility shall be provided by the program manager or other direct care staff at a ratio of 1 staff: 10 clients. Staff shall be available to respond to the needs of clients outside the facility for employment or unsupervised activities.

3. Based on needs identified in client assessments and individual program plans, personal care shall be provided. Such care shall include bathing, bowel and bladder management, care of adaptive personal care devices, hair care, nail care, oral hygiene, personal hygiene, positioning, shaving, and skin care.

4. Based on needs identified in client assessments and individual program plans, individual health care needs shall be provided or arranged. These include dental services; nursing services, including administration of medications if necessary; pharmaceutical services, including monitoring medications and safe storage of medications; physician services; preventative, restorative, and rehabilitation services; and psychological services.

5. Support or training for basic living skills shall be available to residents as needed. Such support or training includes basic self-care skills (eating, bathing, toileting, dressing, etc.); communication skills; health maintenance skills (diet, exercise, hygiene, medications, use of medical services, etc.); financial management skills; housekeeping skills; mobility and transportation skills, including how to access public transportation; safety practices; and use of community services and resources.

6. Group or individual activities shall be scheduled for residents based on service needs and personal choices. A minimum of thirty hours per week of activities shall be made available in accordance with the client's plan of care and cognitive and/or physical condition. This may include scheduled employment activities.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.11
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Treatment and Rehabilitative Care" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.12. Physical Environment and Safety.

(1) A facility must be designed, constructed, equipped and maintained to protect the health and safety of clients and staff.

(2) Floors, walls, and ceilings shall be in good repair.

(3) A facility must be in compliance with applicable fire safety laws, and regulations of the Georgia Safety Fire Commissioner.

(4) A facility must provide sufficient space and equipment in recreation, program, and treatment and rehabilitation areas to provide needed services as required by these rules and as identified in each client's individual, written program plan.

(5) A facility must be wheelchair accessible.

(6) Client rooms must be designed and equipped for adequate care and treatment, comfort, and privacy of clients. Bedrooms must:

(a) Accommodate no more than four clients;

(b) Measure at least 80 square feet per client in multiple client bedrooms and at least 100 square feet in single client bedrooms;

(c) Be an outside room with direct access to a corridor or hallway and with a window space equal to at least one-eighth of the floor area; and

(d) Have a floor at or above grade level.

(7) Each client must be provided with a separate bed of proper size and height for the convenience of the client; a clean, comfortable mattress; clean linen and bedding appropriate to the weather and climate; functional furnishings appropriate to the client's needs; and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

(8) Each resident room must be equipped with or located near lavatory, toilet and bathing facilities. Such facilities used by clients in wheelchairs must be equipped for their use. A functional lavatory, toilet, and bath or shower shall be provided for every five residents or fraction thereof.

(9) A facility must provide a safe, functional, sanitary, and comfortable environment for clients and staff.

(a) Adequate outside ventilation by means of windows, or mechanical ventilation or a combination of the two shall be provided.

(b) An adequate pest control program so that the facility is free of pests and rodents shall be maintained.

(c) An adequate climate control system shall be maintained.

(10) Facilities that have motor vehicles for the transportation of clients shall ensure that vehicles are maintained in a safe condition with insurance coverage. Facility operators shall possess valid driver's licenses for the class of vehicles used for transportation. Safety restraining devices and equipment must be available in vehicles transporting clients with disabilities.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.12
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Physical Environment and Safety" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.13. Disaster Preparedness.

A facility shall have a written and regularly rehearsed disaster preparedness plan approved by the Department. Such plan shall be in accordance with Rules for Disaster Preparedness Plans, Chapter 111-8-16.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.13
Authority: O.C.G.A. § 31-7-3(c).
History. Original Rule entitled "Disaster Preparedness" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.14. Dining and Food Service.

(1) The facility must provide each client with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each client.

(2) At least three meals daily must be provided or made available to each client, at regular times comparable to normal mealtimes in the community. There must be no more than 14 hours between a substantial evening meal and breakfast the following day.

(3) The facility shall provide special eating equipment and utensils, and assistance for clients in need of such services.

(4) Food must be stored, prepared, distributed, and served under sanitary conditions.

(5) Sufficient space, equipment, and durable supplies and utensils for dining shall be maintained appropriate to the client's needs.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.14
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Dining and Food Service" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.15. Variances and Waivers.

The Department upon application or petition may grant variances and waivers to these rules and regulations when it is shown that the rule and regulation is not applicable or to allow experimentation or demonstration of new and innovative approaches to delivery of services.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.15
Authority: O.C.G.A. § 31-2-7.

History. Original Rule entitled "Variances and Waivers" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.16. Enforcement.

The department may refuse to grant a permit for the operation of any facility that does not fulfill the requirements of these rules and regulations and may revoke a permit which has been issued if a facility violates any such rules and regulations. The applicant or permit holder shall be afforded an opportunity for a hearing as provided in O.C.G.A. §§ 31-2-8 or 31-7-2.2 as applicable and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.16
Authority: O.C.G.A. § 31-2-8.
History. Original Rule entitled "Enforcement" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Rule 111-8-71-.17. Severability.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof and such remaining rules or portions thereof shall remain in full force and effect, as if such rule or portions thereof so determined, declared or adjudged invalid or unconstitutional were not originally a part thereof.

Cite as Ga. Comp. R. & Regs. R. 111-8-71-.17
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Severability" adopted. F. Sep. 9, 2013; eff. Sept. 29, 2013.

Subject 111-8-90. RULES AND REGULATIONS FOR X-RAY.

Rule 111-8-90-.01. General Provisions.

(1) Purpose and Scope.

(a) To set forth rules and regulations which implement the mandates of the Radiation Control Act, O.C.G.A. Chapter 31-13, as it relates to the registration and regulation of users of radiation machines.

(b) Except as otherwise specifically provided, these regulations apply to all uses of radiation machines in the healing arts, industry, educational and research institutions.

(2) Human Radiation Exposure. Radiation shall not be applied to individuals except as prescribed by persons licensed to practice in the healing arts or as otherwise provided in

these regulations. Only licensed practitioners and authorized operators shall apply radiation to a person.

(3) Prohibited Use. The operation of any radiation machine in this state is prohibited unless the user is registered with the Department.

(4) Definitions. Unless a different meaning is required by the context of a rule, the terms used in these regulations have the definitions set forth below.

(a) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(b) "Act" means the Radiation Control Act, Chapter 13 of Title 31 of the Official Code of Georgia Annotated.

(c) "Analytical x-ray machine" means any device, including but not limited to x-ray diffraction, x-ray diffractometry, and x-ray spectroscopy, which utilizes x-rays to examine the micro-structure of materials.

(d) "Aperture" means any opening in the external surface, other than a port, which remains open during the production of x-rays.

(e) "Applicant" means the responsible person in authority who applies for registration of the x-ray machine(s).

(f) "Barrier" means attenuating materials used to reduce radiation exposure:

1. "Primary-barrier" is one sufficient to attenuate the useful beam to the required degree as specified in section 111-8-90-.03 of this chapter.

2. "Secondary-barrier" is one sufficient to attenuate the sum of leakage and scattered radiation to the required degree as specified in section 111-8-90-.03 of this chapter.

(g) "Beam-limiting device" or "collimating device" means a device which provides a means to restrict the dimensions of the x-ray field.

(h) "Beam scattering filter" means a filter used in order to scatter a beam of electrons.

(i) "Cabinet x-ray machine" means an x-ray machine with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray machine is intended to:

1. contain at least that portion of a material being irradiated;

2. provide radiation attenuation; and

3. exclude personnel from its interior during generation of radiation.

Included are all x-ray machines designed primarily for the inspection of carryon baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray machine.

(j) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter.

(k) "Certified machine" means any x-ray machine which has one or more certified component(s) as specified in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, Part 1020.30.

(l) "Contact therapy machine" means an x-ray machine used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

(m) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

(n) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure.

(o) "Department" means the Department of Community Health.

(p) "Diagnostic type tube housing" means an x-ray tube housing so constructed that the leakage radiation at a distance of 1 meter from the target cannot exceed 100 mR in 1 hour when the tube is operated at any of its specified ratings.

(q) "Diagnostic x-ray machine" means an x-ray machine designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

(r) "Disposal" for the purpose of these regulations, means the sale, gift, transfer, destruction, disassembly or any disposition of a radiation machine or its parts.

(s) "Dose" as used in these regulations shall mean absorbed dose or dose equivalent as appropriate.

1. "Absorbed Dose" means energy absorbed per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the Rad (see "Rad") or Gray (see "Gray").

2. "Dose equivalent" is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose equivalent is the rem (see "Rem") or Sievert (see "Sievert").

(t) "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

(u) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.

(v) "Existing equipment" means therapy machines subject to these regulations which were manufactured on or before January 1, 1985.

(w) "Exposure" means a measure of the ionization produced in a given volume of air by X- or gamma radiation. The unit of exposure is the Roentgen or coulombs/kilogram.

(x) "Exposure rate" means the exposure per unit of time, i.e., as Roentgens per minute, or mR per hour as measured in air. (coulombs/kilogram/unit time).

(y) "External surface" means the outside surface of the cabinet x-ray machine including the plane across any aperture or port.

(z) "Facility" means the location at which one or more x-ray machines are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

(aa) "Failsafe" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

(bb) "Filtration" means material in the useful beam which preferentially absorbs selected radiations.

1. "Added filtration" means any filtration which is in addition to the inherent filtration.

2. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed tube assembly.

3. "Total Filtration" means the sum of the added filtration and inherent filtration in the useful beam.

(cc) "General purpose radiographic x-ray machine" means any radiographic x-ray machine which, by design, is not limited to radiographic examination of specific anatomical regions.

(dd) "Gray" (Gy) means unit of absorbed dose. One Gy equals 1 Joule of energy deposited in one kilogram of material. One gray equals one hundred rads.

(ee) "Half-value layer" means the thickness of specified material which attenuates the beam of radiation so that the exposure is reduced to one-half of its original value.

(ff) "Healing Arts" means the practice of medicine, chiropractic, dentistry, osteopathy, podiatry, and veterinary.

(gg) "High Radiation Area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirems.

(hh) "Human use" means the administration of radiation to an individual.

(ii) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.

(jj) "Inspection" means an official examination or observation to be performed by the Department including but not limited to, tests, surveys, evaluations and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Department.

(kk) "Irradiation" means the exposure of matter to ionizing radiation.

(ll) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(mm) "Leakage radiation" means radiation emanating through the diagnostic or therapeutic source assembly except for the useful beam.

(nn) "Leakage technique factors" means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:

1. For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of

charge per exposure being 10 millicoulombs, i.e., 10 millampere seconds, or the minimum obtainable from the unit, whichever is larger.

2. For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3. For all other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(oo) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor.

(pp) "New equipment" means x-ray machines subject to these regulations which were manufactured after January 1, 1985.

(qq) "Occupational dose" means exposure of an individual to radiation in the course of employment in which the individual's routine duties involve exposure to radiation.

(rr) "Open beam x-ray installation" means an installation in which the source and all objects exposed to the radiation source are within an area designated as a high radiation area.

(ss) "Operator" means that individual authorized by the registrant to operate the registrant's x-ray machine(s).

(tt) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

(uu) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing.

(vv) "Personnel monitoring equipment" means devices (i.e., film badges, pocket dosimeters, and thermo-luminescent dosimeters) designed to be worn or carried by an individual for the purpose of estimating the dose received.

(ww) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

(xx) "Port" means any opening in the external surface which is designed to remain open during the production of x-rays for the purpose of conveying material to be irradiated into or out of the machine or for partial insertion for irradiation of material whose dimensions do not permit the insertion of the entire object into the cabinet.

(yy) "Practitioner" means a physician licensed in Georgia under authority of Chapter 34 of Title 43 of the Official Code of Georgia Annotated; a chiropractor licensed in Georgia under authority of Chapter 9 of Title 43 of the Official Code of Georgia Annotated; a podiatrist licensed in Georgia under authority of Chapter 35 of Title 43 of the Official Code of Georgia Annotated; a dentist licensed in Georgia under authority of Chapter 11 of Title 43 of the Official Code of Georgia Annotated; or a veterinarian licensed in Georgia under authority of Chapter 50 of Title 43 of the Official Code of Georgia Annotated.

(zz) "Precertified x-ray systems" means a diagnostic x-ray machine produced prior to August 1, 1974 as specified in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, Part 1020.30.

(aaa) "Rad" (radiation absorbed dose) means the unit of absorbed dose. One rad = 100 ergs/gm or .01 Gy.

(bbb) "Radiation" means gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.

(ccc) "Radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirems, or in any 5 consecutive days a dose in excess of 100 millirems.

(ddd) "Radiation detector" means a device which, in the presence of radiation, provides by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(eee) "Radiation Machine" means any device that is designed for the controlled production of radiation or nuclear particles.

(fff) "Radiation Therapist" shall be defined as a physician who has met the requirements for certification by the American Board of Radiology in radiation therapy or by the American Board in general radiology provided that the physician has had two years or more of additional experience in radiation therapy.

(ggg) "Radiation therapy simulation machine" means a radiographic or fluoroscopic x-ray machine specifically designed for localizing the volume to be exposed

during radiation therapy and confirming the position and size of the therapeutic irradiation field.

(hhh) "Registrant" means any user registered with the Department in accordance with these regulations.

(iii) "Registration" means registration of the user(s) of x-ray machine(s) with the Department.

(jjj) "Regulations" means the Department of Health Rules and Regulations for X-Ray, Chapter 111-8-90.

(kkk) "Rem" means a measure of the dose equivalent of any radiation to body tissue in terms of its estimated biological effect relative to a dose received from an exposure to one roentgen (R) of x-rays. For the purpose of these regulations, any of the following is considered to be equivalent to a dose of one rem:

1. An exposure of 1 R of x-, or gamma radiation.

2. A dose of 1 rad (.01 Gy) due to x-, gamma, or beta radiation.

3. A dose of 0.05 rad (5 x 10-4 Gy) due to particles heavier than protons and with sufficient energy to reach the lens of the eye.

4. A dose of 0.1 rad (1 x 10-3 Gy) due to neutrons or high energy protons.

(lll) "Restricted area" (controlled area) means any area to which access is controlled by the registrant for purposes of protection of individuals from exposure to radiation. "Restricted area" shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

(mmm) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58 × 10-4 coulombs/kilogram of air.

(nnn) "Sale" for the purpose of these regulations, means any act where a radiation machine is transferred from one person to another for money or other valuable consideration.

(ooo) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.

(ppp) "Shielded-room radiography" means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in Section .03 of these regulations.

(qqq) "Sievert" (Sv) means a unit of dose equivalent. One sievert equals 100 rem.

(rrr) "Source" means the focal spot (target) of the x-ray tube.

(sss) "Source-image receptor distance" (SID) means the distance from the source to the center of the input surface of the image receptor.

(ttt) "Spot check" means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.

(uuu) "Target" means that part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

(vvv) "Test" means an examination through the use of instrumentation, visual inspection, interviews with individuals, and checks of various devices used in connection with radiation generating equipment to determine compliance with a regulatory requirement.

(www) "Therapy radiation" means the use of an ionizing radiation source for the purpose of treatment.

(xxx) "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

(yyy) "Transfer" for the purpose of these regulations, means the disposing of a radiation machine by any means including, but not limited to gift, sale, bailment, loan or lease.

(zzz) "Unrestricted area" (uncontrolled area) means any area to which access is not directly controlled by the registrant for purposes of protection of individuals from exposure to radiation.

(aaaa) "Unwanted by-product" means ionizing radiation generated by an apparatus whose primary function and design is not intended to produce ionizing radiation.

(bbbb) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(cccc) "User" means any person who possesses a radiation machine which is utilized for the administration of radiation.

(dddd) "Virtual source" means a point from which radiation appears to originate.

(eeee) "X-Ray machine" for the purposes of these regulations means a radiation machine designed for the controlled production of x-rays.

(5) Variances, Waivers, and Exemptions. The Department may, upon application, grant such variances, waivers, or exemptions from the requirements of these regulations as authorized by O.C.G.A. Section 31-2-4.

(6) Inspections.

(a) The Department is the authorized agency empowered to inspect and determine compliance with the Act and these regulations.

(b) Each registrant shall afford the Department at all reasonable times opportunity to inspect radiation machines and the premises and facilities wherein such radiation machines are used.

(c) Each registrant shall make available to the Department for inspection, upon reasonable notice, records maintained by the registrant pursuant to this Chapter.

(d) The Department shall conduct periodic inspections of registrants to determine compliance with the Act and this Chapter.

(e) The Department or its designated representative is authorized under the authority of O.C.G.A. Section 31-5-5(b) to classify as confidential and privileged documents, reports and other information and data obtained by them from persons, firms, corporations, municipalities, counties, and other public authorities and political sub-divisions where such matters relate to:

1. Trade secrets and commercial or financial information furnished to the Department on a privileged or confidential basis. Matters subject to this exemption are those which are customarily held in confidence by the originator. They include, but are not limited to:

(i) Information received in confidence, such as trade secrets, inventions, and proprietary data;

(ii) Technical reports and data, designs, drawings, specifications, formulas, or other types of proprietary information which are furnished to the Department or which are generated or developed by the Department or for the Department under contract.

2. Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Examples of files exempt from disclosure include, but are not limited to:

(i) Names or identifying information regarding individuals.

Discovery shall be subject to the statutory requirements found in O.C.G.A. Section 31-5-5.

(f) Whenever the Department finds that an emergency exists requiring immediate action to protect the public health and safety, the Department may, without notice or hearing, issue an order reciting the existence of such emergency and requiring that such action be taken as is necessary to meet the emergency. Notwithstanding any provision of Chapter 13 of Title 31 of the Official Code of Georgia Annotated, such order shall be effective immediately. Any person to whom such order is directed shall comply therewith immediately but on application to the department shall be afforded a hearing within ten days. On the basis of such hearing the emergency order shall be continued, modified or revoked within 30 days after such hearing, as the Department may deem appropriate under the evidence.

(7) Tests.

(a) The Department has the authority to conduct such reasonable tests as it deems appropriate or necessary in the administration of this Chapter, including, but not limited to, tests of:

1. sources of radiation;

2. facilities wherein sources of radiation are used or stored;

3. radiation detection and monitoring instruments; and

4. other equipment and devices used in connection with utilization or storage of registered sources of radiation.

(8) Requirements for Radiation Protective Shielding.

(a) Each facility shall be provided with such primary barriers and/or secondary barriers as necessary to assure compliance with Section .03(2)(a) and (b) of these Regulations titled "Standards for Protection Against Radiation".

(b) In computing shielding requirements, only identified permanently installed construction materials or permanently installed lead shielding materials shall be considered. Cassettes, cassette holders, (except as specifically permitted elsewhere in this Chapter), patients, or non-permanent materials shall not be used as part of the radiation shielding.

1. For energies up to 1 MeV:

(i) This requirement shall be deemed to be met if the thickness of the barrier(s) is equivalent to that computed in accordance with National Council on Radiation Protection and Measurements (NCRP) Report No.49 "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" or its current revision or replacement.

(ii) A primary barrier in walls shall extend from the floor to a minimum height of 84 inches and shall have a width broad enough to intercept the entire cross section of the useful beam plus an extension of at least one foot (30 cm) on each side of the barrier at the maximum SID used with the maximum beam dimensions permitted by the beam limiting device. All sections of the wall or adjacent areas including the floor that may be struck by the useful beam shall be considered primary barriers.

(iii) In calculating radiation shielding requirements workloads shall be realistic, but in no case, except for intra-oral dental x-ray facilities, less than 15 milliampere minutes (mAm) per week at 100 kVp, or at the maximum stated energy of the x-ray machine if it is less than 100 kVp.

2. For energies of 1 MeV or greater: This requirement shall be deemed to be met if the thickness of barrier(s) is equivalent to that computed in accordance with the National Council on Radiation Protection and Measurements (NCRP) Report No.51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities," or its current revision or replacement.

(c) Non-healing arts facilities shall meet the shielding design criteria described in .01(8)(a) and (b).

(d) During the construction phase, the installation of shielding shall be evaluated pursuant to procedures outlined in NCRP Handbook 49 or NCRP Handbook 51 or its current revision or replacement. The registrant is responsible for ensuring that such evaluation is performed by an individual competent to perform such evaluation.

(e) Facilities may be required to have a radiation integrity survey of the completed installation to assure that:

1. materials used for shielding are not impaired by joints, openings for duct pipes, conduits, etc., passing through or embedded in the wall; and

2. such materials meet the minimum lead equivalency as stated in submitted design.

The registrant is responsible for ensuring that such survey is performed by an individual competent to perform such survey.

(f) The final assessment of the adequacy of the design and construction of structural shielding shall be based on a radiation survey of the completed installation. If the radiation survey shows deficiencies, additional shielding and/or modifications shall be provided to the satisfaction of the Department.

(9) Shielding Design Plan Review.

(a) Shielding designs, to include facility layout and machine orientation, shall be submitted to the Department for approval prior to the construction of a new facility or the modification (i.e., reorientation of equipment, increased workload, exchange of radiation machine, etc.) of an existing facility using radiation machines for:

1. Diagnostic or therapeutic purposes in the healing arts.

2. Non-healing arts applications which includes, but is not limited to, industrial applications.

(b) Radiation shielding designs submitted for review shall contain at least the following information.

1. The location of the radiation machine; Name, Address, Room number; and

2. Travel and traverse limits permitted by the manufacturer; direction(s) of the useful beam; locations of windows and doors; the location of the operator's booth; and the location and dimensions of the x-ray control panel; and

3. The structural composition and thickness or lead equivalency of all walls, doors, partitions, floors, and ceiling of the room(s) when considered as part of the shielding requirements; and

4. The dimensions of the x-ray room(s); and

5. The occupancy of all adjacent areas inclusive of space above and below the x-ray room(s); and

6. The maximum technique factors which are anticipated; and

7. The type and number of examination(s) or treatment(s) which will be performed with the equipment, or

8. The anticipated workload of the radiation machine(s) in milliamp minutes per week (or rads/week at 1 meter for therapy machines only) at the maximum anticipated operating energy.

(c) X-Ray Room Design Requirements:

1. Healing Arts:

   (i) Except for dental, dedicated podiatric and veterinary x-ray facilities, in all x-ray facilities built or modified after the effective date of these regulations, the x-ray room shall have minimum dimensions of 8 feet (2.4 m) by 10 feet (3.0 m) sufficient to assure source- to-image distances equal to those currently accepted in the healing arts to make standard radiographs of anatomical regions.

   (ii) There shall be sufficient work space allotted to the x-ray assistants to set up procedures.

2. Other than healing arts. Sufficient space shall be allotted to adequately perform duties and assure radiation safety.

(d) Radiation Machine Operator's Protective Barrier.

1. Diagnostic x-ray facilities other than dental intraoral, dental panoramic, and veterinary, built or modified after the effective date of these regulations shall have a fixed operator's barrier.

   (i) Design Requirements for fixed operator's barrier.

      (I) The operator shall be allotted not less than 7.5 square feet (.697 sq.m.) of unobstructed floor space in the booth.

      (II) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

      (III) Structural Requirements:

         I. The barrier walls shall be permanently fixed and have a height of at least 7 feet (2.13 m) from the floor.

         II. When a door or movable panel is used as an integral part of the structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

         III. The barrier shall intercept any radiation that has been scattered only once and will ensure that the limit of 100 mrem/wk (1 mSv/week) permitted for personnel exposure shall not be exceeded. Design guidelines should consider 10 mrem/week (.1 mSv/week).

   (ii) Radiation Machine Control Placement:

(I) The x-ray control for the machine shall be fixed within the booth and:

(II) placed so that the operator cannot conveniently leave the protection of the barrier during an exposure, and

(III) will permit the operator to conveniently use available viewing devices.

(iii) Viewing Device Requirements for Medical Facilities:

(I) Each booth or barrier shall be equipped with at least one viewing device which will be so placed that the operator can easily view the patient during any exposure.

(II) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements.

(III) When the viewing system is by electronic means:

I. the camera shall be so located as to accomplish the general requirements, and

II. there shall be an equivalent viewing system as a backup for the primary system.

2. Portable barriers may be substituted for .01(9)(d)1. where fixed barriers are inappropriate for the x-ray procedures but only upon written application to the Department stating the reasons a portable operator's barrier is necessary.

3. Design Requirements for Portable barriers.

(i) The barrier shall meet shielding and viewing requirements of .01(9)(d)1. (i) and (iii).

(ii) Clear instructions on the placement and use of the barrier shall be posted on the operator's side of the barrier.

4. Lead aprons shall be used by persons who assist in procedures where holding or close contact with a patient undergoing an x-ray procedure is required.

(10) Copy of Design Maintained. A copy of the shielding design as submitted to and approved by the Department shall be kept on file at the facility.

(11) Compliance. After receiving written notice that specific areas of non-compliance with these rules and regulations exist in a registered x-ray facility, the registrant shall make required corrections and notify the Department of the action(s) taken within the time authorized by the Department which shall not exceed 60 days.

(12) Impounding.

(a) In the event of an emergency, the department shall have the authority to impound or order the impounding of sources of radiation in the possession of any person who is not equipped to observe or fails to observe the provisions of the Act or these regulations.

(b) The department may release such sources of radiation to the owner thereof upon terms and conditions in accordance with the Act and these regulations or may bring an action in the appropriate superior court for an order condemning such sources of radiation and providing for their destruction or other disposition so as to protect the public health and safety.

(13) Rules and Regulations. Each registrant shall possess a current copy of the Rules and Regulations for X-Ray, Chapter 111-8-90, which shall be maintained in the registered facility.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.01
Authority: Ga. L. 1964, pp. 507, 569, 570; O.C.G.A. §§ 31-13-3, 31-13-5, 31-13-8.
History. Original Rule entitled "General Provisions" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-90-.02. Registration.

(1) Registration.

(a) All users of radiation machines in Georgia are required to register with the Department.

(b) Application for registration shall be on forms provided by the Department.

(c) The user shall complete a separate application for registration for each facility at which he possesses a radiation machine.

(d) The user applying for initial registration shall certify to the Department in his registration application that he has determined through inspection that he is in compliance with these regulations. The user shall also certify that, when registered, he will use his machines in compliance with all standards set by the Department. For purposes of registration, inspections may be performed by employees of the Department. Should the user elect to obtain the services of persons other than employees of the Department, for the purpose of performing an

inspection for certifying to the Department that his facility and machines are in compliance with these regulations prior to initial registration, the user shall insure that the individual possesses one set of the qualifications listed in .02(4):

(e) Additional requirements for initial registration.

1. The user shall submit shielding specifications for each facility for which he is registering.

2. The user is responsible to document that the required shielding was installed in accordance with design specifications. A report certifying test results shall be sent to the Department and a copy maintained at the facility.

   (i) Tests shall be made pursuant to the procedures outlined in the National Council on Radiation Protection: Report 35 Dental X-Ray Protection; Report 49 Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 Mev; Report 51 Radiation Protection Guidelines for 0.1-100 Mev Particle Accelerator Facilities; or, the published guidelines of other recognized authorities in the field of radiation protection.

3. Cabinet x-ray systems in addition to .02(1) of this rule, persons applying for registration shall provide written verification to the Department that the cabinet x-ray system is installed and operating in accordance with the manufacturer's design specifications.

(f) The user of any radiation machine shall not initially place such machine in operation prior to registration with the Department.

(g) Registration of Out of State Machines.

1. When any radiation machine is to be brought into the state of Georgia and operated, the person proposing to bring such machine into the state of Georgia shall give written notice to the Department at least five (5) working days before such machine enters the state. The notice shall include the type of radiation machine the nature, duration, and scope of use; and the exact location(s) of use. Telephone notification may be used in cases where the five day notice would pose an undue hardship, but such notification shall be confirmed in writing as soon as possible thereafter.

2. In addition, the out-of-state person shall comply with all applicable requirements of these regulations and supply the Department with such other information as the Department may reasonably request.

(2) Registration of Particle Accelerators. In addition to (1) of this rule persons applying for registration of particle accelerators shall submit the supplemental information required in

Rule 111-8-90-.05(3) and if the particle accelerator is for human use the information required in Rule 111-8-90-.05(4).

(3) Failure to register as provided in .02(1) shall subject the offending person to a civil penalty not to exceed $1000.00, and any other legal remedies available as required in O.C.G.A. 31-13-15.

(4) Formal Education or Certification plus Experience.

(a) Bachelor's degree in a physical science or mathematics.

Four years of applied health physics experience in a pro-gram with radiation safety problems similar to those in the program to be surveyed.

(b) Bachelor's degree in a physical science or a biological science with a physical science minor, and one year of graduate work in health physics.

Three years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed.

(c) Master's degree in health physics or radiological health.

Two years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed.

(d) Doctor's degree in health physics or radiological health.

One year of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed.

(e) Certification by the American Board of Health physics or by the American Board of Radiology, or be a Fellow, Canadian College of Physicists in Medicine.

One year of applied health physics experience in a program with radiation safety problems similar to those in a program to be surveyed.

(5) The user shall maintain on file the qualifications of the non-Departmental individuals performing the inspection for purposes of initial registration.

(6) Renewal of Registration. Every registrant possessing a radiation machine shall renew registration at intervals as required by the Department.

(7) Report of Changes. The registrant shall notify the Department writing of any changes which would render the information contained in the current registration inaccurate. Notification of any changes in the radiation machine's location, shielding, operation, safety features, or occupancy of adjacent areas must also be made to the Department, and

may require a radiation safety survey and re-registration prior to continued operation of the machine.

(8) Report of Sale, Lease, Transfer, or Disposal. Any person who sells, leases, transfers, or otherwise disposes of a radiation machine shall notify the Department in writing. Written notification shall include, when applicable, the name and address of the new owner or lessee, and/or facility, the date of the transaction, and the model and serial number of the machine or machines.

(9) Exemptions:

(a) Electronic equipment that produces radiation incidental to its operation for other purposes (i.e. television receivers) is exempt from the registration and notification requirements of this part, provided the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mRem per hour at 5 cm. from any accessible surface of such equipment. Production, testing, or factory service of such equipment shall not be exempt.

(b) Radiation machines while inoperable or in transit or storage are exempt from the requirements of these regulations.

(10) Revocation. Registration may be revoked by the Department for failure to comply with or maintain compliance with Chapter 13 of Title 31 of the Official Code of Georgia Annotated or the provisions of this Chapter. Prior to revocation of any registration, the registrant shall be given notice of the grounds for revocation and shall have an opportunity to show cause why the revocation action should not proceed as provided in Article 1 of Chapter 5 of Title 31 of the Official Code of Georgia Annotated.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.02
Authority: Ga. L. 1964, pp. 507, 569, 570; O.C.G.A. §§ 31-13-5, 31-13-8, 31-13-10.
History. Original Rule entitled "Registration" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-90-.03. Standards for Protection against Radiation.

(1) General Provisions.

(a) If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron absorbed dose in rads (grays), one rem (.01 Sv) of neutron radiation may, for purposes of these regulations, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

Neutron energy (MeV)	Number of neutrons per square centimeter for a dose equivalent of 1rem(neutrons/c m2)	Average flux density to deliver 100 millirems (1 millisievert) in 40 hours (neutrons/cm2 per second)
Thermal	$9.7x10^6$	670
0.00001	$7.2x10^6$	500
0.005	$8.2x10^6$	570
0.02	$4.0x10^6$	280
0.1	$1.2x10^6$	80
0.5	$4.3x10^5$	30
1.0	$2.6x10^5$	18
2.5	$2.9x10^5$	20
5.0	$2.6x10^5$	18
7.5	$2.4x10^5$	17
10.0	$2.4x10^5$	17
10 to 30	$1.4x10^5$	10

(b) For determining the doses specified in this section, a dose from x or gamma radiation up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air, at or near the body surface in the region of highest exposure rate.

(c) Dose to the whole body shall include any dose to the entire body or any major portion thereof, gonads, active blood-forming organs, head and trunk, or lens of the eye.

(2) Permissible Doses.

(a) Occupational Exposure

1. Except as provided in .03(2)(a)2., no registrant shall possess, own, use, or receive, sources of radiation in such a manner as to cause an occupationally exposed individual to receive, from all sources of radiation in the possession of the registrant, a dose in excess of the limits in the following table:

	Rems (Sv) Per Calendar Quarter
Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads..	1 ¼ rem (12.5 mSv)
Hands and forearms; feet and ankles..	18-3/4 rem (187.5 mSv)
Skin of whole body..	7 ½ rem (75 mSv)

2. A registrant may permit an occupationally exposed individual to receive a dose to the whole body greater than that permitted under .03(2) (a) 1. provided:

   (i) during any calendar quarter the dose to the whole body from sources of radiation in the possession of the registrant shall not exceed 3 rems (30 mSv);

   (ii) the dose to the whole body when added to the accumulated occupational dose to the whole body shall not exceed 5 (N-18) rems [50(N-18)mSv], where "N" equals the individual's age in years at his last birthday; and

   (iii) the registrant has determined the individual's accumulated occupational dose to the whole body on a Department form, or on a clear and legible record containing all the information required on that form.

3. Individuals under 18 years of age in x-ray training schools or employed in occupations which involve exposure to ionizing radiation shall have a personnel radiation monitoring device and shall not be permitted to receive a dose to the whole body in excess of 10% of the dose permitted in .03(2)(a)1.

(b) Non-Occupational Exposure.

1. The dose limits for individuals employed in occupations which do not normally involve exposure to ionizing radiation shall be one-tenth of the occupational limits under .03(2)(a)1., excluding medical radiation for the purpose of diagnosis or therapy.

2. For the purposes of these regulations the embryo/fetus shall be considered to be a separate entity distinct from the occupationally exposed woman carrying it, and shall not be subject to occupational limits.

3. The embryo/fetus shall not be exposed to doses in excess of 50 mrem in any one month after the pregnancy is known. The total dose equivalent limit to the embryo/fetus shall not exceed 500 mrem over the period of gestation.

(c) Radiation Levels in Unrestricted (Uncontrolled) Areas.

1. Except as authorized by the Department pursuant to .03(2)(c)2., no registrant shall possess, own, or use sources of radiation in such a manner as to create in any uncontrolled area from such sources of radiation in his

possession radiation levels which, if an individual were continuously present in the area, could result in an individual receiving:

(i) a dose in excess of two millirems in any one hour; or

(ii) a dose in excess of 100 millirems in any seven consecutive days.

2. Any registrant or prospective registrant may apply to the Department for proposed limits upon levels of radiation in uncontrolled areas in excess of those specified in .03(2)(c)1., resulting from the applicant's possession or use of sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each uncontrolled area involved. The Department may approve the proposed limits if the applicant demonstrates to the satisfaction of the Department that the proposed limits would not cause an individual to receive doses to the whole body in any period of one calendar year in excess of 0.5 rem (5.0 mSv).

(3) Personnel Monitoring.

(a) Except as provided in .03(3)(c), each registrant shall supply appropriate personnel radiation monitoring devices and shall require the use of such equipment by:

1. Each individual who enters a controlled area under such circumstances that the individual receives, or is likely to receive, a radiation dose in any calendar quarter in excess of 25 percent of the applicable values specified in .03(2)(a)1. for occupational exposure;

2. Each individual under 18 years of age who enters a controlled area under such circumstances that the individual may receive a radiation dose in excess of 10 percent of the applicable value specified in .03(2)(a)1.

3. Each individual who enters a high radiation area.

(b) All individuals required to use personnel monitoring equipment shall be instructed in its proper use and purpose.

(c) Personnel monitoring will not be required for individuals undergoing diagnostic or therapeutic procedures.

(d) When using protective aprons, personnel monitoring shall be worn outside the apron at collar level.

(4) Caution Signs, Labels, and Signals.

(a) Radiation Symbol

1. Except as otherwise authorized by the Department, the symbol prescribed by this section is the conventional three-bladed warning sign commonly used in the radiological professions and shall use the conventional radiation caution colors (magenta or purple on yellow background).

2. In addition to the contents of signs and labels prescribed in these regulations, a registrant may provide any additional information on or near such signs and labels to indicate the nature of the radiation source, type of radiation, limits of occupancy, and similar precautionary information which may be appropriate in aiding individuals to minimize exposure to radiation.

(b) Radiation Areas. Each radiation area, except areas where diagnostic and therapeutic radiation machines are used solely in the healing arts, shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words: CAUTION - RADIATION AREA.

(c) High Radiation Areas. Each high radiation area, except areas where diagnostic and therapeutic radiation machines are used solely in the healing arts, shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words: CAUTION - HIGH RADIATION AREA.

(d) Radiation Generator Warning Signals. Each radiation generator, except radiographic and fluoroscopic radiation machines used solely in the healing arts, which is capable of producing, in any area accessible to individuals, a dose rate in excess of 100 millirems per hour, shall be provided with a warning signal or light at the generator. Such a signal or light shall be so connected as to be activated automatically when the exposure switch is "on" in order to provide adequate warning against entering the area.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.03
Authority: Ga. L. 1964, pp. 507, 569, 570; O.C.G.A. § 31-13-5.
History. Original Rule entitled "Standards for Protection against Radiation" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-90-.04. X-Rays in the Healing Arts.

(1) Scope. This part establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized in accordance with State statutes to engage in the healing arts. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

(2) General Requirements.

(a) Training of Operators who Administer X-ray in the Healing Arts.

1. The registrant shall assure the Department that all radiation machines and associated equipment under his control are operated only by individuals instructed in safe operating procedures.

2. The registrant shall require persons operating his radiation machine and associated equipment to receive, at a minimum, six hours of instruction. The following subject categories shall be covered:

   (i) Protection Against Radiation

      (I) Protective Clothing

      (II) Patient Holding

      (III) Time, Distance, Shielding

      (IV) Radiation Protection Standards

   (ii) Dark Room Techniques

      (I) Developing Chemicals

      (II) Film Protection

      (III) Cassettes

      (IV) Screens

   (iii) Patient Protection

      (I) Beam Limitation

      (II) Setting Up Techniques

      (III) Biological Effects of Radiation

   (iv) Machine Safety

      (I) Machine Functions

      (II) Safety Procedures

      (III) Recognizing Problems

3. Instruction required by .04(2)(a)2. shall begin within 30 days after employment and shall be completed no later than 90 days after date of employment. The registrant shall maintain a record of all training for each operator. Such record shall be made available for Departmental inspection. This rule shall take effect 180 days after the effective date of these regulations.

4. Persons who show written proof that they have received the required instruction are considered to meet the requirements of .04(2)(a)2.

(b) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by at least 0.5 millimeter meter lead equivalent material; and

2. Staff and ancillary personnel who must remain in areas because of their required presence during an x-ray procedure, shall be protected from direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent; and

3. Patients, other than the one being radiographed, who cannot be removed from the x-ray room shall be protected by a barrier of at least .25 mm Pb equivalent or be at least 2 meters from the tube head and the image receptor.

(c) Except for dental intraoral radiography, veterinary, or portable x-ray use, the operator's position at the controls shall be in a protected area that will meet the radiation protection requirements of rule .03(2)(a)1. of these regulations.

(d) Except for therapy exposures, gonad shielding of not less than 0.25 millimeter lead equivalent shall be available and shall be used when the gonads are in the useful beam except when its use will interfere with the diagnostic information on the image receptor.

(e) Individuals shall only be exposed to the useful beam for healing arts purposes except as required by law enforcement officials or their designated representatives in the interest of public safety. This provision specifically prohibits deliberate exposure of persons for non-productive x-ray procedures such as for training, demonstration, or for other non-healing arts purposes.

(f) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. Holding shall be used only when other means of support cannot be utilized.

2. No individual shall be used routinely to hold film or patients.

3. When holding is required, the person holding shall be provided with protective clothing and shall be positioned so that no part of the body is struck by the useful beam.

(g) Portable equipment shall be used only for examinations where it impractical, for medical purposes, to transfer the patient to the x-ray suite.

(3) Information and Maintenance Records and Associated Information.

(a) The registrant shall maintain the following information for each radiation machine for inspection by the Department:

1. Model and serial numbers of x-ray tube housing and generator; and

2. Records of surveys, calibrations, maintenance, and modifications performed on the radiation machine(s) with the names of persons who performed such services.

(b) The vendor shall supply the registrant with a record of all maintenance performed, or parts replaced or installed, written in a clear and legible manner.

(4) Light Fields. When used for aligning or centering an x-ray field, a light field shall have a clearly defined perimeter and have illumination intensity equal to the needs for collimation or alignment. For collimators equipped with beam defining lights, this requirement will be deemed to be met if the illumination at the receptor is visible to the x-ray operator under normal room illumination in all quadrants of the light field.

(5) Darkroom and Film Processors.

(a) Darkrooms used for film processing and/or developing shall be light tight.

(b) Each darkroom shall be equipped with a safelight which will meet or exceed the requirements of the radiographic film. This will be deemed to have been met if the film manufacturer's recommendations are followed.

(c) Except for automatic developing systems, each darkroom shall have and use a solution thermometer and timing device. Sight development shall be prohibited.

(d) The chemical solution used for manual film development shall not be used for periods in excess of two (2) months. Records of solution changes shall be maintained.

(e) When automatic film processing is used it shall be maintained in accordance with the manufacturer's recommendations and a record of cleaning and developer change shall be maintained.

(f) Unexposed film shall not be subject to radiation levels in excess of 0.2 mR during the period of storage.

(g) Unexposed film which is outdated shall not be used for human radiographic procedures.

(6) General Requirements for all Diagnostic Radiation Machines. In addition to other requirements of this part, all diagnostic radiation machines shall meet the following requirements:

(a) Warning Label. The control panel containing the main power switch shall bear the following warning statement, in a manner legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed"

(b) Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(c) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly, measured at a distance of 1 meter in any direction from the source, shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors.

(d) Beam Quality.

1. Half-value layer.

(i) The half-value layer of the useful beam for a given x-ray tube potential shall be no less than the values shown in Table I. If it is necessary to determine the half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (Kilovolts Peak)	Measured Potential (Kilovolts Peak)	Half- value layer (Millimeters of Aluminum)
Below 50	30	0.3

	40	0.4
	49	0.5
50-70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(ii) The requirements of .04(6)(d)1. (i) will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 to 70	1.5 millimeters
Above 70	2.5 millimeters

(iii) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(iv) For capacitor energy storage equipment, compliance with the requirements of .04(6)(d)1. (i) shall be determined with the maximum quantity of charge per exposure.

(v) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

2. Filtration Controls. For radiation machines which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by .04(6)(d)1. (i) or (ii) is in the useful beam for the given kVp which has been selected.

(7) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

(8) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the radiation machine.

(9) Technique Indicators. The technique factors to be used during an exam shall be indicated prior to any exposure. This requirement may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(10) Exposure Timing.

(a) Except in fluoroscopy a device shall be used to terminate and accurately reproduce the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(b) Except for fluoroscopy, dental intraoral and panographic, veterinary, and procedures requiring the use of portable barriers, the exposure switch shall be so located that it cannot be conveniently operated outside of a shielded area.

(c) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second.

(d) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(e) Automatic exposure controls.

1. When an automatic exposure control is provided, indication shall be made on the control panel when this mode of operation is selected.

2. When an automatic exposure control is provided, a backup timer shall be required. The backup timer shall be capable of terminating the exposure at a preset time should the automatic exposure control fail. The preset time shall be consistent with the technique used.

(f) The x-ray production shall be controlled by a deadman switch.

(g) It shall not be possible to make an exposure when the time is set to a zero or off position if either position is provided.

(h) Termination of an exposure shall cause automatic resetting of the timing device to its initial setting or to zero.

(11) Hand-held fluoroscopic screens are prohibited except for law enforcement or forensic requirements, and then only upon approval by the Department.

(12) Fluoroscopic Radiation Machines. All fluoroscopic radiation machines shall meet the following requirements:

(a) Limitation of Useful Beam.

1. Primary Barrier.

(i) Image intensification shall be used with all fluoroscopic machines. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

(ii) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier and image intensifier are in position to intercept the entire useful beam.

2. X-Ray Field.

(i) For image-intensified fluoroscopic equipment, neither the length nor the width of the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID.

The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(b) Spot film devices which are certified components shall meet the following additional requirements:

1. Means shall be provided between the source and the patient for adjustment of the x-ray field size, in the plane of the film, to the size of that portion of the film which has been selected on the spot film selector; and

2. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film; and

3. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

(c) Pre-certified fluoroscopic machines are exempt from the requirements of .04(12)(a) and .04(12)(b) provided that:

1. The machine was in service prior to the date of adoption of these regulations and meets all other applicable requirements for fluoroscopic machines. However, these machines shall be brought up to standards referenced in .04(12)(a) and (b) within three years from the date of adoption of these regulations or be taken out of service and electronically disabled.

2. The shutter mechanism is adjusted so that the x-ray field diameter is limited to the dimensions of the film cassette used during spot filming at a 35 centimeters (14 inches) table-to-image-receptor distance.

3. When spot films are either unnecessary or not required during a portion of the exam, the leading edge of the shutters shall be restricted to the edge of the image intensifier.

(d) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a dead man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(e) Exposure Rate Limits.

1. Entrance Exposure Rate Allowable Limits.

(i) When the automatic brightness control is used, the exposure measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens per minute, except during recording of fluoroscopic images.

(ii) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.

(I) Special means of activation of high level controls shall be required. The high level control shall only be operable when a continuous secondary level of pressure is provided by the operator.

(II) When the high level control is activated the entrance exposure rate shall not exceed 10 R/min. except in the recording of fluoroscopic images.

(III) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(iii) In addition to the other requirements of .04(12)(e)1. (i) and (ii), certified equipment which does not incorporate an automatic exposure control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of beam enters the patient, except during recording of fluoroscopic images or when provided with an optional high level control.

(iv) Non-certified equipment shall not operate at any combination of tube potential and current which will result in an exposure in excess of 10 R/min.

2. Compliance with the requirements .04(12)(e)1. shall be determined as follows:

(i) Movable grids and compression devices shall be removed from the useful beam during the measurement;

(ii) With the source below the table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle;

(iii) With the source above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(iv) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(f) Periodic measurement of Entrance Exposure Rate. The registrant shall cause periodic measurement of entrance exposure rate, including the exposure rate at staff positions around the table and panel, to be made for each fluoroscope by an individual competent to make such measurements. Results of these measurements shall be posted where any fluoroscopist may have ready access to them. An adequate period for such measurements shall be annually or after any maintenance of the unit if such maintenance might affect the exposure rate. Results of the measurements shall include the maximum possible R/minute of the fluoroscope at the maximum kVp and mA used. The posted data shall indicate the technique factors used to determine the data along with the name of the person and/or company performing the measurements and the date the measurements were performed.

1. Fluoroscopes that incorporate automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray machine; and

2. Fluoroscopes that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the radiation machine.

(g) Barrier Transmitted Radiation Rate Limits. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(h) Indication of Potential and Current. During fluoroscopy and cine-fluorography, the kV and the mA shall be continuously indicated.

(i) Source-Skin Distance. The source to skin distance shall not be less than:

1. 38 centimeters (15 inches) on stationary fluoroscopes;

2. 30 centimeters (12 inches) on all mobile fluoroscopes;

3. 20 centimeters (8 inches) for image intensified fluoroscopes, used for specific surgical application;

4. 30 centimeters (12 inches) on stationary precertified fluoroscopes.

(j) Fluoroscopic Timer. Means shall be provided to preset the cumulative "on" time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. Termination of the exposure or a signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on time. Such signal shall continue to sound while x-rays are produced or until the timing device is reset. Audible signals are recommended.

(k) Radiation Therapy Simulation Machines. Radiation therapy simulation shall be exempt from all the requirements of .04(12)(a), .04(12)(e), .04(12)(f) and of .04(12)(j) provided that:

1. Such machines are designed and used so that no individual other than the patient is in the x-ray room during radiography procedures; and

2. Such machines which do not meet the requirements of .04(12)(j) are provided with a means of indicating the cumulative exposure time for each individual patient. Procedures shall require in each case that the timer be reset between examinations.

(13) Radiographic Machines Other Than Fluoroscopic, Dental Intraoral, and Veterinary.

(a) Beam Limitation. The useful beam shall be limited to the area of clinical interest, and shall not be greater than the dimensions of the image receptor.

(b) General Purpose Stationary and Mobile Radiation Machines.

1. Means for stepless independent adjustment in both the longitudinal and transverse direction of the x-ray field and a light for visually defining the perimeter of the x-ray field shall be provided.

2. Means shall be provided to permit adequate light intensity at the film plane when the light field intersects with the image receptor at a 100 cm SID. This will be deemed to be met if a visual outline of the light field is visible at the receptor.

3. Congruence of the x-ray and light fields shall not have a misalignment in excess of 2% of the SID in any one direction and not more than 3% of the SID when measured as the sum of the absolute misalignment in the longitudinal and transverse direction.

(c) Additional Requirements for Stationary General Purpose Radiation Machines. In addition to the requirements of .04(13)(b), all stationary radiation machines shall meet the following requirements:

1. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the film plane with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent; and

2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.

(d) Machines Designed for or Provided With Special Attachments for Mammography.

1. Radiographic machines designed only for mammography and general purpose radiographic machines, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID, except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.

2. This requirement can be met with a machine which performs as prescribed in .04(13)(e).

3. Each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(e) Special Purpose Radiation Machines. Radiation machines which are limited by design to radiographic examinations of a specific anatomical region shall meet the following requirements:

1. The x-ray field in the plane of the image receptor shall be limited such that the field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

2. The center of the x-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor;

3. Section .04(13)(e)2. may be met with a machine that meets the requirements for a general purpose radiation machine as specified in .04(13)(b) or, when alignment means are also provided;

4. For special purpose cephalometric use, an assortment of removable, fixed-aperture, beam-limiting devices sufficient to limit the beam to areas of clinical interest may be used. Each such device shall have clear and permanent markings to indicate the image receptor size and the SID for which it is designed;

5. Special purpose radiographic units will be exempt from the primary barrier requirements of .01(8)(b)1. provided that the tube housing assembly is electronically interlocked to a primary protective barrier, or the tube housing assembly is mechanically fixed such that the entire cross section of the useful beam is always intercepted by a primary barrier sufficient to attenuate the useful beam to the limits specified in .03(2). Secondary barriers shall meet the shielding requirements of .01(8)(b)1.

(f) Radiation Exposure Control Device.

1. Each x-ray control shall meet the following requirements:

   (i) stationary radiation machines shall have the exposure switch permanently mounted in such a way as to prevent the operator from leaving the protected area of the operator's barrier during the exposure;

   (ii) except for unique situations such as those found in intensive care units or operating room suites, mobile and portable radiation machines which are used for greater than 1 week in 1 location, (i.e., 1 room or suite) shall meet the requirements of .04(13)(f)1. (i).

   (iii) The x-ray control device shall provide audible or visual indication observable at or from the operator's protected position whenever x-rays are produced. For certified radiation machines, a signal audible to the operator shall indicate that the exposure has terminated.

2. Portable Equipment.

   (i) Provisions of .04(13)(f) apply except for exposure switch location.

   (ii) The exposure switch shall be so arranged that the operator can stand at least 1.8 meters (six feet) from the patient, the x-ray tube, and the

useful beam unless there is shielding sufficient to assure compliance with .03(2)(a).

(iii) The source-to-skin distance shall be limited to not less than 30 centimeters (12 inches).

(iv) Protective aprons of at least 0.25 mm lead equivalent shall be available and their use shall be required of the operator.

(v) Personnel monitoring is required of all operators.

(vi) Mobile or portable Radiation machines which are used for greater than one week in one location, i.e., (one room or suite of rooms) shall meet the requirements of .01(8).

(g) Structural Shielding.

1. In addition to the requirements in .01(8), diagnostic radiation machines routinely used in one location shall meet the following requirements for structural shielding:

   (i) All areas of the walls, floors, and ceiling exposed to the primary beam shall have primary barriers; and

   (ii) Secondary protective barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers or where primary barrier requirements are less than secondary barrier requirements.

2. For stationary radiation machines and mobile or portable equipment routinely used in one location:

   (i) Except for those unique situations found in such uses as the intensive care unit, operating suite, etc., the operator's station at the controls shall be behind a protective barrier which will intercept any radiation that has been scattered only once.

   (ii) The operator's protective barrier shall be equipped with a glass window of lead equivalency equal to that required of the adjacent barrier, or a mirror system so placed that the entire patient can be seen by the operator while the exposure is made.

   (iii) Facilities constructed or modified after the effective date of these regulations shall have built-in operator's protective barriers which will ensure that the limits specified in .03(2)(a) are not exceeded.

(h) Source-to-Skin Distance.

1. All radiographic machines, except as provided for in .04(13) (h)2., shall be provided with means to limit the source-to-skin distance to not less than 30 centimeters (12 inches).

2. A radiographic machine intended for specific surgical and dental application may be used with an SSD less than 30 centimeters, (12 inches), but in no case less than 20 centimeters (8 inches).

(i) Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(14) Intraoral Dental Radiographic Machines.

(a) Source-to-Skin Distance. Radiation machines designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, i.e., SSD, to not less than 18 centimeters (7 inches), if operable above 50 kVp, or 10 centimeters (4 inches), if not operable above 50 kVp.

(b) Field Limitation.

1. Radiographic machines designed for use with an intra-oral image receptor shall be provided with means to limit the x-ray beam such that the diameter of the useful beam at the end of the cylinder shall not be greater than 7.0 centimeters (2.75 inches). For intraoral rectangular collimation the useful beam at the end of the spacer shall not have a diagonal measurement greater than 7.0 centimeters (2.75 inches). Positioning devices should be used to assure beam alignment.

2. An open ended shielded cylinder, or other open ended shielded spacers that will meet the requirements of .04(14)(a) and (b)1. shall be used.

(c) Structural Shielding.

1. The provisions of .01(8) shall apply, except that National Council on Radiation Protection and Measurements Report No. 35, "Dental X-Ray Protection," or its current revision or replacement, shall be referenced by the Department.

2. When dental x-ray units are installed in adjacent rooms or areas, protective barriers sufficient to reduce the exposure to the requirements of .03(2) shall be provided between the rooms and/or areas.

(d) Operating Procedures.

1. Patient and film holding devices shall be used when the techniques permit.

2. Neither the tube housing nor the position indicating device shall be hand-held during an exposure.

3. Mechanical support of the tube head shall maintain the exposure position without drift.

4. Dental fluoroscopy shall not be used without image intensification and shall meet the requirements of .04(12).

5. Only persons required for the radiographic procedure shall be in the x-ray room during exposure. All persons shall be adequately protected.

6. The operator shall be able to view the patient during an exposure.

7. During each exposure, the operator shall stand at least 1.8 meters (6 feet) from the patient and tube head and outside the path of the useful beam or behind a barrier that meets the requirements of .03(2).

(e) The total filtration in the useful beam shall not be less than the appropriate values stated in .04(6)(d)1.(i) or (ii).

(15) Veterinary Radiographic Installations.

(a) Equipment.

1. The tube housing shall be of the diagnostic type.

2. The primary beam for diagnostic purposes in radiography and fluoroscopy should not be larger than clinically necessary and shall not be greater than the image receptor. Cones, diaphragms, or adjustable collimators capable of restricting the primary beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required in the tube housing.

3. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

4. The exposure switch shall be of a dead-man type.

5. The total filtration permanently in the useful beam shall not be less than the appropriate value stated in .04(6)(d)1.(i) or (ii).

6. A means shall be provided for aligning the center of the x-ray beam with the center of the image receptor prior to an x-ray examination.

7. An easily discernible indicator which shows whether or not x-rays are being produced shall be on the control panel.

8. The installation shall be so arranged that the operator can stand at least six feet from the animal, the x-ray tube and out of the useful beam.

9. Leaded gloves and aprons shall be available for use, and shall be used by all personnel in the room during an exposure.

10. The effectiveness of protective equipment (i.e., gloves, aprons, etc.), shall not be impaired.

(b) Operating Procedures.

1. Only persons whose presence is necessary shall be in the radiographic area during exposure. Protective clothing of at least 0.25 mm lead equivalent shall be provided and shall be worn by all individuals required to be in controlled areas, except when the individuals are entirely behind protective barriers while the equipment is energized.

2. Patient support:

(i) When an animal patient or film must be held in position for radiography, mechanical supporting or restraining devices, or other means of immobilization, shall be used unless human holding is required by the technique.

(ii) If an animal patient must be held or positioned manually, the individual holding the animal shall wear protective gloves having at least 0.5 mm lead equivalency and a protective apron of at least 0.25 mm lead equivalency;

(iii) Personnel monitoring devices shall be used if radiation measurements indicate potential exposure in excess of 25 percent of the applicable values specified in Section .03(2)(a)1. to the head, or trunk of the body.

(c) Fluoroscopy.

1. The provisions of .04(12) shall apply to fluoroscopic equipment.

(d) Structural Shielding. The provisions of .01(8) shall apply except that the National Council on Radiation Protection and Measurements Report No. 36, "Radiation

Protection in Veterinary Medicine," or its current revision or replacement, shall be referenced by the Department.

(16) Therapeutic Radiation Machines of Less Than One MeV.

(a) Leakage Requirements. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified, at the distance specified for the classification of that radiation machine.

1. Contact Therapy Machines. Leakage radiation shall not exceed 100 milliroentgens (.0258 mC/Kg) an hour at five (5) centimeters from the surface of the tube housing assembly.

2. 0-150 kVp Machines.

(i) Machines which were manufactured or installed prior to the date of adoption of these regulations shall not permit radiation leakage in excess of 1 Roentgen (.258 mC/Kg) in one (1) hour at one (1) meter from the source.

(ii) In machines manufactured on, or after the date of adoption of these regulations, leakage radiation shall not exceed 100 mR (.0258 mC/Kg) in one (1) hour at one (1) meter from the source.

3. 151 to 999 kVp Systems. The leakage radiation does not exceed one (1) roentgen (.258 mC/Kg) in one (1) hour at one (1) meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam one meter from the source.

(b) Permanent Beam Limiting Devices. The registrant shall be responsible for assuring that permanent fixed diaphragms or cones used for limiting the useful beam shall provide at least the same protection as required by the tube housing assembly.

(c) Removable and Adjustable Beam Limiting Devices.

1. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful x-ray beam at the maximum kilovoltage and with maximum treatment filter.

2. Adjustable beam limiting devices installed after the effective date of these regulations shall transmit not more than 1 per cent of the useful x-ray beam.

3. Adjustable beam limiting devices installed before the effective date of these regulations shall transmit not more than 5 percent of the useful x-ray beam.

(d) Filter System.

1. The filter system shall be so designed that the filters cannot be accidentally displaced from the useful beam at any possible tube orientation; and

2. The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/Kg) per hour under any operating conditions; and

3. Each filter shall be conspicuously inscribed as to its material of construction and its thickness. For wedge filters, the wedge factor and wedge angle shall appear on the wedge or wedge tray.

(e) Tube Immobilization. The tube housing assembly shall be capable of being immobilized during stationary treatments.

(f) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(g) Timer.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fractions of minutes.

2. The timer shall have a preset time selector and an elapsed time indicator.

3. The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated.

4. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the present time selector through zero time.

5. The timer shall permit accurate presetting and determination of exposure times as short as 1 second.

6. The timer shall not permit an exposure if set at zero.

7. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

(h) Control Panel Functions. The control panel, in addition to the displays required in other provisions of .04(16), shall have:

1. an indication of x-ray production; and

2. means for indicating kV and x-ray tube current; and

3. means for terminating an exposure at any time; and

4. a locking device which will prevent unauthorized use of the radiation machine; and

5. for radiation machines installed after the date of adoption of these regulations, a positive display of specific filter(s) in the beam.

(i) Source-to-Skin Distance. There shall be means of determining the SSD distance to within 1 centimeter.

(j) Low Filtration X-Ray Tubes. Each radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

(k) Calibrations and Spot Checks.

1. Calibrations.

   (i) The calibration of therapeutic radiation machines shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output.

   (ii) The registrant shall insure that such calibration is performed by an individual competent to perform such work.

   (iii) Records of calibrations performed shall be maintained by the registrant for at least 5 years after completion of the calibration.

   (iv) A copy of the most recent radiation machine calibration shall be available at the control panel.

   (v) The radiation machine shall not be used in the administration of radiation therapy unless the calibrations required by .04(16)(k)1. (i) -(iv) have been met.

2. Spot Calibration Checks. Spot calibration checks on radiation machines capable of operation at greater than 150 kVp shall be performed in accordance with written procedures. A record of such checks shall be

maintained for a two (2) year period after completion of the spot-check measurements.

(17) Additional Facility Design Requirements for Therapy Radiation Machines Capable of Operating Above 50 kVp and less than 1 MeV.

(a) Voice Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(b) Viewing Systems.

1. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system, which may also be electronic, shall be available for use in the event of electronic failure.

3. In the event of total failure of patient viewing, therapy shall be discontinued until the system is functioning.

(c) Structural Shielding. In addition to the provisions of .01(8):

1. For existing equipment operating above 125 kVp the required operator's barrier(s) shall be an integral part of the building;

2. For all therapeutic machines operating below 150 kVp, built or modified after the effective date of these regulations, the operator's barrier(s) shall be an integral part of the building;

3. For equipment operating above 150 kVp, the control panel shall be within a protective booth equipped with an interlocked door, or located outside the treatment room.

(d) Additional Requirements for Radiation Machines Capable of Operation Above 150 kVp and less than 1 MeV.

1. All necessary shielding, except for any beam interceptor, shall be provided by fixed barriers;

2. The control panel shall be outside the treatment room;

3. All doors of the treatment room shall be electrically connected to the control panel such that x-ray production cannot occur unless all doors are closed;

4. When the treatment room door is opened during any exposure, the exposure shall terminate immediately;

5. After termination of the exposure, it shall be possible to restore the radiation machine to full operation only upon closing the door, and subsequently reinitiating the exposure at the control panel.

(e) Operating Procedures.

1. Therapeutic radiation machines shall not be left unattended unless the machine is secured.

2. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

3. The tube housing assembly shall not be held by an individual during exposures.

4. (i) For radiation machines operating above 150 kVp, no individual other than the patient shall be in the treatment room during exposures.

   (ii) For machines operating below 150 kVp, no individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of these regulations.

(18) X-Ray and Electron Therapy Machines with Energies of One MeV and Above.

(a) Scope. This part applies to medical facilities using therapy machines with energies of 1 MeV and above. Additional requirements for these machines are found in Section 111-8-90-.05 entitled "Radiation Safety Requirements for Particle Accelerators".

(b) Requirements for Equipment.

1. Leakage Radiation to the Patient Area.

   (i) New equipment shall meet the following requirements:

(I) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

(II) For each machine, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in (.04)(18)(b)l. (i) (I) for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the Department.

(ii) Existing equipment shall meet the following requirements:

(I) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of 2 meters radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(II) For each machine, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in .04(18)(b)1. (ii)(I) for the specified operating conditions. Records of leakage radiation

measurements shall be maintained for inspection by the Department.

2. Leakage Radiation Outside the Patient Area for New Equipment.

   (i) The absorbed dose in rads (grays) due to leakage radiation except in the area specified in .04(18)(b)1. (i) (I) when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in .04(18)(b)1. (i) (I).

   (ii) The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in .04(18)(b)2. (i) for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

3. The registrant shall assure that adjustable or interchangeable beam limiting devices are provided and that such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. Documentation of the transmission factors shall be maintained at the facility for inspection by the Department. The neutron component of the useful beam shall not be included in this requirement.

4. Filters.

   (i) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

   (ii) For equipment manufactured after the effective date of these regulations which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

(I) irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

(II) an interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(III) a display shall be provided at the treatment control panel indicating the filter(s) in use;

(IV) an interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

5. Beam Symmetry. In equipment manufactured after the effective date of these regulations, inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated. It shall be the registrant's responsibility to assure that the above requirements are met and that records of confirming tests are maintained for Departmental inspection.

6. Beam Monitors. All therapy accelerator machines shall be provided with radiation detectors in the radiation head.

   (i) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.

   (ii) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

7. Selection and Display of Dose Monitor Units.

   (i) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

(ii) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

(iii) After termination of irradiation, it shall be necessary to zero before subsequent treatment can be initiated.

(iv) For equipment manufactured after the effective date of these regulations, it shall be necessary after termination of irradiation to manually reset the preselected dose monitor units before irradiation can be initiated.

8. Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

9. Termination of Irradiation by the Dose Monitoring System or Systems.

(i) Each of the required monitoring systems shall be capable of independently terminating irradiation.

(ii) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(iii) If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

10. Termination Switches. It shall be possible to terminate irradiation and equipment movements at any time from the operator's position at the treatment control panel.

11. Timer.

(i) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

(ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(iii) For equipment manufactured after the effective date of these regulations after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

(iv) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.

12. Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(i) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

(ii) An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.

(iii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(iv) An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.

(v) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

(vi) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

13. Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

    (i) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

    (ii) An interlock system shall be provided to prevent irradiation if any selected operations to be carried out in the treatment room do not agree with those selected operations carried out at the treatment control panel.

    (iii) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

    (iv) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

14. Selection of Stationery Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

    (i) Irradiation shall not be possible until a selection of stationery beam therapy or moving beam therapy has been made at the treatment control panel.

    (ii) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

    (iii) An interlock system shall be provided to prevent irradiation if any selected operations to be carried out in the treatment room do not agree with those selected operations carried out at the treatment control panel.

    (iv) The mode of operation shall be displayed at the treatment control panel.

    (v) For new equipment, an interlock system shall be provided to terminate irradiation if:

        (I) movement of the gantry occurs during moving stationary beam therapy; or

(II) movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

(vi) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(I) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.

(II) for new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

(c) Facility and Shielding Requirements. In addition to Section .01(8) of these regulations, the following design requirements shall apply:

1. The treatment control panel shall be located outside the treatment room; and

2. Except for entrance doors or beam interceptors, all the required barriers shall be fixed; and

3. Windows, mirrors, closed-circuit television, or other equivalent viewing devices shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. When the viewing system is by electronic methods, a secondary viewing system, which may also be electronic, shall be available for use in the event of failure of the primary system; and

4. Provision shall be made for two-way aural communication between the patient and the operator at the treatment control panel; and

5. The entrance to the treatment room shall be equipped with a steady, red warning light which operates when, and only when, radiation is being produced; and

6. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is

interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.

(d) Calibrations and Spot Checks.

1. Calibration.

(i) A calibration of all new machines and existing machines not previously surveyed shall be performed prior to the initial irradiation of a patient and thereafter at time intervals not to exceed 12 months, and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. It shall be the responsibility of the registrant to ensure that the individual performing the calibration is competent to perform such calibrations.

(ii) The calibration of a particle accelerator machine shall be performed in accordance with a calibration protocol such as that published by the American Association of Physicists in Medicine in Volume 10, number 6, issue of Medical Physics, or its current revision or replacement.

(iii) Any calibration protocol used must contain the following minimum measurement criteria:

(I) full calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

(II) spot-check measurements shall be performed using a dosimetry system that has been calibrated in accordance with .04(18)(d)1. (iii)(I) of this rule. Alternatively, a dosimetry system spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with .04(18)(d)1. (iii)(I) of this rule. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

(iv) The full calibration of the therapy beam shall include but not be limited to the following determinations:

(I) verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at the specified depth.

(II) the absorbed dose rate at various depths of water for the range of field sized used, for each effective energy, and for each treatment distance used for radiation therapy.

(III) the uniformity of the radiation field and any dependency upon the direction of the useful beam.

(IV) verification of depth-dose data and isodose curves applicable to the specific machine.

(V) verification of transmission factors for all accessories such as wedges shadow trays, etc.

(VI) records of full calibration measurements and dosimetry system calibrations shall be preserved for 5 years after completion of the full calibration.

(VII) a copy of the latest full calibration performed as described in .04(18)(d)1. (iv)(I)-(VI) shall be available at the accelerator facility.

2. Spot-Calibration Checks.

(i) Spot-calibration checks shall be performed on machines subject to .04(18)(b) during calibrations and thereafter at intervals not to exceed one month.

(ii) Such spot-calibration checks shall be in accordance with written procedures and shall include absorbed dose measurements in a phantom at intervals not to exceed one week.

(iii) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check; and

(iv) Records of spot-check measurements performed pursuant to .04(18)(b) shall be maintained by the registrant for a period of 2 years after completion of the spot-check measurements and any necessary corrective actions.

(e) Qualified Expert. The registrant shall determine if a person is an expert qualified by training and experience to calibrate a therapy machine and establish procedures for (and review the results of) spot-check measurements. The registrant shall determine that the person calibrating their therapy machine:

1. is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or x-ray and Radium Physics; or

2. has the following minimum training and experience:

   (i) a Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;

   (ii) one year of full-time training in therapeutic radiological physics; and

   (iii) one year of full-time experience in a radiotherapy facility including personal calibration and spot-check of at least one therapy machine.

(f) Operating Procedures.

1. No individual other than the patient shall be in the treatment room during treatment of a patient.

2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

3. The machine shall not be used in the administration of radiation therapy unless the requirements of .04(18)(d) have been met.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.04
Authority: Ga. L. 1964, pp. 507, 569, 570; O.C.G.A. § 31-13-5.
History. Original Rule entitled "X-Rays in the Healing Arts" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-90-.05. Radiation Safety Requirements for Particle Accelerators.

(1) Scope. This section establishes procedures for the registration and use of particle accelerators for medical and non-medical applications. Additional requirements for medical accelerators are found in Section 111-8-90-.04(18) entitled "Radiation and Electron Therapy Machines with Energies of one MeV and Above."

(2) Registration Requirements. No person shall receive, possess, use, own, or acquire a particle accelerator except as authorized in the accelerator registration issued pursuant to these regulations. The procedures for registration of particle accelerator facilities are included in these regulations.

(3) General Requirements for the Issuance of a Certificate of Registration for Particle Accelerators. In addition to the requirements of .02(1), (2), (6), (7) and (8) of these regulations, the applicant shall submit a supplementary registration application for use of a particle accelerator. Registration will be approved only after the Department determines that:

(a) the applicant is responsible for the use of the accelerator;

(b) the applicant's proposed or existing equipment, facilities, operating and emergency procedures are adequate to protect health and minimize risk to public health and safety or property; and

(c) the issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in this section; and

(d) the applicant has appointed, for medical applications, a physician who is designated on the application as the radiation therapist and other such professional staff necessary to the safe operation and use of the accelerator.

(e) The applicant and/or the applicant's staff has experience in the use of particle accelerators and training sufficient for application to its intended uses; and

(f) The applicant has established a radiation safety committee (composed of one or more persons trained or experienced in the safe use of accelerators) to approve, in advance, proposals for uses of particle accelerators; and

(g) The applicant conducts training programs to assure continued competency for operators of particle accelerators; the protocol shall be in writing.

(4) Human Use of Particle Accelerators. In addition to the requirements of .02 of these regulations, a registration for use of a particle accelerator in the healing arts will be issued only if:

(a) The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of particle accelerator. Membership of the committee shall include physicians expert in

internal medicine, hematology, therapeutic radiology, and the radiological physicist.

(b) The individuals designated on the application as the users are radiation therapists who have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.

(5) Limitations.

(a) No registrant shall permit any person to act as an operator of a particle accelerator until such person:

1. has been instructed in radiation safety and in operating and emergency procedures; and

2. has received copies of, and instruction in, the applicable requirements of these regulations; and

3. has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in their assignment, and be able to demonstrate such knowledge to the Department upon request.

(b) The radiation safety committee, radiological health physicist or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if any one of them deems such action is necessary to protect health and minimize danger to public health and safety or property.

(6) Shielding and Safety Design Requirements. Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with .03(2)(a) and .03(2)(c) of these regulations. This requirement will be deemed to be met if the barriers are constructed in accordance with NCRP Report No.51.

(7) Particle Accelerator Controls and Interlock Systems.

(a) Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(b) Except for portable accelerator, all entrances into a target room or other high radiation area shall be provided with interlocks. When access is gained through any entrance the accelerator shall shut down automatically.

(c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting the tripped interlock and initiating starting up procedures at the main control console.

(d) An emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

(e) Portable accelerators shall be exempt from .06(7)(b) provided that they are not used in one location in excess of 30 days.

(8) Warning Devices.

(a) All locations designated as high radiation areas, and all entrances to such locations, shall be equipped with easily observable red warning lights that operate when, and only when, radiation is being produced.

(b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such a warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas, shall be identified with caution signs, labels and signals in accordance with .03(4) of these regulations.

(9) Operating Procedures.

(a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use;

(b) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency;

(c) All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed one month. Results of such tests shall be maintained at the accelerator facility for inspection by the Department;

(d) Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and available at each accelerator facility;

(e) If, for any reason, it is necessary to intentionally by-pass a safety interlock or interlocks, such action shall be:

1. authorized in writing by the radiation safety committee and/or radiation safety officer; and

2. recorded in a permanent log and a notice posted at the accelerator control console; and

3. terminated as soon as possible.

(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel and shall include instructions in at least the following:

1. the use of the accelerator in such a manner that no person is likely to be exposed to radiation doses in excess of the limits established in these regulations; and

2. methods and occasions for conducting radiation surveys; and

3. methods for controlling access to high radiation areas; and

4. methods and occasions for locking the control panel of the accelerator; and

5. personnel monitoring and the use of personnel monitoring equipment; and

6. methods for minimizing exposure of individuals in the event of an accident; and

7. the procedures for notifying appropriate persons in the event of an accident; and

8. the maintenance of records.

(10) Radiation Monitoring Requirements.

(a) There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and/or repair.

(b) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.

(c) Facility shall have a written procedure concerning the conducting of area surveys and radiation protection surveys of the machine and facility shielding.

(d) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility and made available for Departmental inspection.

(11) Ventilation Systems.

(a) Means shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Chapter 391-3-17 (Rules and Regulations for Radioactive Materials).

(b) A registrant shall not vent, release or otherwise discharge airborne radioactive material to an uncontrolled area except as authorized pursuant to Chapter 391-3-17.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.05
Authority: Ga. L., 1964, pp. 507, 569, 570; O.C.G.A. § 31-13-5.
History. Original Rule entitled "Radiation Safety Requirements for Particle Accelerators" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-90-.06. Radiation Safety Requirements for the Use of Non-Medical X-Ray.

(1) Purpose. This section establishes the requirements for the non- healing arts use of x-rays.

(2) Scope. This section applies to all non-healing arts radiographic, fluoroscopic, and analytical x-ray installations and any apparatus capable of emitting x-rays as either a useful product or an unwanted by-product. The provisions of this section are in addition to and not in substitution for other applicable provisions of these regulations.

(3) General Provisions.

(a) Each registrant shall provide personnel monitoring devices which are calibrated for the appropriate radiations and energies of radiation produced, and these devices shall be used by:

1. Each individual who receives, or is likely to receive, a whole body dose in excess of 25 millirems per week; and

2. Each individual who enters a high radiation area.

(b) Each installation shall be provided with such primary protective barriers and/or secondary protective barriers as are necessary to assure compliance with section .01(8) and .03(2).

(c) All areas in which radiation hazards may arise shall be identified by an appropriate and easily recognizable warning sign as described in .03(4).

(d) Audible or visible signals shall be provided in the vicinity of installations to provide warning during irradiation and shall be activated prior to any exposure.

(e) X-ray tubes shall be provided with protective housing(s) appropriate to the nature of the work to afford adequate protection to personnel. The housing(s) shall be at least equivalent to a therapeutic tube housing.

(f) The operator or radiographer shall be provided with and shall have available for inspection a copy of normal operating and emergency procedures.

(g) A key-operated primary control switch shall be provided such that x-ray production shall not be possible with the key removed.

(h) Manufacturers of radiation machines shall provide for purchasers, and to the Department upon request, manuals and instructions which shall include at least the following technical and safety information:

1. potential, current, and duty cycle ratings of the x-ray generation equipment; and

2. adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the machine; and

3. a schedule of maintenance necessary to keep the machine in compliance with these regulations.

(i) A suitable and functioning survey instrument, calibrated for the energy used, shall be at each installation.

(j) Each entrance or access point to a high radiation area shall be:

1. equipped with a control device which shall cause the radiation generator to turn off automatically upon entry into the area; or

2. maintained locked except during periods when access to the area is controlled.

(k) Each high radiation area shall be arranged in such a way that an individual can quickly leave that area.

(l) Tests of all devices such as interlocks, shutters, and warning lights shall be conducted at intervals not to exceed 3 months for all operable analytical x-ray equipment. Records of such tests shall be maintained for inspection by the Department.

(4) Industrial Radiography.

(a) Cabinet X-ray Installations.

1. The x-ray source and all objects exposed thereto must be contained within a permanent enclosure.

2. All protective enclosures and equipment shall be kept in good repair.

3. Radiation exposure shall not exceed 0.5 mR in any one hour at a distance of five centimeters (2 inches) from any point on the external surface of the cabinet or of any component outside the cabinet when operated under any conditions for which the machine is designed.

4. A control shall be provided that will enable the operator to initiate and terminate the production of x-rays by means other than the safety interlock system or main power control.

5. It shall not be possible to extend any part of the human body through a port into the primary beam.

6. Each door of a cabinet x-ray system shall have a minimum of two operative safety interlocks. One but not both of the required interlocks shall be such that a door opening results in physical disconnection of the energy supply circuit to the high voltage generator, and such disconnection shall not be dependent upon any moving part other than the door. The registrant shall:

   (i) maintain records that verify the existence of dual interlocks.

   (ii) maintain records of any repairs made on the dual interlocks; and

   (iii) certify to the Department that modifications have not been made to the dual interlocks that are not consistent with manufacturer's design specifications. Such certification shall be made to the Department with the application for registration, application for renewal of registration, and as a part of any inspection or investigation conducted by the Department. For purposes of inspection, the Department shall review these records and only that the cabinet x-ray system ceases x-ray production when the door is opened.

7. For cabinet x-ray systems designed for entry by an individual during the normal course of use of the machine, there shall also be provided:

   (i) Audible and visible warning signals within the cabinet which must be activated for at least 10 seconds immediately prior to the first initiation of x-radiation production; and

(ii) A visible signal within the cabinet which shall remain operative for the duration of x-ray production. It shall be automatically initiated prior to x-ray production and terminated with the exposure; and

(iii) Suitable means of egress, so that any person may escape the interior of the cabinet without delay, or an effective means within the cabinet for preventing or terminating production of the x-radiation, and which cannot be reset from the outside of the cabinet.

8. Following interruption of x-ray generation by operating any interlock, the resumption of x-ray generation shall be possible only from the control panel.

(b) Shielded Room Radiographic Installations.

1. Facilities utilizing shielded room radiography shall assure that:

(i) Radiation levels at any point on the exterior of the room do not exceed those specified in .03(2)(c); and

(ii) All the requirements specified in .06(4)(a)7. shall apply.

(iii) Each door of a shielded room shall have a minimum of two operative safety interlocks. One but not both of the required interlocks shall be such that a door opening results in physical disconnection of the energy supply circuit to the high voltage generator.

(c) Open X-ray Installations.

1. Radiation areas in excess of 5 mR/hr shall be identified. A fence, rope or other suitable personnel barrier shall be erected along a 5 mR/hr, or less, contour line.

2. The area described by the temporary barricade shall be suitably posted with caution signs.

3. Suitable personnel monitoring devices for the energy used shall be provided and shall be used by persons in the area. One device shall be a cumulative direct reading device, the other a film badge, or equivalent.

4. During each radiographic operation, either the radiographer or an assistant shall maintain direct vigilance of the operation to insure against unauthorized entry into the radiation area.

5. All persons shall be removed from the radiation area before irradiation is begun.

6. The radiation machine itself, or the place in which the machine is stored, shall be locked in order to prevent unauthorized use.

7. Written records of personnel exposure, safety procedures and scaled drawing of the 5 mR/hr contour line shall be at the work site.

8. Each facility shall have a suitable and functioning survey instrument.

(5) Analytical X-Ray.

(a) Equipment.

1. The leakage radiation from the tube housing shall not exceed a radiation level of 25 milliroentgens in 1 hour at 5 centimeters (2 inches) from the surface of the tube housing at any specified tube rating.

2. Radiation originating within the high voltage power supply (i.e., transformer and rectifiers) shall not exceed a radiation level of 0.5 milliroentgen in 1 hour at every specified rating at a distance of 5 centimeters (2 inches) from the housing of the power supply.

3. For open beam x-ray equipment:

(i) Sufficient warning lights or other equally conspicuous signals that operate only when the primary x-ray beam is released from the beam ports shall be provided in such a manner as to alert individuals to the potential radiation hazard. These signals shall be labeled so that their purpose is easily identified.

(ii) The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked to protect against unauthorized or accidental entry.

(iii) When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.

(iv) Each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator, or a coupling and recording device with beam absorber, has been connected to the port.

4. The radiation level for analytical x-ray equipment in which the primary x-ray beam is completely enclosed shall be less than 2 milliroentgens in 1

hour at 25 centimeters (10 inches) from the apparatus at every specified tube rating.

5. Each analytical system shall be so arranged as to restrict the entry of parts of the body into the primary beam. This may be accomplished by using such arrangements as adequate barriers or interlocks.

6. The analytical x-ray device shall be provided with a protective barrier which absorbs the useful beam behind the specimen under examination.

7. In addition to any other signs or labels required, a sign or label shall be placed on or adjacent to each x-ray tube housing and shall be located as to be clearly visible to any individual who may be working in close proximity to the primary beam path. The sign or label shall read: "CAUTION - HIGH INTENSITY X-RAY BEAM."

8. A warning light with the notation "X-RAY ON," shall be located on the control panel and:

   (i) shall light only when the x-ray tube is activated; and

   (ii) shall be wired in series with the primary electrical circuit so that if the warning light is inactivated x-ray generation is not possible.

9. The coupling between the x-ray tube and the collimator of the diffractometer, camera, or other accessory shall prevent radiation from escaping the coupling.

10. All tube head ports which are not in use shall be secured in the closed position in a manner which will prevent casual opening. Port covers shall offer the same degree of protection as is required of the tube housing.

(b) Operation of Equipment.

1. The registrant shall not permit the routine operation of any equipment that would require an individual to expose any part of his body to the primary beam.

2. Written operating and emergency procedures pertaining to radiation safety shall be established for each facility and shall be posted in a conspicuous location near each unit of analytical x-ray equipment.

3. Only qualified personnel shall be permitted to install, repair or make modifications to the x-ray generating apparatus and the tube housing-apparatus complex.

4. Any temporary alteration to safety devices, such as bypassing interlocks or removing shielding shall be:

   (i) prohibited during normal operation of the equipment;

   (ii) specified in writing and posted near the x-ray tube housing so that other individuals will know the existing status of the x-ray apparatus; and

   (iii) terminated as soon as possible; and

   (iv) recorded and the record maintained for inspection by the Department. This record should contain such information as date alteration was made, type of alteration, length of time unit remained in the altered condition, and signed by the individual who restored the unit to original condition.

5. Interlocks shall not be used to deactivate the x-ray tube except in an emergency or during testing of the interlock system; it shall be possible to restore the machine to full operation only from the control panel.

6. Safety glasses shall be provided and required for use by operators, assistants, and maintenance personnel. Personnel monitoring in the form of ring badges or the equivalent should be utilized.

(c) Surveys. Radiation surveys of all analytical radiation machines shall be performed:

1. following any change in the initial arrangement, number, or type of components in the machine; or

2. following any maintenance requiring the disassembly or removal of a component in the machine; or

3. during the performance of maintenance and alignment procedures, if the procedures require the presence of a primary x-ray beam when any component in the machine is disassembled or removed; or

4. any time a visual inspection of the local components in the machine reveals an abnormal condition; and

5. It shall be the responsibility of the registrant to ensure that such radiation surveys are performed by an individual competent to perform such surveys.

(d) Medical Examination. Operators and personnel routinely assisting in analytical x-ray operation or maintenance shall be instructed regarding the potential physical

hazards of such an x-ray beam. They shall be required to report any evidence of accidental physical injury or accidental exposure to radiation to the individual in charge of radiation protection. That person shall require immediate medical examination of the suspected injury and, if such injury has occurred, shall notify the Department by telephone and in writing within 24 hours.

(6) Non-Medical Fluoroscopy.

(a) Industrial Use:

1. In addition to the applicable provisions of this section .06, provisions shall be made to maintain adequate protection when manipulating or marking objects under examination.

2. "Hand-held" fluoroscopes shall not be used.

3. The exposure rate due to transmission through the image receptor shall not exceed 2 mR/hr at a distance of 10 centimeters (4 inches) from any point on the receptor.

4. The maximum x-ray dose shall not exceed 0.5 mR in any one hour measured at 5 centimeters (2 inches) from any readily accessible machine surface.

5. A method of dosimetry for these systems shall be employed which shall quantitatively define, with an accuracy of + 20 percent, the x-ray dose within the energy range of 30-150 kVp. Any method of film dosimetry, thermoluminescent dosimetry, or electronic instrumentation which shall be capable of this measurement will be acceptable.

6. Any installation for baggage surveillance shall be enclosed and so designed as to prohibit ready access to x-ray generating equipment.

7. It shall not be possible to insert any part of the body into the primary beam.

8. The control panel shall be equipped with a key lock. It shall not be possible to remove the key in the "on" position.

9. A positive pressure switch shall be provided to control the exposure and shall be located such that the operator has a clear view of the radiation machine.

(b) Non-Controlled Areas. Personnel dose limits shall not exceed 10 mR in any one week or 500 mR in any one year.

(7) X-Rays As Unwanted By-Product.

(a) All equipment in which electrons are accelerated to an energy in excess of 5 keV shall be regarded as a potential source of ionizing radiation, such as: electron microscopes, cathode-ray tubes, television and imaging tubes.

(b) All such equipment shall be constructed, installed and operated in such a manner as to provide adequate protection according to these regulations.

(c) Such items of equipment shall be shielded and provided with interlocks so as to ensure that the places where they are used can be regarded as being outside "controlled areas."

(d) The dose rate at any readily accessible point 5 centimeters (2 inches) from the surface of such equipment shall not exceed 0.5 mR/hr.

(8) Instruction of Personnel.

(a) The registrant shall assure that all radiation machines and associated equipment under his control is operated only by individuals instructed in safe operating procedures and competent in the safe use of the equipment. The registrant shall also assure that persons operating his radiation machine and associated equipment have received, at a minimum, two hours of instruction in the following six (6) subject categories:

1. Fundamentals of Radiation Safety:

(i) Characteristics of radiation

(ii) Units of radiation measurement

(iii) Significance of radiation dose and exposure

(I) Radiation protection standards

(II) Biological efforts of radiation

(iv) Sources and levels of radiation

(v) Methods of controlling radiation dose

(I) Working time

(II) Working distances

(III) Shielding

2. Radiation Detection Instrumentation to be Used:

(i) Use of radiation survey instruments

(I) Operation

(II) Calibration

(III) Limitations

(ii) Survey techniques

(iii) Use of personnel monitoring equipment

(I) Film badges

(II) Thermoluminescent dosimeters

(III) Pocket dosimeters

3. Radiographic Equipment to be Used:

(i) Remote handling equipment

(ii) Radiographic exposure devices and sealed sources

(iii) Operation and control of x-ray equipment

4. The Requirements of Pertinent Federal and State Regulations.

5. The Registrant's Written Operating and Emergency Procedures.

6. Case Histories of Radiography Accidents.

(b) Training shall begin within 30 days after employment and shall be completed no later than 90 days after date of employment. The registrant shall maintain a record of all training for each operator. Such record shall be made available for Departmental inspection.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.06
Authority: Ga. L., 1964, pp. 507, 569, 570; O.C.G.A. § 31-13-5.
History. Original Rule entitled "Radiation Safety Requirements for the Use of Non-Medical X-Ray" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-90-.07. Records, Reports and Notifications.

(1) Records and Reports.

(a) Each registrant shall maintain records, in the same units used in this chapter, showing the radiation exposures of all individuals for whom personnel monitoring is required under these regulations. Such records shall be kept on Department forms, in accordance with the instructions contained in that form or in a clear and legible manner containing all the information required on the Department forms. The doses entered on the forms or records shall be for periods of time not exceeding one calendar quarter.

(b) Each registrant shall maintain records, in the same units used in this chapter, showing the results of surveys, safety checks and calibrations required under these regulations.

(c) Records of individual radiation exposure which must be maintained pursuant to the provisions of .07(1)(a) of this Chapter shall be preserved until a date five (5) years after termination of the individual's employment or association with the registrant, or such other time as the Department may determine.

(d) The discontinuance or curtailment of activities does not relieve the registrant of responsibility for retaining all records required by this section.

(e) The Department may require further preservation of records which it determines shall not be destroyed. Records which must be maintained pursuant to this section may be maintained in the form of microfilm.

(f) Each person who possesses a radiation machine shall keep records showing the receipt, transfer, or disposal of such radiation machine and shall make such records available for inspection by the Department upon request.

(g) The registrant shall keep a record of all major maintenance and/or modifications performed on each radiation machine during the period it is under his control. Such record shall be transferred to any subsequent owner of the equipment. Records shall include, but not be limited to, tube housing or x-ray tube insert replacement, any re-orientation of the machine, repair or change of the console or high-voltage supply, or collimator repair.

(2) Notification of Incidents.

(a) Immediate Notification. Each registrant shall immediately notify the Georgia Department of Community Health, Radiological Health Section, Atlanta, Georgia, by telephone and confirming letter of any incident involving any source of radiation possessed by him which may have caused exposure of the whole body of an individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms of any individual to 375 rems or more of radiation.

(b) Twenty-four Hour Notice. Each registrant shall within 24 hours notify the Georgia Department of Community Health, Radiological Health Section, by telephone and confirming letter of any incident involving any source of radiation possessed by him which may have caused exposure of the whole body of any individual to 5 rems or more of radiation; exposure of the skin of the whole body of any individual to 30 rems or more or radiation; of exposure of the feet, ankles, hands, or forearms to 75 rems or more of radiation.

(c) Special Requirements for Reporting. Any report filed with the Department pursuant to .07(2) shall be prepared in such a manner that names of individuals who have received exposure to radiation will be stated in a separate part of the report.

(3) Report to Former Employees and Others of Exposure to Radiation. A registrant, at the request of any individual formerly employed or associated with such registrant (e.g., student, craftsman, etc.), shall furnish to such individual a report of his exposure to radiation as shown in records maintained pursuant to .07(1)(a). Such report shall be furnished within 30 days from the time the request is made and shall cover each calendar quarter of the individual's employment or association involving exposure to radiation, or such lesser period as may reasonably be requested by the individual. The report shall be in writing.

(4) Reports of Overexposures and Excessive Levels.

(a) In addition to any notification required by .07(2), each registrant shall make a report in writing within 30 days to the Georgia Department of Community Health, Radiological Health Section, of:

1. Each exposure of an individual to radiation in excess of any applicable limit set forth in these regulations.

2. Levels of radiation (whether or not involving excessive exposure of any individual) in an uncontrolled area in excess of 10 times any applicable limit set forth in these regulations.

(b) Each report required under .07(4)(a) shall describe the extent of exposure of individuals to radiation, levels of radiation involved, the cause of the exposures, and corrective steps taken or planned to assure against a recurrence.

(c) In any case where a registrant is required to report to the Department any exposure of an individual to radiation, the registrant shall, no later than the making of such report to the Department, also notify the individual of the nature and extent of exposure.

(d) Any report filed with the Department pursuant to this paragraph shall be prepared in such a manner that names of individuals who have received exposure to radiation will be stated in a separate part of the report.

(5) Notice to Employees. Each registrant shall annually advise any individual employed or associated with such registrant of the individual's exposure to radiation as shown in records maintained by the registrant pursuant to .07(1)(a), if requested by the individual.

(6) Instruction of Personnel, Posting of Notices to Employees.

(a) Each registrant shall advise individuals working in a restricted area of reports of radiation exposures which individuals may request in accordance with these regulations.

(b) Any Department documents or instructions sent to the registrant shall be maintained with a current copy of these regulations or posted as required.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.07
Authority: Ga. L., 1964, pp. 507, 569, and 570, O.C.G.A. § 31-13-5, 31-13-9.
History. Original Rule entitled "Records, Reports and Notifications" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-90-.08. Penalties.

(1) Any registrant who violates the provisions of O.C.G.A. Section 31-13-14, or who hinders, obstructs, or otherwise interferes with any representative of the Department in the discharge of official duties in making inspections as provided in O.C.G.A. Section 31-13-5, or in impounding materials as provided in O.C.G.A. Section 31-13-11, shall be guilty of a misdemeanor.

(2) Any registrant who:

(a) Violates any registration provision of Chapter 13 of Title 31 of the Official Code of Georgia Annotated; or any rule, regulation, or order issued thereunder; or any term, condition, or limitation of any registration certificate thereunder; or commits any violation for which a registration certificate may be revoked under this Chapter may be subject to a civil penalty to be imposed by the Department. If the violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty.

(3) Imposition of such civil penalties shall relate to the severity of the violations.

(a) Users are subject to civil penalties not to exceed $1,000 for violations that cause or contribute to the exposure of any persons or the environment to radiation levels in

excess of those levels set forth in these rules. Violations which cause or contribute to such exposure are:

1. Failure of registrant to take action in a timely manner to correct unsafe conditions or equipment of which it was aware or should have been aware;

2. Use of untrained, unskilled, or unauthorized operators/users;

3. Lack of, or failure to follow safety procedures;

4. Unauthorized or improper modifications to machines or other radiation sources or equipment containing such sources; and

5. Lack of sufficient radiation shielding to prevent excessive radiation exposure.

   (i) For purposes of computing the penalty, each day of such violation is a separate violation.

(b) Users are subject to civil penalties not to exceed $500 for other violations, to wit violations that do not cause or contribute to excessive exposure.

   1. For purposes of computing the penalty, each day of such violation is a separate violation.

(c) Users that fail to register in accordance with rule .02(1) of this Chapter are subject to civil penalties not to exceed $1000.

   1. For purposes of computing the penalty, each day of such violation is a separate violation.

(d) In proposing the imposition of civil penalties, the Department shall consider such mitigating circumstances as it deems appropriate. These may include factors such as elapsed time of the violation, the registrant's prior compliance history, or voluntary reporting of the violation by the registrant.

(4) Whenever the Department proposes to subject a registrant to the imposition of a civil penalty, it shall notify such registrant in writing:

(a) Setting forth the date, facts, and nature of each act or omission with which the person is charged;

(b) Specifically identifying the particular provision or provisions of the Code section, rule, regulation, order, or registration involved in the violation; and

(c) Advising of each penalty which the Department proposes to impose and its amount.

(d) Such written notice shall be sent by registered or certified mail by the Department to the last known address of such person. The person so notified shall be granted an opportunity to show in writing, within ten days from receipt of such notice, why such penalty should not be imposed. The notice shall also advise such registrant that, upon failure to pay the civil penalty subsequently determined by the Department, if any, the penalty may be collected by civil action.

(e) Upon receipt of a written response from the registrant alleging that a penalty should not be imposed, the Department shall consider the response and make a final decision on the appropriateness and amount of the penalty. The Department may at its discretion conduct an onsite inspection in order to make a final decision. In making this decision, the Department may, as deemed appropriate by the Department, consider such factors as: errors concerning the amount or nature of the penalty, corrective action taken by the registrant, or disposal of machines or equipment by the registrant.

(f) The Department shall inform the registrant of its final decision by registered or certified mail to the last known address of the registrant. Within 10 days of receipt of the Department's final determination concerning the civil penalty, the registrant may request an appeal pursuant to the Georgia Administrative Procedures Act, O.C.G.A. 50-13-1, et seq.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.08
Authority: Ga. L. 1964, pp. 507, 569, and 570; O.C.G.A. § 31-13-15.
History. Original Rule entitled "Penalties" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-90-.09. Enforcement.

(1) The administration and enforcement of these rules shall be as prescribed in Chapter 13 of Title 31 of the Official Code of Georgia Annotated, and Chapter 13 of Title 50 of the Official Code of Georgia Annotated. The Department's action revoking or denying a registration applied for under this Chapter or the imposition of civil penalties imposed pursuant to this Chapter shall be preceded by notice and opportunity for a hearing and shall constitute a contested case within the meaning of Chapter 13 of Title 50 of the Official Code of Georgia Annotated.

(2) The Department may, without regard to the availability of other remedies, including administrative remedies, seek an injunction against the continued operation of an unregistered radiation machine or the continued operation of a radiation machine in violation of this Chapter or of any regulation of the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-90-.09
Authority: O.C.G.A. §§ 31-13-5, 31-13-15.

History. Original Rule entitled "Enforcement" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Subject 111-8-91. RULES AND REGULATIONS FOR LASER RADIATION.

Rule 111-8-91-.01. Definitions.

For the purpose of these rules, the term:

(a) "Department" means the Department of Community Health of the State of Georgia;

(b) "Injury" means any discernible, unintentional damage to tissue (such as eye or skin), resulting from exposure to laser radiation; or untoward biologic effects due to air contamination produced as a result of laser radiation; or electrical shock or burns sustained as a result of operation of a laser;

(c) "Laser radiation" means any electromagnetic radiation emitted from a laser system and includes all reflected radiation and any secondary radiation, or other forms of energy resulting from the primary laser beam;

(d) "Laser System" means any device, machine, apparatus, or other facility, that applies a source of energy to a gas, liquid, crystal, or other solid substances or combination thereof in a manner that electromagnetic radiations of a relatively uniform wave length are amplified and emitted in a coherent beam, including but not limited to electromagnetic waves in the range of visible, infrared or ultraviolet light, capable of transmitting the energy thus generated in a manner that may be harmful to living tissues;

(e) "Person" means the State or any agency or institution thereof, any municipality, political subdivision, public or private corporation, individual, partnership, association, or other entity, and includes any officer or governing or managing body of any municipality, political subdivision or public or private corporation.

Cite as Ga. Comp. R. & Regs. R. 111-8-91-.01
Authority: Ga. L. 1964, p. 499 *et seq*., as amended, O.C.G.A. § 31-13-5.
History. Original Rule entitled "Definitions" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-91-.02. Registration.

(1) No person may possess or operate a laser system without first registering, in writing, with the Department within thirty (30) days after the effective date of these regulations, the laser system, except as provided in paragraph (2) of this rule.

(2) Any person acquiring a laser system after the effective date of these rules and regulations shall register, in writing, with the Department the laser system within thirty (30) days after the date of acquisition.

(3) Any person possessing or operating a registered laser system may be required by the Department to re-register the system at intervals considered necessary by the Department to maintain a current inventory of the laser system.

(4) If any person possessing or operating a laser system considers the registration of each source of laser radiation by type or strength to be impractical, he may apply, in writing, to the Department for blanket registration of the laser system. The Department may approve blanket registration of the laser system after considering the information submitted in the application and determining that registration of each source of laser radiation by type or strength is impractical.

(5) All applications for any registration shall be in writing, on forms provided by the Department. Applications for any registration shall provide the following information:

(a) name and address of person possessing or operating the laser system;

(b) identification and type of the laser system;

(c) location of the laser system;

(d) for continuous-wave lasers, the maximum power level at which the laser can be operated;

(e) for pulse lasers, the maximum energy per pulse, pulse duration, and the maximum pulse repetition rate at which the laser can be operated;

(f) the wavelength at which laser can be operated; and

(g) other pertinent information that may be required by the Department to ascertain the identification, type, location, and operational characteristics of the laser system.

Cite as Ga. Comp. R. & Regs. R. 111-8-91-.02
Authority: Ga. L. 1964, p. 499 *et seq*., as amended, O.C.G.A. § 31-13-5.
History. Original Rule entitled "Registration" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-91-.03. Injury Reporting.

Any person possessing or operating a laser system shall report, in writing, to the Department within fifteen (15) days of detection of any injury to an individual, regardless of severity or extent, in the course of operating, handling, servicing, or manufacturing a laser system.

Information as the Department might require concerning the injury shall be made available to the Department.

Cite as Ga. Comp. R. & Regs. R. 111-8-91-.03
Authority: Ga. L. 1964, p. 499 *et seq*., as amended, O.C.G.A. § 31-13-5.
History. Original Rule entitled "Injury Reporting" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-91-.04. Report of Discontinuance.

Every person who has registered a laser system and who permanently discontinues the operation of, or permanently disposes of, his laser system shall notify the Department, in writing, within thirty (30) days of such action.

Cite as Ga. Comp. R. & Regs. R. 111-8-91-.04
Authority: Ga. L. 1964, p. 499 *et seq*., as amended, O.C.G.A. § 31-13-5.
History. Original Rule entitled "Report of Discontinuance" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-91-.05. Laser System Exempt from Registration.

No person may be required to register a laser system which cannot be energized or which is in transit.

Cite as Ga. Comp. R. & Regs. R. 111-8-91-.05
Authority: Ga. L. 1964, p. 499 *et seq*., as amended, O.C.G.A. § 31-13-5.
History. Original Rule entitled "Laser System Exempt from Registration" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Rule 111-8-91-.06. Enforcement.

The administration and enforcement of these rules and regulations shall be in accordance with Code of Georgia Annotated § 31-13-10.

Cite as Ga. Comp. R. & Regs. R. 111-8-91-.06
Authority: Ga. L. 1964, pp. 499, 518, O.C.G.A. §§ 31-13-10, 31-13-5.
History. Original Rule entitled "Enforcement" adopted. F. Oct. 9, 2020; eff. Oct. 29, 2020.

Subject 111-8-100. RULES AND REGULATIONS FOR PROXY CAREGIVERS USED IN LICENSED HEALTHCARE FACILITIES.

Rule 111-8-100-.01. Legal Authority.

These rules are adopted and published pursuant to the Official Code of Georgia Annotated (OCGA) §§ 31-7-2.1 and 43-26-12.

Cite as Ga. Comp. R. & Regs. R. 111-8-100-.01
Authority: O.C.G.A. §§ 31-7-2.1 and 43-26-12.
History. Original Rule entitled "Legal Authority" adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.

Rule 111-8-100-.02. Title and Purpose.

These rules, known as the Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, set forth the requirements for designated proxy caregivers performing health maintenance activities in connection with certain licensed healthcare facilities subject to regulation by the department.

Cite as Ga. Comp. R. & Regs. R. 111-8-100-.02
Authority: O.C.G.A. §§ 31-2-9, 31-7-2.1 and 43-26-12(a)(9).
History. Original Rule entitled "Title and Purpose" adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.

Rule 111-8-100-.03. Definitions.

In these rules, unless the context otherwise requires, the terms set forth herein shall mean the following:

(a) "Administrative action" means the initiation of a contested case as defined in the Georgia Administrative Procedure Act (APA), O.C.G.A. § 50-13-2(2) against a licensed facility for violation of licensing requirements.

(b) "Client(s)" means a person or persons receiving services through the licensed facility. Clients include such terms as residents, consumers, patients and program participants.

(c) "Competency-based training" means training which is tied to an identified set of skills and knowledge and requires demonstration and documentation of an acceptable level of performance of a task or achievement of an outcome.

(d) "Complex wound care" means the specialized nursing care that is required for certain wounds. Typically, the following kinds of wounds require complex care: wounds in the lower extremity of diabetic patients, pressure ulcers, chronic venous ulcers, wounds following extensive necrotic processes caused by infections (Fournier's and other), and chronic wounds related to vasculitis and immunosuppressive therapy that have not healed using simple care.

(e) "Department" means the Department of Community Health, its agents and employees.

(f) "Health maintenance activities" are limited to those activities that, but for a disability, a person could reasonably be expected to do for himself or herself. Such activities are typically taught by a registered professional nurse, but may be taught by an attending physician, advanced practice registered nurse, physician assistant, or directly to a patient and are part of ongoing care. Health maintenance activities are those activities that do not

include complex care such as administration or intravenous medications, central line maintenance, and complex wound care; do not require complex observations or critical decisions; can be safely performed and have reasonable precise, unchanging directions; and have outcomes or results that are reasonably predictable. Health maintenance activities conducted pursuant to these rules shall not be considered the practice of nursing.

(g) "Individual with a disability" or "disabled individual" means an individual who has a physical or mental impairment that substantially limits one or more major life activities and who meets the criteria for a disability under state or federal law.

(h) "Inspection" means any examination by the department or its representatives of a licensed healthcare facility, including but not necessarily limited to the premises, and staff, persons in care, and documents pertinent to initial and continued licensing so that the department may determine whether a facility is operating in compliance with licensing requirements. The term "inspection" includes any survey, complaint investigation, monitoring visit, or other inquiry conducted for the purpose of making a compliance determination with respect to licensing requirements.

(i) "Legally authorized representative" means the person legally authorized to act on behalf of the individual with a disability with respect to providing consent to medical treatment or procedures not prohibited by law which may be suggested, recommended, prescribed or directed by a duly licensed physician or as otherwise authorized by law. The representative is not authorized to act on behalf of the individual with a disability to provide consent until a medical determination has been made that the individual with a disability lacks decision-making capacity regarding medical treatment or the ability to communicate such decision by any means.

(j) "Licensed healthcare professional" means an individual who is licensed and authorized under Georgia law to perform certain healthcare practices. The term includes physicians, advance practice registered nurses, physician's assistants, registered nurses, pharmacists, physical, speech and occupational therapists who are functioning within their scopes of licensed practice. The term does not include licensed practical nurses, certified nursing assistants or medication aides.

(k) "Licensed healthcare facility" or "licensed facility" means any agency, institution, entity or person subject to regulation by the department under Chapters 7, 13, 22, 23, 44 and Title 31; paragraph (8) of subsection (d) of Code Section 31-2-4; Chapter 5 of Title 26; and Article 7 of Chapter 6 of Title 49 of the Official Code of Georgia Annotated, except hospitals, residential mental health facilities, nursing homes, intermediate care facilities for the mentally retarded, Medicare-certified home health agencies and hospices.

(l) "Licensed residential facility" means a licensed facility which serves as the home, either temporarily or permanently, of an individual with a disability. Such facilities are licensed as assisted living communities, personal care homes, community living arrangements, residential drug abuse treatment programs and traumatic brain injury facilities.

(m) "Proxy caregiver" means an unlicensed person or a licensed health care facility that has been selected by a disabled individual or a person legally authorized to act on behalf of such individual to serve as such individual's proxy caregiver, provided that such person shall receive training and shall demonstrate the necessary knowledge and skills to perform documented health maintenance activities, including identified specialized procedures, for such individual.

(n) "Training" means teaching proxy caregivers the necessary knowledge and skills to perform health maintenance activities for disabled individuals.

(o) "Written plan of care" means the specific set of written instructions which have been determined necessary, usually by a registered professional nurse, to implement the written orders of the attending physician or an advanced practice registered nurse or physician assistant working under a nurse protocol agreement or job description respectively. The written plan of care must specify the frequency of training and evaluation requirements for the proxy caregiver, including additional training when changes in the written plan of care necessitate added duties for which such proxy caregiver has not previously been trained.

Cite as Ga. Comp. R. & Regs. R. 111-8-100-.03
Authority: O.C.G.A. §§ 31-7-2.2, 31-9-2, 43-26-12(a)(9).
History. Original Rule entitled "Definitions" adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.
Amended: F. Apr. 16, 2018; eff. May 6, 2018.

Rule 111-8-100-.04. Use of Proxy Caregivers and Informed Consent.

(1) **Proxy Caregiving Permitted.** Licensed facilities, may allow proxy caregivers to perform health maintenance activities for individuals with disabilities who are being served by or through the licensed facility, as authorized in these rules, provided that the individual with a disability or legally authorized representative has executed a written informed consent.

(2) **Written Informed Consent.** No licensed facility will permit a proxy caregiver to provide health maintenance activities by or through the licensed facility unless the individual with a disability, or the legally authorized representative has executed an informed consent. The written informed consent must contain the following information:

(a) a definition of health maintenance activities as set forth in the law;

(b) the actual health maintenance activities to be performed;

(c) an explanation that such health maintenance activities are to be provided pursuant to the written orders of an attending physician, advance practice registered nurse or physician's assistant working under protocol or job description as further detailed in the written plan of care;

(d) the name(s) of the proxy caregiver(s) who are being authorized to provide health maintenance activities;

(e) a disclosure that Georgia law now allows licensed healthcare professionals to train unlicensed proxy caregivers to provide the specific health maintenance activities listed on the written plan of care;

(f) an acknowledgement that proxy caregivers are not licensed healthcare professionals and do not have the same education and training as licensed healthcare professionals. Therefore, there may be additional health risks associated with receiving this care from proxy caregivers who may not recognize an important change in the individual's medical condition requiring assessment and/or treatment;

(g) an acknowledgment that the individual with a disability, or the legally authorized representative consents and is willing to take such risks;

(h) that the informed consent is conditioned upon the proxy caregiver(s) being determined by an appropriately qualified licensed healthcare professional to have the knowledge and skills necessary to perform safely the specific health maintenance activities listed on the consent;

(i) a statement that the informed consent for any proxy caregiver designated to deliver health maintenance activities may be withdrawn orally or in writing by the individual with a disability or the legally authorized representative by informing the proxy caregiver and any licensed facility through which the proxy caregiver may be operating; and

(j) an authorization for such health maintenance activities to be provided which is signed and dated by the individual with a disability or the legally authorized representative.

(3) **Proxy Caregivers Functioning Independently in Licensed Residential Facilities.** Where the licensed residential facility permits the individual with a disability or the legally authorized representative to hire a proxy caregiver directly to perform tasks that are appropriately classified as health maintenance activities, the licensed residential facility must do the following:

(a) Develop and enforce written policies and procedures which do not conflict with the requirements of the law and these rules, and which outline the following:

1. The scope of the health maintenance activities that proxy caregivers are permitted to perform;

2. The notification procedures that will be utilized when either the proxy caregiver observes a change in the condition of the individual with a

disability which may require evaluation/treatment by a licensed healthcare professional, or there is a change in the care being provided through the licensed residential facility that might impact the performance of health maintenance activities; and

3. The safety and security precautions that will be employed in the licensed residential facility to protect clients being served from harm by proxy caregivers who are independent and not under the control of the facility.

(b) Maintain a copy of the written informed consent which meets the requirements of rule 111-8-100-.04(2) and appears to be properly executed by the individual with a disability or the legally authorized representative

(c) Maintain a copy of the written plan of care for the individual with a dis ability which has been developed by a licensed healthcare professional pursuant to written orders of an attending physician, or an advanced practice registered nurse or physician assistant working under a nurse protocol agreement or job description respectively.

(d) Determine that the written plan of care provided specifies the health maintenance activities to be performed, the frequency of training and evaluation for the proxy caregiver and the kinds of changes in the written plan of care that would necessitate additional training for the proxy caregiver.

(e) Maintain current documentation signed by a licensed healthcare professional which reflects that the proxy caregiver has been determined to have the knowledge and skills necessary to perform safely the required health maintenance activities for the individual client.

(f) Verify that there is a back-up proxy caregiver service plan which has been put in place for the individual with a disability which addresses at a minimum the following:

1. The notification procedures and contact information that will be utilized when the proxy caregiver and/or licensed facility staff observe a change in the condition of the individual with a disability which may require evaluation/treatment by a licensed healthcare professional;

2. The alternative resources to be used to provide needed health maintenance activities in the event that the proxy caregiver is not available for any reason; and

3. The notification procedures and contact information that will be utilized if staff members of the licensed facility become aware of a potentially unsafe situation involving the client and the proxy caregiver.

(g) Ensure that the proxy caregiver is familiar with emergency evacuation procedures.

(4) **Licensed Facilities Delivering Services Through Proxy Caregivers.** Where the licensed facility employs, contracts or refers proxy caregivers to deliver health maintenance activities to individuals with disabilities receiving services through the licensed facility, the licensed facility must do the following:

(a) Develop and enforce written policies and procedures, which do not conflict with the requirements of the law and these rules and which outline the following:

1. The scope of the health maintenance activities that proxy caregivers are permitted to perform;

2. The notification procedures that will be utilized when the proxy caregiver observes a change in the condition of the individual with a disability which may require evaluation/treatment by a licensed healthcare professional; and

3. The safety and security precautions that will be employed by the licensed facility to protect clients being served by the licensed facility from harm by proxy caregivers.

(b) Disclose to individuals with disabilities who are potential clients of the licensed facility or the legally authorized representative the following:

1. The manner in which proxy caregivers are used to deliver health maintenance activities and the general professional qualifications of the staff providing supervision to the proxy caregivers;

2. Whether there are additional charges for such proxy caregivers and the amount that would be charged;

3. The manner in which the licensed facility ensures that clients are permitted to designate and change proxy caregivers;

4. The qualifications of the licensed healthcare professionals who develop written plans of care for the clients and provide training; and

5. The frequency of competency-based skills determinations and the extent of trainings provided to proxy caregivers.

(c) Ensure that the individual with a disability or the legally authorized representative has executed a written informed consent which meets the requirements of rule 111-8-100-.04(2).

(d) Ensure that a written plan of care is developed for the individual with a disability by a licensed healthcare professional in accordance with the written orders of an

attending physician, an advanced practice registered nurse or physician's assistant working under a nurse protocol agreement or job description respectively, and that such plan of care specifies the frequency of training and evaluation requirements for the proxy caregiver and when additional training will be required for new duties added to the written plan of care for which the proxy caregiver has not been previously trained. The licensed facility must either use the written plan of care form made available by the Department or another form containing all the required elements.

(e) Ensure that the written plan of care is implemented by appropriately trained proxy caregivers who have been specifically designated by the individual with a disability or the legally authorized representative.

(f) Maintain documentation of the specific training that was provided on the health maintenance activities that the proxy caregiver performs. The documentation must include a competency-based skills checklist completed by the licensed healthcare professional. The checklist must reflect that the proxy caregiver has personally demonstrated to the satisfaction of the licensed healthcare professional the necessary knowledge and skills to perform safely the specific health maintenance activities. There must be a separate skills checklist for each health maintenance activity that the proxy caregiver provides. For the medication administration training, the facility must use the curriculum established by DCH and any associated checklist.

(g) Maintain supporting documentation reflecting that the employee or contractor serving as the proxy caregiver has the basic qualifications as represented, e.g. no findings of abuse, neglect or exploitation entered against the individual in the nurse aide registry, a satisfactory report of motor vehicle driving record where the proxy caregiver may be transporting clients and a satisfactory criminal records check where required by other rules applicable to the specific licensed facility.

(h) Maintain written evidence of satisfactory performances on initial and annual skills competency determinations utilizing skills competency checklists which have either been made available by the department or developed and completed by appropriately licensed healthcare professionals. The competency-based skills checklists must reflect a testing of the knowledge and observation of the skills associated with the completion of all of the discrete tasks necessary to do the specific health maintenance activity in accordance with accepted standards of care.

Cite as Ga. Comp. R. & Regs. R. 111-8-100-.04
Authority: O.C.G.A. §§ 31-7-2.2, 31-9-2, 43-26-12(a)(9).
History. Original Rule entitled "Use of Proxy Caregivers and Informed Consent" adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.
Amended: F. Apr. 16, 2018; eff. May 6, 2018.

Rule 111-8-100-.05. Training and Other Requirements for Proxy Caregivers.

(1) **Training Curricula.** A licensed facility utilizing proxy caregivers must employ a written training curricula developed by appropriately licensed healthcare professionals which ensures that the proxy caregiver accurately demonstrates how to do the required health maintenance activities correctly and safely. At a minimum, the training curricula used for proxy caregivers must include the following:

(a) Learning objectives which relate specifically to the health maintenance activities to be performed;

(b) Content knowledge and skills that are required to accomplish the learning objectives;

(c) Learning activities that will be utilized to provide instruction on knowledge and skills required;

(d) The results of the Test of Functional Health Literacy (TOFHLA) used as an assessment tool to individualize necessary training for the specific skills if the caregiver does not have a high school diploma or a general equivalency degree (G.E.D.);

(e) Satisfactory and independent completion of the required skills competency checklists relating to the specific health maintenance activities to be performed before an appropriately licensed healthcare professional;

(f) The use of skills competency checklist forms when made available by the department for the specific health maintenance activities to be performed or other skills checklist forms that include all of the competencies in the correct order as contained on the forms made available by the department and as required for the specific client; and

(g) Satisfactory evidence of routine evaluations of continued skills competencies by an appropriately licensed healthcare professional, at least annually if not assessed more frequently as specified on the written plan of care.

(2) **Licensed Facilities Providing Medication Administration.** A licensed facility may use proxy caregivers to administer medications to an individual with a disability unless the use of proxy caregivers is subsequently prohibited or modified by regulations applicable to a specific type of licensed facility adopted after the effective date of these rules. In the absence of more specific requirements, the licensed facility using proxy caregivers for medication administration must meet the following conditions:

(a) The individual with a disability or the legally authorized representative has provided a written informed consent which meets the requirement of these rules;

(b) The medications and administration being provided have been determined by an appropriately licensed healthcare professional to be health maintenance activities that may be safely performed by properly trained proxy caregivers; and

(c) The proxy caregiver has been trained in accordance with these rules and determined through completion of a skills competency checklist before an appropriately licensed healthcare professional to have the knowledge and skills necessary to perform the specific health maintenance activities in accordance with the written plan of care.

(3) **Medication Administration Curriculum.** Licensed facilities that employ or contract with proxy caregivers to provide medication administration must maintain documentation reflecting that the facility has trained these proxy caregivers in accordance with the medication administration training curriculum established by DCH.

(4) The training on medication administration must be provided by an appropriately licensed healthcare professional, e.g. registered professional nurse, advance practice registered nurse, physician's assistant, pharmacist or physician and must be individualized and supplemented as appropriate to meet the unique needs of the individual with a disability being served.

(5) Where a new medication is ordered, a licensed healthcare professional must be contacted to ensure that no additional training is required prior to the caregiver providing assistance with the new medication. The date, time and the outcome of the contact with the licensed healthcare professional must be documented in the individual's record. Where additional training is required prior to the caregiver providing assistance, such training will be provided and documented by a licensed healthcare professional.

(6) Proxy caregivers providing medication assistance must be proficient in reading and following detailed written instructions in English, recording understandable written entries in the client's records, communicating effectively with the client and have achieved at least a minimum score of 75 on the Test of Functional Health Literacy for Adults (TOFHLA).

(7) **Prohibited Assistance.** The licensed facility providing medication management services must not train or permit proxy caregivers to provide the following assistance with medications:

(a) Mixing, compounding, converting, or calculating medication doses, except for measuring a prescribed amount of liquid medication, breaking a scored tablet, crushing a tablet or adding water or other liquid to laxatives and nutritional supplements when such substance preparations are being done in accordance with a specific written prescription;

(b) Preparing syringes for intravenous injection or the administration of medications intravenously;

(c) Administering any intravenous medications and the first dose of any subcutaneous or intramuscular injection;

(d) Interpreting a "PRN" (as needed) medication order when the order does not identify the resident behaviors or symptoms which would trigger the need for the medication and/or does not identify the appropriate dosing and is not specifically authorized on the written plan of care;

(e) Irrigating or debriding agents used in the treatment of skin conditions;

(f) Assisting in the administration of sample or over the counter medications where there is no written doctor's order providing amount and dosing instructions; and

(g) Assisting in the administration of any medication to a client without appropriate evidence of a written order signed by an appropriately licensed healthcare professional; and

(h) Performing any health maintenance activities where the licensed health care professional has determined that either the care required no longer meets the definition of health maintenance activities or the proxy caregiver has not demonstrated the knowledge and skill necessary to perform the health maintenance activities safely.

(8) **Maintaining Records on Medication Administration.** Where the licensed facility manages medications for an individual with a disability, the licensed facility must maintain a daily Medication Assistance Record (MAR) for each person who receives assistance. At a minimum, the MAR must include the name of the specific person receiving assistance, any known allergies, the name and telephone number of the individual's health care provider, the name, strength and specific directions for the medications being managed, and a chart for staff who provide assistance to record initials, time and date when medications are taken, refused or a medication error is identified (e.g. missed dosage). The staff providing the assistance must immediately update the MAR for each individual each time the medication is offered or taken.

(a) The licensed facility must make medication information concerning the descriptions of medication, dosing, side effects, adverse reactions and contraindications for each medication being administered to the individual with a disability immediately available for reference by proxy caregivers providing medication assistance. The licensed facility must utilize a properly indexed medication information notebook or folder which contains information about only the medications for which the caregivers are providing assistance.

(b) Proxy caregivers provided by the licensed facility who provide assistance with medications must document in the client's record any unusual reactions to the medications and provide such information to the individual with a disability, legally authorized representative, if any, and healthcare provider as appropriate.

(9) **Competency Evaluations for Specialized Health Maintenance Activities.** Where the health maintenance activity to be performed has multiple discrete tasks that must be performed in proper sequence to deliver safe care, the licensed healthcare professional must ensure that the skills competency checklist properly sequences all necessary tasks. The licensed healthcare professional must verify by direct observations and sign documentation that the proxy caregiver can complete all tasks required satisfactorily in proper sequence from memory without prompting or assistance of any kind. Competency to perform specialized health maintenance activities must be reevaluated whenever the health maintenance activities change, and on a regularly recurring schedule as determined appropriate by the licensed healthcare professional on the written plan of care. The schedule for such re-evaluations must take into consideration the nature of the health maintenance activities to be performed and the condition of the client. At a minimum, such reevaluations by the licensed healthcare professional must occur no less frequently than annually.

Cite as Ga. Comp. R. & Regs. R. 111-8-100-.05
Authority: O.C.G.A. §§ 31-7-2.2, 43-26-12(a)(9).
History. Original Rule entitled "Training and Other Requirements for Proxy Caregivers" adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.
Amended: F. Apr. 16, 2018; eff. May 6, 2018.

Rule 111-8-100-.06. Variances and Waivers.

(1) The Department may, in its discretion, grant variances and waivers of specific rules upon application or petition filed on forms provided by the Department. The Department may establish conditions which must be met by the licensed facility in order to operate under the variance or waiver granted.

(a) **Variance.** A variance may be granted by the Department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety, and care of the individuals with disabilities exist and will be met in lieu of the exact requirements of the rule or regulations in question.

(b) **Waiver.** The Department may dispense entirely with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, care, and rights of the individuals being served; and

(c) **Experimental Variance or Waiver.** The Department may grant variances and waivers to allow experimentation and demonstration of new and innovative approaches to delivery of services upon a showing by the applicant or petitioner

that the intended protections afforded by the rule or regulation which is the subject of the request are met and that the innovative approach has the potential to improve service delivery without compromising health, safety, individuals' rights, or other relevant standards.

(2) The decision of the Department regarding either granting or denying the application of the governing body of the licensed facility for a waiver or variance is not subject to further administrative review. The governing body may file a petition for judicial review in the appropriate superior court.

(3) Where the Department has denied the application for a waiver or variance in writing, the Department will not consider a subsequent application for the same waiver or variance as a new application unless the applicant includes new evidence of a substantial change in the circumstances which formed the basis for the initial request.

Cite as Ga. Comp. R. & Regs. R. 111-8-100-.06
Authority: O.C.G.A. §§ 31-2-9, 31-7-2.1, 31-7-12, 50-13-9.1 and 50-13-19.
History. Original Rule entitled "Variance and Waivers" adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.

Rule 111-8-100-.07. Enforcement.

A licensed facility which permits proxy caregivers to deliver health maintenance activities is subject to inspection by the Department to determine compliance with the requirements contained in the Rules and Regulations for Proxy Caregivers Used in Licensed Healthcare Facilities, Chapter 111-8-100 or other licensure regulations applicable to the specific licensed facility. A licensed facility which is determined not to be in compliance with these rules or other rules applicable to the licensed facility, is subject to civil and administrative actions brought by the Department to enforce licensing requirements as provided by law and rules. Such actions will be initiated in compliance with the Georgia Administrative Procedures Act, O.C.G.A. § 50-13-1*et seq.*, O.C.G.A. § 31-2-11 and the Rules and Regulations for General Licensing and Enforcement Requirements, Chapter 111-8-25.

Cite as Ga. Comp. R. & Regs. R. 111-8-100-.07
Authority: O.C.G.A. §§ 31-7-2.1 and 31-7-2.2 and 50-13-1*et seq.*
History. Original Rule entitled "Enforcement of Licensing Requirements" adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.

Rule 111-8-100-.08. Severability.

In the event that any rule, sentence, clause or phrase of any of the rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions thereof shall remain in full

force and effect as if such rule or portions thereof so determined, declared or adjudicated invalid or unconstitutional were not originally part of these rules.

Cite as Ga. Comp. R. & Regs. R. 111-8-100-.08
Authority: O.C.G.A. § 31-7-2.1.
History. Original Rule entitled "Severability" adopted. F. Jul. 18, 2011; eff. Aug. 7, 2011.

Chapter 111-9. PUBLIC HEALTH.

Subject 111-9-1. REPEALED.

Rule 111-9-1-.01. Legal Authority.

Cite as Ga. Comp. R. & Regs. R. 111-9-1-.01
Authority: 42 U.S.C. Sec. 1786, 7 C.F.R. Sec. 246.1, O.C.G.A. Sec. 50-13-1 et al.
History. Original Rule entitled "Legal Authority" adopted. F. Apr. 14, 2010; eff. May 4, 2010.
Repealed: F. Jan. 4, 2012; eff. Jan. 24, 2012.

Rule 111-9-1-.02. Title and Purpose.

Cite as Ga. Comp. R. & Regs. R. 111-9-1-.02
Authority: 42 U.S.C. Sec. 1786, 7 C.F.R. Secs. 246.2, 246.3.
History. Original Rule entitled "Title and Purpose" adopted. F. Apr. 14, 2010; eff. May 4, 2010.
Repealed: F. Jan. 4, 2012; eff. Jan. 24, 2012.

Rule 111-9-1-.03. Definitions.

Cite as Ga. Comp. R. & Regs. R. 111-9-1-.03
Authority: 42 U.S.C. Sec. 1786, 7 C.F.R. Sec. 246.2.
History. Original Rule entitled "Definitions" adopted. F. Apr. 14, 2010; eff. May 4, 2010.
Repealed: F. Jan. 4, 2012; eff. Jan. 24, 2012.

Rule 111-9-1-.04. Purpose and Administration.

Cite as Ga. Comp. R. & Regs. R. 111-9-1-.04
Authority: 42 U.S.C. Sec. 1786, 7 C.F.R. Secs. 246.1, 246.3.
History. Original Rule entitled "Purpose and Administration" adopted. F. Apr. 14, 2010; eff. May 4, 2010.
Repealed: F. Jan. 4, 2012; eff. Jan. 24, 2012.

Rule 111-9-1-.05. Vendor Terms and Conditions.

Cite as Ga. Comp. R. & Regs. R. 111-9-1-.05
Authority: 42 U.S.C. Sec. 1786, 7 C.F.R. Secs. 246.4, 246.12.

History. Original Rule entitled "Vendor Terms and Conditions" adopted. F. Apr. 14, 2010; eff. May 4, 2010.
Repealed: F. Jan. 4, 2012; eff. Jan. 24, 2012.

Rule 111-9-1-.06. Vendor Administrative Review, Hearings and Appeals.

Cite as Ga. Comp. R. & Regs. R. 111-9-1-.06
Authority: O.C.G.A. Secs. 50-13-1 et al., 42 U.S.C. Sec. 1786, 7 C.F.R. Sec. 246.18.
History. Original Rule entitled "Vendor Administrative Review, Hearings and Appeals" adopted. F. Apr. 14, 2010; eff. May 4, 2010.
Repealed: F. Jan. 4, 2012; eff. Jan. 24, 2012.