Rules and Regulations of the State of Georgia

Department 480 RULES OF GEORGIA STATE BOARD OF PHARMACY

Current through Rules and Regulations filed through November 30, 2021

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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 day 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.

Chapters 480-1 entitled "Organization", 480-2 entitled "Reciprocity", 480-3 entitled "Examination Requirements", 480-4 entitled "License Requirements", 480-5 entitled "Hospital Inspections", 480-6 entitled "Penalties", 480-7 entitled "Duties of Chief Drug Inspector" have been adopted. Filed and effective June 30, 1965.

Rule 480-7-.02 has been adopted. Filed September 9, 1966; effective September 28, 1966.

Chapter 480-8 entitled "Dangerous Drugs - Defined" has been adopted. Filed September 22, 1967; effective October 11, 1967.

Chapters 480-1 to 480-8 have been repealed and new Chapters adopted. Chapters 480-9 entitled "Depressant or Stimulant or Potential for Abuse Drugs, Defined", 480-10 entitled "Pharmacy Regulations", 480-11 entitled "Code of Professional Conduct", 480-12 entitled "Manufacturer's Requirements", 480-13 entitled "Hospitals, Nursing Homes, Extended Care Facilities", 480-14 entitled "Drug Inspectors, Classifications, Qualifications", 480-15 entitled "Penalties", 480-16 entitled "Duties of Chief Drug Inspector" have been adopted. Filed October 6, 1970; effective October 26, 1970.

Emergency Rule 480-17-0.1, entitled "Narcotic Drugs-Defined," containing Rule 480-17-0.1-.01, was filed and effective on July 2, 1971 to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule, as specified by the Agency.

Chapter 480-17, entitled "Narcotic Drugs-Defined," containing Rule 480-17-.01, has been adopted superseding Emergency Rule 480-17-0.1-.01. Filed October 5, 1971; effective October 25, 1971.

Rule 480-8-.01 has been amended by the adoption of subparagraph (d). Filed October 20, 1971; effective November 9, 1971.

Rule 480-13-.02 has been adopted. Filed February 4, 1972; effective February 24, 1972.

Subparagraph (1)(d) of Rule 480-3-.01 has been amended; subparagraph (1)(e) of said Rule has been repealed and subparagraphs (1)(f)(g)(h) and (i) renumbered as (1)(e)(f)(g) and (h). Filed February 20, 1973; effective March 12, 1973.

Rule 480-4-.02 has been repealed and a new Rule 480-4-.02 adopted. Filed February 20, 1973; effective March 12, 1973.

Emergency Rule 480-9-0.2-.01(c) 4. has been adopted. Filed and effective on September 6, 1973, to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule, as specified by the Agency.

Emergency Rule 480-9-0.2-.01(c) 4. has been repealed. Filed November 9, 1973; effective November 29, 1973.

Chapter 480-9 has been repealed and a new Chapter 480-9, of the same title, containing Rule 480-9-.01, adopted. Filed November 9, 1973; effective November 29, 1973.

Rule 480-2-.01 has been amended by the repeal of paragraphs (3), (4), (5), and (6) and by the adoption of new paragraphs (3), (4), (5), (6), (7), and (8). Filed August 2, 1974; effective August 22, 1974.

Rule 480-3-.01 has been amended by the repeal of subparagraph (1)(b). Filed August 2, 1974; effective August 22, 1974.

Rule 480-4-.02 has been amended by the adoption of paragraph (5). Filed August 2, 1974; effective August 22, 1974.

Rule 480-6-.01 has been amended by the repeal of paragraph (4) and by the adoption of a new paragraph (4). Filed August 2, 1974; effective August 22, 1974.

Rule 480-7-.01 has been amended by the repeal of paragraph (5) and by the adoption of a new paragraph (5). Filed August 2, 1974; effective August 22, 1974.

Rule 480-7-.02 has been amended by the repeal of paragraph (6) and by the adoption of a new paragraph (6). Filed August 2, 1974; effective August 22, 1974.

Rule 480-14-.01 has been repealed and a new Rule 480-14-.01 adopted. Filed August 2, 1974; effective August 22, 1974.

Rule 480-15-.01 has been repealed and a new Rule 480-15-.01 adopted. Filed August 2, 1974; effective August 22, 1974.

Emergency Rule 480-18-0.3, entitled "Certain Patent Medicines 'O. T. C.' Items, and Other Chemical Preparations Exempted from Georgia Controlled Substances Act," containing Rules

480-18-0.3-.01, 480-18-0.3-.02, and 480-18-0.3-.03, was filed and effective on October 1, 1974, to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding said Emergency Rule, as specified by the Agency.

Emergency Rule 480-19-0.4, entitled "Schedule V Exemptions and Record-Keeping Under Georgia Controlled Substances Act," containing Rule 480-19-0.4-.01, was filed and effective on October 1, 1974, to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule, as specified by the Agency.

Emergency Rule 480-20-0.5, entitled "Registration Requirements Under Georgia Controlled Substances Act," containing Rule 480-20-0.5-.01, was filed and effective on October 1, 1974, to remain in effect for a period of 120 days or until a permanent Rule is adopted covering the same subject matter superseding said Emergency Rule, as specified by the Agency.

Emergency Rule 480-21-0.6, entitled "Fertile Seed of Marijuana, Cannabis or Cannabis Sativa L," containing Rule 480-21-0.6-.01, was filed and effective on October 10, 1974, to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule, as specified by the Agency.

Rule 480-10-.01 has been repealed and a new Rule 480-10-.01 adopted. Filed November 13, 1974; effective December 3, 1974.

Chapter 480-18, entitled "Certain Patent Medicines 'O.T.C.' Items and Other Chemical Preparations Exempted from Georgia Controlled Substances Act," containing Rules 480-18-.01 through 480-18-.03, has been adopted superseding Emergency Rule 480-18-0.3. Filed November 13, 1974; effective December 3, 1974.

Chapter 480-19, entitled "Schedule V Exemptions and Record-Keeping Under Georgia Controlled Substances Act," containing Rule 480-19-.01, has been adopted superseding Emergency Rule 480-19-0.4. Filed November 13, 1974; effective December 3, 1974.

Chapter 480-20, entitled "Registration of Manufacturers, Wholesalers, and Distributors," containing Rule 480-20-.01, has been adopted superseding Emergency Rule 480-20-0.5. Filed November 13, 1974; effective December 3, 1974.

Chapter 480-21, entitled "Fertile Seed of Marijuana, Cannabis or Cannabis sativa L," containing Rule 480-21-.01, has been adopted superseding Emergency Rule 480-21-0.6. Filed November 13, 1974; effective December 3, 1974.

Rule 480-16-.01 has been amended by the repeal of paragraph (5) and by the adoption of new paragraphs (5) and (6). Filed March 20, 1975; effective April 9, 1975.

Chapter 480-22, entitled "Requirements of a Prescription Under Georgia Controlled Substances Act," containing Rule 480-22-.01, has been adopted. Filed March 20, 1975; effective April 9, 1975.

Rule 480-8-.01 has been amended by the repeal of subparagraph (c) and by the adoption of a new subparagraph (c). Filed September 3, 1975; effective September 23, 1975.

Rule 480-18-.02 has been repealed and a new Rule 480-18-.02 adopted. Filed September 3, 1975; effective September 23, 1975.

Rule 480-3-.02 has been adopted. Filed May 3, 1976; effective May 23, 1976.

Rule 480-3-.02 has been amended. Filed August 24, 1976; effective September 13, 1976.

Rule 480-4-.05 has been adopted. Filed August 24, 1976; effective September 13, 1976. Subparagraph (e) of Rule 480-14-.01 has been amended. Filed August 24, 1976; effective September 13, 1976.

Rule 480-20-.02 has been adopted. Filed August 24, 1976; effective September 13, 1976.

Chapter 480-23, entitled "Procedural Rules," containing Rule 480-23-.01, has been adopted. Filed August 24, 1976; effective September 13, 1976.

Paragraph (3) of Rule 480-10-.02 has been amended. Filed October 6, 1976; effective October 26, 1976.

Chapter 480-13 has been repealed and a new Chapter 480-13, entitled "Hospitals, Nursing Homes, Long Term Care Facilities, Pharmaceutical Services," containing Rules 480-13-.01 through 480-13-.10, adopted. Filed January 24, 1977; effective February 13, 1977.

Paragraph (4) of Rule 480-2-.01 has been amended. Filed March 3, 1977; effective March 23, 1977.

Subparagraph (1)(a) of Rule 480-6-.01 has been amended. Filed March 3, 1971; effective March 23, 1977.

Paragraphs (1) and (5) of Rule 480-7-.01 have been amended. Filed March 3, 1977; effective March 23, 1977.

Paragraphs (1) and (6) of Rule 480-7-.02 have been amended. Filed March 3, 1977; effective March 23, 1977.

Rule 480-11-.01 has been amended by the repeal of subparagraph (c) and by the adoption of a new subparagraph (c). Filed March 3, 1977; effective March 23, 1977.

Rule 480-3-.01 has been amended by the repeal of subparagraphs (g) and (h) and by the adoption of new subparagraphs (g) and (h). Filed December 14, 1977; effective January 3, 1978.

Rule 480-2-.01 has been amended by the adoption of paragraph (9). Filed March 17, 1978; effective April 6, 1978.

Rule 480-4-.05 has been repealed and a new Rule 480-4-.05 adopted. Filed July 28, 1978; effective August 17, 1978.

Rule 480-3-.02 has been repealed and a new Rule 480-3-.02 adopted. Filed March 19, 1980; effective April 8, 1980.

Chapter 480-13 has been repealed and a new Chapter 480-13, entitled "Hospitals," containing Rules 480-13-.01 through 480-13-.10, adopted. Filed May 5, 1980; effective May 25, 1980.

Chapter 480-24, entitled "Nursing Homes, Long Term Care Facilities," containing Rules 480-24-.01 through 480-24-.06, has been adopted. Filed May 5, 1980; effective May 25, 1980.

Emergency Rule 480-25-0.6, entitled "Dangerous Drugs," containing Rule 480-25-0.6-.01, was filed on June 17, 1980, effective June 12, 1980, the date of adoption, to remain in effect for a period of 120 days or until the effective date of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Emergency Rule 480-25-.0.6 has been repealed and Emergency Rule 480-25-0.7, of the same title, adopted. Filed September 25, 1980; effective September 22, 1980, the date of adoption, to remain in effect for a period of 120 days or until the effective date of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Chapter 480-25, entitled "Dangerous Drugs," containing Rule 480-25-.01, has been adopted. Filed December 30, 1980; effective January 19, 1981.

Rule 480-3-.02 has been repealed and a new Rule 480-3-.02 adopted. Filed April 24, 1981; effective May 14, 1981.

Rule 480-3-.01 has been amended by the repeal of subparagraph (a) and by the adoption of a new subparagraph (a). Filed July 23, 1981; effective August 12, 1981.

Rule 480-24-.04 has been amended by the repeal of paragraph (4) and by the adoption of a new paragraph (4). Filed February 15, 1982; effective March 7, 1982.

Rule 480-4-.04 has been amended by the repeal of paragraph (1) and by the adoption of a new paragraph (1). Filed March 26, 1982; effective April 15, 1982.

Rule 480-4-.05 has been repealed and a new Rule 480-4-.05 adopted. Filed March 26, 1982; effective April 15, 1982.

Rule 480-6-.01 has been amended by the repeal of subparagraph (1)(a) and paragraph (4) and by the adoption of a new subparagraph (1)(a) and a new paragraph (4). Filed March 26, 1982; effective April 15, 1982.

Rule 480-7-.01 has been amended by the repeal of paragraphs (1) and (5) and by the adoption of new paragraphs (1) and (5). Filed March 26, 1982; effective April 15, 1992.

Rule 480-7-.02 has been amended by the repeal of paragraphs (1) and (6) and by the adoption of new paragraphs (1) and (6). Filed March 26, 1982; effective April 15, 1982.

Rule 480-24-.04 has been amended by the repeal of subparagraph (2)(e) and by the adoption of a new subparagraph (2)(e). Filed March 26, 1982; effective April 15, 1982.

Chapter 480-26, entitled "Fees," containing Rule 480-26-.01, has been adopted. Filed March 26, 1982; effective April 15, 1982.

Rule 480-3-.01 has been amended by the repeal of subparagraph (a) and by the adoption of a new subparagraph (a). Filed August 27, 1982; effective September 16, 1982.

Rule 480-4-.06 has been adopted. Filed August 27, 1982; effective September 16, 1982.

Rule 480-24-.06 has been repealed and a new Rule 480-24-.06 adopted. Filed February 15, 1983; effective March 7, 1983.

Rule 480-10-.13 has been adopted. Filed August 2, 1983; effective August 22, 1983.

Chapter 480-1 has been repealed and a new Chapter 480-1 adopted. Filed October 18, 1983; effective November 7, 1983.

Rule 480-2-.01 has been amended by the repeal of paragraph (9). Filed October 18, 1983; effective November 7, 1983.

Rule 480-3-.01 has been repealed and a new Rule 480-3-.01 adopted. Filed October 18, 1983; effective November 7, 1983.

Rule 480-4-.02 has been amended by the repeal of paragraphs (1) and (4) and by the adoption of new paragraphs (1) and (4). Filed October 18, 1983; effective November 7, 1983.

Rule 480-6-.01 has been amended by: the repeal of subparagraphs (1)(b) and (1)(c) and paragraph (2) and by the adoption of a new subparagraph (1)(b) and a new paragraph (2); and, by renumbering subparagraph (1)(d) as (1)(c). Filed October 18, 1983; effective November 7, 1983.

Rule 480-7-.01 has been amended by the repeal of paragraph (2) and by the adoption of a new paragraph (2). Filed October 18, 1983; effective November 7, 1983.

Rule 480-7-.02 has been amended by: the repeal of paragraphs (2) and (3) and by the adoption of a new paragraph (2); and by renumbering paragraphs (4), (5), and (6) as (3), (4) and (5), respectively. Filed October 18, 1983; effective November 7, 1983.

Rule 480-3-.01 has been amended by the repeal of subparagraph (g) and by the adoption of a new subparagraph (g). Filed October 31, 1983; effective November 20, 1983.

Rule 480-4-.02 has been amended by the repeal of paragraphs (3) and (4) and by the adoption of new paragraphs (3) and (4). Filed December 13, 1983; effective January 2, 1984.

Rule 480-3-.01 has been amended by the repeal of subparagraph (a) and by the adoption of a new subparagraph (a). Filed March 9, 1984; effective March 29, 1984.

Chapters 480-8 and 480-21 have been repealed. Filed March 9, 1984; effective March 29, 1984.

Chapter 480-25 has been repealed and a new Chapter 480-25 entitled "Nuclear Pharmacies and Pharmacists," containing Rules 480-25-.01 through 480-25-.13 adopted. Filed March 9, 1984; effective March 29, 1984.

Rule 480-24-.04 has been amended by the repeal of subparagraph (7)(c) and by the adoption of a new subparagraph (7)(c). Filed August 7, 1984; effective August 27, 1984.

Chapter 480-14 has been repealed and a new Chapter entitled "Drugs and Narcotics Agents, Classifications, Qualifications," containing Rule 480-14-.01, adopted. Filed September 21, 1984; effective October 11, 1984.

Chapter 480-16 has been repealed and a new Chapter entitled "Additional Responsibilities of Drugs and Narcotics Agency," containing Rule 480-16-.01, adopted. Filed September 21, 1984; effective October 11, 1984.

Rule 480-11-.01 has been amended by the repeal of subparagraph (f) and by the adoption of a new subparagraph (f). Filed April 17, 1985; effective May 7, 1985.

Chapter 480-26 has been repealed and a new Chapter 480-26 of the same title, containing Rule 480-26-.01, adopted. Filed June 17, 1985; effective July 7, 1985.

Chapter 480-21, entitled "Home Health Care Pharmacies," containing Rules 480-21-.01 through 480-21-.08, was filed on August 30, 1985; effective September 19, 1985.

Paragraph 480-2-.01 has been repealed and a new paragraph 4802-01(4) adopted. Filed September 20, 1985; effective October 10, 1985.

Chapter 480-8, entitled "Prison Clinic Pharmacies," containing Rules 480-8-.01 through 480-8-.09, has been adopted. Filed December 27, 1985; effective January 16, 1986.

Rule 480-25-.03 has been amended by the repeal of subparagraph (2)(b)3.(ii) and by the adoption of a new subparagraph (2)(b)3.(ii). Filed January 13, 1986; effective February 2, 1986.

Rule 480-25-.04 has been amended by the repeal of paragraph (2) and by the adoption of a new paragraph (2). Filed January 13, 1986; effective February 2, 1986.

Rule 480-25-.10 has been amended by the adoption of subparagraph (d). Filed January 13, 1986; effective February 2, 1986.

Rule 480-26-.01 has been amended by the adoption of subparagraphs (a)6., (b)5. and (b)6.; and, by the repeal of subparagraph (c) and by the adoption of a new subparagraph (c). Filed January 13, 1986; effective February 2, 1986.

Rule 480-3-.01 has. been amended by the repeal of subparagraphs (d) through (h) and by the adoption of subparagraphs (d) through (g). Filed February 21, 1986; effective March 13, 1986.

Rule 480-3-.02 has been repealed. Filed February 21, 1986; effective March 13, 1986.

Rule 480-3-.01 has been amended by the repeal of subparagraph (e) and by the adoption of a new subparagraph (e). Filed August 11, 1986; effective August 31, 1986.

Rule 480-26-.01 has been amended by the repeal of subparagraphs (b)3. and 4. and by the adoption of new subparagraphs (b)3. and 4.; said Rule has also been amended by the adoption of subparagraphs (c)8. through (c)12. Filed September 4, 1986; effective September 24, 1986.

Rule 480-4-.06 has been repealed and a new Rule adopted. Filed October 30, 1986; effective November 19, 1986.

Chapter 480-27, entitled "Computer Regulations" containing Rules 480-27-.01 to 480-27-.07 has been adopted. Filed November 26, 1986; effective December 16, 1986.

Rule 480-10-.14 has been adopted. Filed February 4, 1987; effective February 24, 1987.

Rule 480-13-.06 has been amended by the adoption of subparagraph (3)(d). Filed February 4, 1987; effective February 24, 1987.

Rule 480-10-.15 has been adopted. Filed July 14, 1987; effective August 3, 1987.

Rule 480-16-.01 has been amended by the adoption of paragraph (7). Filed July 14, 1987; effective August 3, 1987.

Chapter 480-28, entitled "Practitioner Dispensing of Drugs," containing Rules 480-28-.01 to 480-28-.11, was filed on September 15, 1987; effective October 5, 1987.

Rule 480-4-.02 has been repealed and a new Rule adopted. Filed November 2, 1987; effective November 22, 1987.

Rule 480-18-.01 has been amended by the adoption of subparagraph (f). Filed November 2, 1987, effective November 22, 1987.

Rule 480-24-.04 has been amended by the repeal of paragraph (1) and by the adoption of a new paragraph (1). Filed July 21, 1988; effective August 10, 1988.

Rule 480-26-.01 has been amended by the repeal of subparagraph (c) and by the adoption of a new subparagraph (c). Filed July 21, 1988; effective August 10, 1988.

Rule 480-2-.01 has been amended by the repeal of paragraph (5) and the adoption of a new paragraph (5). Filed September 27, 1988; effective October 17, 1988.

Chapter 480-24 has been repealed and a new Chapter 480-24, of the same title, containing Rules 480-24-.01 to 480-24-.06, adopted. Filed June 14, 1989; effective July 4, 1989.

Rule 480-26-.01 has adopted subparagraph 7. and Rule 480-26-.01 has been repealed and a new Rule of the same title adopted. Filed September 19, 1989; effective October 9, 1989.

Chapter 480-29, entitled "Special Pharmacy Permits for Colleges of Pharmacy," containing Rules 480-29-.01 to 480-29-.04, was adopted. Filed September 19, 1989; effective October 9, 1989.

Rule 480-1-.06(c) has repealed subparagraphs 1., 3., and 4. and adopted new subparagraphs. Filed February 1, 1990; effective February 21, 1990.

Chapter 480-30, entitled "Dispensing of Drugs Under Authority of Job Description or Nurse Protocol," containing Rules 480-30-.01 to 480-30-.07, was adopted. Filed March 23, 1990; effective April 12, 1990.

Subparagraph (d) of Rule 480-30-.03 has been repealed and a new subparagraph adopted. Filed October 17, 1990; effective November 6, 1990.

Rule 480-7-.02 has been repealed and a new Rule, same title, adopted; Rule 480-7-.03 has been adopted. Filed February 21, 1992; effective March 12, 1992.

Subparagraph (c) of Rule 480-27-.04 has been repealed and a new subparagraph adopted. Filed July 31, 1992; effective August 20, 1992.

Rule 480-26-.01 has been amended. Filed September 4, 1992; effective September 24, 1992.

Rule 480-3-.01 has been amended. Filed October 9, 1992; effective October 29, 1992.

Chapter 480-31 entitled "Patient Counseling" containing Rule 480-31-.01 has been adopted. Filed November 24, 1992; effective January 1, 1993, as specified by the Agency.

Rules 480-8-.01, .06, 480-27-.07 have been amended; Rule 480-10-.15 has been repealed and a new Rule adopted; Chapter 480-32, entitled "Electronic Transfer of Prescription," containing Rule 480-32-.01 has been adopted. Filed February 10, 1993; effective March 2, 1993.

Rule 480-26-.01 has been amended. Filed May 10, 1993; effective May 30, 1993.

Rule 480-10-.12 has been repealed and a new Rule of the same title adopted. Filed September 7, 1993; effective September 27, 1993.

Subparagraph 1. of Rule 480-11-.01 has been adopted. Filed June 15, 1994; effective July 5, 1994.

Emergency Rule 480-9-0.8-.01(d) was filed November 19, 1993, effective November 16, 1993, the date of adoption to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding this Emergency Rule, as specified by the Agency. This Emergency Rule was adopted to protect the health, safety and welfare of the public. (Emergency Rule will not be published; copies may be obtained from the Agency.)

Rule 480-13-.06 has been amended. Filed November 7, 1994; effective November 27, 1994.

Chapter 480-3 entitled "Outpatient Clinic Pharmacies" containing Rules 480-33-.01 to 480-33-.10 has been adopted. Filed June 7, 1995; effective Jun. 27, 1995.

Rule 480-32-.01 has been amended. Filed July 6, 1995; effective July 26, 1995.

Rule 480-31-.01 has been adopted. Filed November 6, 1995; effective November 26, 1995.

Rule 480-2-.01 has been repealed and a new Rule, same title, adopted. Filed December 29, 1995; effective January 18, 1996.

Rule 480-27-.04 has been amended and Chapter 480-34 entitled "Controlled Substances" adopted. Filed July 8, 1996; effective July 28, 1996.

Rule 480-7-.04 has been adopted and Rule 480-26.01 amended. Filed January 15, 1997; effective February 4, 1997.

Rule 480-24-.06 has been amended. Filed May 21, 1997; effective June 10, 1997.

Rule 480-10-.02 has been amended. Filed August 12, 1997; effective September 1, 1997.

Rule 480-2-.01 and 480-3-.01 have been amended. Filed August 29, 1997; effective September 18, 1997.

Rule 480-10-.01 has been repealed and a new Rule adopted. Filed September 26, 1997; effective October 16, 1997.

Rule 480-34-.02 has been adopted. Filed September 26, 1997; effective October 16, 1997.

Rules 480-10-.17 and 480-24-.07 have been adopted; Rules 480-11-.01, 480-22-.01 and 480-24-.01 have been amended. Filed April 8, 1998; effective April 28, 1998.

Rule 480-10-.16 has been adopted. Filed April 23, 1998; effective May 13, 1998.

Rule 480-24-.06 has been amended by the repeal of subparagraph (2)(b)4. and by the adoption of new subparagraph (2)(b)4. and 5. Filed August 17, 1998; effective September 6, 1998.

Rules 480-4-.03, .04 and .05 have been repealed and new Rules 480-4-.03, .04 and .05 adopted. Filed September 10, 1998; effective September 30, 1998.

Rules 480-21-.04, 480-25-.08 and 480-33-.05 have been amended. Filed September 29, 1998; effective October 19, 1998.

Rule 480-7-.04 has been amended. Filed October 27, 1998; effective November 16, 1998.

Chapters 480-1, 480-2, 480-3, 480-4, 480-6 and 480-12 have been repealed and new Chapters adopted. Filed March 21, 2001; effective April 10, 2001.

Chapter 480-9 has been repealed; New Chapter entitled "Multiple Drugs in Single-Dosing Containers" has been adopted. Filed June 28, 2001; effective July 18, 2001.

Chapter 480-7 has been repealed and a new Chapter 480-7 adopted. Filed August 6, 2001; effective August 26, 2001.

Chapter 480-5 has been repealed; New Chapter entitled "Board Actions and Code of Conduct" adopted. Chapter 480-8 has been repealed; New Chapter, same title adopted. Filed September 28, 2001; effective October 18, 2001.

Chapter 480-26 has been repealed and a new Chapter adopted. Filed February 19, 2002; effective March 11, 2002.

Chapters 480-16, 480-17, 480-20, and 480-21 have been repealed and new Chapters adopted. Rule 480-23-.01 has been repealed and a new Rule adopted. Filed February 20, 2002; effective March 12, 2002.

Chapters 480-18 and 480-24 have been repealed and new Chapters adopted. Filed February 25, 2002; effective March 17, 2002.

Chapter 480-11 has been repealed. Chapters 480-25 and 480-29 have been repealed and new Chapters adopted. Filed June 13, 2002; effective July 3, 2002.

Chapters 480-13, 480-22, 480-27, 480-28, 480-30 and 480-33 have been repealed and new Chapters adopted. Filed July 24, 2002; effective August 13, 2002.

Rule 480-34-.03 has been adopted. Filed January 3, 2003; effective January 23, 2003.

Rule 480-7-.07 has been adopted. Filed January 29, 2003; effective February 18, 2003.

Chapter 480-10 has been repealed and a new Chapter adopted. Filed March 5, 2003; effective March 25, 2003.

Rules 480-10-.02 and .06 have been amended. Filed May 1, 2003; effective May 21, 2003.

Rule 480-14-.01 has been repealed and new Rule adopted. Filed August 14, 2003; effective September 3, 2003.

Chapter 480-11 entitled "Pharmaceutical Compounding" has been adopted. Filed April 19, 2004; effective May 9, 2004.

Rule 480-2-.02 has been repealed and a new Rule adopted. Filed July 28, 2004; effective August 17, 2004.

Chapters 480-7A entitled "Listed Chemical Wholesale Distributor" and 480-35 entitled "Pharmacist Modification of Drug Therapy" have been adopted. Chapter 480-19 has been repealed and a new Chapter adopted. Filed August 31, 2005; effective September 20, 2005.

Rule 480-10-.16 has been amended. Filed December 9, 2005; effective December 29, 2005.

Rule 480-2-.03 has been amended. Filed February 2, 2006; effective February 22, 2006.

Rules 480-27-.01, .02, .04, .05, .07, and .10 have been repealed and new Rules adopted.

Chapter 480-32 has been repealed. Filed August 18, 2006; effective September 7, 2006.

Rules 480-11-.01 to .07, .09, and .10 have been repealed and new Rules adopted. Filed November 22, 2006; effective December 12, 2006.

Rule 480-7-.01 has been repealed and a new Rule adopted. Filed February 22, 2007; effective March 14, 2007.

Rule 480-10-.18 has been adopted. Filed September 17, 2007; effective October 7, 2007.

Chapter 480-15 has been repealed and a new Chapter adopted. Rules 480-22-.01 and .14 have been repealed and new Rules adopted. Rule 480-22-.12 has been amended. Filed November 14, 2007; effective December 4, 2007.

Rules 480-13-.01, .03, and .04 have been repealed and new Rules adopted. Filed March 13, 2008; effective April 2, 2008.

Rules 480-27-.01, .02, .04, and 480-31-.01 have been amended. Rule 480-27-.04 has been retitled. Filed January 23, 2009; effective February 12, 2009.

Rule 480-24-.04 has been amended. Filed May 15, 2009; effective June 4, 2009.

Rule 480-3-.03 has been amended. Filed January 25, 2010; effective February 14, 2010. Paragraph 480-13-.04 has been repealed and a new paragraph 480-13-.04 adopted. Filed July 26, 2010; effective August 15, 2010.

Chapter 480-15 has been repealed and a new Chapter adopted. Chapter 480-36 entitled "Retail Pharmacy Requirements for Remote Prescription Drug Order Processing" has been adopted. Filed February 21, 2011; effective March 13, 2011.

Rule 480-15-.02 amended. F. Sept. 1, 2011; eff. Sept. 21, 2011.

Rules 480-19-.01 and .02 repealed and readopted. F. Nov. 28, 2011; eff. Dec. 18, 2011.

Rules 480-19-.03, .04, .05 adopted. F. Nov. 28, 2011; eff. Dec. 18, 2011.

Rule 480-22-.12 adopted. F. Nov. 29, 2011; eff. Dec. 19, 2011.

E.R. 480-34-.8-.4 adopted. F. Jun. 12, 2012; eff. Jun. 11, 2012, as specified by the agency. This rule to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

E.R. 480-34-0.9-.05 adopted. F. Jun. 27, 2012; eff. Jun. 27, 2012, as specified by the agency. This rule to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rule 480-34-.04 adopted. F. Aug. 16, 2012; eff. Sep. 5, 2012.

E.R. 480-34-0.10-.06 adopted. F. Aug. 28, 2012; eff. Aug. 28, 2012. This rule to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

E.R. 480-34-0.11-.07 adopted. F. Sep. 10, 2012; eff. Sep. 10, 2012. This rule to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

ER. 480-34-0.12-.08. F. Oct. 10, 2012; eff. Oct. 10, 2012. This rule to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rule 480-34-.04 repealed and readopted. F. Nov. 16, 2012; eff. Dec. 6, 2012.

Rules 480-11-.02, 480-13-.01, 480-13-.06, 480-16-.02, 480-22-.04, 480-22-.07, 480-27-.05 amended and 480-13-.04 repealed and readopted. F. Dec. 14, 2012; eff. Jan. 3, 2013.

New Rule 480-10-.19 adopted. F. Feb. 18, 2013; eff. Mar. 10, 2013.

Rule 480-2-.04 amended. F. May 7, 2013; eff. May 27, 2013.

ER. 480-34-0.13-.08, 480-34-0.14-.09, 480-34-0.15-.10 adopted. F. Oct. 15, 2013; eff. Sept. 18, 2013. These rules to remain in effect for a period of 120 days or until the adoption of permanent

Rules covering the same subject matter superseding these Emergency Rules, as specified by the Agency.

Rule 480-34-.04 amended. F. Oct. 15, 2013; eff. Nov. 4, 2013.

Rules 480-1-.01 and 480-6-.01 amended. Rule 480-2-.05 amended and title changed to "Reciprocity. Amended." F. Nov. 18, 2013; eff. Dec. 8, 2013.

Rules 480-1-.02, 480-10-.20, 480-34-.05 adopted, Rules 480-5-.03, 480-11-.02, 480-13-.04, 480-34-.04 amended. F. Dec. 19, 2013; eff. Jan. 8, 2014.

ER. 480-34-0.16-.04. F. Jan. 10, 2014; eff. Jan. 10, 2014 adopted. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rule 480-11-.01 amended. F. Jan. 28, 2014; eff. Feb. 17, 2014.

Rules 480-10-.21 and 480-16-.08 adopted. F. Apr. 4, 2014; eff. Apr. 24, 2014.

ER. 480-34-0.18-.04. F. May 29, 2014; eff. May 27, 2014 adopted. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rules 480-2-.03, 480-3-.03, 480-11-.02 amended. Chapters 480-38 entitled "General Information," 480-39 entitled "Pleadings," 480-40 entitled "Motions and Pre-Hearing Procedures," 480-41 entitled "Service," 480-42 entitled "Intervention," 480-43 entitled "Evidence; Subpoenas," 480-44 entitled "Taking of Testimony by Deposition or Interrogatory," 480-45 entitled "Hearings," 480-46 entitled "Consolidation," and 480-47 entitled "Briefs and Post-Hearing Procedure" adopted. F. June 20, 2014; eff. July 10, 2014.

Rule 480-34-.04 amended. F. July 17, 2014; eff. Aug. 6, 2014.

ER. 480-34-0.19-.04. F. Aug. 29, 2014; eff. Aug. 29, 2014 adopted. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

ER. 480-34-0.20-.04. F. Sep. 3, 2014; eff. Sep. 3, 2014 adopted. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

ER. 480-34-0.21-.06. F. Sep. 17, 2014; eff. Sep. 17, 2014 adopted. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rule 480-6-.02 adopted. Rules 480-22-.04 and 480-27-.05 amended. F. Sep. 17, 2014; eff. Oct. 7, 2014.

Chapter 480-48 entitled "Delivery by Mail" adopted. F. Sep. 22, 2014; eff. Oct. 12, 2014.

Rules 480-11-.02, 480-11-.08, 480-34-.04 amended. Rule 480-34-.06 adopted. F. Nov. 26, 2014; eff. Dec. 16, 2014.

Rules 480-1-.01, 480-5-.04, 480-6-.01, 480-6-.02, 480-7-.01, 480-7-.04, 480-20-.02, 480-25-.12, 480-38-.04, 480-40-.04 amended. F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 480-23-.01 amended. F. Dec. 22, 2014; eff. Jan. 11, 2015.

ER. 480-34-0.22-.07. F. Jan. 28, 2015; eff. Jan. 28, 2015 adopted. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rules 480-6-.02, 480-34-.06 amended. F. Jan. 23, 2015; eff. Feb. 12, 2015.

Rules 480-25-.01, .08, 480-35-.02 amended. F. Apr. 20, 2015; eff. May 10, 2015.

ER. 480-34-0.23-.07, ER 480-34-0.24-.08 adopted. F. May 14, 2015; eff. May 13, 2015. These rules to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding these Emergency Rules, as specified by the Agency.

Rules 480-2-.05, 480-48-.01, .02 amended. Rule 480-48-.03 adopted. F. May 14, 2015; eff. June 3, 2015.

ER. 480-34-0.25-.07 adopted. F. June 30, 2015; eff. June 30, 2015. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rules 480-6-.01, 480-6-.02, 480-7-.01, 480-7-.03, 480-7-.05, 480-8-.02, 480-15-.02, 480-18-.02, 480-33-.02 amended. Chapter 480-49 entitled "Default on Obligations" adopted. F. June 29, 2015; eff. July 19, 2015.

ER. 480-34-0.26-.07, ER 480-34-0.27-.09 adopted. F. July 21, 2015; eff. July 21, 2015. These rules to remain in effect for a period of 120 days or until the adoption of permanent Rules covering the same subject matter superseding these Emergency Rules, as specified by the Agency.

Rules 480-22-.04, 480-22-.12, 480-27-.02 amended. F. July 27, 2015; eff. Aug. 16, 2015.

Rule 480-34-.07 adopted. F. July 27, 2015; eff. Aug. 16, 2015.

Rule 480-22-.03 amended. F. July 30, 2015; eff. Aug. 19, 2015.

ER. 480-34-0.28-.07 adopted. F. Sep. 1, 2015; eff. Sep. 1, 2015. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rules 408-22-.15, 480-34-.08, 480-34-.09, 480-49-.02 adopted. Rule 480-34-.07 amended. F. Sep. 18, 2015; eff. Oct. 8, 2015.

ER. 480-34-0.29-.04 adopted. F. Oct. 8, 2015; eff. Oct. 8, 2015. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rules 480-16-.03, 480-34-.04, 480-34-.07, 480-37-.02 amended. Chapter 408-50 entitled "Drug Disposal and Authorized Collectors" adopted. F. Jan. 20, 2016; eff. Feb. 9, 2016.

ER. 480-34-0.30-.10 adopted. F. Apr. 22, 2016; eff. Apr. 22, 2016. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rule 480-15-.03 amended. Rule 480-15-.06 adopted. F. May 17, 2016; eff. June 6, 2016.

Rules 480-2-.03, 480-3-.03, 480-22-.11 amended. Rule 480-34-.10 adopted; superseding ER. 480-34-0.30-.10. F. June 22, 2016; eff. July 12, 2016.

ER. 480-34-0.31-.11 adopted. F. Dec. 14, 2016; eff. Dec. 14, 2016. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rule 480-2-.06 adopted. Rule 480-13-.05 amended. F. Feb. 27, 2017; eff. Mar. 19, 2017.

ER. 480-34-0.33-.12 adopted. F. Apr. 21, 2017; eff. Mar. 31, 2017. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rules 480-10-.02, 480-48-.02 amended. Rule 480-10-.18 repealed. Rule 480-49-.03 adopted. F. May 24, 2017; eff. June 13, 2017.

ER. 480-34-0.34-.12 adopted. F. July 13, 2017; eff. June 29, 2017. This rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rule 480-10-.01 amended. Rule 480-34-.11 adopted. F. Oct. 3, 2017; eff. Oct. 23, 2017.

Rules 480-7-.05, 480-13-.03 amended. Rules 480-24-.08, 480-34-.12 adopted. F. Feb. 22, 2018; eff. Mar. 14, 2018.

Rule 480-7-.07 amended. Chapters 480-7B entitled "Durable Medical Equipment Suppliers", 480-51 entitled "Interchangeable Biological Products" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.

ER. 480-34-0.35-.12 adopted. F. Nov. 5, 2018; eff. Nov. 5, 2018. This Rule to remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency.

Rules 480-7B-.03, 480-34-.13, .14 adopted. Rule 480-35-.03 amended. F. Nov. 19, 2018; eff. Dec. 9, 2018.

Rules 480-13-.01, 480-13-.04 amended. Rule 480-34-.15 adopted. F. May 9, 2019; eff. May 29, 2019.

Rule 480-11-.02 amended. F. Nov. 6, 2019; eff. Nov. 26, 2019.

Chapter 480-10A entitled "Central Filling Regulations" adopted. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Rule 480-13-.05 amended. F. Feb. 4, 2020; eff. Feb. 24, 2020.

ER. 480-36-0.36-.08, 480-48-0.37-.04 adopted. F. Mar. 20, 2020; eff. Mar. 20, 2020. These Rules shall remain in effect for a period of 120 days or until the adoption of a permanent Rules covering the same subject matter superseding this Emergency Rules, as specified by the Agency

ER. 480-10-0.38-.22 adopted. F. Mar. 27, 2020; eff. Mar. 27, 2020. This Rule shall remain in effect for a period of 120 days or until the adoption of a permanent Rule covering the same subject matter superseding this Emergency Rule, as specified by the Agency

ER. 480-22-0.39-.16, 480-15-0.40-.07 adopted. F. Apr. 2, 2020; eff. Apr. 1, 2020. These Rules shall remain in effect for a period of 120 days or until the adoption of a permanent Rules covering the same subject matter superseding this Emergency Rules, as specified by the Agency

ER. 480-2-0.41-.04 adopted. F. May 18, 2020; eff. May 18, 2020. This Rule shall remain in effect for the duration of the public health emergency and for a period of not more than 120 days thereafter, as specified by the Agency.

Note: ER 480-36-0.42-.08, 480-48-0.43-.04, 480-22-0.44-.16, 480-15-0.45-.07, 480-2-0.46-.05 issued to Agency on August 5, 2020, but subsequently not filed.

ER. 480-11-0.47-.11 adopted. F. Mar. 9, 2021; eff. Mar. 9, 2021. This rule shall remain in effect for the duration of the public health emergency and for a period of not more than 120 days thereafter, as specified by the Agency.

Rules 480-6-.02, 480-10-.02, 480-11-.04, 480-18-.05, 480-33-.05, 480-36-.03 amended; Rule 480-10-.18 adopted. F. Apr. 13, 2021; eff. May 3, 2021.

Rule 480-10-.12 amended. F. Apr. 20, 2021; eff. May 10, 2021.

Note: Rule 480-6-.02, correction of non-substantive typographical error in paragraph (18) *". service shall be made on the Executive Director., ..."* corrected to *". service shall be made on the Executive Director, ..."* (i.e., deletion of period after Director), as requested by the Board. Effective July 20, 2021.

Chapter 480-1. ORGANIZATION.

Rule 480-1-.01. Organization of the Board.

The Georgia State Board of Pharmacy consists of eight (8) members who are commissioned by the Governor. The public may obtain information from the Board, and make submissions and requests to the Board by contacting the Executive Director of the State Board of Pharmacy at the Department of Community Health, 2 Peachtree Street, S.W., 6th Floor, Atlanta, Georgia 30303.

Cite as Ga. Comp. R. & Regs. R. 480-1-.01
Authority: O.C.G.A §§ 26-4-20, 26-4-21, and 26-4-27.
History. Original Rule entitled "Organization of Board" was filed and effective on June 30, 1965.
Amended: Rule repealed and a new Rule of the same title adopted. Filed October 6, 1970; effective October 26, 1970.
Amended: Rule repealed and a new Rule of the same title adopted. Filed October 18, 1983; effective November 7, 1983.
Repealed: New Rule, same title adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.
Amended: F. Nov. 18, 2013; eff. Dec. 8, 2013.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 480-1-.02. Executive Director.

(1) The Board may appoint by a majority vote a person to serve as Executive Director of the Board who shall serve at the pleasure of the Board. Such appointment must be approved by the Board of Community Health.

(2) The Executive Director shall be vested with the following powers:

   (a) To hire such personnel as the Board approve and deems necessary to carry out its function, and with Board approval, to appoint professional qualified persons to serve as members of peer review committees;

(b) To issue subpoenas to compel access to documents or other materials related to the fitness of any licensee, registrant, or applicant to practice or where reasonable grounds exist for the belief that a violation of the laws relating to the practice of pharmacy has taken place;

(c) To issue subpoenas for witnesses and documentary evidence, upon approval of the President of the Board, or in his absence, the Vice President.

(d) To issue notices of hearing with the approval of the Board;

(e) With the approval of the Board, enter into contracts as are deemed necessary to carry out this chapter to provide for all services required of the Board;

(f) To act as the custodian of records for the Board; and

(g) To accept service of civil actions and administrative appeals on behalf of the Board.

(3) In the absence of the Executive Director, the Director of the Georgia Drugs and Narcotic Agency shall serve as the Assistant Executive Director and shall have all the powers of the Executive Director.

Cite as Ga. Comp. R. & Regs. R. 480-1-.02
Authority: O.C.G.A. §§ 43-1-19, 26-4-20, 26-4-24, 26-4-27, 26-4-28, 26-4-28.1, 26-4-29.
History. Original Rule entitled "Executive Director" adopted. F. Dec. 19, 2013; eff. Jan. 8, 2014.

Chapter 480-2. LICENSURE AS A PHARMACIST.

Rule 480-2-.01. Applicants for Licensure by Examination.

Applicants for licensure by examination must complete an application on a form approved by the Georgia State Board of Pharmacy ("Board"), have attained the age of majority, be of good moral character, have graduated and received a professional degree from a college or school approved by the Board, as provided in Rule 480-2-.02, have completed an internship program approved by the Board, as provided in Rule 480-2-.03, have sucessfully passed examinations approved by the Board and have paid the requisite fee.

Cite as Ga. Comp. R. & Regs. R. 480-2-.01
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-41, 26-4-37, 26-4-74.
History. . Original Rule entitled "Reciprocity" was filed and effective on June 30, 1965.
Amended: Rule repealed and a new Rule of the same title adopted. Filed October 6, 1970; effective October 26, 1970.
Amended: Filed August 2, 1974; effective August 22, 1974.
Amended: Filed March 3, 1977; effective March 23, 1977.
Amended: Filed March 17, 1978, effective April 6, 1978.
Amended: Filed October 18, 1983; effective November 7, 1983.

Amended: Filed September 20, 1985; effective October 10, 1985.
Amended: Filed September 27, 1988; effective October 17, 1988.
Repealed: New Rule, same title, adopted. F. Dec. 29, 1995; eff. Jan. 18, 1996.
Amended F. Aug. 29, 1997; eff. Sept. 18, 1997.
Repealed: New Rule entitled "Applicants for Licensure by Examination" adopted F. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-2-.02. Education.

Applicants applying for a license to practice pharmacy by examination must be a graduate of:

(1) A generally recognized school or college of pharmacy located in the United States, being one who has obtained candidate status or is approved by the American Council on Pharmaceutical Education (A.C.P.E.); or

(2) A school or college of pharmacy located outside of the United States, provided that graduates of such foreign schools or college may be deemed qualified to apply to practice as pharmacists or pharmacy interns if and only if the Board, after a review of the graduate's verified academic records, finds that the graduate is qualified and, in the case of a graduate who seeks licensure as a pharmacist, has passed the Foreign Pharmacy Graduate Equivalency Examination (FPGEC), and the Test of Spoken English, and the Test of English as a foreign language, all administered by the National Association of Boards of Pharmacy. (NABP)

Cite as Ga. Comp. R. & Regs. R. 480-2-.02
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-41, 26-4-4226-4-46.
History. Original Rule entitled "Education" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.
Repealed: New Rule of same title adopted. F. July 28, 2004; eff. Aug. 17, 2004.

Rule 480-2-.03. Experience Requirements.

Applicants applying for licensure by examination must complete 1500 hours of pharmacy internship or its equivalent as provided by the Board. An applicant for licensure by examination shall submit to the Board a certification that states that the applicant has satisfied the required 1500 hours of pharmacy practice experience, which shall include practice experience in both a retail and hospital practice setting, in accordance with the standards set by the Board. An applicant for examination shall submit the certification in writing and signed under oath by a duly authorized representative of the applicant's school or college of pharmacy on a form approved by the Board.

(1) Pharmacy Internship Licenses.

(a) Applicants shall file an application with the Board for pharmacy internship licensure and pay the license fee. The pharmacy intern license must be issued before experience begins.

(b) The following persons may register as pharmacy interns:

1. Any student who is currently enrolled in a generally recognized school or college of pharmacy approved by A.C.P.E., or a newly created school or college of pharmacy which has been granted either precandidate or candidate status by A.C.P.E., provided that proof of enrollment in a school or college of pharmacy is submitted to the Board.

2. Any graduate of a generally recognized school or college of pharmacy approved by A.C.P.E. for the purpose of obtaining the practical experience for licensure as a pharmacist; and

3. Any individual who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate for the purpose of obtaining practical experience for licensure as a pharmacist.

(c) Licenses shall be valid for five (5) years or until such intern is expelled, suspended, dismissed or withdraws from an approved school, becomes licensed as a pharmacist, or has taken and failed the Board examination for the third time, whichever comes first. Intern licenses may be renewed at the discretion of the Board.

1. Individuals who have established educational equivalency by meeting the requirements of Rule 480-2-.02 must obtain 1500 hours of practical pharmacy experience under the instruction of a licensed pharmacist.

2. Individuals who are attending a school or college of pharmacy approved by the A.C.P.E. shall show proof of instruction by a licensed pharmacist, and that such 1500 hours were acquired after enrollment at an accredited school or college of pharmacy.

(d) The 1500 hours of pharmacy internship shall include practice experience in both a retail and hospital pharmacy practice setting, in accordance with the standards set by the Board.

(2) Each school or college of pharmacy must submit, on an annual basis, for the Board's approval, a summary of course and experiences, as well as the internship credit hours for each course and experience, which are to be used for the B.S. program or the Pharm. D. program. Each school of pharmacy must also submit for Board approval, on an annual basis a list of preceptors in the internship programs. The Board reserves the right to approve or disapprove any individual courses, experience programs or preceptors.

(3) Other Qualifying Experience:

(a) Any intern wishing to obtain internship credit for work in a research and /or industrial program must first submit a request for approval of the program to the Board along with an outline of the program from the individual who will supervise the intern in this program. If approved by the Board, the hours will be awarded in accordance with the standards set by the Board.

(b) At the discretion of the Board, the Board may accept internship hours for serving in the Armed Services and working under the direct supervision of a registered pharmacist. Documentation of experience must be signed by a registered pharmacist. An intern must petition the Board to receive credit.

(c) The Board may give internship credit to an applicant that has demonstrated to the satisfaction of the Board that such applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements. An applicant must petition the Board to receive credit.

Cite as Ga. Comp. R. & Regs. R. 480-2-.03
Authority: O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-37, 16-13-41, 16-13-43, 16-13-74, 26-3-8, 26-4-5, 26-4-27 to 26-4-29, 26-4-41, 26-4-42, 26-4-46, 26-4-47, 26-4-60, 26-4-80, 26-4-82, 26-4-86 to 26-4-88, 26-4-110, 26-4-111, 26-4-113.
History. Original Rule entitled "Experience Requirements" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.
Amended: F. Feb. 2, 2006; eff. Feb. 22, 2006.
Amended: F. June 20, 2014; eff. July 10, 2014.
Amended: F. June 22, 2016; eff. July 12, 2016.

Rule 480-2-.04. Examinations.

(1) For licensure, an individual must successfully pass the NAPLEX, a jurisprudence examination approved by the Board and a practical examination approved by the Board.

(a) An individual is not eligible to take the examinations for licensure until such individual has graduated from an approved college or school of pharmacy and has completed all internship requirements.

(2) The NAPLEX examination is made available throughout the year, with the jurisprudence and practical portions of the examinations being given at specified times. Applications must be in the Board office in accordance with the deadlines established by the Board.

(a) Candidates for a Georgia license are required to make a minimum grade of 75 on the NAPLEX examination. Applicants are also required to obtain a minimum score of 75 on the Georgia Practical examination, and a minimum score of 75 on the jurisprudence examination. A score of less than 70 on any section of the Georgia practical examination invalidates all the scores from that administration of the Georgia Practical examination; and

(3) The Board will provide reasonable accommodation to a qualified applicant with a disability in accordance with the Americans with Disabilities Act (ADA). The request for an accommodation by an individual with a disability must be made in writing and received in the Board's office by the application deadline along with appropriate documentation, as indicated in the Request for Disability Accommodation Guidelines.

Cite as Ga. Comp. R. & Regs. R. 480-2-.04
Authority: O.C.G.A. 26-4-27, 26-4-4 and 26-4-42.
History. Original Rule entitled "Examinations" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.
Amended: F. May 7, 2013; eff. May 27, 2013.

Rule 480-2-.05. Reciprocity.

(a) In order for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist from the Board, an applicant shall:

(1) Complete an applicant form supplied by the National Association of Boards of Pharmacy (NABP) to apply for licensure with the Georgia State Board of Pharmacy. This application should be filed with NABP, and then with the Board for further review by the Board and an investigation by the Georgia Drugs and Narcotics Agency (GDNA), if necessary. If so requested, an applicant must produce evidence satisfactory to the Board or the GDNA which shows the applicant has the age, moral character, background, education, and experience demanded of applicants for registration by examination under O.C.G.A. 26-4 and by this chapter.

(2) Have attained the age of majority;

(3) Be of good moral character;

(4) Have possessed at the time of initial licensure as a pharmacist, all qualifications necessary to have been eligible for licensure at that time in this state;

(5) Have presented to the Board proof of initial licensure by examination and proof that such license is in good standing;

(6) Have presented to the board proof that any other license granted to the applicant by any other state is not currently suspended, revoked, or otherwise restricted for any reason except nonrenewal or for the failure to obtain the required continuing education credits in any state where the applicant is currently licensed, but not engaged in the practice of pharmacy;

(7) Have successfully passed a jurisprudence examination approved by the Board on Georgia's pharmacy laws and Board regulations, and a practical examination approved by the Board;

(8) If requested by the Board, have personally appeared for an interview with a member of the Board;

(9) Have paid the fees specified by the Board.

(b) No applicant may be granted a license by reciprocity if that person has failed the examination for licensure as a pharmacist in this state.

(c) No applicant shall be eligible for reciprocity unless the state in which the applicant is licensed as a pharmacist also grants license reciprocity to pharmacist duly licensed by examination in this state under like circumstances.

Cite as Ga. Comp. R. & Regs. R. 480-2-.05
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-41, 26-4-42, 26-4-46, 26-4-47.
History. Original Rule entitled "Reciprocity" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.
Amended: Title changed to "Reciprocity. Amended." F. Nov. 18, 2013; eff. Dec. 8, 2013.
Amended: F. May 14, 2015; eff. June 3, 2015.

Rule 480-2-.06. Temporary Licenses.

(1) As used in this rule:

(a) "Military" means the United States armed forces, including the National Guard;

(b) "Military spouse" means a spouse of a service member or transitioning service member;

(c) "Pharmacy resident" means a graduate who received a professional degree from a college or school approved by the board, as provided for in Rule 480-2-.02, who has been accepted for a post-graduate clinical training position in this State;

(d) "Service member" means an active or reserve member of the United States armed forces, including the National Guard;

(e) "Transitioning service member" means a member of the military on active duty status or on separation leave who is within 24 months of retirement or 12 months of separation.

(2) Temporary licenses for service members, transitioning service members, and military spouses.

(a) A service member may qualify for a temporary pharmacist license by examination where the applicant:

1. Has submitted a completed application for licensure by examination on a form approved by the Board, paid the requisite fee, and requested a temporary license;

2. Has graduated and received a professional degree from a college or school approved by the board, as provided for in Rule 480-2-.02;

3. Has completed an internship program approved by the Board, as provided for in Rule 480-2-.03; and

4. Has successfully passed the NAPLEX.

(b) A service member, transitioning service member, or military spouse may qualify for a temporary pharmacist license by reciprocity where the applicant:

1. Has completed an applicant form supplied by the National Association of Boards of Pharmacy (NABP) to apply for licensure with the Georgia State Board of Pharmacy. This application should be filed with NABP, and then with the Board for further review by the Board and an investigation by the Georgia Drugs and Narcotics Agency (GDNA), if necessary. If so requested, an applicant must produce evidence satisfactory to the Board or the GDNA which shows the applicant has the age, moral character, background, education, and experience demanded of applicants for registration by examination under O.C.G.A. 26-4 and by this chapter;

2. Has presented to the board proof that any other license granted to the applicant by any other state is not currently suspended, revoked, or otherwise restricted for any reason except nonrenewal or for the failure to obtain the required continuing education credits in any state where the applicant is currently licensed, but not engaged in the practice of pharmacy;

3. Has successfully passed the NAPLEX;

4. Has paid the requisite fee, is eligible for the practical examination, and has requested a temporary license; and

5. Holds a license from another state for which the training, experience, and testing substantially meet or exceed the requirements under this State to obtain a pharmacist license; and if the applicant is a service member or transitioning service member, has obtained a specialty, certification, training or experience in the military while a service member which substantially meets or exceeds the requirements to obtain a license in this state.

(c) Any temporary license issued to a service member, transitioning service member, or military spouse shall be valid for a period of six months from the date of

issuance of the license and shall expire at the end of the six month period or upon the passage of the practical examination and issuance of a permanent license, whichever is earlier.

(3) Temporary licenses for pharmacy residents.

(a) A pharmacy resident may apply for temporary pharmacist licensure where the applicant has:

1. Has submitted a completed application for licensure on a form approved by the Board, paid the requisite fee, and requested a temporary license;

2. Has attained the age of majority;

3. Has completed an internship program approved by the Board, as provided for in Rule 480-2-.03; and

4. Has submitted evidence that the applicant has been accepted for a pharmacy resident position in this state.

(b) Any temporary license issued to a pharmacy resident shall expire at the end of the month following the third Board meeting conducted after the issuance of such license and may not be reissued or renewed.

(4) All other temporary licenses.

(a) An applicant may qualify for temporary pharmacist licensure where the applicant has:

1. Has submitted a completed application for licensure on a form approved by the Board and paid the requisite fee;

2. Has attained the age of majority;

3. Has graduated and received a professional degree from a college or school approved by the board, as provided for in Rule 480-2-.02;

4. Has completed an internship program approved by the Board, as provided for in Rule 480-2-.03; and

5. Has submitted evidence of an emergency situation justifying such temporary license.

(b) Any temporary license issued to a pharmacy resident shall expire at the end of the month following the third Board meeting conducted after the issuance of such license and may not be reissued or renewed.

Cite as Ga. Comp. R. & Regs. R. 480-2-.06
Authority: O.C.G.A. §§ 26-4-20, 26-4-27, 26-4-28, 26-4-41, 26-4-42, 26-4-43, 26-4-44.2, 43-1-34.
History. Original Rule entitled "Temporary Licenses" adopted. F. Feb. 27, 2017; eff. Mar. 19, 2017.

Chapter 480-3. RENEWALS, INACTIVE LICENSES, AND CONTINUING EDUCATION.

Rule 480-3-.01. Pharmacist Renewals.

(1) Each pharmacist license will expire and must be renewed by December 31st of the even numbered years. Licenses not renewed by December 31st of the even number years may be late renewed by January 31st of the following year by payment of the current renewal fee, plus an additional late renewal fee of 50% of the renewal fee.

(2) Any license not renewed by January 31st of the year following the renewal date deadline, shall automatically become classified as "Administratively Revoked".

   (a) The practice of pharmacy with an expired or administratively revoked license is prohibited by law, and practice during this period may result in disciplinary action for unlicensed practice.

Cite as Ga. Comp. R. & Regs. R. 480-3-.01
Authority: O.C.G.A. Secs. 26-4-24, 26-4-28, 26-4-37, 26-4-40, 26-4-44, 26-4-53, 26-4-72, 26-4-77, 43-1-4, 43-1-19.
History. Original Rule entitled "Examination" adopted. F. and eff. June 30, 1965.
Amended: F. Oct. 6, 1970; eff. October 26, 1970.
Repealed: New Rule entitled "Examination Requirements: adopted. F. Feb. 20, 1973; eff. Mar. 12, 1973.
Amended: F. Aug. 2, 1974; eff. Aug. 22, 1974.
Amended: F. Dec. 14, 1977; eff. Jan. 3, 1978.
Amended: F. July 23, 1981; eff. Aug. 12, 1981.
Amended: F. Aug. 27, 1982; eff. Sept. 16, 1992.
Repealed: New Rule of same title adopted. F. October 18, 1983; eff. Nov. 7, 1983.
Amended: F. Oct. 31, 1983; eff. Nov. 20, 1983.
Amended: F. Mar. 9, 1984; eff. Mar. 29, 1984.
Amended: F. Feb. 21, 1986; eff. Mar. 13, 1986.
Amended: F. Aug. 11, 1986; eff. Aug. 31, 1986.
Amended: F. Oct. 9, 1992; eff Oct. 29, 1992.
Amended: F. Aug. 29, 1997; eff. Sept. 18, 1997.
Repealed: New Rule entitled "Pharmacist Renewals" adopted. F. Mar. 21, 2001; eff. Apr 10, 2001.

Rule 480-3-.02. Inactive License.

(1) Pharmacists who wish to have their license placed on inactive status may do so by requesting such status in writing, with an explanation of the request, to the Board.

Pharmacists requesting inactive status must have an active license in good standing which includes meeting the continuing education requirements as outlined in Board Policy.

(a) Pharmacists who wish to retain their license may apply for an inactive status as outlined in 480-3-.02(1). Pharmacists holding an inact ive license may not practice pharmacy. An individual with an inactive license does not have to meet the continuing education requirements for subsequent renewal periods.

(2) Pharmacists who wish to reactivate their license must complete and submit the proper application and meet the requirements of the Board for reactivation as set forth in Board Policy.

Cite as Ga. Comp. R. & Regs. R. 480-3-.02
Authority: O.C.G.A. Secs. 26-4-44, 26-4-44.1, 43-1-22.
History. Original Rule entitled "Fees" adopted. F. May 3, 1976; eff. May 23, 1976.
Amended: F. Aug. 24, 1976; eff. Sept. 13, 1976.
Repealed: New Rule of same title adopted. F. Mar. 19, 1980; eff. Apr. 8, 1980.
Repealed: New Rule of same title adopted. F. Apr. 24, 1981; eff. May 14, 1981.
Repealed: F. Feb. 21, 1986; eff. Mar. 13, 1986.
Amended: New Rule entitled "Inactive License" adopted. f. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-3-.03. Continuing Pharmacy Education.

(1) The Georgia State Board of Pharmacy has the statutory responsibility and authority for the requirement of continuing education as prerequisite for a license renewal.

(2) The purpose of continuing education for pharmacists is to maintain and enhance the professional competency of pharmacists licensed to practice in Georgia for the protection of the health, safety and welfare of the people of the State of Georgia.

(3) As a requirement for the biennial renewal of his/her license, a pharmacist must complete not less than thirty (30) hours of approved continuing education.

(4) One hour of C.E. is defined as 0.1 C.E.U. Each pharmacist in the State of Georgia must obtain 30 hours of continuing education or 3.0 C.E.U.'s per biennium for license renewal.

(a) Certificates documenting that 30 hours of approved continuing education or 3.0 C.E.U.'s must be completed and dated within the biennium.

(5) A pharmacist licensed before or during the first six (6) months of the biennium (January to June), shall be required to obtain 30 hours of C.E. A pharmacist licensed during the following twelve (12) months (June to July) shall be required to obtain 15 hours of C.E. A pharmacist licensed during the last six (6) months of the biennium shall be exempt from continuing education for that biennium only.

(6) In the event of an audit and a pharmacist fails to submit certificates, which document his/her required continuing education credits, the Board will not process his/her request to renew the license until the continuing education requirements are provided to the Board.

(a) The pharmacist may not carry over continuing education credits from one licensing period to the next.

(b) Nothing is meant to prohibit representatives from the Georgia Drugs and Narcotics Agency (GDNA) from assisting, auditing, or verifying a pharmacist's continuing education certificates as needed.

(c) Each licensed pharmacist shall maintain these certificates of attendance at continuing education meetings for a period of two (2) years from the date of the preceding renewal period.

(7) The staff of the Georgia Board of Pharmacy may audit, or otherwise select randomly, the continuing education of a percentage of licensees as determined by the Board.

(8) The Board may accept continuing education approved by other Boards of Pharmacy where such continuing education meets the requirements established by the Board.

(9) Approval of providers and sponsors shall be as follows:

(a) All providers and sponsors of continuing education must be approved by the Board.

(b) American Council on Pharmaceutical Education (A.C.P.E.) approved providers shall submit documentation to the Board of such approval every two (2) years and have blanket approval.

(c) All other providers shall request approval of programs as a provider on the program approval form each time a program is presented. Nothing in these rules are meant to prohibit the Board and/or GDNA from establishing a program or programs which can be granted special program approval(s) by the Board, and which may be utilized on more than one occasion or whenever such program or programs are presented by the Board or GDNA during a biennium.

(10) The following criteria for quality shall be used for the approval of providers:

(a) There shall be an administrative authority charged with the responsibility of maintaining the criteria for quality in continuing education programming for each provider.

(b) The administration shall be stable and an established procedure shall exist that insures an orderly transfer of responsibilities in the event there is a change in administration.

(c) Providers shall present a program or activity based on the needs of the target audience or the timeliness of the topic.

(d) Program objectives and rationale shall be stated.

(e) Providers shall give adequate, advanced promotional information, material about target audience, goals and objectives, program content, faculty credentials and fees.

(f) Each approved provider of continuing education in the State of Georgia shall provide a means of registration of the participants at each program and a record of attendance shall be maintained for a period of five (5) years. The provider shall also furnish to each participant, adequate documentation of his successful completion of the program.

(g) There shall be a method of program evaluation established and a statement of the evaluation process planned shall accompany each application. (The Board may supply sample forms.)

(11) Providers shall furnish each participant with adequate documentation of this or her participation in the program. Information shall include:

(a) Name and license number in each state of participant;

(b) Name of provider;

(c) Name of program;

(d) Hours/C.E.U. completed;

(e) Date of completion;

(f) Authorized signature.

(12) The provider shall develop policies and procedures for the management of grievances. (This does not have to be submitted to the Board.)

(13) The facility shall be appropriate and adequately equipped to support the delivery of the program.

(14) Approval of programs shall be as follows:

(a) Acceptable forms of continuing education shall be as follows:

1. Institutes, seminars;

2. Lectures, conferences, workshops;

3. Correspondence and electronically delivered courses that are A.C.P.E. approved.

(b) The following are not acceptable as continuing educations programs: welcoming remarks, business sessions, unstructured demonstrations, degree programs, or medical continuing education programs which are not A.C.P.E. or Georgia Board approved.

(15) All continuing education providers seeking approval of the continuing education program by the Georgia Board shall submit a program approval form for each program presented. These forms should be submitted sixty (60) days in advance. The Board may exempt programs from this advance time requirement period as set forth by Board policy.

Cite as Ga. Comp. R. & Regs. R. 480-3-.03
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-45, 26-4-80.
History. Original Rule entitled "Continuing Pharmacy Education" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.
Amended: F. Jan. 25, 2010; effective Feb. 14, 2010.
Amended: F. June 3, 2011; eff. June 23, 2011.
Amended: F. June 20, 2014; eff. July 10, 2014.
Amended: F. June 22, 2016; eff. July 12, 2016.

Chapter 480-4. DUPLICATE WALL CERTIFICATES AND\OR LICENSES.

Rule 480-4-.01. Duplicate Wall Certificates and/or Licenses.

(1) Duplicate wall certificates and pocket licenses may be obtained by completing the proper application from the Board's office and filing said application with the proper fee, which will be considered by the Board for approval. The acceptable reasons for requesting a duplicate wall certificate and/or pocket license are as follows:

(a) The wall certificate or pocket license has been lost or destroyed, or

(b) The licensee has had a legal change of name.

(2) The applicant for the duplicate wall certificate and/or pocket license must submit supporting documentation as required by the Board.

Cite as Ga. Comp. R. & Regs. R. 480-4-.01
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28.
History. Original Rule entitled "Physical Impairment" adopted. F. and eff. June 30, 1965.
Repealed: New Rule of same title adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.

Repealed: New Rule entitled "Duplicate Wall Certificates and/or Licenses" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-4-.02. Repealed.

Cite as Ga. Comp. R. & Regs. R. 480-4-.02
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37.
History. Original Rule entitled "Experience Requirements" adopted. F. and eff. June 30, 1965.
Repealed: New Rule of same title adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule of same title adopted. F. Feb. 20, 1973; eff. Mar. 12, 1973.
Amended: F. Aug. 2, 1974; eff. Aug. 22, 1974.
Amended: F. Oct. 18, 1983; eff. Nov. 7, 1983.
Amended: F. Dec. 13, 1983; eff. Jan. 2, 1984.
Repealed: New Rule of same title adopted. F. Nov. 2, 1987; eff. Nov. 22, 1987.
Repealed: F. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-4-.03. Repealed.

Cite as Ga. Comp. R. & Regs. R. 480-4-.03
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-76, 43-1-19.
History. Original Rule entitled "Delinquent Renewals" adopted. F. and eff. June 30, 1965.
Repealed: New Rule of same title adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Late Pharmacist Renewals" adopted. F. Sept. 10, 1998; eff. Sept 30, 1998.
Repealed: F. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-4-.04. Repealed.

Cite as Ga. Comp. R. & Regs. R. 480-4-.04
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-76, 43-1-19.
History. Original Rule entitled "Duplicate Licenses" adopted. F. and eff. June 30, 1965.
Repealed: New Rule of same title adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Amended: F. Mar. 26, 1982; eff. Apr. 15, 1982.
Repealed: New Rule entitled "Reinstatement of Expired Licenses" adopted. F. Sept. 10, 1998; eff. Sept. 30, 1998.
Repealed: F. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-4-.05. Repealed.

Cite as Ga. Comp. R. & Regs. R. 480-4-.05
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-76, 43-1-19.
History. Original entitled "Biennial Renewal Fees" adopted. F. Aug. 24, 1976; eff. Sept. 13, 1976.
Repealed: New Rule of same title adopted. F. July 28, 1978; eff. Aug. 17, 1978.
Repealed: New Rule entitled "Late Pharmacist Renewals" adopted. F. Mar. 26 1982; eff. Apr. 15, 1982.
Repealed: New Rule entitled "Duplicate Licenses" adopted. F. Sept. 10, 1998; eff. Sept. 30, 1998.
Repealed: F. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-4-.06. Repealed.

Cite as Ga. Comp. R. & Regs. R. 480-4-.06
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37.
History. Original Rule entitled "Continuing Pharmacy Education" adopted. F. Aug. 27, 1982; eff. Sept. 16, 1982.
Repealed: New Rule of same title adopted. F. Oct. 30, 1986; eff. Nov. 19, 1986.
Amended: F. Feb. 1, 1990; eff. Feb. 21, 1990.
Repealed: F. Mar. 21, 2001; eff. Apr. 10, 2001.

Chapter 480-5. BOARD ACTIONS AND CODE OF CONDUCT.

Rule 480-5-.01. Suspension, Revocation, or Other Actions on Licenses Issued by the Board.

Under the authority granted by the Georgia Pharmacy Practice Act, O.C.G.A. T. 26, Ch. 4, and O.C.G.A. Section 43-1-19, the Georgia State Board of Pharmacy ("Board") shall have the power to reprimand, cancel, suspend, revoke, or otherwise restrict any license or permit issued by the Board. The specific grounds for disciplinary action are found in O.C.G.A. Section 43-1-19 and O.C.G.A. T. 26, Ch. 4, and O.C.G.A. T. 16, Ch. 13. The Board shall have such duty, power, and authority as may be necessary to enforce O.C.G.A. T. 26, Ch. 4, O.C.G.A. T. 26, Ch. 3 and O.C.G.A. T. 16, Ch. 13, and any rules promulgated by the Board pursuant thereto.

Cite as Ga. Comp. R. & Regs. R. 480-5-.01
Authority: O.C.G.A. Secs. 43-1-19, 26-4-49, 26-4-60, 26-4-113, 26-4-115, 16-13-37.
History. Original Rule entitled "Hospital Inspections" adopted. F. and eff. June 30, 1965.
Amended: F. Oct. 6, 1970; effective Oct. 26, 1970.
Repealed: New Rule entitled "Suspension, Revocation, or Other Actions on Licenses Issued by the Board" adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-5-.02. Responsibility of Owners and Pharmacist-In-Charge for Actions of License or Permittee.

When the Board finds that a pharmacy, manufacturer, wholesale distributor, researcher or reverse drug distributor has violated the provisions of O.C.G.A. T. 16, Ch. 13, O.C.G.A. T. 26, Ch. 3, O.C.G.A. T. 26, Ch. 4 and/or the rules of the Board, the Board may issue any disciplinary order to any corporate owner, officer, owner, partner, or pharmacist-in-charge of the pharmacy, manufacturer, wholesale distributor, researcher or reverse drug distributor.

Cite as Ga. Comp. R. & Regs. R. 480-5-.02
Authority: O.C.G.A. Secs. 43-1-19, 26-4-27, 26-4-28, 26-4-60, 26-4-82, 26-4-110, 26-4-113, 26-4-115.
History. Original Rule entitled "Responsibility of Owners and Pharmacist-In-Charge for Actions of Licensee or Permittee" adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-5-.03. Code of Professional Conduct.

The Board is authorized to take disciplinary action for unprofessional conduct. Consistent with the authority to assure that licensees operate in a professional manner and the Board's responsibility to protect the public health with a safe, dependable and sufficient supply of medication, the Board establishes a Code of Professional Conduct which shall apply to and be observed by all persons engaged in the practice of pharmacy in the State of Georgia.

(a) Ethics. No pharmacist, intern, extern, technician, or pharmacy owner shall engage in any conduct in the practice of pharmacy or in the operation of a pharmacy which tends to reduce the public confidence in the ability and integrity of the profession of pharmacy, or endangers the public health, safety and welfare, or have been guilty of any fraud, misrepresentation, culpable negligence, concealment, dishonest dealings, fix, scheme or device, or breach of trust in the practice of pharmacy or in the conduction of business related to prescriptions, drugs or devices.

(b) Patient Self-Referral. No pharmacist, employee or agent thereof acting on his/her behalf, shall offer, agree to accept, or receive compensation in any form for the referral of professional services to or from another health care provider or entity. This prohibition includes any form of fee division or charging of fees for the referral of patients.

(c) Error or Uncertain Prescriptions. No pharmacist or pharmacy intern/extern shall compound or dispense any prescription, which, in his/her professional opinion, contains any error omission, irregularity or ambiguity. Upon receipt of such prescription, the pharmacist, pharmacy intern/extern shall contact the prescriber and confer with him/her before dispensing the prescription. No pharmacist or intern/extern shall dispense any medication by virtue of a prescription if said pharmacist or intern has any doubt existing in his mind that such prescription is not legitimate.

(d) Betrayal of Confidence. A pharmacist shall not discuss with the patient or representative such matters that should be discussed only with the prescriber.

(e) Diagnosis or Treatment. No pharmacist or employee of a pharmacy shall diagnose, treat, prescribe for, or attempt to do so, any disease, illness, or organic disorder. This limitation shall not be construed to prevent a licensed pharmacist from advising individuals on matters concerning simple ailments, first aid measures, sanitary matters, or the merits and qualities of medicines, nor shall it prevent the full practice of pharmacy as provided in O.C.G.A. Section 26-4-4.

(f) Coded Prescriptions. No pharmacist, pharmacy intern, or extern shall compound or dispense any prescription that is coded. A "coded" prescription is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength and directors for its use, other than normal letters, numbers, words, symbols or other media recognized by the profession of pharmacy as a means for conveying information by prescription. No symbol, word or any other device shall be used in lieu of the name of said preparation.

(g) False or Misleading Advertising. No pharmacist or licensed pharmacy shall disseminate through any communication media any false, misleading or fraudulent advertising.

(h) Changes in Prescriptions. No pharmacist, pharmacy intern or extern shall supply medications or devices which contain an ingredient or article different in any manner from the medication or device that is prescribed upon a prescription unless prior approval has been obtained from the prescriber thereof. Such difference shall immediately be recorded upon said prescription after being approved by said prescriber, showing the date, time and method of ascertaining the said approval.

(i) Prescription Sub-Stations. No pharmacist, employer or employee of a licensed pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Board, from which to solicit, accept or dispense prescriptions.

(j) Physician Agreements. No pharmacist or licensed pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with an physician or other practitioner for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement if any kind, whereby in any way a patient's free choice of a pharmacist or licensed pharmacy is or may be limited.

(k) Independent Judgment and Practices. No pharmacist shall offer or engage in professional pharmaceutical services under any terms and conditions that shall tend to interfere with or impair the free and complete exercise of professional judgment and skill of a pharmacist or enter into any agreement that denies the public the right of free choice of pharmacists or pharmacies.

(l) Return of Prescriptions. Except as authorized by Rule 480-10-.17, no pharmacist or employer or employee of a pharmacy may knowingly place in the stock of any pharmacy any part of any prescription dispensed to, or compounded for, any patient of any pharmacy and returned by said patient.

(m) Evasion of Code of Professional Conduct. No pharmacist, licensed pharmacy or employee or agent thereof, shall act in any way to evade the rules and regulations of the Board and the laws applying to licensed pharmacies and pharmacists, interns, externs and technicians, but may apply methods of their own to enhance compliance with said laws, rules and regulations. Said persons shall be responsible for being acquainted with said laws, rules and regulations, and ignorance of said laws, rules, regulations shall not be a valid defense of the same.

(n) Refusal to Fill Prescription. It shall not be considered unprofessional conduct for any pharmacist to refuse to fill any prescription based on his/her professional judgment or ethical or moral beliefs.

(o) Valid Prescription Drug Orders. Prescription drugs shall be dispensed only pursuant to a valid prescription drug order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription. A pharmacist shall have the

same corresponding liability for prescriptions as an issuing practitioner as set forth in 21 C.F.R. as such regulation exists on January 1, 2013. Valid prescription drug orders shall include those issued by a physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state, or of any state or territory of the United States, to prescribe dangerous drugs or controlled substances or both.

(p) Violations of the Code of Professional Conduct. The above set out Code of Professional Conduct is expressly adopted by the Board and shall govern the conduct of all those admitted to practice pharmacy in their capacities as pharmacists, all those issued licenses as a pharmacy in their capacities as licensees and all pharmacy interns/externs in their capacities as pharmacy interns/externs. A license to practice pharmacy or a permit to operate a licensed pharmacy confers to vested right to the holder thereof, but is a conditional privilege revocable for cause. The primary purpose of this Code of Professional Conduct is the protection of the profession of pharmacy and the public health, safety and welfare. It is the responsibility of the Board to purge the profession of those unworthy to practice pharmacy or operate pharmacies in this state. It is the obligation of every licensed pharmacy holder and every licensed pharmacist to give unlimited cooperation and assistance to the Board in the discharge of this responsibility. Violation of this code may subject the violator to suspension or revocation of any license issued to him/her by the Board and/or public reprimand, fines, probation, letters of concern or other disciplinary actions deemed appropriate by the Board.

Cite as Ga. Comp. R. & Regs. R. 480-5-.03
Authority: O.C.G.A. §§ 43-1-19, 26-4-4, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-110, 26-4-113, and 26-4-115.
History. Original Rule entitled "Code of Professional Conduct" adopted. F. Sept. 28, 01; eff. Oct. 18, 2001.
Amended: Title changed to "Code of Professional Conduct. Amended." F. Dec. 19, 2013; eff. Jan. 8, 2014.

Rule 480-5-.04. Imparied Pharmacists, Interns and Externs.

Pursuant to O.C.G.A. T.26, Ch. 4 and O.C.G.A. Section 43-1-19, whenever a pharmacist, intern or extern becomes unfit to practice pharmacy with reasonable skill and safety by reason of a mental or physical condition including impairment due to the use of alcohol, narcotics, stimulants, or other habit-forming drugs, the Board has the duty and authority to place appropriate conditions or limitations on that person's license, including conditions or limitations on that person's license, including suspension or revocation. Whenever such pharmacist, intern or extern is impaired or has otherwise endangered the public health and welfare while engaged in the practice of pharmacy, and any other Board licensee is aware of such impairment he/she has the obligation and duty to notify the Board of such impaired persons and their actions.

Cite as Ga. Comp. R. & Regs. R. 480-5-.04
Authority: O.C.G.A. §§ 43-1-19, 26-4-27, 26-4-28, 26-4-60.
History. Original Rule entitled "Impaired Pharmacists, Interns or Externs" adopted. F. Sept. 28, 01; eff. Oct. 18, 2001.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 480-5-.05. Cost Recovery.

For any order issued in resolution of a disciplinary proceeding before the Board, the Board may direct any licensee found guilty of a charge involving a violation of any drug laws or rules to pay to the Board a sum not to exceed the reasonable cost of the investigation, and prosecution of the case and, in any case, not to exceed $25,000.00. The costs to be assessed shall be fixed by the Board and the costs so recovered shall be paid to the State of Georgia.

Cite as Ga. Comp. R. & Regs. R. 480-5-.05
Authority: O.C.G.A. Secs. 43-1-19, 26-4-27, 26-4-28.
History. Original Rule entitled "Cost Recovery" adopted. F. Sept. 28, 01; eff. Oct. 18, 2001.

Chapter 480-6. PHARMACY LICENSES.

Rule 480-6-.01. Pharmacy Licenses.

(1) Application for license:

(a) Applications must be filed with the Georgia State Board of Pharmacy located at the Department of Community Health, 2 Peachtree Street, 6th Floor, Atlanta, GA 30303, along with the required fee.

(b) Application for the licensing of a pharmacy will be considered on the basis of the application filed and an approval letter received from the Director of the Georgia Drugs and Narcotics Agency certifying the pharmacy possesses the necessary facilities and equipment for a license.

(c) The application fee shall NOT be refundable.

(2) Every pharmacy shall be under the direct charge of a registered pharmacist whose name shall appear on the license. In the event such pharmacist whose name shall appear on said license shall no longer be in charge of a pharmacy, the Board shall be notified immediately and shall be notified, at the same time, of the successor registered pharmacist.

(3) Licenses shall not be transferable. Licenses become null and void upon the sale, or change of mode of operation of the business.

(4) Licenses shall be renewed every two years and expire on June 30th of each odd year and may be renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st of the odd year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

Cite as Ga. Comp. R. & Regs. R. 480-6-.01
Authority: O.C.G.A. §§ 26-4-20, 26-4-21, 26-4-27, 26-4-28, 26-4-60, 26-4-100, 26-4-101, 26-4-102, 26-4-103, 26-4-104, 26-4-105, 26-4-110, 26-4-111, 43-1-4, 43-1-19.
History. Original Rule entitled "To Provide for the illegal Dispensing of and Filling of Prescriptions for Drugs, Medicines, and Poisons" adopted. F. and eff. June 30, 1965.
Repealed: New Rule entitled "Pharmacy Licenses" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Amended: F. Aug. 2, 1974; eff. Aug. 22, 1974.
Amended: F. Mar. 3, 1977; eff. Mar. 23, 1977.
Amended: F. Mar. 26, 1982; eff. Apr. 15, 1982.
Amended: F. Oct. 18, 1983; eff. Nov. 7, 1983.
Repealed: New Rule of same title adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.
Amended: F. Nov. 18, 2013; eff. Dec. 8, 2013.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.
Amended: F. June 29, 2015; eff. July 19, 2015.

Rule 480-6-.02. Nonresident Pharmacy Permit.

(1) Effective April 1, 2015, it shall be unlawful for any person, pharmacy, or facility located outside this state to ship, mail, or deliver prescription drugs orders into this state or to advertise its services, personally or through an in-state third party, unless such person, pharmacy or facility holds a pharmacy license pursuant to O.C.G.A. Section 26-4-110.1, or holds a nonresident pharmacy permit pursuant to O.C.G.A. Section 26-4-114.1, or is otherwise exempt from Georgia registration as a matter of Georgia law.

(2) Application for a non-resident pharmacy permit:

(a) Applications must be filed with the Georgia State Board of Pharmacy located at 2 Peachtree Street, NW, 6th Floor, Atlanta, Georgia 30303, along with the required fee.

(b) The Board requires information from each applicant for a nonresident pharmacy permit on its application, including but not limited to, the following:

1. The name, full business address, and telephone number of the applicant;

2. All trade or business names used by the applicant;

3. Address, telephone numbers, and the names of contact persons for each facility used by the applicant for the records, storage, handling, and distribution of prescription drugs into this state;

4. Address, telephone number and name of agent of service for the applicant;

5. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship);

6. The name(s) of the owner and/or operator of the pharmacy, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the incorporation, and the name of the parent company, if any; or

(iv) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.

7. Where operations are conducted at more than one location by a single pharmacy, each such location shall be permitted by the Board;

8. Proof of a valid, unexpired license, permit, or registration to operate a pharmacy in the compliance with the laws and rules of each state in which the applicant receives and dispenses prescription drug orders;

9. The names and license numbers of the pharmacist-in-charge of each facility involved in dispensing drugs to residents of this state and evidence that the pharmacist(s) are licensed and in good standing in the state where they are located;

10. Information necessary to demonstrate compliance with O.C.G.A. T. 50, Ch. 36;

11. Evidence satisfactory to the Board that the applicant in is compliance with all laws and investigations from each regulatory or licensing agency in which the applicant holds a license; and

12. If dispensing sterile or nonsterile compounding for practitioners to use in patient care in the practitioner's office, a copy of the most recent inspection report that is no older than two (2) years before the date of application was submitted and which is from an inspection conducted by the regulatory or licensing agencies of the jurisdiction in which the applicant is located that indicates compliance with the Board's rules and regulations and compliance with USP-NF standards for pharmacies performing sterile and nonsterile compounding, or another inspection approved by or conducted by the Board.

(3) Registration of a nonresident pharmacy permit will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the GDNA certifying the applicant possesses the necessary qualifications for a permit.

(4) Application fees and renewal fees shall be set by the Board in a fee schedule and shall not be refundable.

(5) Permits may be denied for failure to comply with rules of the Board, for failure to meet the minimum qualifications for a permit, for the conviction by an owner or pharmacist of a felony involving the practice of pharmacy or the distribution of drugs, for false representations on an application, and for any other good cause related to evidence of misfeasance or malfeasance by the applicant.

(6) Permits become null and void upon the sale, transfer or change of mode of operation or location of the business. Prior to the sale, transfer or change in mode of operation or the location of the business, the nonresident pharmacy may apply for such change by submitting a Board- approved application to the Board, and paying a fee. The permits of nonresident pharmacies will not become void if proper application is made and approved prior to the change.

(7) Permits are issued for two years and expire on June 30th of each odd-numbered year, and may be renewed for two years upon the payment of the required fee for each place of business and the filing of a completed application for renewal. Applicants for renewal must submit such evidence as requested by the Board including, but not limited to evidence of certain inspection reports on compounding and the status of the licenses of the pharmacy and pharmacists in the state of location. If the application for renewal is not made and the fee not paid before September 1st of the odd-numbered year, the permit shall lapse and shall not be renewed, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.

(8) The denial of a nonresident pharmacy permit and the denial of the renewal of a nonresident pharmacy permit shall not be considered a contested case under the provisions of O.C.G.A. T. 50, Ch. 13, but the applicant shall be entitled to an appearance before the Board.

(9) Nonresident pharmacy permit holders shall comply with all the recordkeeping requirements of the state in which they are located and licensed for all prescriptions shipped, mailed or delivered to patients or practitioners in the State of Georgia, but shall be maintained a minimum of two (2) years. Nonresident pharmacy permit holders shall notify the Board of each location where the required records are being maintained, and such records must be readily retrievable and produced to the Board within fifteen (15) business days, upon written request.

(10) In addition to labeling requirements required by the state where the nonresident pharmacy is located, the permit holders shall label the drugs dispensed with the following minimum information:

(a) The name and address of the dispenser;

(b) The serial number and date of the prescription or of its filling;

(c) The name of the prescriber;

(d) The name of the patient;

(e) The name of the drug dispensed;

(f) The direction for use and cautionary statements; and

(g) Identification of the pharmacist filling the prescription.

(11) Nonresident pharmacy permit holders shall comply with the Board's rules and regulations on delivery of prescriptions by mail in Board Chapter 480-48.

(12) Nonresident pharmacy permit holders shall comply with the laws and rules and regulations of the state where such pharmacies are located.

(13) Nonresident pharmacy permit holders who compound drugs must comply with the federal compounding laws as required in Board Chapter 480-11.

(14) Nonresident pharmacy permit holders shall maintain a toll-free telephone number operational during the permit holder's regular hours of operation, but not less than six days per week for a minimum of 60 hours per week, in order to provide patient counseling. Such toll-free number shall be capable of receiving inbound call from patients to the permit holder, and such number shall be on file with Board and shall be included on the label affixed to each container of all dispensed and distributed drugs sent into the State of Georgia.

(15) Nonresident pharmacy permit holders must notify the Board within five (5) business days of the receipt of any final order or decision by any other licensing board or federal agency of the imposition of disciplinary action or restriction by such other licensing board or federal agency. A final order or decision includes a consent order or agreement and is any decision, regardless whether there still exists an appellate right to the state or federal courts. Any revocation or suspension of a state or federal license or permit will result in the immediate suspension of the nonresident pharmacy permit pending a final decision by the Board.

(16) Within 72 hours, nonresident permit holders must update the Board of any change in pharmacist-in-charge of shipping into Georgia by completing forms provided by the Board and including such pharmacist licensure information and criminal history. Where a criminal background check cannot be completed within the seventy-two (72 hours) contemplated by this section, nonresident pharmacy permit holders must still update the Board of any change in pharmacist-in-charge of shipping into Georgia by completing forms provided by the Board and including such pharmacist licensure information, but shall have up to fifteen (15) business days to provide criminal history information.

(17) Nonresident pharmacy permit holders shall cooperate with the Board in any investigation involving prescription drugs distributed by such permit holder into this state or related to the permit holder's compounding practices. The permit holder shall respond within ten (10) business days to all communications from the Board or its designee. Failure to respond or cooperate with the Board shall be grounds for the immediate suspension of the nonresident pharmacy permit, pending a hearing on further disciplinary action by the Board. Failure to cooperate with the Board is grounds for disciplinary action by the Board.

(18) Notices to nonresident pharmacy permit holders shall be made on the agent of record with the Board. If notices are returned as undeliverable or unclaimed, service shall be made on the Executive Director, and any disciplinary proceedings shall proceed, or if a final decision, the decision shall become effective.

(19) If, in the course of investigation of a nonresident pharmacy permit holder or applicant, an onsite inspection by the Board or its designee is required, the permit holder or applicant shall be responsible for the cost of such onsite inspection.

(20) A nonresident pharmacy permit may be revoked or suspended or otherwise disciplined for any reason that a permit may be denied, for failure to comply with this rule, for disciplinary action by other states and federal agencies, for conduct causing bodily or psychological injuries to a resident of this state, and for failure to comply with Board laws and other applicable rules as provided herein.

(21) If a nonresident pharmacy holder has an affiliate as defined by O.C.G.A. § 26-4-119, it shall annually file a disclosure statement identifying all such affiliates no later than June 30 every year.

Cite as Ga. Comp. R. & Regs. R. 480-6-.02
Authority: O.C.G.A. §§ 26-3-8, 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-83, 26-4-85, 26-4-110, 26-4-110.1, 26-4-114.1, 26-4-119, 43-1-19.
History. Original Rule entitled "To Provide for the Revocation and Suspensions of Licenses and Registration for Certain Causes" adopted. F. and eff. June 30, 1965.
Repealed: F. Oct. 6, 1970; eff. Oct. 26, 1970.
Adopted: New rule entitled "Nonresident Pharmacy Permit." F. Sep. 17, 2014; eff. Oct. 7, 2014.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.
Amended: F. Jan. 23, 2015; eff. Feb. 12, 2015.
Amended: F. June 29, 2015; eff. July 19, 2015.
Amended: F. Apr. 13, 2021; eff. May 3, 2021.
Note: Correction of non-substantive typographical error in paragraph (18), "... service shall be made on the Executive Director., ..." corrected to "... service shall be made on the Executive Director, ..." (i.e., deletion of period after Director), as requested by the Board. Effective July 20, 2021.

Rule 480-6-.03. Repealed.

Cite as Ga. Comp. R. & Regs. R. 480-6-.03
Authority: Ga. Code 84-1309.
History. Original Rule entitled "Substitution" adopted. F. and eff. June 30, 1965.

Repealed: F. Oct. 6, 1970; eff. Oct. 26, 1970.

Chapter 480-7. PERMITS.

Rule 480-7-.01. Manufacturer's Permit.

(1) Applications for registration for a manufacturer's permit must be filed with the Office of the Georgia State Board of Pharmacy ("Board") with the required fee.

(2) Registration of a manufacturer will be considered on the basis of the application filed, fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a permit.

(3) Application fees shall NOT be refundable.

(4) Permits shall not be transferable. Permits become null and void upon the sale, or change of mode of operation of the business, or location of business.

(5) Licenses are renewed for two years and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st of the odd numbered year, the license shall lapse and shall not be renewed, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.

(6) Upon request by the Board or its designee, any manufacturer holding a permit issued by the Board that causes a dangerous drug or controlled substance product to be marketed or distributed in this state shall provide, at no cost to this state, a quantity of one gram or more of the pure compound of each such product to the Georgia Drugs and Narcotics Agency. Such quantities of pure compound will only be used for testing and analysis purposes.

   (a) All quantities of a pure compound provided to the Georgia Drugs and Narcotics Agency will be accounted for using a perpetual inventory system, and a copy of each product inventory will be available for review by the manufacturer providing the compound upon written request to the Board.

   (b) As the manufacturer is required by this subsection to submit the dangerous drug or controlled substance for analysis, the results of any chemical analysis shall be considered a trade secret within the meaning of Code Section 50-18-72(b)(1).

Cite as Ga. Comp. R. & Regs. R. 480-7-.01
Authority: O.C.G.A. §§ 16-13-35, 16-13-45, 16-13-72, 26-4-20, 26-4-27 to 26-4-29, 26-4-60, 26-4-111, 26-4-113, 26-4-115, 26-4-120, 26-4-131, 43-1-19, 50-18-72.
History. Original Rule entitled "Rules and Regulations Concerning the Chief Drug Inspectors Office" was filed and effective on June 30, 1965.

Amended: Rule repealed and a new Rule entitled "Manufacturer's Permit" adopted. Filed October 6, 1970; effective October 26, 1970.
Amended: Filed August 2, 1974; effective August 22, 1974.
Amended: Filed March 3, 1977; effective March 23, 1977.
Amended: Filed March 26, 1982; effective April 15, 1982.
Amended: Filed October 18, 1983; effective November 7, 1983.
Repealed: New Rule, same title, adopted. F. Aug. 6, 2001; eff. Aug. 26, 2001.
Repealed: New Rule of same title adopted. F. Feb. 22, 2007; eff. Mar. 4, 2007.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.
Amended: F. June 29, 2015; eff. July 19, 2015.

Rule 480-7-.02. Drug Wholesale, Distribution Permits.

(1) Definitions. For the purpose of this chapter, definitions include:

(a) Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(b) Blood component means that part of blood separated by physical or mechanical means.

(c) Brokerage means a firm engaged in buying, selling, or distributing prescription drugs.

(d) Drug sample means unit of a prescription drug that is not intended to be sold to, maintained by, or sold by any licensed pharmacy.

(e) Manufacturer means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling of a prescription drug.

(f) Prescription drug means any drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(g) Wholesale distribution means distribution, or brokerage, of prescription drugs to persons other than a consumer or patient, but does not include:

1. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section,"emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy or other practitioner of the healing arts, except that total sales of such drugs shall not exceed five percent (5%) of the total dosage units for the transferor retail pharmacy.

2. The sale, purchase, or trade of a drug, or the dispensing of a drug pursuant to a prescription;

3. The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives; or

4. The sale, purchase, or trade of blood and blood components intended for transfusion.

h) Wholesale distributor means anyone engaged in wholesale distribution or brokerage of prescription drugs, including but not limited to, manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and whole drug warehouses, independent wholesale drug traders, brokerage firms, and retail pharmacies that conduct whole distributions.

Cite as Ga. Comp. R. & Regs. R. 480-7-.02
Authority: O.C.G.A. Secs. 26-4-111, 26-4-120, 43-1-19, 26-4-37, 16-13-72, 16-13-35, 26-4-5, 26-4-27, 26-4-28, 26-4-113, 26-4-115.
History. Original Rule entitled "Minimum Equipment for Prescription Department" was filed on September 9, 1966; effective September 28, 1966.
Amended: Rule repealed and a now Rule entitled "Wholesale, Distributor or Supplier Licenses" adopted. Filed October 6, 1970; effective October 26, 1970.
Amended: Filed August 2, 1974; effective August 22, 1974.
Amended: Filed March 3, 1977; effective March 23, 1977.
Amended: Filed March 26, 1982; effective April 15, 1982.
Amended: Filed October 18, 1983; effective November 7, 1983.
Repealed: New Rule, same title, adopted. F. Feb. 21, 1992; eff. Mar. 12, 1992.
Repealed: New Rule entitled "Drug Wholesale, Distribution Permits" adopted. F. Aug. 6, 2001; eff. Aug. 26, 2001.

Rule 480-7-.03. Drug Wholesale Distribution Licensing Requirements.

(1) Every drug wholesale distributor, wherever located, who engages in drug wholesale distribution into, out of, or within the State of Georgia must be licensed by the Georgia State Board of Pharmacy in accordance with the laws and regulations of this State before engaging in wholesale distribution of prescription drugs.

(2) Minimum Required Information for Licensure: The Board requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license.

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business names used by the licensee:

(c) Address, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(d) The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship); and

(e) The name(s) of the owner and/or operator of the licensee, including:

1. If a person, the name of the person;

2. If a partnership, the name of each partner, and the name of the partnership;

3. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the incorporation; and the name of the parent company, if any;

4. If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.

(f) Where operations are conducted at more than one location by a single drug wholesale distributor, each such location shall be licensed by the Board.

(g) Every drug wholesale distributor in this state, which is licensed by the Board, is required to be located in a commercially zoned business district and possess the appropriate local business license in order to conduct business. No drug wholesale distributor may be located in or operate out of a residential dwelling, building, or location, or a building, dwelling or location attached to a residential location. A drug wholesale distributor located in a hospital pharmacy or a retail pharmacy is deemed to meet this requirement.

(3) Applications for Licensure.

(a) Registration of a drug wholesaler distributor will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the GDNA certifying the applicant possesses the necessary qualifications of a license.

(b) Application fees shall not be refundable.

(c) Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business.

(d) Licenses are renewed for two years and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

(e) Changes in any information in this section shall be submitted to the Board prior to such change.

(4) Minimum Qualifications.

(a) The Board will consider the following factors in determining eligibility for licensure for persons who engage in the wholesale distribution of prescription drugs:

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

2. Any felony convictions of the applicant under Federal, State, or local laws;

3. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

5. Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

6. Compliance with licensing requirements under previously granted licenses, if any;

7. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by drug wholesale distributors; and

8. Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The Board reserves the right to deny a license to any applicant if it determines that the granting of such a license would not be in the public's interest.

(5) Personnel. The licensed wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

(6) Violations:

(a) A license issued to a wholesale distributor pursuant to this part shall be subject to revocation or suspension upon conviction of the license holder for violations of Federal, State, or local drug laws and/or regulations.

(b) Violation of any of the provisions of any applicable Board laws or rules shall be grounds for the suspension or revocation of the license issued hereunder.

(c) Any revocation or suspension of a license pursuant to this part shall be carried out pursuant to the Georgia Administrative Procedure Act, O.C.G.A. Title 50 Chapter 13.

(d) Drug samples shall not be sold in any licensed pharmacy.

(7) Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drugs Distribution Records. The following are required for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees.

(a) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

3. Have a quarantine area for storage or prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened; 4. Be maintained in a clean and orderly condition; and 5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

1. Access from outside the premises shall be kept to a minimum and be well controlled.

2. The outside perimeter of the premises shall be well lighted.

3. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

4. All facilities shall be equipped with an alarm system to detect entry after hours.

5. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription drugs or chemicals shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia (USP) Compendium.

1. If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

2. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

3. The record keeping requirements in subparagraph (f) of this section shall be followed for all stored drugs.

(d) Examination of materials.

1. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

2. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

3. The record keeping requirements in subparagraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) Returned, damaged, and outdated prescription drugs.

1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

2. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

3. If the conditions under which a prescription drugs has been returned cast doubt on the drug's safety, identify, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which the drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drugs has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

4. The record keeping requirements in subparagraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) Record keeping:

1. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

   (i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs are shipped;

   (ii) The identity and quantity of the drugs received and distributed or disposed of; and

   (iii) The date of receipt and distribution or other disposition of the drugs.

(g) For each person or firm, whether located inside or outside the State of Georgia, to which a drug wholesale distributor, located inside the State of Georgia, sells to, ships to, delivers to, or otherwise distributes drugs to, such drug wholesale

distributor shall request and maintain a copy of that person or firm's current license or permit which authorizes them to purchase, buy, receive, or otherwise possess drugs.

1. NO drug wholesale distributor, located inside the State of Georgia, may ship to, sell to, or otherwise deliver a dangerous drug or controlled substance to a person or firm unless that person or firm holds a license or permit which authorizes them to purchase, buy, receive or otherwise possess drugs.

(h) Nothing in this chapter or Georgia law authorizes any drug wholesale distributor, located inside the State of Georgia, to sell, ship, or otherwise distribute any drugs to any person or firm located outside the United States of America or its territories without first receiving written permission to do so from the Board. Such permission can only be granted by the Board after it has received a written request from the drug wholesale distributor giving the details of the proposed transaction. The Board reserves the right to have the GDNA investigate any and all such requests, and the Board reserves the right to deny any such request.

(i) Inventories and all records required under this rule shall be made available for inspection and photocopying by any authorized official of a government agency charged with enforcement of these regulations for a period of two (2) years following deposition of the drugs.

(j) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be made readily available for authorized inspection during the retention period. Records kept at a central record keeping location apart from the inspection site and not electronically retrievable, shall be made available for inspection within two (2) working days of a request by an authorized official of any governmental agency charged with enforcement of these regulations.

(8) Written Policies and Procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies the following:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the FDA or other Federal, State, or local law enforcement or other government agency, including the Georgia State Board of Pharmacy;

2. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

3. Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or natural emergency.

(d) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(9) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officer, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(10) Compliance with Federal, State, and local laws. Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(a) Wholesale drug distributors shall permit the Georgia State Board of Pharmacy and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operation procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, Local, and DEA regulations.

(11) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

Cite as Ga. Comp. R. & Regs. R. 480-7-.03
Authority: O.C.G.A. §§ 43-1-19, 26-4-37, 26-4-120, 26-4-27, 26-4-28, 26-4-113, 26-4-115, 16-13-35, 16-13-72, 16-13-72.1, 26-4-20, 26-4-60.
History. Original Rule entitled "Wholesale Distributor Licensing Requirements" adopted. F. Feb. 21, 1992; eff. Mar. 12, 1992.
Repealed: New Rule entitled "Drug Wholesale Distribution Licensing Requirements" adopted. F. Aug. 6, 2001; eff. Aug. 26, 2001.
Amended: F. June 29, 2015; eff. July 19, 2015.

Rule 480-7-.04. Researcher's Permit.

(1) Applications for registration must be filed with the Office of the Georgia State Board of Pharmacy ("Board") with the required fees.

(2) Registration of a Researcher will be considered on the basis of the application filed and a report from the director of the GDNA certifying the applicant possesses the necessary qualifications for a permit.

(3) Application fees shall NOT be refundable.

(4) Permits shall not be transferable. Permits become null and void upon the change of mode, operation and/or location of the permit-holder.

(5) Permits are renewable every two (2) years and expire on June 30th of the even- numbered years. Permits may be renewed upon the payment of the required renewal fee and the filing of the renewal application form. If the application is not made and the fee not pa id before September 1st of the even-numbered year, the permit shall lapse and shall not be renewable except by application f or a new permit.

(6) Minimum Qualifications:

(a) The Board will consider the following factors in determining eligibility for persons or entities applying for permits to engage in research.

1. Any convictions of the applicant under any Federal, State, or local laws related to dangerous drugs or controlled substances;

2. Any felony convictions of the applicant under any Federal, State, or local laws;

3. The applicant's past experience in research related to dangerous drugs including controlled substances;

4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug research;

5. Suspension or revocation by Federal, State or local government of any permit currently or previously held by the applicant for drug research;

6. Compliance with the requirements under previously granted permits or licenses, if any;

7. Compliance with requirements to maintain and/or make available to the State licensing or permitting authority or to Federal, State or local law enforcement officials those records required to be maintained by researchers;

8. Any other factors or qualifications such as age, education, training, etc. the Board considers relevant to be inconsistent with the public health and safety; and

9. Having a Peace Officer Certification suspended or revoked by the Georgia Peace Officers Standard and Training (POST) or other professional licensing authority.

(b) The Board reserves the right to deny a permit to any applicant if it deter mines that the granting of such a permit would not be in the public interest.

(7) Storage and Security:

(a) All drugs including dangerous drugs and controlled substances shall be stored at appropriate temperatures and under appropriate conditions in accordance with labeled requirements or those published in the current edition of an official compendium, such as the United States Pharmacopoeia (USP) Compendiums;

(b) All facilities used for storage of drugs including dangerous drugs and controlled substances shall be of suitable size and construction to facilitate cleaning, maintenance and proper operations; and shall provide security from unauthorized entry as approve d by the Board or GDNA.

1. All such facilities will be located in an appropriately zoned district, such as a college, school, university, law enforcement off ice, or commercial area. No permit will be issued to any researcher whose facility is located in a residential area, dwelling, or location. The Board may choose to grant an exception to this rule upon receipt of a written request from such applicant stating the reason for such an exemption.

(8) Record Keeping and Accountability:

(a) Researchers shall establish and maintain records of all transactions regarding receipt, distribution or other disposition of dangerous drugs or controlled substances.

(b) All records required by these regulations shall be retained for a minimum period of two (2) years following any disposition of any drugs received.

(c) Such records shall be kept at the storage site or shall be immediately retrievable by computers or other electronic means for authorized inspection during the retention period.

(9) Sanctions and Penalties:

(a) The Board under these regulations shall have the power to suspend or revoke any permit issued or to reprimand or to fine, not to exceed $500 per violation, the holder of such permit when such holder shall have:

1. Become unfit or incompetent;

2. Been convicted of a felony or any other crime involving moral turpitude;

3. Violated any Pharmacy laws or rules or regulations promulgated by the Board, or violated any other state, federal, or local laws and rules related to drugs.

4. The Board may refuse to grant a permit or renewal to any person, firm, corporation, agency, department or other entity for any of the grounds set forth in O.C.G.A. Section 26-4-49 and/or 26-4-60 of the Georgia Pharmacy Practice Act.

Cite as Ga. Comp. R. & Regs. R. 480-7-.04
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-49, 26-4-60, 26-4-120.2.
History. Original Rule entitled "Researcher's Permit" adopted. F. Jan. 15, 1997; eff. Feb. 4, 1997.
Amended: F. Oct 27, 1998; eff. Nov. 16, 1998.
Amended: F. Aug. 6, 2001; eff. Aug. 26, 2001.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 480-7-.05. Reverse Distributors.

(1) Every firm, whether located inside or outside the State of Georgia, which receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant located in the State of Georgia which holds a permit or license to dispense or possess drugs, shall be known as a Reverse Distributor or a Reverse Drug Distributor.

(2) In order or any Reverse Distributor, wherever located, to engage in the business of receiving drugs for destruction, return credit, or other disposal from a registrant located in Georgia, it must be licensed as a Reverse Distributor by the Georgia State Board of Pharmacy ("Board").

(3) The minimum information required by the Board in order to register a Reverse Distributor will be the same as required under Rule 480-7-.03(2).

(4) The minimum requirements for applications for registration as a Reverse Distributor with the Board will be the same as required under Rule 480-7-.03(3).

(5) Personnel: The licensed Reverse Distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the process of receiving drugs for destruction, credit return, or other means of disposal. Each such person shall have a working knowledge of the requirements for the law and rules for handling such drugs.

(6) Violations:

(a) A license issued to a Reverse Distributor pursuant to this part may be subject to revocation or suspension upon conviction of the license holder of or an employee of a reverse distributor for violations related to federal, state or local laws and/or rules.

(b) Violation of any provisions of any applicable Board Rules shall be grounds for the suspension, revocation, or other sanctions of the permit issued hereunder.

(c) Any action taken on a license pursuant to this part shall be carried out pursuant to the Georgia Administrative Procedure Act, O.C.G.A. Title 50, Chapter 13.

(7) Minimum requirements for the storage and handling of prescription drugs and or the establishment and maintenance of prescription drug distribution records by Reverse Distributors. A Reverse Distributor shall follow the same requirements as listed under Board Rule 480-7-.03(7), except as follows:

(a) A Reverse Distributor does not have to maintain a separate quarantine area for storing drugs which are outdated, damaged, etc., as noted under Rule 480-7-.03;

(b) A Reverse Distributor does not have to maintain drugs under controlled temperature and humidity as required under Rule 480-7-.03;

(c) A Reverse Distributor does not have to ensure the condition of drugs that are received or shipped as required under Rule 480-7-.03(7)(d) or (e);

(d) Prior to a Reverse Distributor removing drugs from a registrant, the Reverse Distributor must generate paperwork, a copy of which must be provided to and

maintained by the registrant and a copy to be maintained by the Reverse Distributor, both for two (2) years, which at minimumrecords the following:

1. The date and time that the drugs left or were taken from the registrant;

2. A complete inventory of the drugs being transferred to the Reverse Distributor;

3. The name, Board permit number, address, and telephone number of the Reverse Distributor removing the drugs;

4. The name and signature of the responsible person representing the Reverse Distributor physically removing the drugs;

5. The name and signature of the pharmacist representing a pharmacy or responsible person representing another type of registrant transferring the drugs to the Reverse Distributor and the name and principal address of the pharmacy or other registrant from which the drugs are removed; and

6. Any and all other information required under Ga. Comp. R. & Reg. c. 480-50 and applicable federal law and regulation.

(e) Upon a Reverse Distributor's receipt of drugs from a registrant by contract or common carrier, the Reverse Distributor must generate paperwork, a copy of which must be maintained by the Reverse Distributor for two (2) years, which at minimum records the following:

1. The date and time that the drugs were received by the Reverse Distributor;

2. A complete inventory of the drugs received by the Reverse Distributor;

3. The name and signature of the pharmacist representing a pharmacy or responsible person representing another type of registrant sending the drugs to the Reverse Distributor and the name and principal address of the pharmacy or other registrant from which the drugs are sent; and

4. Any and all other information required under Ga. Comp. R. & Reg. c. 480-50 and applicable federal law and regulation.

Cite as Ga. Comp. R. & Regs. R. 480-7-.05
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-113, 26-4-115.
History. Original Rule entitled "Reverse Distributors" adopted. F. Aug. 6, 2001; eff. Aug. 26, 2001.
Amended: F. June 29, 2015; eff. July 19, 2015.
Amended: F. Feb. 22, 2018; eff. Mar. 14, 2018.

Rule 480-7-.06. Background Investigations of Applicants.

Whenever a person or firm applies for licensure under this Chapter, the GDNA has the authority to conduct whatever thorough background investigation necessary to ensure the applicant meets all **the requirements of this Chapter.**

Cite as Ga. Comp. R. & Regs. R. 480-7-.06
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-29.
History. Original Rule entitled "Background Investigations of Applicants" adopted. F. Aug. 6, 2001; eff. Aug. 26, 2001.

Rule 480-7-.07. Credit for Returned Expired Drugs.

(1) Effective with all drug orders placed on or after July 1, 2002, all wholesale drug distributors shall make adequate provisions for the return of outdated prescription drugs, both full and partial containers, for up to six months after the labeled expiration date for prompt full credit or replacement.

(2) Wholesale drug distributors shall establish a written policy consistent with O.C.G.A. Section 26-4-115(c)providing for the return of outdated prescription drugs sold to a client by such wholesale drug distributor. Such policy may include a procedure for the drugs to be returned to the drug manufacturer, may include a requirement that the drugs be returned in the original containers in which it was purchased, and may include the use of a reverse drug distributor. Said policy shall be available to the Board or its agents upon request.

(3) The Board has determined the following listed drugs will be exempt from the requirements of this provision as they are essential to health care treatment and have an expiration date of less than one year from the date such drug is manufactured:

   (a) Influenza Vaccines

(4) In order to be eligible for full credit or replacement, the drug must be received by the wholesale drug distributor, or if not the wholesale drug distributor, its agent designated in its return policy, no later than the sixth month from the labeled expiration date. A signed delivery receipt shall constitute evidence of the drugs having been returned.

(5) Prompt full credit to the purchaser shall occur within sixty days from the date the return drugs were received by the wholesale drug distributor or its designated agent. If the wholesale drug distributor determines that the drugs were not returned within six months of the labeled expiration date, or were not returned consistent with the written return policy, then the wholesale drug distributor shall notify said purchaser in writing within thirty (30) days of the receipt of the drugs of its intent not to give full credit or replacement. Wholesale drug distributors shall maintain documentation supporting its refusal to give full credit or replacement for a period of two (2) years. Such documentation shall be available to the Board or its agent upon request.

(a) "Full credit" shall be defined to include a cash refund or credit with the drug wholesale distributor for the purchase price of the drug as established by drug invoice less a reasonable fee for handling of the returned drugs. A reasonable fee shall not be more than 7% of the total invoice price of the returned drugs.

(6) In lieu of full credit, a wholesale drug distributor may elect to replace the drug. Said replacement drug must be a drug of like value mutually agreed upon by the wholesale drug distributor and the original drug purchaser. Said replacement drug must be sent to the original drug purchaser within sixty (60) days from the date of return.

(7) Wholesale drug distributors shall maintain records of all credits and replacements made under this rule for a period of two (2) years and such record shall be made available to the Board or its agent upon request.

(8) The submission of drugs by a purchaser licensed by the Board in State of Georgia for refund or credit to a wholesale drug distributor pursuant to O.C.G.A. Section 26-4-115 and this rule when said drugs are in a container other than the one in which it was purchased, when said drugs were not purchased from that wholesale drug distributor, or when the drugs were purchased for a pharmacy or facility outside the State Of Georgia shall constitute fraudulent and unprofessional conduct and may subject the purchaser to disciplinary action by the Board.

(9) The return of drugs under this rule shall also be consistent with all other applicable Federal, State, and local laws and regulations.

Cite as Ga. Comp. R. & Regs. R. 480-7-.07
Authority: O.C.G.A.§§ 26-4-27, 26-4-28, 26-4-115.
History. Original Rule entitled "Credit for Returned Expired Drugs" adopted. F. Jan. 29, 2003; eff. Feb. 18, 2003.
Amended: F. Mar. 21, 2018; eff. Apr. 10, 2018.

Chapter 480-7A. LISTED CHEMICAL WHOLESALE DISTRIBUTOR.

Rule 480-7A-.01. Definitions.

(1) **Board.** Board means the Georgia State Board of Pharmacy.

(2) **Brokerage**. Brokerage means any firm or broker who arranges for the buying for resale, selling, transferring, or otherwise arranging to distribute dangerous drugs, controlled substances, or listed chemicals, whether or not such firm physically handles, receives, distributes, or bills for the actual drug product.

(3) **Broker.** Broker means any individual, corporation, corporation division, partnership, association, or other entity which assists in arranging a transaction of a listed chemical by negotiating contracts, serving as an agent or intermediary, or fulfilling a formal obligation to complete a transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and a transporter, or by receiving any form of compensation for so doing.

(4) **DEA.** DEA means the U.S. Department of Justice Drug Enforcement Administration.

(5) **Designated Representative.** Designated Representative means a person designated by a listed chemical wholesale Distributor who will serve as the designated representative of the listed chemical wholesale distributor with the Board and GDNA who is actively involved in and aware of the actual daily operation of the listed chemical wholesale distributor.

(6) **Distribute or Distribution**. Distribute or distribution means to sell, offer to sell, broker, give away, transfer, whether by passage of title, physical movement, or both; deliver or offer to deliver a listed chemical or drug. The term does not mean to administer or dispense.

(7) **Excessive**. Excessive means any sale, distribution, purchase, or transfer of a quantity of any listed chemical by a retail store which the wholesale distributor deems or judges to in excess of routine sales for that particular store.

(8) **GBI.** GBI means the Georgia Bureau of Investigation.

(9) **GDNA.** GDNA means the Georgia Drugs and Narcotics Agency.

(10) **Listed Chemical.** Listed Chemical means any drug or product containing a chemical defined by the Board as a listed chemical in 480-7A-.02 and/or designated as a listed chemical by law.

(11) **Listed Chemical Wholesale Distributor**. Listed Chemical Wholesale Distributor means any firm named under O.C.G.A. 16-13-30.3 (b.1) as a Wholesale Distributor which sells, transfers, purchases for resale, sells for resale, or otherwise furnishes any product containing a drug or listed chemical to a retail outlet.

(12) **Listed Chemical Wholesale Distributor Permit.** Listed Chemical Wholesale Distributor Permit means a permit issued by the Board to a wholesale distributor to distribute listed chemical products to retail outlets.

(13) **Manufacturer.** Manufacturer means any firm which is engaged in the manufacturing, preparing, propagating, processing, repackaging, or labeling of a dangerous drug, controlled substance, or a listed chemical for distribution.

(14) **Manufacturing Pharmacy.** Manufacturing pharmacy means a drug manufacturer who holds a manufacturing pharmacy permit issued by the Board authorizing such firm to manufacture, but not distribute, drugs in this state.

(15) **Police Chief of a Municipality.** Police Chief of a Municipality means the Chief of Police of a municipality located in the State of Georgia, or an officer or person otherwise authorized by the Police Chief to act in his or her behalf in regards to O.C.G.A. 16-13-30.3.

(16) **Reportable Transaction.** Reportable transaction means a report generated regarding a transaction in which a retail store orders and receives what the listed chemical wholesale distributor deems to be an excessive quantity of any listed chemical products.

(17) **Retail Outlet.** Retail Outlet means a grocery store, general merchandising store, drug store, or other entity or person whose activities with listed chemicals is almost exclusively to sales for personal use, directly to walk-in customers, in face to face transactions by direct sales.

(18) **Sheriff of a County**. Sheriff of a County means either the Sheriff of a county located in the State of Georgia, or a deputy or person otherwise authorized by the Sheriff to act on his or her behalf in regards to O.C.G.A. 16-13-30.3.

(19) **Wholesale Distributor**. Wholesale Distributor means:

(a) A firm as defined by O.C.G.A. 26-4-5(41) and holding a wholesaler pharmacy permit issued by the Board and licensed under O.C.G.A. 16-13-113, which authorizes a firm to distribute dangerous drugs, controlled substances, and listed chemicals; or

(b) A firm as specified by O.C.G.A. 16-13-30.3 which is authorized to distribute certain drugs or listed chemicals as specified by paragraph (b.1) of that statute, and has been issued a chemical wholesale distributor permit by the Board under O.C.G.A. 16-13-30.3.

(20) **Wholesaler Pharmacy.** Wholesaler Pharmacy means a firm holding a permit issued by the Board to distribute drugs at wholesale, not at retail, and which permit authorizes a firm to distribute dangerous drugs, controlled substances, and listed chemicals. A wholesaler pharmacy is not intended to be, nor should it be considered a retail, hospital, clinic or any other type of pharmacy which has separate permits issued by the Board.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.01
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-4-5, 26-4-27, 26-4-28, 26-4-113.
History. Original Rule entitled "Definitions" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.02. Listed Chemicals.

Drugs or chemicals which are restricted by the Board or by law to wholesale distribution only by a firm licensed by the Board as a listed chemical wholesale distributor or a wholesale distributor, which are also known as listed chemicals, are as follows:

(1) Pseudoephedrine or a product containing any quantity of this drug, except as follows:

(a) Pediatric products labeled pursuant to federal regulation as primarily intended for administration to children under 12 years of age according to label instructions; and

(b) Products that the Board, upon application of a manufacturer, exempts because the product is formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine or its salts or precursors.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.02
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4.
History. Original Rule entitled "Listed Chemicals" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.03. Restriction on the Distribution of Listed Chemicals.

Chemicals listed in 480-71-.02 may only be distributed to retail outlets by a listed chemical drug wholesale distributor licensed by the Board, or a wholesale distributor licensed by the Board. In order for any person or firm to conduct an act of brokerage for any dangerous drug, controlled substance, or listed chemical which is received by retail outlet or pharmacy in this state, regardless of where the shipment originates, such person or firm is required to be licensed as a wholesale distributor or a listed chemical wholesale distributor. Any manufacturer which distributes a drug to any wholesale distributor or listed chemical wholesale distributor located in the State of Georgia must have been issued the appropriate wholesale distributor permit from the Board. Having been issued a manufacturing pharmacy permit by the Board does not authorize a manufacturing firm to distribute drugs to any firm located in this state.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.03
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-4-113.
History. Original Rule entitled "Restriction on the Distribution of Listed Chemicals" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.04. Requirements for licensure as a Listed Chemical Wholesale Distributor.

(1) Listed chemical wholesale distributors that provide services within this State, whether the listed chemical wholesale distributor is located within this State or outside this State, shall be licensed by the Board and shall biennially renew their permit or license with the Board using an application provided by the Board.

(2) Where listed chemical wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the Board.

(3) A person or firm holding a valid permit issued by the Board and licensed as a wholesale distributor under Code Section 26-4-113 shall not be required to obtain an additional license under this Code section; Wholesale distributors licensed under Code Section 26-4-113 shall be subject to the provisions of this Code section in the same manner as chemical wholesale distributors licensed under this Code section.

(4) Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business.

(5) The Board requires the following and such additional information as found on an approved Board application from each listed chemical wholesale distributor as part of the initial licensing procedure and as part of any biennial renewal of such license:

(a) The name, trade or business name, full business address, and telephone number of the applicant. Trade or business names cannot be identical to that of another Board licensee.

(b) The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship).

(c) Name(s) of the owner and operator of the licensee (if not the same person), including:

(i) If a person: the name, address, and social security number;

(ii) If a partnership: the name, address, and social security number of each partner, and the name of the partnership and federal employer identification number;

(iii) If a corporation: the name, address, social security number, and title of each corporate officer and director, the corporate names, the name of the State of incorporation, federal employer identification number, and the name of the parent company, if any; the name, address, and social security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter;

(iv) If a sole proprietorship: the full name, address, and social security number of the sole proprietor, and the name and federal employer identification number of the business entity;

(v) If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and

(vi) Any other relevant information that the Board requires.

(d) Name(s), address(es), telephone number(s), date(s) of birth of a person(s) to serve as the designated representative(s) for listed chemicals and additional information as required.

(e) A non-refundable application and/or renewal fee as determined by the Board and set forth in the fee schedule.

(6) By submitting an application for licensure as a listed chemical wholesale distributor, said applicant consents to a criminal background check of the applicant, all personnel involved in the operations of the listed chemical wholesale distributor, all shareholders involved in operations, and anyone owning or being involved in operations to determine if an applicant or others associated with the ownership, management, or operations of the listed chemical wholesale distributor has committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state laws, at the applicant's expense, and will be sufficient to include all states of residence since the person has been an adult.

(7) Each facility which engages in listed chemical wholesale distribution must undergo an inspection on behalf of the Board by an agent with the GDNA for the purpose of inspecting the in-state listed chemical wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board but no less than once every three (3) years.

(8) Each facility which is located outside the State and engages in listed chemical wholesale distribution must undergo a background investigation by GDNA on behalf of the Board and be approved by the GDNA prior to being approved for licensure, and as necessary submit to an inspection by either GDNA or an agent contracted with by GDNA.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.04
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-4-28, 26-4-111 to 26-4-113, 26-4-115.
History. Original Rule entitled "Requirements for Licensure as a Listed Chemical Wholesale Distributor" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.05. Denial of Licensure as a Listed Chemical Wholesale Distributor.

(1) An application for a license or permit provided for in this chapter may be denied by the Board for reasons including, but not limited to:

(a) Furnishing false or fraudulent material information in any application filed under this rule or Chapter 13 of Title 16;

(b) Being convicted of a crime under any state or federal law;

(c) Having his or her federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances or listed chemicals;

(d) Violating the provisions of Chapter 4 of Title 26 or Chapter 13 of Title 16;

(e) Being located in a place of residence;

(f) Failing to maintain effective controls against the diversion of products containing listed chemicals to unauthorized persons or entities; and/or

(g) Any other factors or qualifications provided by law or that the Board considers relevant to and consistent with the public health and safety.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.05
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-4-113, 26-4-115, 43-1-19.
History. Original Rule entitled "Denial of Licensure as a Listed Chemical Wholesale Distributor" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.06. Records and Recordkeeping; Reporting Requirements.

(1) Listed chemical wholesale distributors and other wholesale distributors shall, at a minimum, maintain records regarding the distribution of listed chemicals as follows:

(a) Produce and maintain, for a minimum of three years from the date of the transaction, inventories and records of all transactions regarding the receipt, sale, credit, transfer, disposition, and distribution of all listed chemicals to any firm, person, or retail outlet located in this State. Inventories and records shall be made available for inspection and photocopying by any authorized agent of any State or federal agency for a period of three (3) years following their creation date.

(b) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any State and federal governmental agency charged with enforcement of these rules.

(c) Maintain an up to date list of firms, persons or retail outlets with whom they do business in regards to listed chemicals.

(2) Listed chemical wholesale distributors and other wholesale distributors shall, at a minimum, maintain and provide documents and reports regarding the distribution of listed chemicals as follows:

(a) Supply a copy of their Board issued permit to any firm, person, or retail outlet in this state which has received, purchased, or gained access to any product containing a listed chemical.

(b) Supply each firm, person, or retail outlet with a copy of all records involving sales, credits, transfers or the like whenever such transaction involves a product containing a listed chemical.

(c) Report to GDNA of shortages or losses of listed chemicals within seven (7) business days.

(d) Within seven days, notify the GDNA of any purchases of a product containing a listed chemical from the listed chemical wholesale distributor which the wholesaler judges to be excessive, or have knowledge or suspicion of said purchases being used in the unlawful manufacture of a controlled substance or file with the GDNA any reportable transaction. A reportable transaction should be sent to the attention of the Director of the GDNA. Such reports should be sent to GDNA located at 40 Pryor Street, SW - Suite 2000 in Atlanta, Georgia 30303.

(e) Upon verbal or written request from the GDNA, the GBI, or the sheriff of a county or the police chief of a municipality located in this state, submit reports to account for the transactions of any listed chemicals with persons or firms located within this state; such transactions shall include all sales, distribution, or transactions dealing with products containing a listed chemical; All such records shall be submitted by the distributor within two working days.

(3) Any and all retail outlets or persons receiving a listed chemical product from a licensed listed chemical wholesale distributor, licensed by this State, are required to maintain records of all such transactions for a minimum of three years, and upon request, by law enforcement officials, are required to provide such records for review within five business days, with failure to provide such records accounting for the presence of such products shall result in the embargo or seizure of such products.

(4) Changes in any information required on the initial application shall be submitted to the Board no less than 30 days prior to such change.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.06
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-4-28, 26-4-112, 26-4-113, 26-4-115.
History. Original Rule entitled "Records and Recordkeeping; Reporting Requirements" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.07. Requirements for Storage, Handling, Transport, and Shipment of Listed Chemicals.

The following are required for the shipping, transporting, storage and handling of listed chemicals, and for the establishment and maintenance of listed chemical wholesale distribution records by listed chemical wholesale distributors and other wholesale distributors and their officers, agents, representatives, and employees:

(1) All facilities at which listed chemicals are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

(a) Be of suitable construction to ensure that all listed chemicals in the facilities are maintained in accordance with official compendium standards, such as USP/NF;

(b) Be of suitable size and construction to facilitate cleaning, maintenance, and proper listed chemical wholesale distribution operations;

(c) Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(d) Have a quarantine area for storage of listed chemicals that are outdated, damaged, deteriorated, misbranded, adulterated, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;

(e) Be maintained in a clean and orderly condition; and

(f) Be free from infestation of any kind.

(g) Shall be a commercial location and not a personal dwelling or residence.

(h) Shall be duly registered with the DEA and in compliance with all applicable laws and rules for the storage, distribution, shipping, handling, and transporting of listed chemicals.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.07
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-4-28, 26-4-113, 26-4-115.
History. Original Rule entitled "Requirements for Storage, Handling, Transport, and Shipment of Listed Chemicals" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.08. Security.

(1) All facilities used for listed chemical wholesale distribution shall be secure from unauthorized entry:

(a) Access from outside the premises shall be kept to a minimum and be well-controlled;

(b) The outside perimeter of the premises shall be well-lighted;

(c) Entry into areas where listed chemicals are held shall be limited to authorized personnel;

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(4) All facilities shall be equipped with inventory management and control systems that protect against and detect and document any instances of theft, diversion, or counterfeiting.

(5) Listed chemical wholesale distributors should possess and maintain in good working order technology and equipment that allows the listed chemical wholesale distributor to authenticate, track, and trace listed chemicals. The technology and equipment shall satisfy any standards set by the Board for such technology and equipment. The technology and equipment shall be used, as required by the Board, to conduct "for cause" and random tracking, tracing, and authentication of listed chemicals.

(6) Listed chemical wholesale distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(7) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.08
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-4-27, 26-4-28, 26-4-115.
History. Original Rule entitled "Security" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.09. Storage.

All listed chemicals shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such listed chemicals, or with requirements in the current edition of an official compendium such as the USP/NF.

(1) If no storage requirements are established for a listed chemical, the listed chemical may be held at "controlled" room temperature, as defined in an official compendium such as USP/NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, and/or logs shall be utilized to document proper storage of listed chemicals.

(3) Packaging of the listed chemicals should be in accordance with an official compendium such as USP/NF and identify any compromise in the integrity of the listed chemicals due to tampering or adverse storage conditions.

(4) The record-keeping requirements in 480-7A-.06 shall be followed for the listed chemical wholesale distribution of all listed chemicals.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.09
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-4-27, 26-4-28, 26-4-115.
History. Original Rule entitled "Storage" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.10. Returned, Damaged, and Outdated Listed Chemicals.

(1) Any drug or device that is outdated, damaged, deteriorated, misbranded, adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other listed chemicals until they are returned to either the manufacturer or wholesale distributor from which it was acquired or destroyed.

(a) When listed chemicals are adulterated, or misbranded, notice of the adulteration, or misbranding shall be provided to the Board and manufacturer or wholesale distributor from which it was acquired within three (3) business days.

(b) Any listed chemical returned to a manufacturer or wholesale distributor shall be kept under proper conditions for storage, handling, and shipping, transporting, and documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale distributor to which the drugs are returned.

(2) Any listed chemical whose immediate or sealed outer or secondary containers or labeling are adulterated or misbranded shall be quarantined and physically separated from other listed chemicals until they are returned to either the manufacturer or wholesale distributor from which it was acquired or destroyed.

(a) When the immediate or sealed outer or secondary containers or Labeling of any listed chemical are adulterated or misbranded notice of the adulteration or misbranding shall be provided to the Board and manufacturer or wholesale distributor from which it was acquired within three (3) business days.

(3) Any listed chemical that has been opened, outdated, or used, shall be identified as such, and shall be quarantined and physically separated from other drugs or devices until they are returned to the manufacturer or wholesale Distributor from which acquired or destroyed via distribution to a reverse distributor.

(4) The record-keeping requirements in 480-7A-.06 of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated listed chemicals, as provided by law, and such action shall be consistent with relating the drugs.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.10
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-3-7 to 26-3-9, 26-3-16, 26-4-27, 26-4-28.
History. Original Rule entitled "Returned, Damaged, and Outdated Listed Chemicals" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.11. Violations.

A license issued to a listed chemical wholesale distributor pursuant to this part may be subject to revocation, fines, suspension, or otherwise disciplined as provided by law, for reasons, including but not limited to the following:

(1) The permit or license holder being convicted or being arrested, charged and sentenced for violations of Federal, State, or local laws and/or regulations relating the drugs.

(2) Violating any of the provisions of any applicable Board laws or rules.

(3) If any owner, officer, designated representative, or other significant person employed by the permit holder has:

(a) Furnished false or fraudulent material information in any application filed under this Code section;

(b) Been convicted of a crime under any state or federal law;

(c) Had his or her federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances or listed chemicals;

(d) Violated the provisions of Chapter 4 of Title 26 or Chapter 13 of Title 16;

(e) Failed to maintain effective controls against the diversion of listed chemical products to unauthorized persons or entities.

(f) Failed to comply with the reporting requirements of this chapter; or

(g) Made a false statement in a report or record required by this chapter or State law.

(4) The adulteration or misbranding of any listed chemical;

(5) The receipt of any listed chemical that is adulterated, misbranded, stolen, obtained by fraud or deceit, or the delivery or proffered delivery of such chemical for distribution.

(6) The alteration, mutilation, destruction, forging, obliteration, or removal of the whole or any part of the labeling of a listed chemical or the commission of any other act with respect to a listed chemical that results in the listed chemical being misbranded;

(7) Failing to maintain records to verify the sale, transfer, or distribution of any and all chemical products to a firm, person or retail outlet in this State.

(8) Failing to maintain or provide records or submit to an inspection as required by any Rule or laws of this State;

(9) Providing the Board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of any rule or law of this State.

(10) Failing to obtain a license or operating without a valid permit or license when a permit or license is required;

(11) Obtaining or attempting to obtain a listed chemical by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a listed chemical;

(12) Failing to report any violations of the rules or law regarding listed chemicals.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.11
Authority: O.C.G.A. Secs. 16-13-30.3, 16-13-30.4, 26-3-7 to 26-3-9, 26-4-27, 26-4-28, 26-4-113, 26-4-115, 43-1-19.
History. Original Rule entitled "Violations" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-7A-.12. Licensure Exception.

Notwithstanding any other provision of this chapter, no person shall be required to obtain a license or permit for the sale, receipt, transfer, or possession of a listed chemical product when:

(a) Such lawful distribution takes place in the usual course of business between agents or employees of a single regulated person or entity; or

(b) A listed chemical product is delivered to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman.

Cite as Ga. Comp. R. & Regs. R. 480-7A-.12
Authority: O.C.G.A. Secs. 16-13-30.4, 26-4-27, 26-4-28.
History. Original Rule entitled "Licensure Exception" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Chapter 480-7B. DURABLE MEDICAL EQUIPMENT SUPPLIERS.

Rule 480-7B-.01. Definitions.

(1) "Board" shall mean the Georgia Board of Pharmacy.

(2) "Designated representative" means an individual proposed by a DME supplier and approved by the Board as the supervisor or manager responsible for ensuring the DME supplier's compliance with all state and federal laws and regulations pertaining to practice as a DME supplier.

(3) "Durable medical equipment" or "DME" shall mean equipment for which a prescription is required, including repair and replacement parts for such equipment, and which

(a) Can withstand repeated use;

(b) Has an expected life of at least three years;

(c) Is primarily and customarily used to serve a medical purpose;

(d) Generally is not useful to a person in the absence of illness or injury; and

(e) Is appropriate for use in the home.

(4) "Durable medical equipment supplier" or "DME supplier" means a person or entity that provides durable medical equipment to a consumer and submits a claim for reimbursement by a third party, either directly or through a contractual arrangement.

(5) "GDNA Agent" or "GDNA Agents" shall mean the director, a deputy director or a special agent of the Georgia Drugs and Narcotics agency.

Cite as Ga. Comp. R. & Regs. R. 480-7B-.01
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-51.
History. Original Rule entitled "Definitions" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.

Rule 480-7B-.02. DME Supplier Licensing Requirements.

(1) **Licensing requirement.** A person or entity located in the State of Georgia that provides durable medical equipment to a consumer and submits a claim for reimbursement by a third party, either directly or through a contractual arrangement, and any Medicare enrolled out-of-state DME manufacture or wholesale distributor that provides durable medical equipment to consumers in this state and who holds a valid license from another state must hold a license issued by the Board. Licensure as a DME supplier will be

considered on the basis of the completion of a Board approved application filed with the Board, payment of a fee, a report from GDNA certifying that the applicant possesses the necessary qualifications for licensure including meeting all safety standards and requirements established by the Board, satisfactory licensure status in other states, and if located in the State of Georgia, maintenance of an office or place of business in the State of Georgia. When reviewing an application, the Board may determine that a person or entity accredited by an organization recognized by the federal Centers for Medicare and Medicaid Services has met all or some of the requirements for licensure.

(2) **Applications Licensure as a DME supplier.**

(a) The Board requires the following information from each DME supplier as part of the initial licensing procedure:

1. The name, full business address, and telephone number of the applicant;

2. All trade of business names used by the applicant;

3. Address, telephone number(s), and the name(s) of the proposed designated representative(s) for the facility and evidence showing the qualifications of the proposed designated representative(s) to serve;

4. The type of ownership or operations (i.e. partnership, corporation, or sole proprietorship);

5. The name(s) of the owner and/or operator of the applicant, including:

   (i) If a person, the name of the person;

   (ii) If a partnership, the name of each partner and the name of the partnership;

   (iii) If a corporation, the name and title of each corporate officer and director, the corporate names, the name of the incorporation, and the name of the parent company, if any;

   (iv) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity;

6. If located out of state, proof of a valid, unexpired license to operate as a DME supplier in the compliance with the laws and rules of the other state; and

7. Information necessary to demonstrate compliance with O.C.G.A. Title 50, Chapter 36.

(b) Application fees and renewal fees shall be set by the Board in a fee schedule and shall not be refundable.

(c) Applications are only valid for one year.

(3) **Denial of Applications for Licensure.**

Applications for licensure may be denied for failure to meet the minimum qualifications for a license, failure to comply with the laws or regulations of this State, the United States or any other state having to do with DME suppliers, making false representations on an application, failure to meet the safety standards established by the Board, or for any other grounds set forth in O.C.G.A. §§ 26-4-60 and 43-1-19. The denial of an application for licensure shall not be considered a contested case under the provisions of O.C.G.A. T. 50, Ch. 13, but the applicant shall be entitled to an appearance before the Board.

(4) **Term of license.**

Licenses are issued for thirty-six months, expire on June 30th of every third year, and may be renewed for three years upon the payment of the required fee for each place of business and the filing of a completed application for renewal. If the application for renewal is not made and the fee not paid before September 1st of the third year, the license shall lapse and shall not be renewed, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.

(5) **Licenses are Location Specific and Non-Transferable**. Where operations are conducted at more than one licensed place of business by a DME supplier, each place of business shall be licensed by the Board, and each place of business requires a separate application for licensure. If a licensed business moves locations, the license does not transfer to the new location and a new application is required.

(6) **Exemption from Licensure Requirement**.

(a) The following persons and entities are not required to obtain a DME supplier license from the Board, unless such person or entity has a separate company, corporation, or division that is in the business of supplying durable medical equipment to consumers and submits a claim for reimbursement by a third party:

1. Pharmacies and pharmacists.

2. Hospitals.

3. Ambulatory surgical centers.

4. Health care facilities owned or operated by the state or federal government.

5. Skilled nursing facilities.

6. Assisted living facilities.

7. Health care practitioners who:

   (i) Provide durable medical equipment within the scope of practice of the health care practitioner's profession; and

   (ii) Are licensed in the State of Georgia to practice the health care practitioner's profession.

8. Suppliers of insulin pumps and related supplies or services;

9. Manufacturers or wholesale distributors that do not sell or rent durable medical equipment directly to consumers;

10. Renal dialysis providers licensed under O.C.G.A. § 31-44-4 and persons or entities that distribute devices necessary to perform home renal dialysis to patients with chronic kidney disease; and

11. Suppliers of osteogenesis stimulators, transcutaneous electrical nerve stimulators, pneumatic compression devices, and related supplies or services.

(b) Facilities that meet the criteria established in O.C.G.A. Section 26-4-6 are not required to be licensed as DME Suppliers.

Cite as Ga. Comp. R. & Regs. R. 480-7B-.02
Authority: O.C.G.A. §§ 26-4-5, 26-4-6, 26-4-27, 26-4-28, 26-4-51, 26-4-60, 43-1-19, 50-36-1, 50-36-2.
History. Original Rule entitled "DME Supplier Licensing Requirements" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.

Rule 480-7B-.03. Designated Representatives for DME Suppliers.

(1) **Requirement for Designated Representatives.** The Board shall only issue a license to a DME supplier if a qualified individual has been approved as a designated representative for the DME supplier. The designated representative will provide sufficient and qualified supervision of the DME supplier's place of business, ensuring compliance with all state and federal laws and regulations. The designated representative shall ensure the protection of the public health and safety in the handling, storage, warehousing, distribution, and shipment of durable medical equipment in the DME supplier's place of business. Where operations are conducted at more than one licensed place of business by a DME supplier, each licensed place of business shall have at least one designated representative present.

(2) **Qualifications of Designated Representatives.** In order to serve as a designated representative, an individual shall:

(a) Be at least 18 years of age;

(b) Submit a Board approved personnel certification form as part of the DME supplier's application to the Board;

(c) Attest to the knowledge and understanding of applicable state and federal laws and regulations relating to the distribution of durable medical equipment, knowledge and understanding of quality control systems, and knowledge and understanding of the United States Pharmacopeia of federal Food and Drug Administration standards relating to the safe storage, handling, and transport of durable medical equipment;

(d) Consent to provide the necessary information to conduct, and pay for a background check to be conducted by the Board, its agent or a firm or firms approved by the Board, which background check will include a criminal history, driver license history and other information as the Board deems necessary, and will authorize the Board and the Georgia Drugs and Narcotics Agency to receive the results; and

(e) If the designated representative is a licensed pharmacist, provide the state(s) of licensure, license number(s), and license status(es) of said license(s).

(3) **Notice to Designated Representative.** Any notice made to a DME supplier licensee shall be made to the designated representative on record with the Board. If notices are returned as undeliverable or unclaimed, service shall be made on the Executive Director, and any disciplinary proceedings shall proceed, or if a final decision, the decision shall become effective.

Cite as Ga. Comp. R. & Regs. R. 480-7B-.03
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-51, 26-4-60.
History. Rule number reserved. F. Mar. 21, 2018; eff. Apr. 10, 2018.
Original Rule entitled "Designated Representatives for DME Suppliers" adopted. F. Nov. 19, 2018; eff. Dec. 9, 2018.

Rule 480-7B-.04. Compliance with investigations.

A DME supplier licensee shall cooperate with the Board in any investigation involving durable medical equipment distributed by such DME supplier licensee from, into, or within this State. The licensee shall respond within ten (10) business days to all communications from the Board or its designee. Failure to respond or cooperate with the Board shall be grounds for the immediate suspension of the DME supplier license, pending a hearing on further disciplinary action by the Board. Failure to cooperate with the Board is grounds for disciplinary action by the Board.

Cite as Ga. Comp. R. & Regs. R. 480-7B-.04
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-51, 26-4-60.
History. Original Rule entitled "Compliance with investigations" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.

Rule 480-7B-.05. Required Reporting to the Board.

(1) **State or Federal Actions.** A DME supplier licensee must notify the Board within ten (10) business days of the receipt of any final order or decision by any other licensing board or federal agency of the imposition of disciplinary action or restriction by such other licensing board or federal agency in which a license or privilege was suspended or revoked. A final order or decision includes a consent order or agreement and is any decision, regardless whether there still exists an appellate right to the state or federal courts. Any revocation or suspension of a state or federal license or permit may result in the immediate suspension of the DME license by the Board, pending a final decision by the Board.

(2) **Felony convictions**. A DME supplier licensee, its owner, or designated representative who is convicted under the laws of this state, the United States, or any other state, territory, or country of a felony shall be required to notify the Board of the conviction within ten (10) days of the conviction. The failure to notify the Board of a conviction shall be considered grounds for revocation of the DME supplier license.

Cite as Ga. Comp. R. & Regs. R. 480-7B-.05
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-28.2, 26-4-51, 26-4-60.
History. Original Rule entitled "Required Reporting to the Board" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.

Rule 480-7B-.06. Retention of Records, Safety Standards, Security, and Operations.

(1) **Consumer counseling.** All personnel engaged in delivery or in-home maintenance and repair of durable medical equipment shall instruct the patient or patient's caregiver on how to use the durable medical equipment provided.

(2) **Continuing education.** Written annual education plan procedures for each classification of personnel must be made available to the Board upon request that includes the following information: description of training content, training method, frequency, and issuance of individual certificates of competence.

(3) **Background Checks.** DME suppliers shall conduct background checks on any person who will have direct contact with patients. Such background check will include at a minimum criminal history. The background check shall be maintained on such persons as long as the person is still performing services for the DME supplier.

(4) **Receipt of complaints from consumers.** DME suppliers shall maintain a telephone number operational during the licensee's regular hours of operation in order to provide support for consumers. Such number shall be capable of receiving inbound calls from consumers to the licensee, and such number shall be on file with Board, and shall be included with any material sent to the consumer with the durable medical equipment.

(5) **Delivery by mail**. A DME supplier that uses delivery by mail is accountable to the Board to arrange for the appropriate mailing/shipping process. The DME supplier shall provide a method by which a patient or patient's caregiver can notify the DME supplier as to any irregularity in the delivery of their DME to include but not be limited to: timeliness of delivery; condition of the DME upon delivery; and failure to receive the DME ordered. A DME supplier using delivery by mail shall document the instances when DME have been compromised during shipment and delivery by mail or when the DME does not arrive in a timely manner, and shall maintain such documentation for two (2) years. In addition, the DME supplier shall maintain reports of patient complaints and internal/external audits about timeliness of deliveries, condition of the DME when received by patient including situations when it was compromised in delivery, the wrong equipment was provided, and the patient failed to receive the DME. Such records shall be provided to the Board, upon request.

(6) **Records.**

(a) A DME supplier shall maintain records for all devices shipped, mailed or delivered to patients in the State of Georgia for a period of at least two (2) years. DME suppliers shall notify the Board of each location where the required records are being maintained, and such records must be readily retrievable and produced to the Board or a GDNA Agent upon request. If the DME supplier is out located out of state, the records must be received by the Board or GDNA within fifteen (15) days of the written request.

(b) A DME supplier shall maintain records of all education plan procedures and certificates of competence, for each employee, for a period of at least two (2) years. A DME supplier shall maintain background checks for each person having in-home contact with a customer for the period that such person remains affiliated with the DME supplier. DME suppliers shall notify the Board of each location where the required records are being maintained, and such records must be readily retrievable and produced to the Board or GDNA Agent upon request. If the DME supplier is out located out of state, the records must be received by the Board or GDNA within fifteen (15) days of the written request.

Cite as Ga. Comp. R. & Regs. R. 480-7B-.06
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-51, 26-4-60.
History. Original Rule entitled "Retention of Records, Safety Standards, Security, and Operations" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.

Rule 480-7B-.07. Inspections.

GDNA Agents, on behalf of the Board, may initially and/or periodically inspect a DME Supplier applicant's or licensee's office or place of business within this state. During such inspection, the GDNA Agents shall have the authority to inspect the facility and all inventories, and shall have the authority to examine, copy, or remove all records, including but not limited to purchase and sales records, repair records, employee records, background checks, and training records. At the conclusion of an inspection, the GDNA Agent(s) conducting the inspection shall have the responsibility of providing to such applicant or licensee a copy of a written inspection report on which any deficiencies or violations are made along with any recommendations. If a follow-up inspection is required due to deficiencies, the Board may charge the applicant or licensee a fee for the re-inspection as provided in its fee schedule established pursuant to paragraph (37) of subsection (a) of Code Section 26-4-28 to cover the cost of such inspection.

Cite as Ga. Comp. R. & Regs. R. 480-7B-.07
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-51, 26-4-60.
History. Original Rule entitled "Inspections" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.

Chapter 480-8. PRISON CLINIC PHARMACIES.

Rule 480-8-.01. Definitions.

For purposes of these Rules and Regulations, the following definitions apply:

(a) Prison Clinic Pharmacy. Prison Clinic Pharmacy is defined as that portion of a prison correctional facility which is engaged in distribution of drugs, medications, devices, and other materials used in the prevention diagnosis and treatment of injury, illness and disease (hereinafter referred to as "drugs"); and which is registered with the Georgia State Board of Pharmacy pursuant to Chapter 26-4 of the Official Code of Georgia Annotated.

(b) Prison Clinic Pharmacy License. Prison Clinic Pharmacy licenses are issued by the Georgia State Board of Pharmacy to those said Prison Clinic Pharmacies, pursuant to the provisions of Chapter 26-4 of the Official Code of Georgia Annotated, whereas the license shall be subject to special prison clinic pharmacy regulations as set forth herein, but exempt from other certain regulations and requirements. To obtain the prison clinic pharmacy license, there must be a Director of Pharmacy Services.

(c) Inpatient. In-patient shall mean an inmate who is confined to an infirmary bed and is in the custody of and assigned to an institution operated under the authority of the Georgia Department of Corrections, or any county or municipal political subdivision.

(d) Outpatient. Out-patient shall mean an inmate who is in the custody of and assigned to an institution operated under the authority of the Georgia Department of Corrections, or any county or municipal political subdivision.

(e) Standard ward inventory. The Director of the prison clinic pharmacy or their pharmacist designee may, in the best interest of the patients served, establish one or more lists of the

kind and quantity of legend drugs to be kept at one or more locations at all times within the said prison clinic and such stocks of legend drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy or their pharmacist designee.

(f) Prison Clinic Administrator. The Prison Clinic Administrator is that individual prison official who is designated as the person responsible for the operation of the portion of a prison or other correctional institution responsible for the health care of the facility's inmates.

Cite as Ga. Comp. R. & Regs. R. 480-8-.01
Authority: O.C.G.A. Sec. 26-4-27, 26-4-28, 26-4-10, 26-4-37.
History. Original Rule entitled "Dangerous Drugs--Defined" adopted. F. Sept. 22, 1967; eff. Oct. 11, 1967.
Amended: F. Oct. 6, 1970; eff. Oct. 26, 1970.
Amended: F. Oct. 20, 1971; eff. Nov. 9, 1971.
Amended: F. Sept. 3, 1975; eff. Sept. 23, 1975.
Repealed. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Amended: Rule entitled "Definitions" adopted. F. Dec. 27, 1985; eff. Jan. 16, 1986.
Amended: F. Feb. 10, 1993; eff. Mar. 2, 1993.
Repealed: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-8-.02. Registration.

(1) Every prison clinic pharmacy, wherever located within the State of Georgia must be licensed by the Georgia State Board of Pharmacy ("Board") in accordance with the laws and regulations of this State. All prison clinic pharmacies shall renew biennially by June 30th of the odd-numbered years with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those prison clinic pharmacies as follows:

(2) Minimum Required Information for Licensure: The Board requires the following information from each prison clinic pharmacy as part of the initial licensing procedure and as part of any renewal of such license.

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business names used by the licensee;

(c) Address, telephone numbers, and the name(s) of the Prison Clinic Administrator;

(d) The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship); and

(e) The name(s) of the owner and/or operator of the licensee, including;

1. If a person, the name of the person;

2. If a partnership, the name of each partner, and the name of the partnership;

3. If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.

4. If a corporation, the name and title of each corporate officer and director, the corporate names and the name of the State of incorporation; and the name of the parent company, if any.

(f) Where operations are conducted at more than one location by a single prison clinic pharmacy, each such location shall be licensed by the Board.

(3) Administration of Applications for Licensure.

(a) Registration of a prison clinic pharmacy will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.

(b) Application fees shall not be refundable.

(c) Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business.

(d) Licenses are renewed for two years periods and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

(e) Changes in any information in this section shall be submitted to the Board prior to such change.

(4) Minimum Qualifications.

(a) The Board will consider the following factors in determining eligibility for licensure for person(s) in charge of the facility and are applying for a prison clinic pharmacy:

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

2. Any felony convictions of the applicant under Federal, State, or local laws;

3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

4. Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant.

5. Compliance with licensing requirements under previously granted licenses, if any;

6. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained prison clinic pharmacies; and

7. Other factors or qualifications the Board considered relevant to and consistent with the public health and safety. 8. The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

Cite as Ga. Comp. R. & Regs. R. 480-8-.02
Authority: O.C.G.A. §§ 26-4-37, 26-4-27, 26-4-28, 26-4-110, 26-4-111, 26-4-113, 16-13-35, 16-13-37, 43-1-19, 26-4-60, 26-4-20.
History. Original Rule entitled "Registration" adopted. F. Dec. 27, 1985; eff. Jan. 16, 1986.
Repealed: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.
Amended: F. June 29, 2015; eff. July 19, 2015.

Rule 480-8-.03. Personnel.

The personnel shall be as follows:

(a) Director. Each prison clinic pharmacy shall be directed by a pharmacist hereinafter referred to as the Director of Pharmacy, who is licensed to engage in the practice of pharmacy in this State, and who is knowledgeable in and thoroughly familiar with the specialized functions of prison clinic pharmacies. The Director of Pharmacy shall be responsible for all activities of the prison clinic pharmacy, and for meeting the requirements of the Georgia Pharmacy Laws and Rules and Regulations of the Board of Pharmacy. The Director of Pharmacy shall work on a full-time or part-time basis, consistent with the needs of the institution.

(b) Supportive personnel. The Director of Pharmacy of a prison clinic pharmacy shall be assisted by a sufficient number of additional pharmacists and ancillary personnel in ratios consistent with state pharmacy laws and regulations, as may be required to operate such

pharmacy competently, safely, and to meet the needs of the patients of the prison clinic facility.

1. The Director of Pharmacy shall insure that trained ancillary personnel shall be employed. The Director of Pharmacy shall develop and implement written policies and procedures to specify the duties to be performed by such ancillary personnel. These policies and procedures shall, at a minimum, specify that ancillary personnel are personally and directly supervised by a licensed pharmacist and are not assigned duties which may be performed only by licensed pharmacists.

2. Secretarial and clerical assistance and support shall be provided as required to assist with the record keeping, report submission, and other administrative duties, provided such personnel do not perform any dispensing duties.

3. Supervision. All of the activities and operations of each prison clinic pharmacy shall be personally and directly supervised by its Director of Pharmacy. All functions and activities of ancillary personnel shall be personally and directly supervised by an adequate number of licensed pharmacists to insure that all such functions and activities are performed competently, safely and without risk of harm to patients. Personal supervision can only be accomplished by the physical presence of a licensed pharmacist in the prison clinic pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-8-.03
Authority: O.C.G.A. § 26-4-37, 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Personnel" adopted. F. Dec. 27, 1985; eff. Jan. 16, 1986.
Repealed: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-8-.04. Absence of Pharmacist.

The following regulations shall be followed in the absence of a Pharmacist:

(a) General. When a registered pharmacist is not physically present in the prison clinic pharmacy, written policies and procedures shall be prepared in advance by the Director of Pharmacy for the provision of drugs to the medical staff and other authorized personnel of the prison clinic by use of night cabinets and/or by access to the pharmacy.

(b) Night cabinets. Access to drugs, in the absence of a licensed pharmacist, shall be by locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area to which only specifically authorized personnel as indicated by written policies and procedures may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Director of Pharmacy shall, in conjunction with the appropriate committee of the prison clinic, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

1. Such drugs are available therein, properly labeled, with drug name, strength, lot number and expiration date;

2. Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

3. Whenever access to such cabinet(s) shall have been gained, written physician's orders and proofs of use for controlled substances are provided;

4. All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and,

5. Written policies and procedures are established to implement the requirements of the subsection.

(c) Access to pharmacy. Whenever any drugs are not available from floor supplies of night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy pursuant to the physician's order and the requirements of this subsection. Only one designated, licensed medical staff member (R.N., L.P.N. or Clinic Associate) in any given 8-hour shift may have access to the pharmacy and may remove drugs from there. Such licensed medical personnel shall be designated in writing by the Director of Pharmacy of the prison clinic and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be given by the Director of Pharmacy, who shall require, at a minimum, the following records and procedures:

1. Removal of any drug from the pharmacy by an authorized medical staff member must be recorded on a suitable form showing name of drug, strength, amount, date, time and signature of the authorized medical staff member.

2. The container from which the drug is removed shall be placed conspicuous location so as to be promptly reviewed and inspected by a pharmacist coming on duty.

(d) Emergency kits/crash carts. Drugs may be provided for use by authorized personnel by emergency kits, provided such kits meet the following requirements:

1. Emergency kit drugs defined. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk or harm to patients;

2. Drugs included. The Director of Pharmacy and the medical staff of the prison clinic shall jointly determine the drugs, by identity and quantity to be included in emergency kits;

3. Storage. Emergency kits shall be stored in limited access areas and sealed to prevent unauthorized access, and to insure a proper environment for preservation of the drugs contained.

4. Labeling--exterior. The exterior of emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by the Board and proper documentatoin of such approval is maintained;

5. Labeling--interior. All drugs contained in emergency kits shall be labeled in accordance with such State and Federal Laws and Regulations which pertain thereto; and shall also be labeled with such other and further information as may be required by the medical staff of the prison clinic to prevent misunderstanding or risk or harm to the patients;

6. Removal of drugs. Drugs shall be removed from emergency kits only pursuant to a valid physician's order, by authorized medical personnel, or by a pharmacist of the institutional facility;

7. Notification. Whenever an emergency kit is opened, the pharmacy shall be notified; and the pharmacy shall re-stock the kit within a reasonable time (no later than a Pharmacist's next visit to institution) so as to prevent risk or harm to patients. In the absence of a pharmacist, at least one emergency kit will be made available for exchange. In the event the kit is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

8. Inspections. Each emergency kit shall be opened and its contents inspected by the pharmacy at least once every ninety (90) days. Upon completion of inspection, the emergency kit shall be re-sealed.

9. Policies and Procedures. The director of Pharmacy shall, in conjunction with the medical staff of the prison clinic, develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

(e) Authoritative, current antidote information as well as the telephone number of the regional poison control information center should also be readily available in areas outside the pharmacy where emergency kits are stored.

Cite as Ga. Comp. R. & Regs. R. 480-8-.04
Authority: O.C.G.A. Section 26-4-37, 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Absence of Pharmacist" adopted. F. Dec. 27, 1985; eff. January 16, 1986.
Repealed: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-8-.05. Physical Requirements.

Physical Requirements are as follows:

(a) Area. A prison clinic pharmacy shall have within the institution which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this section and the Georgia Pharmacy Laws. The prison clinic pharmacy space required shall be a minimum of 150 square feet. This includes all areas which are assigned and under the direct control of the Director of Pharmacy.

(b) Equipment and materials. Each prison clinic pharmacy shall have sufficient equipment and physical facilities for proper dispensing, and storage of drugs. The equipment and physical facilities shall include the following:

1. Dispensing area, including:

   (i) Refrigerator in operating condition with a thermometer for monitoring the temperature;

   (ii) Sink in working condition with both hot and cold running water;

   (iii) Graduates of assorted sizes;

   (iv) Two (2) spatulas and one (1) pill counting tray;

   (v) Typewriter, word processor, or computer with label printer;

   (vi) Class A or equivalent and assorted metric and apothecary weights if not electronic; and,

   (vii) Such other equipment as deemed necessary by the Director of Pharmacy to support the scope of practice of the pharmacy.

2. Storage and receiving area;

3. Manufacturing and packaging area; and,

4. Office space area.

(c) Variances.

1. The Director of Pharmacy may submit to the Board a typed request for a variance to these provisions relating to minimum equipment requirements. Stated reasons for application for variances must be included in the submitted request. A variance shall be granted by the Board only when, in the judgement of the Board, there are sound reasons for doing so that relate to the necessary or efficient delivery of health

care. After consideration by the Board, the Director of Pharmacy will be notified by the Board's decision in writing.

2. If approved, said letter(s) will serve as the proof of the Board's approval for variances indicated in the letter, and must be posted next to the Georgia Drugs and Narcotics Agency inspection report.

(d) Each prison clinic pharmacy shall maintain a reference library of, at a minimum, the following:

1. Copies of and/or computer/electronic access to, current reference materials appropriate to the individual pharmacy practice; The Georgia Pharmacy Practice Act; The Georgia Controlled Substances Act; and The Rules of the Georgia State Board of Pharmacy. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution;

2. Compability charts if IV solutions are being prepared in the pharmacy;

3. Current antidote information and the telephone number of a poison control center conspicuously displayed;

4. Other reference materials as may be determined by the Board to meet the current practice standards.

(e) Storage. All durgs shall be stored in designated areas within the prison clinic pharmacy which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage cabinets and unit dose carts in the medication area shall be locked when the said area is not in attendance by medical staff personnel.

(f) Controlled drug storage for Schedule II drugs. An enclosed controlled room with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet adequately locked that is permanently affixed to the structure is acceptable.

(g) Unattended areas. Whenever any area of a prison clinic pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.

(h) Security. All areas occupied by a prison clinic pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel. The Director of Pharmacy shall designate in writing, by name and specific area, those persons who shall have access to particular areas within the pharmacy. These areas shall meet the security requirements of Federal and State Laws and Regulations. Only those persons so authorized shall be permitted to enter these areas.

Cite as Ga. Comp. R. & Regs. R. 480-8-.05
Authority: O.C.G.A. Sec. 26-4-37, 26-4-27, 26-4-28, 26-4-110, 26-4-111..
History. Original Rule entitled "Physical Requirements" adopted. F. Dec. 27, 1985; eff. Jan. 16, 1986.
Repealed: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-8-.06. Drug Distribution and Control.

Drug Distribution and Control shall be as follows:

(a) General. A drug distribution system is the entirety of that mechanism by which a practitioner's prescription drug order is executed, from the time the prescriber transmits the order either orally or in writing to an authorized health professional through the time the ordered drug is administered to the patient or delivered to the patient for self-administration.

(b) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution control, and accountability for drugs. The other professional staff of the prison clinic shall cooperate with the Director in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials so as to achieve this purpose. Accordingly the Director shall be responsible for, at a minimum, the following:

1. The drugs must be identified up to the point of administration;

2. The pharmacy must receive a direct copy or mechanical copy of a physician's order before the first dose of medication is dispensed except as defined by prison clinic stat order policy;

3. Utilization of a pharmacy-generated patient profile. This shall be the official record of medications dispensed to the patient. The patient profile shall be maintained under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:

   (i) Given and last name;

   (ii) DOC I.D. Number or any other assigned I.D. Number;

   (iii) Date of birth;

   (iv) Sex;

   (v) Dorm or permanent housing assignment;

   (vi) Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;

(vii) Identification or differentiation of controlled substances;

(viii) Selected medical data; and

(ix) Sensitivities and allergies to drugs and foods.

4. Maintaining no more than a 7 day's supply of unit dose medication with prison clinic labeling or no more than a 30-day supply of maintenance medication with retail labeling.

5. Establishment of specifications or use of compendial specifications for procurement of drugs, chemicals, and biologicals, subject to approval of the appropriate committee of the prison clinic;

6. Participation in development of a drug formulary for the prison clinic;

7. Filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;

8. Maintaining and making available a sufficient inventory of antidotes and other emergency drugs. Current antidote information, telephone numbers of regional poison control center(s) and other emergency assistance organizations, and such other materials and information as may be deemed necessary shall also be maintained;

9. Records of all transactions of the prison clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;

10. Participation in those aspects of the prison clinic patient care evaluation program which relate to pharmaceutical material utilization and effectiveness, and,

11. Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.

(c) Labeling. Labeling shall include:

1. For use inside the prison clinic, all drugs dispensed by a prison clinic pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.

2. For use outside the prison clinic or institution, all drugs dispensed by a prison clinic pharmacy to inmates housed outside the prison clinic or those about to be released or on leave shall be labeled with the following information:

(i) Name, address and telephone number of the prison clinic pharmacy;

(ii) Date and identifying serial number;

(iii) Full name of patient;

(iv) Name of drug, (brand or generic) and strength;

(v) Directions for use to the patient;

(vi) Name of practitioner prescribing;

(vii) Require precautionary information regarding controlled substances; and,

(viii) Such other and further accessory cautionary information as may be required or desirable for proper use and safety to the patient.

(d) Discontinued drugs. The Director of Pharmacy shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the prison clinic pharmacy for proper disposition according to the following:

1. The following method of destruction of non-controlled substances is approved by the Board for medications dispensed to patients residing in a prison facility. When non-controlled drugs are expired, discontinued from use or the patient for whom they are ordered expires, the drugs shall be immediately removed from the active stock and inventoried by a pharmacist, along with another licensed healthcare professional or a corrections officer. The completed inventory shall be signed and dated by those two individuals. The original inventory shall be maintained by the facility for two years, and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs can either be:

   a. Placed in a secure storage area at the facility separated from edications with active orders. The drugs can be destroyed at the facility by the pharmacist and another licensed healthcare practitioner designated by the facility. However, before the destruction can take place, it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction along with the inventory for two years. This record shall include at a minimum the date, time, personnel involved with the destruction and the method of destruction; or

   b. The drugs for destruction are removed from the pharmacy by transfer to a reverse distributor with a current permit issued by the Board and a record of the following is maintained by the Prison Clinic for at least two years:

      (1) An inventory of the drugs to be transferred including the names of the drugs, the dosage form(s) of the drugs and the quantity of the drugs; the inventory shall be

verified by a pharmacy representative and a representative of the reverse distributor;

(2) The date and time the drugs were taken from the pharmacy;

(3) The name, Board permit number, address and telephone number of the destruction firm removing the drugs;

(4) The name and signature of the responsible person representing the reverse distributor who is physically removing the drug(s);

(5) The name and signature of the Pharmacist representing the pharmacy transferring the drug(s) to the reverse distributor.

2. The following methods of destruction of controlled substances are approved by the Board of Pharmacy:

   (a) A securely attached wooden or metal cabinet will be made available within a locked limited-access area. When controlled drugs are discontinued or the patient expires, the medication shall be pulled form the active stock immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional or a correction officer. The inventory must be recorded into a permanent record and the drugs shall then be placed in the aforementioned cabinet. This medication would remain within the locked cabinet until such time that it is removed for destruction.

      1. The pharmacist will establish a form, which shall include the following data:

         i. Date of discontinuance or inventory date;

         ii. Name of patient;

         iii. Name of issuing pharmacy;

         iv. Identifying serial numbers;

         v. Name and strength of drug; and

         vi. Quantities of drugs in containers when inventoried.

      2. A licensed pharmacist must destroy the drugs in the presence of at least two witnesses.

      3. Inventory of the drugs included in the final destruction must be taken with one copy retained by the facility. The inventory shall be certified by all three witnesses present at the destruction in the following format:

"We whose signatures appear below, certify that these controlled substances have been recondiled, accounted for, and destroyed at _____(location) on _____ (date) _____o'clock.

Name of drug

Strength of drug

_____

(Signature and Title)

_____

(Signature and Title)

_____

(Signature and Title)

4. The Board and/or the GDNA may prohibit any pharmacist or prison clinic facility from utilizing this method.

(b) A method of off site destruction allowable by the Board is as follows:

1. The drugs to be destroyed shall be immediately removed from the active stock and stored in a separate and secure location in the pharmacy until they are transferred. When the drugs are transferred to a reverse distributor licensed by the Georgia Board, an inventory including the names of the drugs, the dosage forms of the drugs and the quantities of drugs is taken and witnessed by an authorized representative of the prison clinic pharmacy and the responsible person representing the reverse distributor.

2. The prison clinic pharmacy must maintain a receipt/record with the following information: the date and time the drugs were taken from the pharmacy; the name, Board permit number, address and telephone number of the reverse distributor removing the drugs; the inventory of the drugs; the name, signature and title of the responsible person representing the reverse distributor; and the name, signature and title of the pharmacy representative transferring the drugs. This receipt/record must be maintained by the prison clinic pharmacy for a minimum of two years.

(e) Prescription Drug orders. Drugs may be dispensed from the prison clinic pharmacy only upon written orders, direct or copies thereof, of authorized practitioners.

1. Authorization. The appropriate committee of the prison clinic shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.

2. Abbreviations. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the prison clinic.

3. Requirements--orders for drugs for use by inpatients. Orders for drugs for use by in-patients shall, at a minimum, contain:

   (i) Patient name and dorm or permanent housing assignment;

   (ii) Drug name, strength, directions for use; and

   (iii) Date and physician's signature.

4. Requirements--orders for drugs for use by outpatients. Orders for drugs for use by outpatients shall at a minimum, contain all of the items required by Rule 480-8-.06(e)3., and in addition:

   (i) Dispensing quantity; and

   (ii) Practitioner's address and Drug Enforcement Administration permit number, if applicable.

(f) Accountability of Controlled Drugs--Proof of Use of controlled substances on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the prison clinic, shall be submitted to the pharmacy, on forms provided by the pharmacy.

1. Proof of use forms shall specify at a minimum:

   (i) Name of drug, strength, and dosage form;

   (ii) Dose;

   (iii) Name of ordering physician. This shall include, at a minimum, the initial and last name;

   (iv) Given and last name of inmate, DOC I.D. Number, or any other assigned I.D. Number;

   (v) Date and time of administration to patient;

(vi) Signature of individual administering the drug, which shall include at a minimum, the initial, last name and title;

(vii) Documentation of destruction of all unused portions by two signature verifications of two licensed staff members;

(viii) Proof of receipt of medications that bears identifying serial numbers; and

(ix) Date the medication was issued and the date that the proof of use form was returned.

2. Use of computer hard copy is permitted where such copy meets all other requirements of the law.

3. Any prison clinic pharmacy licensed by the Board and in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for oral administration provided:

   (i) The controlled substance is the remainder of a single-dosage unit; and

   (ii) The single-dosage unit from which the ordered dose prepared is the nearest possible size to the dose ordered.

4. Perpetual inventory of Schedule II controlled substances shall be required and accountability of said drugs shall be by proof of use form.

(g) Recall. The Director of Pharmacy shall develop and implement a recall procedure to assure that all drugs within the prison included on the recall are returned to the prison clinic pharmacy for proper disposition.

(h) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering physician, the pharmacy, and to the appropriate committee of the prison clinic. An appropriate entry on the patient's record shall also be made.

(i) Records and reports. The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board or its employees. These shall include, at a minimum, the following:

1. Patient profile;

2. Proof of use documents;

3. Reports of suspected adverse drug reactions;

4. Inventories of night cabinets and emergency kits/crash carts;

5. Inventories of the pharmacy;

6. Biennial controlled substances inventories;

7. Alcohol and flammables reports; and

8. Such other records and reports as may be required by Law and Rules and Regulations of the Board of Pharmacy.

(j) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a prison clinic for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said prison clinic or by an inventory replacement system. These drugs may be administered only pursuant to a physician's order. This physician's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A survey of usage trends of each standard ward inventory shall be made monthly. Such records shall be maintained for a period of two (2) years.

Cite as Ga. Comp. R. & Regs. R. 480-8-.06
Authority: O.C.G.A. Sec. 26-4-37, 26-3-4, 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-80, 26-4-83, 26-4-110, 16-13-39, 16-13-41, 16-13-72, 16-13-73, 16-13-74.
History. Original Rule entitled "Drug Distribution and Control" adopted. F. Dec. 27, 1985; eff. January 16, 1986.
Amended: F. Feb. 10, 1993; eff. Mar. 2, 1993
Repealed: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-8-.07. Administration of Drugs.

(a) General. The Director of Pharmacy may assist in the training of correctional personnel for assisting in the administration of medications. A record of satisfactory participation in the course is placed in the Correctional Officer's personnel file.

(b) Self-administration. The Director of Pharmacy shall assist in the development and implementation of policies and procedures concerning self-administration of medications.

Cite as Ga. Comp. R. & Regs. R. 480-8-.07
Authority: O.C.G.A. Sec. 26-4-37, 16-13-39, 16-13-72, 26-3-4, 26-3-7, 26-3-8, 26-3-16, 26-4-27, 16-4-28, 26-4-29, 26-4-110, 26-4-27, 26-4-28, 26-4-110, 26-4-111, 26-4-85.
History. Original Rule entitled "Administration of Drugs" adopted. F. Dec. 27, 1985; eff. January 16, 1986.
Amended: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-8-.08. Drugs from Outside Sources.

Drugs from outside sources shall include, but not be limited to, drugs brought to the facility by inmates. All such drugs shall be subject to all the rules and regulations promulgated by the Board. The Director of Pharmacy shall establish written policies and procedures relating to drugs brought into the institution. Administration shall be pursuant to an authorized practitioner's order only. If such drugs are not to be administered, the medication shall be destroyed by the Director of Pharmacy or qualified designee as required by law. Nothing in this section shall prohibit another method of accomplishing the intent of this section provided such method is approved by an agent of the Board of Pharmacy and documentation of approval is maintained.

Cite as Ga. Comp. R. & Regs. R. 480-8-.08
Authority: O.C.G.A. Sec. 26-4-37, 26-4-27, 26-4-28, 26-4-60.
History. Original Rule entitled "Drugs from Outside Sources" adopted. F. Dec. 27, 1985; eff. January 16, 1986.
Repealed: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Rule 480-8-.09. Inspection.

Inspection shall include:

(a) Monthly. The Director of Pharmacy shall no less than once per month, personally or by qualified designee, inspect all matters within his jurisdiction and responsibility and make appropriate written records of such inspections. Such inspections shall, at a minimum, verify that:

1. Drugs are dispensed only by registered pharmacists;
2. Ancillary pharmacy personnel are properly directed and supervised;
3. Disinfectants and drugs for external use are stored separately and apart from drugs for internal use or injection;
4. Drugs requiring special storage conditions to insure their stability are properly stored;
5. No outdated drugs are stocked in the prison clinic pharmacy or the facility it serves;
6. Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and medical personnel;
7. Verification of standard ward inventory and medication accountability, including such up dating, if applicable, are maintained;
8. All necessary and required security and storage standards are met;
9. Measure conversion tables and charts are available;

10. All policies and procedures of the director and of appropriate committees of the prison clinic relevant to pharmacy are followed; and

11. All discontinued and out-dated medications are returned to the pharmacy for proper disposition.

(b) Board Inspection. The Board, by its qualified designee, shall regularly inspect all aspects of the management and operation of all prison clinic pharmacies in the State to verify compliance with the Law, these Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety and welfare of patients of the prison clinic serviced by the pharmacy are protected. A written report shall be filed with the Board, the Director of Pharmacy, and the Prison Clinic Administrator. Any discrepancies or deficiencies noted shall be corrected within a reasonable time. Written notice of such corrective actions shall be filed with the Board of Pharmacy within thirty (30) days after receipt of the inspection report.

(c) Every registrant shall ensure that all controlled substances and/or dangerous drugs are purchased from and returned to firms licensed by the Georgia Board. This can be accomplished by maintaining a copy of those firms' current Georgia Board of Pharmacy permit.

Cite as Ga. Comp. R. & Regs. R. 480-8-.09
Authority: O.C.G.A. § 26-4-37, 26-4-27, 26-4-28, 26-4-29, 26-4-110, 26-4-115 .
History. Original Rule entitled "Inspection" adopted. F. Dec. 27, 1985; eff. January 16, 1986.
Repealed: New Rule, same title adopted. F. Sept. 28, 2001; eff. Oct. 18, 2001.

Chapter 480-9. MULTIPLE DRUGS IN SINGLE-DOSING CONTAINERS.

Rule 480-9-.01. Definitions.

For purposes of these Rules and Regulations, the following definition applies:

(a) Multi-Drug Single-Dosing Container. A multi-drug single-dosing container is a customized single-dosing package labeled by a pharmacy for a specific patient, and such package contains two or more solid, oral dosage form drugs to be administered to or taken by a specific patient at the same dosage time from a single container.

Cite as Ga. Comp. R. & Regs. R. 480-9-.01
Authority: Ga. Code Section 79A-909. Effective November 29, 1973.
History. Original Rule was filed on October 6. 1970; effective October 26, 1970.
Amended: Emergency Rule 480-9-0.2-.01(c)4. was filed on September 6, 1973; effective September 6, 1973 for a period of 120 days or until the adoption of a permanent Rule superseding this Emergency Rule as specified by the Agency.

Amended: Filed November 9, 1973; effective November 29, 1973.
Repealed: New Rule entitled "Definitions" adopted. F. Jun. 28, 2001; eff. Jul. 18, 2001.

Rule 480-9-.02. Labeling.

Each individual, customized, multi-drug single-dosing container shall bear a label, which at a minimum, contains the following:

(a) The name of the patient;

(b) The name of the prescribing practitioner of each drug;

(c) The name, address, and telephone number of the pharmacy issuing the multi-drug single dosing container;

(d) The identifying serial number assigned to the prescription drug order for each drug contained therein;

(e) The name, strength, physical description, and total quantity of each drug contained therein;

(f) The directions for use, and/or time of administration or time to be taken for each individual multi-drug single-dosing container; and

(g) Either the dispensing or preparation date, as well as a beyond use (expiration) date for each drug contained in the multi-drug single-dosing container; The expiration date of each drug included therein shall not be longer than one (1) year from the date of preparation of the multi-drug single-dosing container.

Cite as Ga. Comp. R. & Regs. R. 480-9-.02
Authority: O.C.G.A. Secs. 26-3-16, 26-4-27, 26-4-80, 16-13-34, 16-13-73.
History. Original Rule entitled "Labeling" adopted. F. Jun. 28, 2001; eff. Jul. 18, 2001.

Rule 480-9-.03. Conditions.

The conditions for allowing Multi-drug Single-dosing containers shall be as follows:

(a) The number of drugs placed in one package cannot exceed the capacity of the container in order to prevent damage to the individual dosage forms;

(b) The total quantity of drugs dispensed may not be more than a thirty-four (34) day supply;

(c) The labels must be of sufficient size to properly and clearly label each container of a thirty-four (34) days or less drug supply with all information required by state and federal law and rules;

(d) The integrity of each individual multi-drug single-dosing container shall be maintained until the last drug dose is administered t or taken by the patient;

(e) Once a multi-drug single-dosing container has been properly labeled and dispensed to a patient, and this same container is returned to the pharmacy, the drugs packaged in such container are considered adulterated and may not be eturned to the pharmacy stock. Drugs may be redispensed only under the following conditions:

1. Drugs repackaged for and redispensed only to the same patient to which the drugs were originally dispensed or;

2. Whenever a patient has an allergic reaction to any drug contained in a multi-drug single-dosing container and this drug is discontinued from the patient's treatment, a pharmacy cannot repackage and redispense any drug(s) which were packaged with the discontinued drug in the single-dosing container, because any such drug is then considered to be adulterated as defined under O.C.G.A. 26-3.

3. Unopened unit-dose drugs packaged only by the original drug manufacturer dispensed to and returned only by a Long Term Care facility patient for Medicaid credit;

4. A multi-drug single-dosing container must be tamper evident in such a manner to prevent the container from being either reclosed or designed to show evidence of having been opened;

(f) Whenever a drug(s) in such a container previously dispensed to a patient has/have been discontinued, the remaining container(s) must be returned to the dispensing pharmacy for the removal of the discontinued drug(s) from the container for destruction. Except as provided for in paragraph 480-9-.03(5)(a)1, once the discontinued drug(s) has/have been removed, the pharmacy may repackage the drug(s) to be continued and once again only dispense them to the patient to whom they were originally dispensed. Under no circumstances may any of the renaining or discontinued drug(s) be returned to the drug stock of the pharmacy or dispensed to any patient other than the patient to whom the drugs were originally dispensed, as specified in 480-9-.03(5),(6) and (7).

(g) At the time of administration, nothing in this rule is meant to prevent a nurse or a patient specified caregiver from removing a discontinued drug(s) from a container to be wasted as directed by a pharmacist or from retaining up to a 72 hour supply of the continued drug(s) in the original container in order to maintain a patient on his or her continuing drug administration schedule;

(h) Any pharmacist or pharmacy using multi-drug single-dosing container must implement policies and procedures which will exclude any drug(s) which have the following characteristics from being utilized in such packaging:

1. The USP-DI monograph or official labeling requires dispensing in the original container;

2. The drugs are incompatible with packaging components or each other;

3. The drugs require special packaging.

Cite as Ga. Comp. R. & Regs. R. 480-9-.03
Authority: O.C. G.A. Secs. 26-3-8, 26-3-16, 26-4-27, 26-4-80, 16-13-73, 16-13-15.
History. Original Rule entitled "Conditions" adopted. F. June 28, 2001; eff. Jul. 18, 2001.

Rule 480-9-.04. Redispensing by a Different Pharmacy.

(1) Whenever a patient or the patient's caregiver requests a pharmacy to dispense medication in a multi-drug single-dosing container(s) which has/have been previously labeled and dispensed by another pharmacy, the following guidelines must be utilized:

(a) Whenever a patient or the patient's caregiver requests a pharmacy to remove drugs from containers previously dispensed by another pharmacy, and redispensed such drugs in a multi-drug single-dosing container(s), that pharmacy must first receive written permission from the patient or the patient's caregiver in the form of written and signed statement from that same patient or patient's caregiver. Each statement must be kept on file at the pharmacy, along with the corresponding redispensing log, as described in 480-9-.04(b), for a period of two (2) years.

(b) Whenever a pharmacy receives a written request, as described above in 480-9-.04(a) to redispense drugs in a multi-drug single-dosing container(s), and such drugs have been previously dispensed by another pharmacy, the pharmacy choosing to redispense must maintain a redispensing log using the following record keeping guidelines in addition to any record keeping already required by state and federal law or rules/regulations. The pharmacy is then considered the dispensing pharmacy. For each drug redispensed, this log must include at a minimum:

1. The name, address, and telephone number of the redispensing pharmacy;

2. The date the drug was redispensed;

3. The name and address of the patient;

4. The serial number on the label of the originally dispensed prescription drug container;

5. The name, address, and telephone number of the pharmay originally dispensing the drug;

6. The serial number assigned to the drug by the redispensing pharmacy;

7. The name, quantity, and identifying logo or numbers of the drug as it was originally dispensed and is now being redispensed;

8. The expiration date assigned to the drug being redispensed, with such date being no longer than one (1) year from the date of redispensing;

9. The name of the prescribing practitioner;

10. The directions for administration or taking as written by the prescribing physician;

11. Any special labeling information or instructions;

12. The name or initials of the pharmacist verifying the redispensed drug against the log and/or the original drug container;

(c) All redispensing logs, statements, and other such records required by this section are required to be maintained by the pharmacy for a minimum of two (2) years. Any and all such records shall be made available for inspection and/or copying by the Georgia Drugs and Narcotics Agency. The conditions on the use of the multi-drug single-dosing containers found in Rule 480-9-.03 also apply to the pharmacy redispensing pursuant to this rule.

Cite as Ga. Comp. R. & Regs. R. 480-9-.04
Authority: O.C.G.A. Secs. 26-3-8, 26-4-27, 26-4-80, 16-13-34, 16-13-39, 16-13-73, 16-13-15.
History. Original Rule entitled "Redispensing by a Different Pharmacy" adopted F. Jun. 28, 2001; eff. Jul. 18, 2001.

Rule 480-9-.05. Exceptions.

This rule does not apply to the labeling of multi-drug single-dosing containers dispensed by a hospital pharmacy to inpatients located within the same building as or on the immediate grounds where the hospital pharmacy is located.

Cite as Ga. Comp. R. & Regs. R. 480-9-.05
Authority: O. C.G.A. Secs. 26-3-16, 26-4-27, 26-4-28, 26-4-80, 26-4-110, 16-13-21, 16-13-34, 16-13-41, 16-13-77.

History. Original Rule entitled "Exceptions" adopted. F. Jun. 28, 2001; eff. Jul 18, 2001.

Chapter 480-10. RETAIL PHARMACY REGULATIONS.

Rule 480-10-.01. Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security.

(1) Every retail pharmacy, possessing or having possessed any controlled substances and/or dangerous drugs, within a period of two years, and/or possessing any record related to the same, which is required to be kept by O.C.G.A. T. Ch. 16-13, shall exercise diligent care in protecting such controlled substances and/or dangerous drugs and/or records related to the same from loss or theft.

(a) Every licensed retail pharmacy shall ensure that all controlled substances and/or dangerous drugs are purchased from and/or returned to firms holding a current permit issued by the Georgia State Board of Pharmacy (Board). This requirement can be met by a pharmacy maintaining a copy of such firms' current Georgia Board permit.

(2) All controlled substances and/or dangerous drugs shall be kept in the prescription department, accessible only to an authorized person, except where contained in a collection receptacle compliant with state and federal law and regulation.

(3) The Georgia Drugs and Narcotics Agency (GDNA) shall have the authority to conduct inspections of any place or premises used by any such licensed retail pharmacy in relation to such controlled substances and/or dangerous drugs and/or any records pertaining to their acquisition, dispensing, disposal, or loss.

(4) The GDNA shall have the authority to examine, copy, or remove all such records, and to examine, copy, remove, or inventory all such controlled substances and/or dangerous drugs.

(a) It shall be the responsibility to such person possessing such controlled substances and/or dangerous drugs and/or records to make the same available for such inspection, copying, examination, or inventorying by said GDNA.

(b) At the conclusion of an inspection, the GDNA personnel examining said drugs and/or records shall have the responsibility of providing to such retail pharmacy a copy of an inspection report on which any deficiencies or violations are made along with any recommendations, if any, concerning the satisfactory storage, keeping, handling and security of controlled substances and/or dangerous drugs.

(5) Any person possessing controlled substances and/or dangerous drugs and/or records may request that such an inspection be made, and upon receipt of such written request, the

GDNA Director shall make, or cause to be made, without reasonable delay, an inspection in compliance with said request.

Cite as Ga. Comp. R. & Regs. R. 480-10-.01
Authority: O.C.G.A. §§ 16-13-34, 16-13-39, 16-13-45, 16-13-46, 26-3-17, 26-4-4, 26-4-27 to 26-4-29, 26-4-110, 26-4-113, 26-4-115.
History. Original Rule entitled "Narcotic Drugs: Inspection, Records Security" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Controlled Substances: Inspection, Records Security" adopted. F. Nov. 13, 1974; eff. Dec. 3, 1974.
Repealed: New Rule entitled "Controlled Substances and Dangerous Drugs: Retention of Records, Security and Inspection" adopted. F. Sept. 26, 1997; eff. Oct. 16, 1997.
Repealed: New Rule entitled "Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security" adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.
Amended: F. Oct. 3, 2017; eff. Oct. 23, 2017.

Rule 480-10-.02. Prescription Department, Requirement, Supervision, Hours Closed.

(1) For the purpose of this rule, the following definitions shall apply:

(a) "Direct supervision" shall mean that a pharmacist is physically present, providing care at the address listed on the pharmacy license, and is in the prescription department, consultation room, vaccination room, or areas where over-the-counter drugs, devices, or durable medical equipment are displayed. The supervising pharmacist is professionally responsible and accountable for all activities performed by authorized pharmacy personnel and is available to provide assistance and direction to authorized pharmacy personnel. This shall not require a pharmacist to maintain a direct line of sight to authorized pharmacy personnel. The supervising pharmacist shall provide a final check of prepared products and document final checks before any prescription drug is dispensed.

(b) "Pharmacy care" shall mean those services related to the interpretation, evaluation, or dispensing of prescription drug orders, the participation in drug and device selection, drug administration, and drug regimen reviews, and the provision of patient counseling related thereto.

(c) "Preparation" shall mean the functions of preparing a prescription to be dispensed, including product selection, data entry into a pharmacy dispensing system, and any other functions required to have the prescription ready to be verified, checked, and dispensed by a pharmacist or pharmacy intern working under the direct supervision of a pharmacist

(d) "Pharmacy" shall mean all areas of a facility when the prescription department is not closed or locked separately from the facility or only the area of the

prescription department in those facilities where the prescription department is locked and separated.

(e) "Prescription Department" shall mean an area set aside for the preparation and dispensing of prescription drugs. In a facility offering other departments and types of merchandise not requiring a pharmacist to be open for business, this term shall apply only to the area in which prescriptions are prepared and dispensed.

(f) "Vaccination room" is an area adjacent to the pharmacy where vaccinations are administered.

(g) "Consultation room" is an area adjacent to the pharmacy where patient or customer consultations are done, and more in-depth pharmacy care may be provided.

(2) Except for pharmacy benefit manager retail pharmacies and retail pharmacies located in the same space as hospital pharmacies, the owner, manager or proprietor of each pharmacy shall designate an area, room or rooms, which shall be known as the "Prescription Department," and which is primarily devoted to activities related to prescriptions, including preparation and dispensing.

(3) A licensed pharmacist shall be in charge of each pharmacy. His or her name shall be upon the application for the license of the pharmacy; he or she shall be the pharmacist in charge of and have supervision of not more than one pharmacy at one time; and he or she shall be responsible and accountable for the conduction of business related to prescriptions within and access to said retail pharmacy.

(a) This regulation is not intended to prohibit any pharmacist from engaging in the practice of pharmacy at more than one pharmacy, if conducted in compliance with the other provisions of this rule and regulation.

(b) This regulation does not prohibit a pharmacist from being in charge of one separately licensed Home Health Care Pharmacy, as defined by Board Rule 480-21, and/or one Nursing Home Pharmacy, and/or one Long Term Health Care Facility Pharmacy, as both are defined in Board Rule 480-24, in addition to being in charge of a retail pharmacy, licensed under Rule 480-10, as long as each pharmacy is operated under the same ownership and is located under the same roof, provided that there is a physical separation of the two pharmacies and separate inventories are maintained for the two pharmacies.

(4) Except for pharmacy benefit manager retail pharmacies and retail pharmacies located in the same space as hospital pharmacies, a Licensed Pharmacist shall be present and on duty in a licensed retail pharmacy as follows:

(a) Entire business establishments which are licensed under O.C.G.A. § 26-4-110 as a pharmacy shall have a pharmacist on duty at all times the pharmacy is open for business as follows:

1. Such times when the pharmacist is absent from the pharmacy cannot exceed three (3) hours daily, or more than one and one half (11/2) hours at any one time. If a pharmacist is absent less than five minutes from the prescription department, this absence is not considered an "absence" within the meaning of this rule and will not require a posted notice, provided that the prescription department's security is not compromised.

2. In the absence of a pharmacist from the pharmacy, the area designated as the prescription department shall be closed and locked in such a manner as to prevent unauthorized entry; and

3. Whenever the pharmacist is absent from the pharmacy, a sign shall be prominently displayed on the entrance to the prescription department announcing "Prescription Department Closed" and such sign shall be clear and legible with letters not less than three (3) inches in size.

4. The pharmacist on duty shall be responsible and accountable for the direct supervision of all personnel working in the pharmacy or prescription department. Pharmacy technicians and pharmacy interns/externs can continue preparation of a prescription when the pharmacist is in the immunization or consultation room or is providing pharmacy care services.

(b) If a pharmacy is located in a general merchandising establishment, or if the owner of a business licensed as a pharmacy so chooses, a portion of the space in the business establishment may be set aside and permanently enclosed or otherwise secured; only the permanently enclosed area shall be subject to provisions of this rule and shall be licensed as a pharmacy;

1. In such cases, the area to be licensed or registered as a pharmacy shall be permanently enclosed with a partition built from the floor to the ceiling or in a manner which meets security guidelines submitted to and approved by the Board and upon inspection by the GDNA;

2. In the absence of a pharmacist from the Prescription Department, consultation room, vaccination room, and area where over-the-counter drugs, devices, and durable medical equipment are displayed, the area designated as the Prescription Department shall be closed and locked in such a manner as to prevent unauthorized entry; and

3. Whenever the pharmacist is absent from the Prescription Department, consultation room, vaccination room, and area where over-the-counter drugs, devices, and durable medical equipment are displayed, a sign shall be

prominently displayed on the entrance to the Prescription Department announcing "Prescription Department Closed" and such sign shall be clear and legible with letters not less than three (3) inches in size.

4. If a pharmacist is absent less than five minutes from the prescription department, this absence is not considered an "absence" within the meaning of this rule and will not require a posted notice, provided that the prescription department's security is not compromised. No prescription shall be dispensed in the absence of a licensed pharmacist. The pharmacist on duty shall be responsible and accountable for the direct supervision of all personnel working in the pharmacy or prescription department. Pharmacy technicians and pharmacy interns/externs can continue preparation of a prescription when the pharmacist is in the immunization or consultation room or is providing pharmacy care services.

(5) If a retail pharmacy license and hospital pharmacy license occupy the same physical space, nothing shall prohibit one nursing supervisor from having access to the pharmacy in accordance with Board Rule 480-13-.04(8).

Cite as Ga. Comp. R. & Regs. R. 480-10-.02
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-82, 26-4-110, 26-4-110.1
History. Original Rule entitled "Prescription Department, Requirement, Supervision, Hours Closed" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Amended: F. Oct. 6, 1976; eff. Oct. 26, 1976.
Amended: F. Aug. 12, 1997; eff. Sept. 1, 1997.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.
Amended: F. May 1, 2003; eff. May 21, 2003.
Amended: F. May 24, 2017; eff. June 13, 2017.
Amended: F. Apr. 13, 2021; eff. May 3, 2021.

Rule 480-10-.03. Location of Dangerous Drugs (Legend Drugs), Controlled Substances, and Poisons.

(1) All drugs or devices which bear, or are required to bear, upon the package, the words "Caution, Federal Law Prohibits Dispensing Without Prescription","Rx Only", or words of like import, shall be stored within the prescription department of the pharmacy possessing such drugs or devices; and

(2) All dangerous drugs (legend drugs), controlled substances, or poisons shall be kept in the prescription department, and shall be kept from the public in a secure manner.

Cite as Ga. Comp. R. & Regs. R. 480-10-.03
Authority: O.C.G.A. Secs. 16-13-37, 26-4-27, 26-4-28, 26-4-87.
History. Original Rule entitled "Location of 'Legend' Drugs and Patent Drugs" adopted. F. Oct. 6, 1970; eff. Oct.

26, 1970.
Repealed: New Rule entitled "Location of Dangerous Drugs (Legend Drugs), Controlled Substances, and Poisons" adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.04. Sufficient Space in Prescription Department.

There shall be provided within the prescription department of each pharmacy sufficient shelf, drawer, counter or cabinet space for the neat and orderly storage of all drugs, equipment, publications and other items kept therein. In addition, there shall be such clear floor space within each prescription department as to permit pharmacists, interns/externs, and/or technicians employed therein, to adequately, safely, and accurately fulfill their duties, related to prescriptions and drugs. The minimum floor space of a retail pharmacy shall be 150 square feet.

Cite as Ga. Comp. R. & Regs. R. 480-10-.04
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Sufficient Space in Prescription Department" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.05. Refrigeration.

There shall be provided within each prescription department adequate facilities for the proper storage of drugs or devices which require refrigeration, and such drugs or devices shall be stored therein in such manner as to preserve their therapeutic activity.

Cite as Ga. Comp. R. & Regs. R. 480-10-.05
Authority: O.C.G.A. Secs. 26-3-16, 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Refrigeration" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.06. Licensure, Applications, and Display of License and Renewal Certificate.

(1) Licensure and Applications

(a) Every retail pharmacy must be licensed by the Board in accordance with the laws and regulations of this State. As used in these rules, a "retail pharmacy" shall mean all pharmacies, except hospital, clinic, prison, and specialty pharmacies, located in this state where pharmacy is practiced as defined in O.C.G.A. §§ 26-4-4 and 26-4-5, and shall mean every pharmacy benefit manager, as defined in O.C.G.A. § 26-4-110.1, providing services or benefits in this State that constitute the practice of pharmacy as defined in O.C.G.A. § 26-4-4.

(b) All retail pharmacies shall renew biennially by June 30th of the odd-numbered years with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those retail pharmacies who comply with this rule.

(c) Certificates of registration shall be issued only to those retail pharmacies who meet the following requirements:

1. Submission of an application with the following information:

   i. The name, full business address, and telephone number of the licensee;

   ii. All trade or business names used by the licensee;

   iii. Address, telephone number, and the name of the Pharmacist in Charge;

   iv. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship); and

   v. The name(s) of the owner and/or operator of the licensee, including:

      (I) If a person, the name of the person;

      (II) If a partnership, the name of the partnership and the name of each partner;

      (III) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; or

      (IV) If a corporation, the corporate name, the name and title of each corporate officer and director, the state of incorporation; and the name of the parent company, if any.

   vi. Where operations are conducted at more than one location by a single retail pharmacy, each such location shall be licensed by the Board.

2. Payment of an application fee. Application fees shall not be refundable.

3. Filing a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.

(c) Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business.

(d) Licenses are renewed for two year periods and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each

place of business and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed except by application for a new license.

(e) Changes in any information in this rule shall be submitted to the Board prior to such change.

(f) The Board will consider the following factors in determining eligibility for licensure of applicants in charge of the facility who are applying for a retail pharmacy license:

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

2. Any felony convictions of the applicant under Federal, State, or local laws;

3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

4. Suspension or revocation by Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;

5. Compliance with licensing requirements under previously granted licenses, if any;

6. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by retail pharmacies; and

7. Other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(g) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

(2) The pharmacist's wall certificate issued by the Georgia State Board of Pharmacy (Board), along with the current renewal license of each full-time Pharmacist, employed at the pharmacy, shall be displayed in a conspicuous place, near the prescription department where such pharmacist is actively engaged in the practice of Pharmacy;

(a) While employed in a pharmacy on a full-time basis, if a pharmacist has not yet received their Board issued Pharmacist Wall Certificate, in its place such pharmacist shall post a copy of their current Board issued pocket license card;

(b) Any pharmacist employed on a part-time basis at a pharmacy shall post a copy of their current Board issued pocket license instead of posting their Pharmacist Wall Certificate; and

(c) Any pharmacist employed as a relief or "prn" pharmacist need not post any type of Board issued license, but such pharmacist must maintain and present upon request their current Board issued pocket license.

(3) Any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from this, or any other rule, must be posted and/or displayed next to the current Board of Pharmacy renewal permit; and

(4) No pharmacist or intern/extern shall display his or her license in any pharmacy where he or she is not employed or engaged in the practice of pharmacy, and shall not knowingly permit any other person to use his or her license for the purpose of misleading anyone to believe that such person is the holder or recipient of said license or intern certificate.

(5) Every pharmacy benefit manager providing services or benefits in this state which constitutes the practice of pharmacy as defined in Code Section 26-4-4 shall be licensed as a retail pharmacy in this state and shall comply with the provisions of 26-4-110 as required under 26-4-110.1(b).

Cite as Ga. Comp. R. & Regs. R. 480-10-.06
Authority: O.C.G.A. Secs. 16-13-35, 16-13-37, 26-4-27, 26-4-28, 26-4-110, 26-4-111, 26-4-113.
History. Original Rule entitled "Display of License and Renewal Certificate" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Licensure, Applications, and Display of License and Renewal Certificate" adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.
Amended: F. May 1, 2003; eff. May 21, 2003.

Rule 480-10-.07. Sanitation.

No Pharmacy shall operate a prescription department which is under unclean, unsanitary, overcrowded, or unhealthy conditions, or under any condition which endangers the health, safety or welfare of the public.

Cite as Ga. Comp. R. & Regs. R. 480-10-.07
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Sanitation" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.08. Storage of Equipment.

The required equipment of a pharmacy shall be in a clean condition and shall be stored in a clean and sanitary manner. When not in use, vessels shall be inverted upon a clean towel or suspended upon a rack.

Cite as Ga. Comp. R. & Regs. R. 480-10-.08
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Storage of Equipment" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.09. Oral Prescription Drug Orders.

Only a licensed pharmacist or a licensed pharmacy intern/extern, acting under the direct personal supervision of a licensed pharmacist, may accept an oral prescription drug order of any nature, and upon so accepting such prescription drug orders, the pharmacist or intern/extern shall immediately reduce the same to writing.

Cite as Ga. Comp. R. & Regs. R. 480-10-.09
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-80, 26-4-82.
History. Original Rule entitled "Oral Prescriptions" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Oral Prescription Drug Orders" adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.10. Prescription Drug Order Copies.

(1) Only a licensed pharmacist or a licensed pharmacy intern/extern, acting under the direct supervision of a licensed pharmacist, may prepare, receive, read, or transfer a copy of a prescription drug order to any person, and then only to a licensed pharmacist or licensed pharmacy intern/extern, acting under the direct supervision of a licensed pharmacist, who is authorized to receive and give such information as follows:

(a) When a copy of prescription drug order is received manually, meaning without the use of a computer or other electronic means, the person receiving such copy shall immediately reduce the information to writing by creating a hard-copy prescription drug order which, besides the required prescription data, should include at a minimum the following information;

1. The name of the pharmacist or pharmacy intern/extern who received the prescription drug order;

2. The name of the transferring pharmacy and its telephone number along with the name of the pharmacist or pharmacy intern/extern who provided the information for the prescription drug order copy;

3. The date the prescription drug order copy was received.

(b) When a prescription drug order copy is sent and handled manually, meaning without the use of a computer or other electronic means, the person giving such copy shall record immediately upon his or her hard copy prescription drug order the following information:

1. That a copy of the prescription has been given and the prescription drug order is null and void, with the word "VOID" being marked on its face;

2. The name of the pharmacy, and telephone number, where the prescription drug order was transferred;

3. The name of the pharmacist, or pharmacy intern/extern who received the transferred prescription drug order information; and

4. The date on which the prescription drug order was transferred.

(c) When a prescription drug order copy is either sent or received by aid of a computer, or other electronic means, the pharmacist or pharmacy intern/extern should use the procedures for prescription drug order transfers detailed in Rule 480-27-.07.

Cite as Ga. Comp. R. & Regs. R. 480-10-.10
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-80, 26-4-82.
History. Original Rule entitled "Prescription Copies" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Prescription Drug Order Copies" adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.11. Outdated, Deteriorated Drugs.

The Pharmacist in Charge of each Pharmacy shall cause examination of the stock of the prescription department, of that Pharmacy, by persons qualified to do so, and shall cause to be removed from stock all out-dated and deteriorated drugs, and such shall be done at regular intervals of not more than six months duration, and under no circumstances will any Pharmacy or Pharmacist permit any drug or device to be dispensed which bears a date of expiration which has been reached, or any drug or device which is in a deteriorated condition.

Cite as Ga. Comp. R. & Regs. R. 480-10-.11
Authority: O.C.G.A. Secs. 26-3-16, 26-4-27, 26-4-28.
History. Original Rule entitled "Outdated, Deteriorated Drugs" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.12. Minimum Equipment for Prescription Departments.

(1) No pharmacy licensed in accordance with O.C.G.A. T. 26, Ch. 4, shall engage in the practice of filling, compounding or dispensing prescriptions unless it shall possess the following items:

(a) Copies of and/or computer or electronic access to current reference materials appropriate to the individual pharmacy practice. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(b) The telephone number of a poison control center. This number shall be conspicuously posted within the prescription department.

(c) Current copies of and/or computer or electronic access to the following:

1. Georgia Pharmacy Practice Act, O.C.G.A. T. 26, Ch. 4;

2. Georgia Controlled Substances Act & Dangerous Drug Act, O.C.G.A. T. 16, Ch. 13; and

3. Official Rules of the Georgia State Board of Pharmacy.

(d) Equipment (appliances):

1. Refrigerator in operating condition with a thermometer; and

2. Sink in working condition with both hot and cold running water.

(e) Weighing and labeling:

1. If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance;

2. Appropriate prescription labels consistent with the requirements of the Georgia Drug and Cosmetic Act, O.C.G.A. Title 26, Chapter 3; and

3. Appropriate auxiliary labels that should be used in the pharmacist's professional judgment.

(f) Other equipment:

1. Graduates of assorted sizes;

2. Two mortars and pestles of assorted sizes;

3. Two spatulas;

4. One pill counting tray;

5. Ointment slab, tile or ointment paper pad;

6. Stirring rods;

7. Typewriter, word processor or computer with label-printer; and

8. Any other equipment necessary for a specialized practice setting where such a specialized practice takes place.

(g) Adequate supply of drugs most commonly prescribed (ONLY to be on hand after a permit has been issued by the Board).

(h) Assorted sizes and types of child-resistant dispensing containers.

(2) The pharmacist-in-charge of a facility may submit to the Georgia State Board of Pharmacy a typed request for a variance to these provisions relating to minimum equipment requirements. Stated reasons for application for variances must be included in submitted request. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for doing so which relate to the necessary or efficient delivery of health care.

(a) Any variance granted by the Board must be in writing, and this variance must be posted in the pharmacy next to the current Board issued permit/renewal certificate.

Cite as Ga. Comp. R. & Regs. R. 480-10-.12
Authority: O.C.G.A. §§ 16-3-16, 26-3-8, 26-4-27, 26-4-28, 26-4-110, 50-13-9.1.
History. Original Rule entitled "Minimum Equipment for Prescription Department" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule of same title adopted. F. Sept. 7, 1993; eff. Sept. 27, 1993.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.
Amended: F. Apr. 20, 2021; eff. May 10, 2021.

Rule 480-10-.13. Syringes for Injections.

Pharmacies shall keep syringes for injections behind the dispensing counter in their prescription departments and in no other place. No person other than a licensed pharmacist or a pharmacy intern/extern, acting under the direct supervision of a licensed pharmacist, shall sell, distribute, exchange, or give, to any person a hypodermic syringe or needle designed or marketed primarily for human use. No hypodermic needle or syringe shall be sold by a pharmacist or pharmacy intern/extern, acting under the direct supervision of a licensed pharmacist, if such person has reasonable cause to believe that it will be used for an unlawful purpose.

Cite as Ga. Comp. R. & Regs. R. 480-10-.13
Authority: O.C.G.A. Secs. 16-13-32, 16-13-34, 26-3-16, 26-4-27, 26-4-28.
History. Original Rule entitled "Injectable Syringes" adopted. F. Aug. 2, 1983; eff. Aug. 22, 1983.

Repealed: New Rule entitled "Syringes for Injections" adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.14. Destruction of Controlled Substance Drugs and Dangerous Drugs.

(1) All controlled substances which are outdated or expired must be disposed of in a manner which generates a DEA Form 41 (Drug Destruction Form), a copy of which must be retained by the pharmacy. Such controlled substances can be disposed of by one of the following:

(a) Representatives of the Georgia Drugs and Narcotics Agency (GDNA);

(b) Agents of the U.S. Drug Enforcement Administration (DEA); or

(c) A reverse distributor holding a current permit issued by the Georgia State Board of Pharmacy (Board).

(2) Dangerous drugs which are outdated or expired must be disposed of by a reverse distributor holding a current permit issued by the Georgia State Board of Pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-10-.14
Authority: O.C.G.A. Secs. 16-13-34, 16-13-39, 16-13-71, 26-4-27, 26-4-28.
History. Original Rule entitled "Destruction of Controlled Substance Drugs" adopted. F. Feb. 4, 1987; eff. Feb. 24, 1987.
Repealed: New Rule entitled "Destruction of Controlled Substance Drugs and Dangerous Drugs" adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.15. Requirements of a Prescription Drug Order.

A Prescription Drug Order (defined as a "lawful order of a Practitioner for a Drug or Device for a specific patient") shall include, but not be limited to the following information as well as any information required by Rule 480-22:

(1) Full name and address of the patient;

(2) Name, address of the prescribing practitioner and DEA registration number in the case of controlled substances;

(3) Date of issuance;

(4) Name, strength, if needed, dosage form and quantity of drug prescribed;

(5) Directions for use by the patient;

(6) Refills authorized, if any;

(7) If a written Prescription Drug Order, prescribing practitioner's signature; and

(8) A serial number assigned by the Pharmacist so that Prescription Drug Orders may be filed in a numerical and retrievable sequence.

Cite as Ga. Comp. R. & Regs. R. 480-10-.15
Authority: O.C.G.A. Secs. 16-13-34, 16-13-41, 16-13-74, 26-4-27, 26-4-28, 26-4-37, 26-4-80.
History. Original Rule entitled "Requirements of a Prescription" adopted. F. July 14, 1987; eff. Aug. 3, 1987.
Repealed: New Rule entitled "Requirements of a Prescription Drug Order" adopted. F. Feb. 10, 1993; eff. Mar. 2, 1993.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.16. Security System Approval.

As set forth by O.C.G.A. 26-4-110, the Board may provide in its rules and regulations the manner in which the prescription department of a retail pharmacy may be secured. This requirement will be met in the following manner:

(1) Any retail pharmacy located in a general merchandising establishment which does not have a prescription department set aside and permanently enclosed with a partition from floor to ceiling as set forth in O.C.G.A. 26-4-110, must submit to the Board in writing a request to approve its particular security system accompanied by a detailed description of that security system. This request must be made prior to a pharmacy receiving its retail pharmacy permit;

(a) Any retail pharmacy located in a general merchandising establishment which chooses to close its prescription department for more than three (3) hours per day, and more than one and one half (1 1/2) hours at any one time, MUST have its prescription department permanently enclosed with a partition from floor to ceiling;

(b) Any retail pharmacy located in a general merchandising establishment in which the prescription department is not permanently enclosed and utilizes ONLY an electronic security system to separate the prescription department from the rest of the business establishment, MAY NOT close for more than three (3) hours per day, nor more than one and one half (1 1/2) hours at any one time. Board approval of a pharmacy's electronic security system, without the presence of a permanent partition, does not exempt a pharmacy from this requirement.

(2) Each security system description shall be reviewed and either approved or disapproved by the Board.

(3) The Board shall notify the pharmacy submitting the security description in writing as to whether or not the Board approves or disapproves the system. In cases in which a system is not approved, the Board may submit suggestions or reasons as to why the system was not acceptable.

(4) Upon receiving a written approval of a security system, a pharmacy MUST maintain a copy of the Board's approval letter, along with a copy of the security system description, making both available in the pharmacy for inspection by the GDNA. This requirement can be met by posting the approval letter with the last GDNA inspection report.

(5) Any change in a security system must first be approved in writing by the Board and a copy of the approval maintained by the pharmacy.

(6) In the case of multiple retail pharmacies being operated by a parent corporation, the parent corporation may submit a request for a blanket approval of the same security system to be used by all pharmacies operated by that corporation. A copy of the written Board approval and the system description must be maintained at each pharmacy operated by the corporation. Thereafter, any new pharmacy operated by that corporation may utilize the same security system which was previously approved by the Board.

(7) Whenever a corporation or business entity operates multiple pharmacies, each of which has a secured prescription department, whether or not it is an electronically secured or permanently enclosed area, the pharmacist in charge (PIC) shall develop a method, approved by the Board, of allowing authorized access to that area. This method may consist of a Board approved lockbox containing a key, security access code, or other means by which security is maintained. Nothing in this rule is meant to prevent the PIC from having the authority to limit access to such area in regards to non-pharmacy related persons.

(a) Before any such pharmacy can utilize a method of such access, a description of this method, including details of any lockbox to be utilized, must be submitted to the Board for approval.

1. A corporation or business entity may choose to utilize the same method of access to secure a key or access code for each pharmacy it operates in the State of Georgia by notifying the Board in writing. A copy of the Board approved method must be attached to the last GDNA inspection report. Any change in such method must be approved by the Board.

(b) Upon approving or disapproving a method, the Board will notify the pharmacy of such in writing. A copy of such approvals must be posted by the pharmacy with the last GDNA inspection report. When a method is not approved, the Board may offer suggestions as to what must be done before the method can be approved.

(8) All pharmacies licensed on or after January 1, 2006 that utilize a drive-through system for the delivery of drugs, or any currently licensed pharmacy that relocates or has construction or modification of the pharmacy or pharmacy department on or after January

1, 2006 that creates a drive-through or alters an existing drive-through system for delivery of drugs, must submit the construction and security plans for utilization of a pharmacy drive-through to the Board before such construction or modification, and any such drive-through must be approved by the Board and must meet the requirements set forth herein. For purposes of this rule, a pharmacy drive-through is a delivery method by which a patient, or their designated agent, hereafter referred to as "patient", leaves a prescription to be filled or receives a filled prescription drug at the licensed pharmacy location other than by physically being inside the pharmacy.

(a) Any Pharmacy Drive-Through must include a window of transparent material, measuring no less than 2 X 3 feet. The window must be placed in a wall of the prescription department or pharmacy. A pharmacist must be able to observe the patient through the window, whether or not the patient is in a drive-through lane directly next to the window or in a drive-through lane which is one lane over from the window. There shall be no more than two drive-through lanes with the lane farthest from the pharmacy/prescription department drive-through window being no more than twenty-four feet from the window.

(b) Any Pharmacy Drive-Through that utilizes a pneumatic tube system, through which prescription drug orders are received from the patient or prescription drugs are dispensed to the patient, must meet the following standards:

1. Secured carriers must be utilized in the pneumatic tube system;

2. Tubes must be constructed in a manner as to prevent access by unauthorized persons;

3. The tube must originate in the prescription drug area of the pharmacy, be accessible only by a pharmacist or personnel in the pharmacy and must terminate in a secure terminal in the drive-through.

(c) Access to the pneumatic tube system must be constructed in such a way as to provide protection from the natural elements for the patient accessing the prescription.

(d) Any Pharmacy Drive-Through must be inspected by a GDNA Special Agent prior to utilization. Such Special Agent must file an inspection report with the Board with a recommendation for approval or non-approval.

(9) All pharmacies licensed prior to January 1, 2006 that utilize drive-throughs that do not comply with subsection 8(a) through (d) shall be grandfathered in.

Cite as Ga. Comp. R. & Regs. R. 480-10-.16
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-87, 26-4-110.
History. Original Rule entitled "Security System Approval" adopted. F. Apr. 23, 1998; eff. May 13, 1998.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Amended: F. Dec. 9, 2005; eff. Dec. 29, 2005.

Rule 480-10-.17. Return and Reuse of Drugs in a Long Term Care Facility.

(1) "Long-term care facility" means an intermediate care home, skilled nursing home, or intermingled home subject to regulation as such by the Department of Human Resources.

(2) "Eligible drugs" means unit dosage drugs which have been paid for or reimbursed through the Department of Medical Assistance under O.C.G.A. Title 49, Chapter 4, Article 7.

(3) "Unit dosage drug" means a dangerous drug under O.C.G.A. Title 16, Chapter 13, which is individually packaged by the manufacturer to contain only one dosage unit of the drug and which includes on such individual packaging the brand or generic name, strength, lot number, and expiration date of such drug.

(4) A pharmacist or pharmacy may receive eligible drugs for credit or reuse from long-term care facilities provided that:

   (a) The drugs were originally dispensed by that pharmacist or pharmacy to the facility;

   (b) The pharmacist has assurance from a person in responsible charge of the drugs at the facility that the drugs have been stored in accordance with the manufacturer's recommendations and USP standards;

   (c) The drugs are still in the manufacturer's packaging with the expiration date and lot number and the integrity of the product and package have been maintained;

   (d) The drugs are not expired and have a minimum of six (6) months remaining on the expiration date; and

   (e) Under the pharmacist's professional judgment the drugs are appropriate for return and reuse.

(5) Any pharmacist or pharmacy accepting eligible drugs for return or reuse must adopt written policies and procedures governing such drugs to assure compliance with Section (4) of this Rule. Such procedures and policies shall be established and implemented by the pharmacist-in-charge.

(6) A pharmacist or pharmacy which has accepted drugs for return in accordance with Section (4) of this Rule, may only re-dispense said drugs for reuse to a resident of a long-term care facility whose drugs are eligible for payment or reimbursement by the Department of Medical Assistance according to O.C.G.A. Title 49, Chapter 4, Article 7.

Cite as Ga. Comp. R. & Regs. R. 480-10-.17
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-53, 26-4-152.3, 49-4-152.3.
History. Original Rule entitled "Return and Reuse of Drugs in a Long Term Care Facility" adopted. F. Apr. 8, 1998; eff. Apr. 28, 1998.
Repealed: New Rule of same title adopted. F. Mar. 5, 2003; eff. Mar. 25, 2003.

Rule 480-10-.18. Pharmacy Anti-Steering and Transparency Act and Affiliates.

If a retail pharmacy has an affiliate as defined by O.C.G.A. § 26-4-119, it shall annually file a disclosure statement identifying all such affiliates no later than June 30 every year.

Cite as Ga. Comp. R. & Regs. R. 480-10-.18
Authority: O.C.G.A. § 26-4-119.
History. Original Rule entitled "Utilization of Unused Prescription Drugs" adopted. F. Sept. 17, 2007; eff. Oct. 7, 2007.
Repealed: F. May 24, 2017; eff. June 13, 2017.
Adopted: New Rule entitled "Pharmacy Anti-Steering and Transparency Act and Affiliates." F. Apr. 13, 2021; eff. May 3, 2021.

Rule 480-10-.19. Use of Automated and or Robotic Pharmacy Systems.

(a) As used in this rule, the following terms shall mean:

(1) "Automated pharmacy systems" (APS) means a mechanical system that perform operations or activities, other than compounding or administration, relative to storage, packaging, and labeling of medication for the purpose of dispensing of medication to a patient or patient's agent.

(2) "Robotic pharmacy systems" (RPS) means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, and labeling of medication for the purpose of distribution (dispensing) of medication to a patient or a patient's agent.

(3) "Board" shall mean the Georgia State Board of Pharmacy.

(b) A Georgia licensed retail pharmacy may use automated pharmacy systems or robotic pharmacy systems in the preparation of medication for dispensing provided such systems meet the following requirements:

(1) The system collects, controls, and maintains all transaction information;

(2) The system is located within the licensed pharmacy, or if in a general merchandising store, within the pharmacy department;

(3) Medication loaded into the system can be visually identified as well as identified by bar code or other such secondary identification system to ensure the proper medication is being placed into and recognized as the correct medication by the system;

(4) The system has adequate security systems and procedures to prevent unauthorized access to the system;

(5) The system complies with federal laws and state regulations;

(6) The system maintains patient confidentiality;

(7) The system provides a visual image or a description of the medication at final verification.

(8) The system can only be accessed by personal code.

(c) Each retail pharmacy utilizing an APS or RPS must maintain documentation, as to type of equipment, serial numbers, content, policies and procedures, on-site in the pharmacy for review by an agent of the Board.

(d) The filling/stocking of all medications in the APS or RPS shall be performed by licensed pharmacist, licensed pharmacy intern or a registered pharmacy technician under the direct, on-site supervision of a licensed pharmacist. An electronic or hard copy record of medications produced by the system shall be maintained for 2 years, and shall include identification of the person stocking/filling the system, and if a pharmacy intern or registered pharmacy technician, the name of the pharmacist providing the supervision.

(e) Access to and limits on access to the APS or RPS must comply with state and federal laws and regulations. Proper identification and access control, including electronic passwords, biometric identification, unique credentials or other coded identification, must be authorized by the pharmacist on duty. A record of who was assigned the identifications, credentials or passwords must be maintained for 2 years in order to ascertain who accessed the APS or RPS.

(f) The pharmacist in charge ("PIC") of the retail pharmacy is responsible for maintaining all records pertaining to the access, usage, audits and maintenance of the systems. These records must be readily accessible and available for inspection upon request by an agent of the Board. In addition, the PIC is responsible for developing and maintaining policies and procedures to assign, discontinue, or change access to the system, insure that access to the medications comply with state and federal regulations, and insure that the system is filled/stocked.

(g) The pharmacist in charge is responsible to assure that the APS or RPS is in good working order.

(h) Any pharmacist utilizing the APS or RPS must assure that the system is accurately producing the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.

(i) Any retail pharmacy utilizing an APS or RPS in violation of this rule is subject to disciplinary action which may include, but is not limited to, a restriction on the authority to utilize an APS or RPS.

(j) Nothing herein shall relieve a pharmacist of the professional responsibility to verify the accuracy of the medication being dispensed prior to its being delivered to the patient or the patient's agent

Cite as Ga. Comp. R. & Regs. R. 480-10-.19
Authority: O.C.G.A§§ 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-83, 26-4-84, 26-4-88, 26-4-110, 26-4-111, 26-4-113 and 43-1-19.
History. Original Rule entitled "Use of Automated and or Robotic Pharmacy Systems" adopted. F. Feb. 18, 2013; eff. Mar. 10, 2013.

Rule 480-10-.20. Required Notifications to the Board.

(1) For purposes of this rule, the following terms shall means as follow:

(a) "Board" shall mean the Georgia Board of Pharmacy;

(b) "Immediate notification" shall mean written notification sent within twenty-four hours of the event;

(c) "Significant adverse drug reaction" shall mean any reaction which requires any medical treatment beyond a consultation between Pharmacist/patient, Pharmacist/Prescriber, patient/prescriber or Pharmacist/patient/Prescriber; and

(d) "Written notification" shall mean in writing and sent by statutory overnight delivery or by email.

(2) The following occurrences require immediate notification to the Board at its address of record, unless otherwise provided:

(a) Permanent closing of a licensed pharmacy. Notification shall include the name and contact information for the person responsible for maintaining the pharmacy records after the pharmacy has closed and location of the records.

(b) Change of ownership or location of a licensed pharmacy. Since a pharmacy license cannot be transferable, unless such change has been previously approved by the Board following the submission of the appropriate applications, the existing

pharmacy license is void and there is no continuing authority to operate as a pharmacy.

(c) Change in management of a licensed pharmacy.

(d) Change of the pharmacist in charge of a licensed pharmacy. When the Board receives notice that a pharmacy no longer has a pharmacist in charge and no replacement pharmacist in charge is named, the pharmacy's license is suspended pending further action by the Board.

(e) Any theft or loss of drugs or devices of a licensed pharmacy. This notification must also be made to the Georgia Drugs and Narcotics Agency, and if involving controlled substances, the pharmacy must comply with Rule 480-16-.06.

(f) Any known conviction of any employee of a licensed pharmacy of any state or federal drug laws, not previously reported.

(g) Disasters or accidents involving the licensed pharmacy.

(h) Thefts or break-ins at the licensed pharmacy.

(i) Theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law.

(j) Occurrence at a licensed pharmacy of a significant adverse drug reaction by a customer or person receiving medication dispensed or compounded by the licensed pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-10-.20
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, and 26-4-112.
History. Original Rule entitled "Required Notifications to the Board" adopted. F. Dec. 19, 2013; eff. Jan. 8, 2014.

Rule 480-10-.21. Purchase or Receipt of Drugs by a Pharmacy.

All pharmacies are required to purchase or receive dangerous drugs and/or controlled substances from a firm licensed by this state as a drug wholesaler, distributor or manufacturer.

Cite as Ga. Comp. R. & Regs. R. 480-10-.21
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, and 26-4-113.
History. Original Rule entitled "Purchase or Receipt of Drugs by a Pharmacy" adopted. F. Apr. 4, 2014; eff. Apr. 24, 2014.

Chapter 480-10A. CENTRAL FILLING REGULATIONS.

Rule 480-10A-.01. Definitions.

For purposes of these Rules and Regulations, the following definitions apply:

(1) "Board" shall mean the Georgia Board of Pharmacy.

(2) "Originating Pharmacy" shall mean the licensed retail pharmacy from which a prescription is physically received and dispensed to the patient or patient's caregiver which is outsourcing prescription filling services. This pharmacy shall be the dispensing pharmacy.

(3) "Central Fill Pharmacy" shall mean a pharmacy which is permitted by the state in which it is located to prepare prescription orders for dispensing pursuant to a valid prescription transmitted to it by an originating pharmacy and to return the labeled and filled prescriptions to the originating pharmacy for delivery to the ultimate user.

Cite as Ga. Comp. R. & Regs. R. 480-10A-.01
Authority: O.C.G.A. § 26-4-60.
History. Original Rule entitled "Definitions" adopted. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Rule 480-10A-.02. Licensing and Contracting.

(1) All pharmacies providing central filling services to retail pharmacies in Georgia must be appropriately licensed in Georgia.

(2) A central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of an originating pharmacy only if the parties have a contractual relationship permitting such activity or share a common owner.

   (a) The contract or agreement shall outline the services to be provided and the responsibilities and accountabilities of each pharmacy, in relation to such services, in compliance with federal and state laws, rules and regulations.

   (b) Central prescription filling of controlled substances requires compliance with all Drug Enforcement Administration ("DEA") regulations permitting a central fill pharmacy to fill prescriptions for controlled substances on behalf of an originating pharmacy as well as state laws, rules and regulations.

(3) The originating and central fill pharmacy shall be jointly responsible for all prescriptions filled utilizing central fill services.

Cite as Ga. Comp. R. & Regs. R. 480-10A-.02
Authority: O.C.G.A. § 26-4-60.
History. Original Rule entitled "Licensing and Contracting" adopted. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Rule 480-10A-.03. Reserved.

Cite as Ga. Comp. R. & Regs. R. 480-10A-.03
Authority: O.C.G.A. § 26-4-60.
History. Reserved. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Rule 480-10A-.04. Policies and Procedures.

(1) A licensed retail pharmacy that desires to provide and/or use central prescription filling services must maintain policies and procedures, which are readily retrievable for submission to the Board or Georgia Drugs and Narcotics Agency ("GDNA") upon request.

(a) The policies and procedures must include:

1. A clear description of the activities in the prescription filling process to be performed by each pharmacy;

2. An outline of the responsibilities of each pharmacy;

3. An outline of the accountabilities of each pharmacy;

4. A list of the names, addresses, telephone numbers, and all license/registration numbers for the pharmacies participating in the central prescription filling;

5. Guidelines for:

(i) Protection of the confidentiality and integrity of patient information;

(ii) Maintenance of appropriate records to identify the names, initials, or identification codes and specific activities of each pharmacist who performed any processing; and

(iii) Compliance with all federal and state laws, rules, and regulations pertaining to the central filling of prescriptions.

Cite as Ga. Comp. R. & Regs. R. 480-10A-.04
Authority: O.C.G.A. § 26-4-60.
History. Original Rule entitled "Policies and Procedures" adopted. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Rule 480-10A-.05. Transmission and Labeling.

(1) The transmission and labeling of controlled substance prescriptions processed utilizing central fill services must comply with all federal and state laws, rules, and regulations.

(2) The originating pharmacy must comply with the minimum required information for the patient record system and all requirements of a prescription drug order as outlined in the Georgia law and Board rules prior to sending a prescription to the central fill pharmacy.

(3) All prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile.

(4) All transmission records must include the following:

(a) "CENTRAL FILL" written on the face of a prescription if it is a hard copy prescription,

(b) The name, address, telephone number, Georgia license number, and DEA registration number (if the prescription is a controlled substance), of the central fill pharmacy to which the prescription has been transmitted,

(c) Number of refills already dispensed and number of refills remaining (if applicable),

(d) The name of the originating pharmacy pharmacist transmitting the prescription, and

(e) The date of transmittal.

(5) All receipt of transmission records must include all information included in subsection 4 and the name, address, telephone number, Georgia license number, and DEA registration number (if the prescription is a controlled substance), of the originating pharmacy transmitting the prescription.

(6) The label affixed to the container of a dangerous drug or other non-controlled substance filled by a central fill pharmacy must contain the following:

(a) Date of fill or refill,

(b) The originating pharmacy name, address, and telephone number,

(c) The central fill pharmacy's unique identifier,

(d) The serial number of the prescription,

(e) The name of the patient,

(f) The name of the prescribing practitioner,

(g) Name of supervising physician if applicable,

(h) Expiration date of the dispensed drug, and

(i) The directions for use and cautionary statements, if any, contained in such prescription or required by law.

Cite as Ga. Comp. R. & Regs. R. 480-10A-.05
Authority: O.C.G.A. § 26-4-60.
History. Original Rule entitled "Transmission and Labeling" adopted. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Rule 480-10A-.06. Information Systems, Record Keeping, and PDMP Compliance.

(1) The originating and central fill pharmacies must share common electronic files or have appropriate technology to allow secure access to sufficient information necessary or required to process and dispense the prescription.

(2) The originating pharmacy shall be responsible for maintaining compliance with the Prescription Drug Monitoring Program for all qualifying prescriptions pursuant to O.C.G.A. § 16-13-59 including those filled utilizing central fill services.

(3) The record keeping of prescriptions processed utilizing central fill services must comply with all federal and state laws, rules, and regulations.

(4) The originating pharmacy must have a pharmacist, pharmacy intern, pharmacy extern, or pharmacy technician sign for the receipt of all prescriptions received from the central fill pharmacy.

(a) Such receipts must be maintained as a part of the prescription record. Receipts shall include the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the originating pharmacy employee accepting delivery.

(b) The pharmacist on duty at the originating pharmacy must verify the receipt of all controlled substances.

(5) The originating pharmacy is responsible for maintaining records of the processing of all prescriptions entered into their information system including prescriptions filled at a central fill pharmacy.

(a) The information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the originating pharmacy's prescriptions.

Cite as Ga. Comp. R. & Regs. R. 480-10A-.06
Authority: O.C.G.A. § 26-4-60.
History. Original Rule entitled "Information Systems, Record Keeping, and PDMP Compliance" adopted. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Rule 480-10A-.07. Patient Counseling.

(1) It shall be the responsibility of the pharmacist on duty at the originating pharmacy to perform patient counseling of all prescriptions.

(2) The central fill pharmacy shall not perform patient counseling on behalf of the originating pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-10A-.07
Authority: O.C.G.A. § 26-4-60.
History. Original Rule entitled "Patient Counseling" adopted. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Rule 480-10A-.08. Notification to Patients.

(1) An originating pharmacy that utilizes central filling services must, prior to outsourcing the prescription, notify patients that prescription filing may be outsourced to another pharmacy.

   (a) The patient shall have the choice to not have the prescription outsourced.

   (b) Notification may be provided through the use of a sign located in the originating pharmacy which is clearly visible to and readable by the public.

Cite as Ga. Comp. R. & Regs. R. 480-10A-.08
Authority: O.C.G.A. § 26-4-60.
History. Original Rule entitled "Notification to Patients" adopted. F. Nov. 15, 2019; eff. Dec. 5, 2019.

Chapter 480-11. PHARMACEUTICAL COMPOUNDING.

Rule 480-11-.01. Definitions.

(1) "Administer" or "administration" means the provision of a unit dose and/or doses of medication to an individual patient as a result of the order of an authorized practitioner of the healing arts.

(2) "Barrier Isolator" means an isolator specifically designed for compounding pharmaceutical ingredients or preparations in an aseptic environment.

(3) "Biological safety cabinet" means a ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

(4) "Board of Pharmacy" or "Board" means the Georgia State Board of Pharmacy.

(5) "Class 100 Environment" or "ISO Class 5" means an atmospheric environment which contains fewer than 100 particles 0.5 microns or larger in diameter per cubic meter of air.

(6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or de vice as the result of a practitioner's prescription drug order or initiative based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine and regularly observed prescribing patterns. Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(7) "Component" means any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.

(8) "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.

(9) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(10) "Device" means an instrument, apparatus, contrivance, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label,"Caution: federal or state law requires dispensing by or on the order of a physician" or "Rx Only."

(11) "Dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient, patient's caregiver, or patient's agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a patient.

(12) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(13) "Drug" means:

(a) Articles recognized as drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or animals; and

(d) Articles intended for use as a component of any articles specified in subparagraph (a), (b), or (c) of this paragraph but does not include devices.

(14) Drug regimen review includes but is not limited to the following activities:

(a) Evaluation of any prescription drug order and patient record for:

1. Known allergies;

2. Rational therapy-contraindications;

3. Reasonable dose and route of administration; and

4. Reasonable directions for use.

(b) Evaluation of any prescription drug order and patient record for duplication of therapy;

(c) Evaluation of any prescription drug order and patient record for the following interactions:

1. Drug-drug;

2. Drug-food;

3. Drug-disease; and

4. Adverse drug reactions.

(d) Evaluation of any prescription drug order and patient record for proper utilization, including over utilization or under utilization, and optimum therapeutic outcomes.

(15) "Enteral" means within or by way of the intestine.

(16) "FDA" means the United States Food and Drug Administration.

(17) "GDNA" means the Georgia Drugs and Narcotics Agency.

(18) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a

nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or rule.

(19) "Nonprescription drug" means a drug which may be sold without a prescription drug order and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and/or the federal government.

(20) "Parenteral" means an injectable sterile preparation of drugs for administration by any other means than through the gastrointestinal tract.

(21) "Patient counseling" means the oral communication by the pharmacist of information, as defined in the law and the rules of the Board, to the patient, patient's caregiver, or patient's agent, in order to improve therapy by ensuring proper use of drugs and devices.

(22) "Pharmaceutical" means a compound to be used as a medicinal drug.

(23) "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy. This recognizes a pharmacist as a learned professional who is authorized to provide patient services and pharmacy care.

(24) "Pharmacist in charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of such pharmacy and personnel.

(25) "Pharmacy" means any place licensed in accordance with the laws and rules of this state wherein the possessing, displaying, compounding, dispensing, or selling of drugs may be conducted, including any and all portions of the building or structure leased, used, or controlled by the licensee in the conduct of the business or profession licensed by the Board at the address for which the license was issued.

(26) "Practitioner" or "practitioner of the healing arts" means a physician, dentist, podiatrist, or veterinarian and shall include any other person licensed under the laws of this state to use, mix, prepare, dispense, prescribe, and administer drugs in connection with medical treatment to the extent provided by the laws of this state.

(27) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.

(28) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the law and the rules of the Board, prior to dispensing the drug as part of a drug regimen review.

(29) "Sterile pharmaceutical" means any dosage form devoid of viable microorganisms, or any other contaminant including, but not limited to, parenterals, injectables, and ophthalmics.

(30) "Sterile Preparations" are those as defined by USP 797.

(31) "USP-NF" means the United States Pharmacopeia and National Formulary.

Cite as Ga. Comp. R. & Regs. R. 480-11-.01
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-37, 26-4-80, 26-4-86.
History. Original Rule entitled "Code of Professional Conduct" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Amended: F. Mar. 3, 1977; eff. Mar. 23, 1977.
Amended: F. Apr. 17, 1985; eff. May 7, 1985.
Amended: F. June 15, 1994; eff. July 5, 1994.
Amended: F. Apr. 8, 1998; eff. Apr. 28, 1998.
Repealed: F. June 13, 2002; eff. July 3, 2002.
Amended: New Rule entitled "Definitions" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule of same title adopted. F. Nov. 22, 2006; eff. Dec. 12, 2006.
Amended: F. Jan. 28, 2014; eff. Feb. 17, 2014.

Rule 480-11-.02. Compounded Drug Preparations.

(1) Compounded drug preparations - Pharmacist/Patient/Prescriber Relationship.

(a) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations that are not commercially available in the marketplace or commercially available in the place as outlined by the restrictions under 12(b). Dispensing of pharmaceutical products shall be consistent with the provisions of O.C.G.A. T. 16, Ch. 13 and T. 26, Ch. 4 relating to the issuance of prescriptions and the dispensing of drugs.

(b) Pharmacists shall receive, store, or use pharmaceuticals that have been manufactured or repackaged in a FDA-registered facility. Pharmacists shall also receive, store, or use pharmaceuticals in compounding preparations that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.

(c) Pharmacists may compound pharmaceuticals prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such preparations compounded at the pharmacy. Preparations compounded in anticipation of a valid prescription drug order shall be properly labeled to include the name of the compounded pharmaceutical, date of compounding, and beyond-use date.

(d) The distribution of non-patient specific compounded preparations for office use by a practitioner, excluding veterinarians, is prohibited. This subsection shall not affect 503b outsourcing facilities ability to provide non-patient specific

compounded preparations for office use by a practitioner. The distribution of compounded preparations, for office administration or emergency dispensing, to a veterinarian shall not exceed 5% of production of compounded preparation in a calendar year by that pharmacy. Amounts produced greater than 5% shall be considered manufacturing and will require separate licensure as a manufacturer.

1. "Emergency Dispensing" shall mean no more than a 96 hour supply dispensed for an urgent condition to an animal patient by a licensed veterinarian with a valid veterinarian-client-patient relationship when timely access to a compounding pharmacy is not available.

(e) Pharmacists must maintain a separate compounding log for each compounded preparation that includes the quantity and amount of each pharmaceutical that is compounded. Pharmacists shall label all compounded preparations that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. T. 16, Ch. 13 and O.C.G.A. T. 26, Chs. 3 and 4, and Board rules and regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

(f) All compounded preparations labeled in accordance with Board rules and regulations regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of O.C.G.A. T. 16, Ch. 13, and T. 26, Chs. 3 and 4.

(2) Compounded drug preparations - Pharmacist for Distribution to Veterinarian.

(a) Only a pharmacy licensed or registered by the Board may distribute compounded preparations to veterinarians licensed in this state for administration or emergency dispensing to their patients in the course of their professional practice, either personally or by an authorized person under their direct and immediate supervision.

(b) A veterinarian shall make a request to the pharmacy for a compounded preparation in the same manner as ordering products from a wholesale pharmaceutical distributor or manufacturer and not by using a prescription drug order.

(c) A pharmacy receiving an order from a veterinarian for a compounded preparation shall maintain such order with its compounding records as required in Rule 480-11-.08 and other rules and regulations of the Board.

(d) Pharmacists shall label all compounded preparations distributed to veterinarian for administration or emergency dispensing to their patients with the following:

1. "By purchase order, Not by prescription",

2. "For Office Use Administration or Emergency Dispensing by a Veterinarian Only - Not for resale",

3. The name of the active ingredients and strengths contained in the compounded preparation,

4. The lot number or identification of the compounded preparation,

5. The pharmacy's name, address and telephone number,

6. The initials of the pharmacist verifying the finished compounded preparation and the date verified,

7. The quantity, amount, size, or weight of the compounded preparation in the container,

8. An appropriate beyond-use (expiration) date of the compounded preparation as determined by the pharmacist in compliance with Board rule and USP-NF standards for pharmacy compounding, and

9. Appropriate ancillary instructions such as storage instructions or cautionary statements, and where appropriate, hazardous drug warning labels.

(e) Pharmacists shall enter into a written agreement with a veterinarian for the veterinarian's use and emergency dispensing of the compounded preparation before providing any compounded preparation to the veterinarian. The written agreement shall provide the following information:

1. The name and address of the veterinarian, license number and contact information.

2. An agreement by the veterinarian that the compounded preparation may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except for a case in which emergency dispensing is required.

3. An agreement by the veterinarian to include on the patient's chart, or medication administration record the lot number and beyond-use date of the compounded preparation administered or dispensed to the patient.

4. The procedures for a patient to report an adverse reaction or to submit a complaint about a compounded preparation.

5. The procedure to be used when the pharmacy has to recall a batch of compounded preparation.

(f) When pharmacists are compounding preparations to be provided to veterinarians for use in patient care or when pharmacists are altering or repackaging such products for veterinarians to use in patient care in the veterinarian's office, the compounding shall be conducted as allowed by applicable federal law and Board rules and shall be in compliance with USP-NF standards for compounding.

(g) Pharmacists may not compound Schedule II, III, IV or V controlled substances, as defined in Article 2 of Chapter 13 of Title 16 without a patient specific prescription drug order.

(h) Nothing in this paragraph shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners employed by an institution or its affiliated entities; provided, however, pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to the other rules and regulations of the Board governing the compounding of pharmaceuticals.

(3) Pharmacists must maintain documentation of proof that the beyond-use date on compounded pharmaceuticals is valid.

(4) Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final verification check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

(5) Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

(6) Pharmacists may use prescription bulk substances in compounding when such bulk substances:

(a) Comply with the standards of an applicable USP-NF monograph, if such monograph exists, including the testing requirements, and the Board rules on pharmaceutical compounding; or are substances that are components of pharmaceuticals approved by the FDA for use in the United States; or otherwise approved by the FDA;

(b) Are manufactured by an establishment that is registered by the FDA; and

(c) Are distributed by a wholesale distributor licensed by the Board and registered by the FDA to distribute bulk substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

(7) Pharmacists shall maintain records of all compounded pharmaceutical products. Pharmacist shall maintain a complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail when such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

(a) This record-keeping requirement does not apply when FDA-approved and labeled sterile injectable drug products, produced by registered pharmaceutical manufacturers, are reconstituted under conditions as allowed by USP 797, and each such sterile drug product must be administered within 24 hours of being reconstituted.

(8) Pharmacists engaged in the compounding of pharmaceuticals shall operate in conformance with Georgia laws and regulations. Non-sterile compounded preparations shall be subject to USP 795. All sterile compounded preparations shall be subject to USP 797.

(9) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.

(10) Special precaution preparations. If drug preparations with special precautions for contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

(11) Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved.

(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet or an appropriate barrier isolator. Other preparations should not be compounded in this cabinet.

(b) Personnel compounding cytotoxic drugs shall wear protective apparel as outlined in the National Institute of Occupation Hazards (NIOSH.) in addition to appropriate compounding attire as described in USP 797.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations.

(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and delivered in a manner to minimize the risk of accidental rupture of the primary container.

(g) Disposal of cytotoxic and/or hazardous wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of cytotoxic and/or infectious waste in a manner so as not to endanger the public health.

(12) Pharmacists shall not engage in the following:

(a) The compounding for human use of a pharmaceutical product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe.

(b) The compounding of any pharmaceutical products that are essentially copies of commercially available pharmaceutical products. However, this prohibition shall not include:

1. The compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,

2. The compounding of a commercially available manufactured pharmaceutical during times when the product is not available from the manufacturer or wholesale distributor,

3. The compounding of a commercially manufactured pharmaceutical that appears on the drug shortages list, or

4. The mixing of two or more commercially available products of which the end product is a commercially available product.

(13) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. Section 26-4-130 shall comply with all the provisions of this rule and other applicable Board laws, rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 480-11-.02
Authority: O.C.G.A. §§ 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-86.
History. Original Rule entitled "Compounded Drug Products" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule entitled "Compounded Drug Preparations" adopted. F. Nov. 22, 2006; eff. Dec. 12, 2006.
Amended: F. Dec. 14, 2012; eff. Jan. 3, 2013.
Amended: F. Dec. 19, 2013; eff. Jan. 8, 2014.
Amended: F. Jun. 20, 2014; eff. Jul. 10, 2014.
Amended: F. Nov. 26, 2014; eff. Dec. 16, 2014.

Amended: F. Nov. 06, 2019; eff. Nov. 26, 2019.

Rule 480-11-.03. Organization and Personnel.

(1) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug preparations containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

(2) Pharmacists who engage in drug compounding, and any other pharmacy personnel, supervised by pharmacists, who assist in drug compounding, shall be competent and proficient in compounding procedures and shall maintain that proficiency through current awareness and training and documentation of that training. Every pharmacist who engages in drug compounding and any other pharmacy staff member who assists in compounding, must be aware of and familiar with all details of these good compounding practices. Records of documentation of training for all personnel must be maintained for a minimum of five (5) years.

(3) All pharmacy personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug preparations from contamination.

(4) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person known at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from direct contact with components, drug preparation containers, closures, in-process materials, and drug preparations until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the preparations being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug preparations.

Cite as Ga. Comp. R. & Regs. R. 480-11-.03
Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28, 26-4-86.
History. Original Rule entitled "Organization and Personnel" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule of same title adopted. F. Nov. 22, 2006; eff. Dec. 12, 2006.

Rule 480-11-.04. Facilities and Equipment.

(1) Facilities.

(a) Pharmacies engaging in compounding shall have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile preparations shall be separate and distinct from the area used for the compounding of non-sterile drug preparations. The area(s) used for compounding of drugs shall be maintained in a good state of repair.

(b) Bulk drugs and other chemicals or materials used in the compounding of prescription drug orders must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(c) Adequate lighting and ventilation shall be provided in all drug-compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute to contamination of any compounded drug preparation. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air dryers or single-use towels.

(d) Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

(2) Equipment.

(a) Equipment used in the compounding of drug preparation shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug preparations shall be of suitable composition so that surfaces that contact components, in-process materials, or drug preparations shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond that desired.

(b) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug preparation beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug preparations, cleaning, sterilization, and maintenance procedures as set forth in Board Rules.

(c) Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

(d) Automatic, mechanical, electronic, or other types of equipment other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug preparations. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(3) Physical requirements for pharmacies compounding sterile parenteral preparations.

(a) A pharmacy compounding or preparing sterile parenteral preparations shall have a designated area for preparing compounded, sterile parenteral preparations as defined in USP 797. This area shall be physically separate from other areas and should be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile parental preparations.

(b) Equipment and supplies for compounding sterile parenteral preparations. A pharmacy compounding sterile parenteral preparations shall have the following minimum equipment and supplies:

1. Laminar airflow hood (ISO 5) located within a clean room, or barrier isolator as described in USP 797;

2. Infusion pumps, if appropriate;

3. Sink, in working condition, with hot and cold running water, which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

4. Facility for light/dark field examination;

5. Appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapy agents;

6. A Class II, vertical flow biological safety cabinet or appropriate barrier isolator, if chemotherapy agents are routinely prepared;

7. Refrigerator/freezer in working condition;

8. If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance;

9. Disposable needles, syringes and other supplies needed for aseptic admixture;

10. Disinfectant cleaning solutions;

11. Handwashing agent with bactericidal action;

12. Disposable, lint free towels or an automatic hand dryer;

13. Appropriate filters and filtration equipment;

14. Disposable masks and sterile, disposable gloves, gowns, hair and shoe covers and goggles when indicated;

15. An oncology drug spill kit, if chemotherapy agents are routinely prepared.

16. For the purpose of emergency or immediate patient care, compounded sterile preparations are exempted from the requirements as outlined in USP 797.

(4) Minimum equipment for pharmacies compounding non-sterile preparations.

(a) A compounding pharmacy must have all equipment required of a pharmacy in Chapter 480-10 of the Board Rules.

(b) Additionally, a compounding pharmacy must have the appropriate equipment for use in compounding as defined in USP Chapters 795 and 797.

(5) References. In addition to references required of a pharmacy, pharmacies compounding sterile pharmaceuticals shall also have a current edition of or electronic access to an established reference on IV stability and incompatibility, such as, Handbook on Injectable Drugs or King's Guide to Parenteral Admixtures, current Federal requirements for sterile compounding and other reference material including but not limited to:

(a) "USP Pharmacists Pharmacopeia",

(6) Variances.

(a) The pharmacist-in-charge may submit to the Georgia State Board of Pharmacy a typed request for a variance to the provisions relating to minimum equipment requirements. The reasons for the request for a variance must be included in the submitted request. A variance shall be granted by the Board only when, in the judgment of the Board, there are sound reasons for doing so that relate to the necessary or efficient delivery of health care. After consideration by the Board, the requestor will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as proof of the Board's approval for the variance indicated in the letter, and must be posted next to the inspection report.

Cite as Ga. Comp. R. & Regs. R. 480-11-.04
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-86, 26-4-110.
History. Original Rule entitled "Facilities and Equipment" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule of same title adopted. F. Nov. 22, 2006; eff. Dec. 12, 2006.

Amended: F. Apr. 13, 2021; eff. May 3, 2021.

Rule 480-11-.05. Drug Compounding Controls.

(1) For compounding of drugs in anticipation of prescription drug orders:

(a) There shall be written procedures for the compounding of drug preparations to assure that the finished preparations have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure. Nothing in these rules shall prohibit or exclude the use of electronic or computer equipment to meet these requirements.

(b) Components for drug preparation compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed/stored in an appropriate container), the new container shall be appropriate and shall be identified with the:

1. Component name; and

2. Weight or measure.

(c) To assure the reasonable uniformity and integrity of compounded drug preparations, written procedures shall be established and followed that describe the tests or examinations to be conducted on the preparation compounded (e.g., degree of weight variation among capsules.) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug preparation. Such control procedures shall include, but are not limited to, the following (where appropriate):

1. Capsule weight variation;

2. Adequacy of mixing to assure uniformity and homogeneity;

3. Clarity, completeness, or pH of solutions.

(d) Appropriate written procedures designed to prevent microbiological contamination of compounded drug preparations purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.

(e) All personnel involved in any step of the compounding process shall be clearly identified in the compounding record. The compounding record must document the following:

1. The ingredients and amounts or volumes used including the source, lot numbers and expiration dates;

2. The order of the mixing or preparation of the preparation including the date mixed;

3. The identity of the pharmacist and any staff member involved in each step of the procedure; and

4. The pharmacy's lot or identification number and expiration date for the compounded drug/ preparation if applicable.

(2) Compounding of drugs for an individual prescription drug order. The pharmacist must document in a readily retrievable manner, the following information:

(a) The ingredients and lot numbers used in the compounding;

(b) The amounts (weights or volumes) of each ingredient;

(c) The order of component mixing;

(d) A description of the compounding process;

(e) The name of the responsible pharmacist and all other personnel involved in each step of the compounding; and

(f) Appropriate written procedures designed to prevent microbiological contamination if the compounded prescription is purported to be sterile.

Cite as Ga. Comp. R. & Regs. R. 480-11-.05
Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28, 26-4-86.
History. Original Rule entitled "Drug Compounding Controls" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule of same title adopted. F. Nov. 22, 2006; eff. Dec. 12, 2006.

Rule 480-11-.06. Labeling and Control of Excess Preparations.

In the case where a quantity of compounded drug preparation is in excess of that to be initially dispensed is prepared, the excess preparation shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity as outlined in Rule 480-11-.07.

Cite as Ga. Comp. R. & Regs. R. 480-11-.06
Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28, 26-4-86.
History. Original Rule entitled "Labeling and Control of Excess Products" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule entitled "Labeling and Control of Excess Preparations" adopted. F. Nov. 22, 2006; eff. Dec. 12, 2006.

Rule 480-11-.07. Control of Components and Drug Preparation Containers and Closures.

(1) Components, drug preparation containers, closures, and bagged or boxed components of drug preparation containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area (e.g., floors) and inspection.

(2) Drug preparation containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug preparation containers, and closures for use in the compounding of drug preparations shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation. Drug preparation containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

(3) Drug preparation containers and closures intended for the compounding of sterile preparations must be handled, sterilized, processed and stored to remove pyrogenic properties to assure that they are suitable for their intended purpose. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug preparation containers and closures used in the preparation of sterile pharmaceuticals. These processes shall be performed by pharmacists or under the pharmacist's supervision.

Cite as Ga. Comp. R. & Regs. R. 480-11-.07
Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28, 26-4-86.
History. Original Rule entitled "Control of Components and Drug Product Containers and Closures" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule entitled "Control of Components and Drug Preparation Containers and Closures" adopted. F.

Nov. 22, 2006; eff. Dec. 12, 2006.

Rule 480-11-.08. Records and Reports.

(1) Any procedures or other records required to be maintained in compliance with this chapter shall be retained for the same period of time as required in chapter 480-10 of the Board Rules for the retention of prescription files.

(2) All records required to be retained under this chapter or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.

(3) Records required under this chapter may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, electronic files or other accurate reproductions of the original records. All records or reports must be producible immediately if requested by the Board or an agent of the GDNA or within forty-eight (48) hours if maintained in a central database.

(4) In addition to standard record and reporting requirements, the following records and reports must be maintained for sterile pharmaceuticals:

   (a) A policy and procedure manual, including policies and procedures for cytotoxic and/or infectious waste, if applicable; and

   (b) Lot numbers and expiration dates of all the components used in compounding sterile prescription drug orders.

   (c) This record-keeping requirement does not apply when FDA approved and labeled sterile injectable drug products, produced by registered pharmaceutical manufacturers, are reconstituted under conditions as allowed by USP 797, and each such sterile drug product must be administered within 24 hours of being reconstituted.

Cite as Ga. Comp. R. & Regs. R. 480-11-.08
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-86.
History. Original Rule entitled "Records and Reports" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Amended: F. Nov. 26, 2014; eff. Dec. 16, 2014.

Rule 480-11-.09. Quality Assurance Program for Compounding and Preparation of Sterile Pharmaceuticals.

(1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and facilities. Appropriate samples of finished preparations shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.

(a) All clean rooms, ante rooms, barrier isolators and laminar flow hoods shall be certified following procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2005) should be performed by a qualified individual no less than every six months whenever the device or room is relocated, altered, or major service to the facility is performed. Appropriate documentation and records shall be maintained.

(b) There shall be written procedures developed requiring sampling if microbial contamination is suspected.

(c) If bulk compounding of parenteral solutions is performed using non-sterile chemicals, extensive end preparation testing must be documented prior to the release of the preparation from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.

(d) There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits.

Cite as Ga. Comp. R. & Regs. R. 480-11-.09
Authority: O.C.G.A. Secs. 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-86.
History. Original Rule entitled "Quality Assurance Program for Compounding and Preparation of Sterile Pharmaceuticals" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule of same title adopted. F. Nov. 22, 2006; eff. Dec. 12, 2006.

Rule 480-11-.10. Exceptions.

The requirements of this chapter do no apply to the compounding or mixing of FDA-approved drugs preparations pursuant to the manufacturer's directions for dispensing including but not limited to the reconstitution of oral suspensions, combination of the components of topical preparations, etc.

Cite as Ga. Comp. R. & Regs. R. 480-11-.10
Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28, 26-4-86.
History. Original Rule entitled "Exceptions" adopted. F. Apr. 19, 2004; eff. May 9, 2004.
Repealed: New Rule of same title adopted. F. Nov. 22, 2006; eff. Dec. 12, 2006.

Chapter 480-12. SPECIALTY PHARMACY PRACTICE.

Rule 480-12-.01. Authority.

The Georgia State Board of Pharmacy ("Board") has the authority to approve accreditation or certification programs for specialty pharmacy practice, included, but not limited to:

(a) Diabetes;

(b) Dyslipidemia;

(c) Asthma; and

(d) Anticoagulation.

Cite as Ga. Comp. R. & Regs. R. 480-12-.01
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28.
History. Original Rule entitled "Manufacturers, Sanitation" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Authority" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-12-.02. Certification.

A certification in the management of a specific disease state recognizes that the pharmacist has demonstrated advanced knowledge and skills in the specified disease state necessary to instruct the patient and to assist in the management of the health care of the patient.

Cite as Ga. Comp. R. & Regs. R. 480-12-.02
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28.
History. Original Rule entitled "Certification" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.

Rule 480-12-.03. Qualifications.

(1) In order to qualify for specialty pharmacy practice certification, the applicant must be a pharmacist currently licensed and in good standing with the State of Georgia, and pass an examination approved by the Board in the specific area of speciality practice. A person who has already passed the examination and meets all requirements may make application to the Board on a form approved by the Board and pay the fee in the amount provided in the Board's fee schedule.

(2) The board has approved the Disease State Management Examinations of the National Association of Boards of Pharmacy, or its successor organization.

(3) Licensed pharmacist who have a specialty pharmacy practice certification must complete a minimum of ten (10) hours of continuing education in each specific area of specialty during each biennium renewal period. The hours obtained herein may be used to fulfill the continuing education requirements as contained in Chapters 480-3-.01 and 480-3-.03.

Cite as Ga. Comp. R. & Regs. R. 480-12-.03
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-45.
History. Original Rule entitled "Qualifications" adopted. F. Mar. 21, 2001; eff. Apr. 10, 2001.

Chapter 480-13. HOSPITAL PHARMACY REGULATIONS.

Rule 480-13-.01. Definitions.

For purposes of these Rules and Regulations, the following definitions apply:

(a) Hospital. As defined by the Department of Human Resources;

(b) Hospital pharmacy. Hospital pharmacy is defined as that portion of a hospital facility which is engaged in the manufacture, production, sale and distribution of drugs, medications, devices, and other materials used in the prevention, diagnosis and treatment of injury, illness and disease (hereinafter referred to as "drugs"); and which is registered with the State Board of Pharmacy pursuant to O.C.G.A. § 26-4-110;

(c) Hospital pharmacy license. Hospital pharmacy license shall mean a pharmacy license issued by the Georgia State Board of Pharmacy to said hospital pharmacies, pursuant to the provisions of O.C.G.A. Sections 26-4-27, 26-4-28 and 26-4-110 whereas the licensee shall be subject to special hospital pharmacy regulations as set forth herein, but exempt from other certain regulations and requirements. To obtain the hospital pharmacy license, there must be employed a Director of Pharmacy.

1. The Board authorizes the holder of a hospital pharmacy license to service patients of Nursing Homes, Long Term Care Facilities or Hospices as long as these entities are under the same ownership as the hospital pharmacy; however, such entities can only be serviced by the hospital pharmacy subject to the requirements as set forth by Georgia State Board of Pharmacy Rules 480-24, the rule for providing services to nursing homes, long term care facilities, and hospices. The hospital pharmacy is prohibited from maintaining standard ward (Floor Stock) inventories in such entities, but, it would allow the hospital pharmacy to supply emergency kits.

(d) In-patient. In-patient shall mean a patient who is confined to the hospital;

(e) Out-patient. Out-patient shall mean a patient who is not an in-patient, including patients on leave of absence;

(f) Remote Location. Remote location shall mean a location away from the hospital or hospital pharmacy located within the United States where a pharmacist reviews and enters patient specific prescription drug orders for a hospital's patients.

(g) Remote Order Entry. Remote order entry shall mean the entry made by a pharmacist licensed in this state, who is an employee or contractor of either a pharmacy licensed in this state or a pharmacy that holds a Georgia nonresident pharmacy permit issued pursuant to Code Section 26-4-114.1, from a remote location anywhere in the United States indicating that the pharmacist has reviewed the patient specific drug order for a hospital patient, has approved or disapproved the administration of the drug for said patient, and has entered the information in the hospital's patient record system.

(h) Remote Order Entry Pharmacist. A remote order entry pharmacist shall mean a pharmacist who is licensed to practice pharmacy in the State of Georgia, who is at a remote location located within the United States, who is an employee or contractor of a pharmacy licensed in this state or that holds a nonresident pharmacy permit issued pursuant to Code Section 26-4-114.1, and who is under contract with or employed by the hospital to review and enter patient specific prescription drug orders for hospital patients when the hospital pharmacy is closed.

(i) Standard ward inventory. The Director of Pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of legend drugs to be kept at one or more locations at all times within said hospital and such stocks of legend drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy or his/her pharmacist designee. A standard ward inventory may be placed on an emergency vehicle licensed with the State Department of Human Resources. A contract or agreement must be signed between the hospital and the ambulance service and filed with the Department of Human Resources Licensure Division and the Georgia Drugs and Narcotics Agency (GDNA) before any legend drugs may be placed on said licensed vehicle. An agreement can be made with only one hospital.

Cite as Ga. Comp. R. & Regs. R. 480-13-.01
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-80, 26-4-83, 26-4-84, 26-4-110.
History. Original Rule entitled "Hospitals, Nursing Homes, Extended Care Facilities, Pharmaceutical Services" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Definitions" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Mar. 13, 2008; eff. Apr. 2, 2008.
Amended: F. Dec. 14, 2012; eff. Jan. 3, 2013.
Amended: F. May 9, 2019; eff. May 29, 2019.

Rule 480-13-.02. Licensure and Registration.

All hospital pharmacies shall renew biennially by June 30th of each odd-numbered year with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those hospital pharmacies which comply with the provisions of O.C.G.A. § 26-4-110, and with these Rules and Regulations.

(a) Minimum Required Information for Licensure. The Board requires the following information from each hospital pharmacy as part of the initial licensing procedure and as part of any renewal of such license:

(b) The name, complete street address for the business, and telephone number of the applicant/licensee;

(c) All trade or business names used by the applicant/licensee;

(d) Address, telephone numbers, and the name(s) of the Hospital Administrator;

(e) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(f) The name(s) of the owner and/or operator of the applicant/licensee, including:

1. If a partnership, the name of each partner, and the name of the partnership;

2. If a sole proprietorship, the complete name of the proprietor;

3. If a corporation, the name and title of each corporate officer and director, the corporate name and the state of incorporation; and the name of the parent company, if any.

(g) Where operations are conducted at more than one location by a single hospital pharmacy, each such location shall be licensed by the Board.

1. Applications for Licensure.

(i) Registration of a hospital pharmacy shall be considered filed with the Board when an application is received by the Board, and the fee is paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license is received by the Board.

(h) Application fees shall not be refundable.

(i) A license shall be null and void upon the sale, transfer or change of mode of operation or location of the business.

(j) Licenses may be renewed for two year periods and shall expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal for each place of business. If the application for renewal is not filed with the Board, and the fee paid before September 1st of each odd numbered year, the license shall lapse and may not be renewed except by application for a new license.

(k) A licensee must submit any change of name, mode of operation or address to the Board prior to such change.

1. Minimum Qualifications.

   (i) The Board shall consider the following factors when determining eligibility for licensure for each person in charge of the facility and when considering an application for a hospital pharmacy license:

      (I) Any convictions of the applicant under any Federal, State, or local laws relating to drugs, wholesale or retail drug distribution, or distribution of controlled substances;

      (II) Any felony convictions of the applicant under any Federal, State, or local laws;

      (III) The furnishing by the applicant of false or fraudulent material or information in any application;

      (IV) Suspension or revocation by any Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;

2. Failure to comply with any licensing requirements under a previously held license, if any;

3. Failure to comply with any requirements to maintain records and/or make available, said records to any State Licensing Authority or to any Federal, State, or local law enforcement officials;

4. Other factors or qualifications the Board considers relevant to and consistent with the public's health and safety;

5. The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

Cite as Ga. Comp. R. & Regs. R. 480-13-.02
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Hospital Pharmacy License" adopted. F. Feb. 4, 1972; eff. Feb. 24, 1972.
Repealed: New Rule entitled "Registration" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule entitled "Licensure and Registration" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-13-.03. Personnel.

(1) Director of Pharmacy. Each hospital pharmacy shall be directed by a pharmacist, hereinafter referred to as the Director of Pharmacy, who is licensed to engage in the practice of pharmacy in this State, and who is knowledgeable in and thoroughly familiar with the specialized functions of hospital pharmacies. The Director of Pharmacy shall be responsible for all activities of the hospital pharmacy, and for meeting the requirements of the Georgia Pharmacy Laws and Rules and Regulations of the Board of Pharmacy. The Director of Pharmacy or his/her pharmacist designee should be employed on a fulltime basis consistent with need.

(2) Supportive personnel. The Director of Pharmacy shall be assisted by a sufficient number of additional pharmacists, and ancillary personnel as may be required to operate such pharmacy competently, safely, and to meet the needs of the patients of the hospital facility.

(a) The Director of Pharmacy shall insure that trained personnel shall be employed in the pharmacy. The Director of Pharmacy shall develop and implement written policies and procedures to specify the duties to be performed by such personnel. These policies and procedures shall, at a minimum, specify that such personnel are personally and directly supervised by a licensed pharmacist and that such personnel are not assigned duties which may be performed only by licensed pharmacists. The Director of Pharmacy shall be responsible for the implementation of the written policies and responsible to the Georgia State Board of Pharmacy for the activities of the pharmacy.

(b) Secretarial and clerical assistance and support shall be provided as required to assist with record keeping, report submission, and other administrative duties, provided such personnel do not perform any dispensing duties.

(c) Any licensed pharmacist performing pharmaceutical duties within the hospital shall operate and fall under the supervision of the Director of Pharmacy.

(3) Supervision. All of the activities and operations of each hospital pharmacy shall be personally and directly supervised by its Director of Pharmacy. All functions and activities of non-licensed pharmacy personnel shall be personally and directly supervised by an adequate number of licensed pharmacists to insure that all such functions and activities are performed competently, safely, and without risk of harm to patients. Personal supervision can only be accomplished by the physical presence of a licensed pharmacist in the hospital.

Cite as Ga. Comp. R. & Regs. R. 480-13-.03
Authority: O.C.G.A §§ 26-4-27, 26-4-28, 26-4-29, 26-4-83, 26-4-84, 26-4-110.
History. Original Rule entitled "Personnel" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Mar. 13, 2008; eff. Apr. 2, 2008.
Amended: F. Feb. 22, 2018; eff. Mar. 14, 2018.

Rule 480-13-.04. Absence of Pharmacist.

(1) General. When a licensed pharmacist is not physically present in the hospital and the pharmacy is closed, written policies and procedures shall be prepared in advance by the Director of Pharmacy for the provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and/or by access to the pharmacy. The policies and procedures may include the use of remote order entry pharmacist to ensure that in-patient needs are met at the hospital when a licensed pharmacist is not physically present. All policies and procedures providing for the use of night cabinets and/or access to the pharmacy when a licensed pharmacist is not physically present shall be made available to the Georgia State Board of Pharmacy, its designee, or a representative of the Georgia Drugs and Narcotics Agency (GDNA), upon request.

(2) A hospital utilizing a remote order entry pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current licensure in the State of Georgia, and the address of each location where the pharmacist will maintain records of remote order entries.

(3) A hospital pharmacy shall be authorized to utilize remote order entry when:

(a) The licensed pharmacist is not physically present in the hospital, the hospital pharmacy is closed, and a licensed pharmacist will be physically present in the hospital pharmacy within 24 hours or the next business day;

(b) When at least one licensed pharmacist is physically present in the hospital; or

(c) When it is a weekend and at least one pharmacist is physically present in another hospital in this state which remotely serves on weekends not more than four other hospitals under the same ownership or management which have an average daily census of less than twelve acute patients.

(4) Before a hospital may engage in remote order entry as provided in this paragraph, the director of pharmacy of the hospital shall submit to the board written policies and procedures for the use of remote order entry. The required policies and procedures to be submitted to the board shall be in accordance with the American Society of Health-System Pharmacists and shall contain provisions addressing:

(a) quality assurance and safety,

(b) mechanisms to clarify medication orders,

(c) processes for reporting medication errors,

(d) documentation and record keeping,

(e) secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to,

(f) access to hospital policies and procedures, confidentiality and security, and

(g) mechanisms for real-time communication with prescribers, nurses, and other care givers responsible for the patient's health care.

(5) Each remote entry record must comply with all recordkeeping requirements and shall identify, by name or other unique identifier, the pharmacist involved in the preview and verification of the order. The remote entry pharmacist shall maintain records of any and all records entered for the hospital for a minimum of two (2) years, and such records shall be readily available for inspection, copying by, or production of upon request by the Board, its designee, or a representative for the Georgia Drugs and Narcotics Agency (GDNA), upon request.

(6) If the board concludes that the hospital's actual use of remote order entry does not comply with this rule or O.C.G.A. 26-4-80, it may issue a cease and desist order after notice and hearing.

(7) Night cabinets. Access to drugs, in the absence of a licensed pharmacist, shall be by locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area to which only specifically authorized personnel as indicated by written policies and procedures may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Director of Pharmacy shall, in conjunction with the appropriate committee of the hospital, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(a) Such drugs are available therein, properly labeled, with drug name, strength, lot number and expiration date;

(b) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(c) Whenever access to such cabinet(s) has been gained, written practitioner's orders and proofs of use for controlled substances must be provided;

(d) All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and

(e) Written policies and procedures are established to implement the requirements of this subsection.

(8) Access to pharmacy. Whenever a drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy pursuant to the practitioner's order and the requirements of this subsection. One nursing supervisor (registered professional nurse or licensed practical nurse) in any given shift may have access to the pharmacy and may remove drugs there from. Such licensed nurse shall be

designated in writing by the Director of Pharmacy of the hospital and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training approved by the Director of Pharmacy, in the proper methods of access, removal of drugs, and records and procedures required. The Director of Pharmacy, or designee, shall document the nurse's competence following the education and training. In addition, such licensed nurse accessing a closed pharmacy must receive specific step-by-step instructions in a policy manual, approved by the Director of Pharmacy, before accessing the pharmacy. At any time that a nurse is accessing a closed pharmacy, the Director of Pharmacy must designate a licensed pharmacist, not a remote order entry pharmacist, who is available to the nurse by telephone, and who, in the event of an emergency, is available to come to the hospital. When a nurse accesses drugs directly from the closed pharmacy, the nurse must:

(a) provide a copy of the order,

(b) document on a suitable form the name of the drug, the strength and amount of the drug removed, the date and time it was removed, and sign the form.

(c) The container from which the drug is removed shall then be placed conspicuously to be promptly reviewed and inspected by the next pharmacist coming on duty. The Director of Pharmacy's policies and procedures must provide that the next pharmacist physically coming into the pharmacy must document that they have reviewed the drugs removed and the orders filled.

(9) Emergency kits/crash carts. Drugs may also be provided for use by authorized personnel by emergency kits/crash carts, provided such kits/carts meet the following requirements:

(a) Emergency kit/crash cart drugs defined. Emergency kit/crash cart drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients;

(b) Drugs included. The Director of Pharmacy and the medical staff of the hospital shall jointly determine the drugs, by identity and quantity, to be included in the emergency kits/crash carts;

(c) Storage. Emergency kits/crash carts shall be sealed and stored in limited access areas to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them;

(d) Labeling - exterior. The exterior of emergency kits/crash carts shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit/crash cart and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by an agent of the Board;

(e) Labeling - interior. All drugs contained in emergency kits/ crash carts shall be labeled in accordance with such State and Federal Laws and Regulations which pertain thereto; and shall also be labeled with such other and further information as may be required by the medical staff of the hospital to prevent misunderstanding or risk of harm to the patients;

(f) Removal of drugs. Drugs shall be removed from emergency kits/crash carts only pursuant to a valid practitioner's order, by authorized personnel, or by a pharmacist of the institutional facility;

(g) Notification. Whenever an emergency kit/crash cart is opened, the pharmacy shall be notified; and pharmacy personnel shall restock and re-seal the kit/cart within a reasonable time so as to prevent risk of harm to patients. In the event the kit/cart is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

(h) Inspections. Each emergency kit/crash cart shall be opened and its contents inspected by a pharmacist at least once every ninety (90) days. Upon completion of inspection, the emergency kit/crash cart shall be re-sealed;

(i) Procedures. The Director of Pharmacy shall, in conjunction with the medical staff of the hospital, develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

(10) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be readily available in areas outside the pharmacy where these drugs are stored.

(11) Nothing in this rule shall be construed to relieve the hospital pharmacy of the requirement of having an on-site pharmacist to provide routine pharmacy services within the hospital in order to qualify as a licensed pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-13-.04
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-80, 26-4-83, 26-4-84, 26-4-110.
History. Original Rule entitled "Absence of Pharmacist" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Mar. 13, 2008; eff. Apr. 2, 2008.
Amended: F. July 26, 2010; eff. Aug. 15, 2010.
Repealed: New Rule with same title adopted. F. Dec. 14, 2012; eff. Jan. 3, 2013.
Amended: F. Dec. 19, 2013; eff. Jan. 8, 2014.
Amended: F. May 9, 2019; eff. May 29, 2019.

Rule 480-13-.05. Physical Requirements. Amended.

(1) **Area.** A hospital pharmacy shall have within the hospital which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this section and the Georgia Pharmacy Laws. The hospital pharmacy space requirements should be a minimum of 10 square feet per hospital bed, which includes all areas assigned and under the direct control of the Director of Pharmacy.

(a) The pharmacy of substance abuse treatment or mental health facility shall be exempt from the minimum square footage requirement provided that the pharmacy receives a satisfactory inspection from the Georgia Drugs and Narcotics Agency that shows that the pharmacy space is sufficient to supply the needs of the patients and that all aspect of the management and operations of the pharmacy comply with the law and the rules of the Board to ensure that the health, safety, and welfare of the patients served by the pharmacy are protected. No application for licensure of a pharmacy of a substance abuse treatment or mental health facility seeking an exemption shall be approved without a satisfactory inspection.

(b) "Mental health facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with psychiatric disorders.

(c) "Substance abuse treatment facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with substance use disorders.

(2) Equipment and supplies. Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. The equipment and physical facilities shall include the following:

(a) Compounding and dispensing area:

1. A refrigerator in operating condition with a thermometer, preferably a biological refrigerator;

2. A sink in operating condition with hot and cold running water;

3. A Class A Balance and an assortment of metric weights if utilizing a Class A Balance or a Class I or II Electronic Balance, if compounding onsite using components which must be weighed;

4. Graduates of assorted sizes;

5. Mortar and pestle;

6. Two (2) spatulas and a counting tray;

7. Typewriter, word processor, or computer with a label printer;

8. Pill tile; and

9. Other equipment as deemed necessary by the Director of Pharmacy.

(b) Parenteral solution additives area as required in 480-13-.06(2)(a);

1. Laminar flowhood; and

2. Facility for light-dark field examination.

(c) Storage and receiving area;

(d) Manufacturing and packaging area; and

(e) Office space area.

(3)

(a) The pharmacy of a substance abuse treatment or mental health facility shall be exempt from (2)(a)(3.), (2)(b)(1.), and (2)(b)(2.) under the following terms and conditions:

1. The Director of Pharmacy attests that the pharmacy will purchase only commercially prepared medications and intravenous preparations;

2. The Director of Pharmacy attests that no compounding will occur on-site;

3. The pharmacy includes the attestations in its application for licensure as a hospital pharmacy; and

4. The pharmacy receives a satisfactory inspection from the Georgia Drugs and Narcotics Agency that shows that in the absence of the equipment, the pharmacy is sufficient to supply the needs of the patients and that all aspect of the management and operations of the hospital pharmacy comply with the law and rules of the Board to ensure that the health, safety, and welfare of the patients served by the pharmacy are protected.

(b) No application for licensure of a pharmacy of a substance abuse treatment or mental health facility seeking an exemption shall be approved without a satisfactory inspection.

(c) "Mental health facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with psychiatric disorders.

(d) "Substance abuse treatment facility" shall mean a specialized hospital, inpatient unit, or other institution that is licensed to provide twenty-four (24) hour care and has as its primary function the diagnosing and treating of patients with substance use disorders.

(4) Each hospital pharmacy shall maintain a reference library which includes, at a minimum, the following:

(a) Copy of and/or electronic or computer access to the latest edition of the Georgia Pharmacy Practice Act, the Georgia Controlled Substances Act and the Rules and Regulations of the Georgia State Board of Pharmacy;

(b) Copies of and/or electronic or computer access to current reference materials appropriate to the practice of the hospital pharmacy;

(c) Copy of and/or electronic or computer access to the latest edition of the American Society of Health-system Pharmacists Formulary Service;

(d) Compatibility charts;

(e) Current drug interaction references;

(f) Current antidote information;

(g) Copy of and/or electronic access or computer access to the latest edition of text and reference works covering theoretical and practical pharmacy, reference materials on general, organic, pharmaceutical and biological chemistry, toxicology, pharmacology, sterilization and disinfection.

(5) **Storage.** All drugs shall be stored in the hospital pharmacy within designated areas which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage cabinets and unit dose carts at the nursing station shall be locked when the station is not in attendance by nursing personnel.

(6) Controlled drug storage for Schedule II drugs. An enclosed controlled room with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet adequately locked that is permanently affixed to the structure is acceptable.

(7) Unattended areas. Whenever any area of a hospital pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.

(8) **Security.** All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel by force. The Director of Pharmacy shall designate in writing, by name and specific area, those persons who shall have access to particular areas within the pharmacy. These areas shall meet the

security requirements of Federal and State Laws and Regulations. Only those persons so authorized shall be permitted to enter these areas.

(9) **Variances.**

(a) The Director of Pharmacy may submit to the Board a typed request for a variance to the provisions relating to minimum equipment requirements. The reasons for the request for a variance must be included. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for granting the variance which relate to the necessary or efficient delivery of health care. After consideration by the Board, the Director of Pharmacy will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as proof of the Board's approval for each variance(s) indicated in the letter, and shall be posted next to the Georgia Drugs and Narcotics Agency inspection report.

Cite as Ga. Comp. R. & Regs. R. 480-13-.05
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-80, 26-4-110.
History. Original Rule entitled "Physical Requirements" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: F. Feb. 27, 2017; eff. Mar. 19, 2017.
Amended: Feb. 4, 2020; eff. Feb. 24, 2020.

Rule 480-13-.06. Drug Distribution Control.

(1) General. A drug distribution system is the entirety of that mechanism by which a prescription drug order is executed, from the time the practitioner transmits the order either orally or in writing to an authorized health professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration.

(2) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the hospital shall cooperate with the Director of Pharmacy in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials to achieve this purpose. The Director of Pharmacy shall establish written procedures for the distribution of parenteral medications to achieve this goal. Accordingly, the Director of Pharmacy shall be responsible for, at a minimum, the following:

(a) The compounding, admixture, and quality control of large volume parenterals is the responsibility of a pharmacist and shall be prepared under a Laminar Flow Hood or utilizing such other equipment to protect the integrity of the product, within the pharmacy department. Individuals who prepare or administer large

volume parenterals must have special training to do so. These functions of IV admixture compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas such as Intensive Care Units, Cardiac Catheterization Laboratories Intensive Care Units, etc., during emergency situations, or during unattended hours of the pharmacy department. When any part of the above functions (preparing, sterilizing, and labeling parenteral medications and solutions) is performed within the hospital but not under direct pharmacist supervision, the Director of Pharmacy shall be responsible for providing written guidelines and for approving the procedures to assure that all pharmaceutical requirements are met;

(b) All drugs must be identified up to the point of administration;

(c) The pharmacy must receive a direct copy, electronic or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by hospital stat order policy;

(d) Utilization of a pharmacy-generated patient profile. The patient profile shall be the official record of medications dispensed to the patient. The patient profile or the ability to generate such profile electronically shall be under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:

1. Given and last name of the patient;
2. Age;
3. Sex;
4. Provisional diagnosis;
5. Room number;
6. Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;
7. Identification or differentiation of controlled substances;
8. Intravenous therapy;
9. Selected medical data;
10. Drug history interview (when possible); and
11. Sensitivities and allergies to drugs and foods;

(e) No more than a 72-hour supply of a patient's medication shall be available at the patient-care area at any time except for those drugs in bulk packages which cannot be repackaged in unit-dose containers;

(f) Manufacture of drugs, if applicable;

(g) Establishment of specifications or use of compendia specifications for procurement of drugs, chemicals, devices and biologicals, subject to approval of the appropriate committee of the hospital;

(h) Participation in the development of a drug formulary for the hospital;

(i) filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;

(j) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs. Current antidote information, telephone numbers of regional poison control center(s) and other emergency assistance organizations, and other material and information as may be deemed necessary shall be maintained;

(k) Records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over the accountability for all pharmaceutical drugs,devices and materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;

(l) Participation in those aspects of the hospital patient care evaluation program which relate to pharmaceutical drug, device and material utilization and effectiveness; and

(m) Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.

(3) Labeling.

(a) For use inside the hospital, all drugs dispensed by a hospital pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.

(b) For use outside the hospital, all drugs dispensed by a hospital pharmacy to patients about to be discharged or on leave of absence shall be labeled with the following information:

1. Name, address, and telephone number of the hospital pharmacy;

2. Date and identifying serial number;

3. Patient's give n and last name;

4. Name of drug, (brand or generic) and strength;

5. Directions for use by patient;

6. Name of prescribing practitioner;

7. Required precautionary information regarding controlled substances; and

8. Such other and further accessory cautionary information as may be required or desirable for proper use by and safety of the patient.

(c) Drugs added to parenteral solutions. Wherever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a licensed pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and the identity of the person so adding.

(4) Discontinued drugs. The Director of Pharmacy shall develop and implement policies and procedures to insure that outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(a) Full doses of controlled substances prepared for administration and not given must be destroyed by a licensed pharmacist or a licensed nurse and one witness. Any portions of controlled substances discontinued and taken from a medication delivery device shall be destroyed by a licensed pharmacist or a licensed nurse and one witness. The two persons witnessing the destruction must sign the destruction record at the time of destruction. The destruction record shall be returned to the pharmacy and must be signed by the pharmacist who is ultimately responsible for the accuracy of the information contained therein.

(b) In accordance with the policies and procedures developed by the Director of Pharmacy, discontinued non-controlled substances dispensed to hospital patients shall be returned to the pharmacy and evaluated by the licensed pharmacist to assure the integrity of the medication. If the integrity can be assured, the medication may be returned to the hospital's drug distribution s system for re-issue. When the integrity cannot be assured, the medication must be separated immediately from the regular drug inventory and destroyed or transferred to a reverse distributor with a current license issued by the Board. The following method of destruction of non-controlled substances is approved by the Board for

medications dispensed to hospital patients or patients residing in nursing homes or long term care units which are part of a hospital facility;

1. Placed in a secure storage area at the facility separated from other medications. The drugs may be destroyed at the facility by the pharmacist and another licensed healthcare practitioner designated by the facility. However, before the destruction can take place, it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction and the inventory for a two year period. This record shall include at a minimum the date, time, and personnel involved with the destruction and the method of destruction; or

2. If the drugs are to be transferred to a reverse distributor with a current license issued by the Board, a record of the following must be maintained by the hospital pharmacy for a minimum of two years:

   (i) An inventory of the drugs to be transferred including the names of the drugs; the dosage form(s) of the drugs and the quantity of the drugs; the inventory shall be verified by a pharmacy representative and a representative of the reverse distributor;

   (ii) The date and time the drugs were taken from the pharmacy;

   (iii) The name, Board permit number, address and telephone number of the destruction firm removing the drugs;

   (iv) The name and signature of the responsible person representing the reverse distributor who is physically removing the drug(s);

   (v) The name and signature of the pharmacist representing the pharmacy transferring the drug(s) to the reverse distributor.

(c) The following methods of destruction of controlled substances are approved by the Board of Pharmacy:

1. A securely attached wooden or metal cabinet within a locked limited-access area shall be used to store the drugs until the drugs are destroyed. When controlled drugs are discontinued or the patient expires, the medication shall be pulled from the active stock immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional. The inventory must be recorded into a permanent record and the drugs shall then be placed in the aforementioned cabinet. This medication shall remain within the locked cabinet until such time as it is removed for destruction.

2. The pharmacist shall establish a form, which shall include the following data:

(i) Date of discontinuance or inventory date;

(ii) Name of patient;

(iii) Name of pharmacy;

(iv) Identifying serial numbers;

(v) Name and strength of the drug; and

(vi) Quantity of the drugs in container(s) at the time of inventory.

3. A licensed pharmacist or licensed nurse and one witness must destroy the drugs.

4. Inventory of the drugs included in the final destruction must be taken with one copy retained by the facility. The inventory shall be certified by the two witnesses present at the destruction in the following format:

   "We, whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____ (location) on _____ (date) at _____ o'clock. "

   Name of drug

   Strength of drug

   Dosage form

   Quantity of drug

   _____

   (Signature and Title)

   _____

   (Signature and Title)

   _____

   (Signature and Title)

5. The Board and/or the GDNA may prohibit any pharmacist or hospital pharmacy from utilizing this method.

(d) A method of off-site destruction allowable by the Board is as follows:

1. The drugs to be destroyed shall be immediately removed from the active stock and stored in a separate and secure location in the pharmacy until the drugs are transferred. When the drugs are transferred to a reverse distributor licensed by the Board, an inventory must be recorded and include the following information: the names of the drugs, the dosage forms of the drugs and the quantities of the drugs taken and witnessed by an authorized representative of the hospital pharmacy and the responsible person representing the reverse distributor.

2. A receipt including the date and time the drugs were taken from the pharmacy; the name, Board permit number, address and telephone number of the reverse distributor removing the drugs; the inventory of the drugs; the name, signature and title of the responsible person representing the reverse distributor; and the name, signature and title of the pharmacy representative transferring the drugs. This receipt/record must be maintained by the hospital pharmacy for a minimum of two years.

(5) Prescription drug orders. Drugs may be dispensed from the hospital pharmacy only upon written orders, direct or mechanical copies thereof, of authorized practitioners.

(a) Authorization. The appropriate committee of the hospital shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.

(b) Abbreviations. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.

(c) Requirements - Prescription drug orders for drugs, devices or materials for use by in-patients. Prescription drugs orders for use by in-patients shall, at a minimum, contain:

1. Patient name and room number;

2. Drug name, strength, directions for use; and

3. Date and practitioner's signature.

(d) Requirements - Prescription drug orders for drugs, devices or materials for use by outpatients. Prescription drug orders for drugs, devices or materials for use by outpatients shall, at a minimum, contain all of the information required by Rule 480-13-.06(5)(c), and in addition include:

1. Quantity to be dispensed;

2. Practitioner's address and Drug Enforcement Administration identification code, if applicable, and

3. Patient's address, if applicable.

(6) Accountability of controlled drugs.

(a) Proof of use of controlled drugs on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the hospital, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:

1. Name of drug, strength, and dosage form;

2. Dose administered;

3. Name of authorized practitioner. This shall include, at a minimum, the initial and last name;

4. Given and last name of the patient;

5. Date and time of administration to the patient;

6. Signature of the individual administering, which shall include at a minimum, the initial, last name, and title;

7. Documentation of the destruction of any and all unused portions by two signature verifications;

8. Proof of receipt of the medications that bears identifying serial numbers; and

9. Date the medication was issued and the date that the proof of use form was returned to the pharmacy.

(b) Anesthesia departments that obtain controlled drugs from the hospital pharmacy must show accountability of the controlled drugs by proof of use as defined above.

(c) Use of computer generated hard copy is permitted where such copy meets all other requirements of the law.

(d) Any hospital pharmacy licensed by the Georgia State Board of Pharmacy and in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:

1. The controlled substance is either a whole dose or a partial dose of a single-dosage unit; and

2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.

(e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.

(7) Recall. The Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper disposition.

(8) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering authorized practitioner, the pharmacy, and to the appropriate committee of the hospital. An appropriate entry on the patient's medical record shall also be made.

(9) Records and reports. The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety and welfare. Such records shall be readily available and subject to inspections by the Board of Pharmacy, the GDNA or its employees. These shall include, at a minimum, the following:

(a) Patient profile;

(b) Proof of use;

(c) Reports of suspected adverse drug reactions;

(d) Inventories of night cabinets and emergency kits/crash carts;

(e) Inventories of the pharmacy;

(f) Biennial controlled substances inventories;

(g) Alcohol and flammables reports; and

(h) Such other records and reports as may be required by state Law and the Rules and Regulations of the Board of Pharmacy.

(10) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a hospital for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said hospital or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order. This practitioner's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A record of administration of drugs administered to patients in ancillary areas such as but not limited to the operating room, emergency room, anesthesiology, and x-ray shall be forwarded to the pharmacy and these medications shall be recorded on the patient profile. A survey of usage trends of each standard ward inventory shall be prepared monthly. Such records shall be retained for a period of two years.

(11) Emergency room dispensing. An authorized practitioner may, when drugs or controlled substances are not otherwise available from a licensed pharmacy, dispense an emergency amount of medication, but only sufficient quantities until such time as medication can be obtained from a pharmacy licensed as a retail pharmacy. Nurses or other unauthorized personnel may not dispense medication from the emergency room. The total act of dispensing shall be performed by an authorized practitioner in accordance with Pharmacy Laws, Rules and Regulations. Such medications shall be labeled as required in Section 480-13-.06(3)(b).

Cite as Ga. Comp. R. & Regs. R. 480-13-.06
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-110.
History. Original Rule entitled "Drug Distribution and Control" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Amended: F. Feb. 4, 1987; eff. Feb. 24, 1987.
Amended: F. Nov. 7, 1994; eff. Nov. 27, 1994.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: F. Dec. 14, 2012; eff. Jan. 3, 2013.

Rule 480-13-.07. Administration of Drugs.

(1) General. Drugs shall be administered only upon the orders of those members of the medical staff who have been granted staff privileges. Drugs shall be administered by authorized licensed personnel in accordance with policies and procedures specified by the appropriate committee of the facility, under applicable Law and Rules and Regulations, and by usual and customary standards of good medical practice. The Director of Pharmacy shall develop and implement policies and procedures concerning self-administration of medication.

(2) Self-administration. Self-administration of drugs by patients shall be permitted only when specifically authorized by the patient's authorized practitioner, provided, however, the patient has been educated and trained in the proper manner of self-administration and

there is no risk of harm to the patient. The Director of Pharmacy shall develop policies and procedures relating to the self-administration of drugs.

Cite as Ga. Comp. R. & Regs. R. 480-13-.07
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Administration of Drugs" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-13-.08. Drugs from Outside Sources.

The Director of Pharmacy shall establish policies and procedures relating to drugs brought into the hospital by patients or patients' family members. Such drugs shall not be administered unless they can be precisely identified. Administration shall be pursuant only to an authorized practitioner's prescription drug order. If such drugs are not to be administered, the medication shall be returned to an adult member of the patient's family or stored by the pharmacy and returned to the patient upon discharge. Medications received from an outside source, but not to be administered, may not be stored on the patient care unit. Nothing in this section shall prohibit another method of accomplishing the intent of this section provided such method is approved by an agent of the Board of Pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-13-.08
Authority: O.C.G.A. Secs. 26-4-27 to 26-4-29, 26-4-110, 26-4-115.
History. Original Rule entitled "Drugs from Outside Sources" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-13-.09. Investigational Drugs.

Investigational drugs shall be properly labeled and shall be administered only under the personal and direct supervision of the principal practitioner- investigator or his/her authorized clinician(s) with prior approval of the appropriate committee(s) of the hospital. Investigational drugs shall be administered in accordance with an approved protocol that includes any requirements for a patient's appropriate informed consent. Nurses may administer such drugs only after they have been educated regarding such drugs by the clinician or the pharmacist. A central unit shall be maintained wherein essential information regarding such drugs may be obtained. Investigational drugs in use shall be properly stored, distributed, and controlled maintaining the confidentiality of patient-medical staff information. The Director of Pharmacy shall be responsible for policies and procedures concerning use of investigational drugs.

Cite as Ga. Comp. R. & Regs. R. 480-13-.09
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Investigational Drugs" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-13-.10. Inspections.

(1) Monthly. The Director of Pharmacy shall no less than once per month, personally or by qualified designee, inspect all matters within his/her jurisdiction and responsibility and make appropriate written records of such inspections. Such inspections shall, at a minimum, verify that:

(a) Drugs are dispensed only by licensed pharmacists or licensed pharmacy interns acting under the direct supervision of a licensed pharmacist;

(b) Non-licensed pharmacy personnel are properly directed and supervised;

(c) Drugs for external use are stored separately, and apart from drugs for internal use or injection;

(d) Drugs requiring special storage conditions to insure their stability are properly stored;

(e) No outdated drugs are stocked in the hospital pharmacy or the facility it serves;

(f) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;

(g) Standard ward inventory (floor stock). Verification of standard ward inventory lists and accountability, including such updating, if applicable, are maintained;

(h) All necessary and required security and storage standards are met;

(i) Metric-apothecaries' weight and measure conversion tables and charts are available;

(j) All policies and procedures of the Director of Pharmacy and of appropriate committees of the hospital relevant to the pharmacy are followed;

(k) All discounted and out-dated medications are returned to the pharmacy for proper disposition; and

(l) Disinfectants and other similar supplies intended for external use are stored separately and apart from drugs intended for internal (oral) or parenteral use.

(2) Board Inspection. The Board of Pharmacy inspections shall be conducted by representatives of the Georgia Drugs and Narcotics Agency (GDNA) no less than once every two (2) years. Such inspections shall include all aspects of the management and operation of all hospital pharmacies in this State to verify compliance with the Pharmacy Laws, the Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety and welfare of patients of the hospital

serviced by the pharmacy are protected. A written report shall be filed with the GDNA, the Director of Pharmacy, and the hospital administrator. Any discrepancies or deficiencies noted shall be corrected within a reasonable time. Written notice of such corrections shall be filed with the GDNA within thirty (30) days after receipt of the inspection notice.

(a) The Director of Pharmacy of each hospital pharmacy shall obtain a copy of the current Board permit of every drug wholesaler and/or reverse distributor from which controlled substances and/or dangerous drugs are purchased and/or returned. Such copies shall be made available during the GDNA's inspection.

Cite as Ga. Comp. R. & Regs. R. 480-13-.10
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Inspection" adopted. F. Jan. 24, 1977; eff. Feb. 13, 1977.
Repealed: New Rule of same title adopted. F. May 5, 1980; eff. May 25, 1980.
Repealed: New Rule entitled "Inspections" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Chapter 480-14. DRUGS AND NARCOTICS AGENCY CLASSIFICATIONS AND MINIMUM REQUIREMENTS FOR SPECIAL AGENTS AND DEPUTY DIRECTOR.

Rule 480-14-.01. Georgia Drugs and Narcotics Agency (GDNA) Classifications and Minimum Requirements for Special Agent and Deputy Director.

The following shall apply to said personnel of the Drugs and Narcotics Agency:

(1) GDNA Special Agent. A GDNA Special Agent shall be a graduate of a recognized school or college of pharmacy and hold a current pharmacist license issued by the Georgia State Board of Pharmacy (Board). Additionally, to qualify as a GDNA Special Agent, the applicant shall have:

(a) Actively practiced pharmacy for at least two (2) years;

(b) No private or public sanctions on his or her pharmacist license or similar licenses issued by the Board, or any other Board of Pharmacy or their equivalent;

1. No prior convictions for any crime other than minor traffic offenses;

2. Successfully passed a personal background investigation;

3. Completed and passed the Georgia Peace Officers Standards and Training (P.O.S.T.) Basic Mandate Training Course to become a Georgia P.O.S.T. Certified Peace Officer within one (1) year of being hired; and

4. Such other experience, qualifications and training as suitable for such employment.

(2) GDNA Deputy Director. A GDNA Deputy Director shall be a graduate of a recognized school or college of pharmacy and hold a current pharmacist license issued by the Board. Additionally, a GDNA Deputy Director shall have at least five (5) years of full-time paid employment as a GDNA Special Agent; or as approved by the Board. A person who has been ten (10) years of full-time, paid employment in an agency similar to the GDNA as long as he or she meets the requirements for a GDNA Special Agent.

Cite as Ga. Comp. R. & Regs. R. 480-14-.01
Authority: O.C.G.A. Secs. 26-4-7, 26-4-28, 26-4-29, 28-4-37.
History. Original Rule f. Oct. 6, 1970; eff. Oct. 26, 1970.
Amended: Original Rule entitled "Inspectors: Procedures, etc." repealed and a new Rule entitled "Drug Inspectors: Classifications, Qualifications, Minimum Requirements of Drug Inspector's Office, State Board of Pharmacy" adopted. F. Aug. 2, 1974; eff. Aug. 22, 1974.
Amended: F. Aug. 24, 1976; eff. Sept. 13, 1976.
Amended: Rule repealed and a new Rule entitled "Drugs and Narcotics Agents Classifications, Qualifications, Minimum Requirements of Drugs and Narcotics Agency, State Board of Pharmacy" adopted. F. Sept. 21, 1984; eff. Oct. 11, 1984.
Amended: New Rule entitled "Georgia Drugs and Narcotics Agency (GDNA) Classifications and Minimum Requirements for Special Agents and Deputy Director" adopted. F. Aug. 14, 2003; eff. Sept. 3, 2003.

Chapter 480-15. PHARMACY TECHNICIANS AND OTHER PHARMACY PERSONNEL.

Rule 480-15-.01. Definitions.

For purposes of this chapter, the following definitions shall apply:

(a) "Board" shall mean the Georgia State Board of Pharmacy.

(b) "Certified pharmacy technician" shall mean a registered pharmacy technician who has either successfully passed a certification program approved by the Board, or has successfully passed an employer's training and assessment program approved by the Board, or has been certified by either the Pharmacy Technician Certification Board (PTCB) or any other nationally recognized certifying body approved by the Board.

(c) "Pharmacist" shall mean an individual currently licensed by this state to engage in the practice of pharmacy.

(d) Pharmacist in charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules

pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of such pharmacy and personnel.

(e) "Pharmacy intern" shall mean an individual who is a student currently enrolled in an approved school or college of pharmacy, has registered with the Board, and has been licensed as a pharmacy intern, or a graduate of an approved school or college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist, or an individual who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate and is currently licensed by the Board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist.

(f) "Pharmacy extern" shall mean an individual who is a student currently enrolled in an approved school or college of pharmacy and who has been assigned by the school or college of pharmacy for the purposes of obtaining practical experience and completing a degree in pharmacy.

(g) "Registered Pharmacy technician" shall mean those support persons registered with the board who are utilized in pharmacies and whose responsibilities are to provide nonjudgmental technical services concerned with the preparation for dispensing of drugs under the direct supervision and responsibility of a pharmacist.

Cite as Ga. Comp. R. & Regs. R. 480-15-.01
Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-84, 26-4-85, 26-4-88, 26-4-110.
History. Original Rule entitled "To Provide for the Illegal Dispensing of and Filling of Prescriptions for Drugs, Medicines and Poisons" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "To Provide for the Dispensing of and Filling of Prescriptions for Drugs, Medicines and Poisons" adopted. F. Aug. 2, 1974; eff. Aug. 22, 1974.
Repealed: New Rule entitled "Definitions" adopted. F. Nov. 14, 2007; eff. Dec. 4, 2007.
Repealed: New Rule of the same title adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Rule 480-15-.02. Registration of Pharmacy Technicians.

(a) Effective August 1, 2011, a pharmacy may only employ registered pharmacy technicians to perform pharmacy technician duties.

(b) In order to be registered as a Pharmacy Technician in this State, an applicant shall:

(1) Submit an application to the Board on the form prescribed by the Board;

(2) Attest that applicant is at least 17 years old;

(3) Attest that applicant is currently enrolled in high school, or has a high school diploma, or has a GED, or has a postsecondary education or college degree;

(4) Consent to, provide the necessary information to conduct, and pay for a background check to be conducted by the Board, its agent or a firm or firms approved by the Board, which background check will include a criminal history, driver license history and other information as the Board deems necessary, and will authorize the Board and the Georgia Drugs and Narcotics Agency to receive the results;

(5) Submit the name and address of employer and place of employment;

(6) Pay application fees; and

(7) If certified, submit evidence of training supporting designation as certified.

(c) The Board may deny registration or conditionally grant registration for any of the reasons set forth in Code sections 26-4-60 or 43-1-19. This includes convictions, pleas of nolo contendere and guilty pleas related to misdemeanor crimes of moral turpitude or marijuana and to felonies. In addition, no pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.

(d) The denial of an application for registration as a pharmacy technician shall not be a contested case and the applicant shall not be entitled to a hearing under the Georgia Administrative Procedures Action, O.C.G.A. T. 50, Ch. 13, but such applicant may be entitled to an appearance before the Board.

(e) A registration, once issued, is renewable biennially, upon payment of a fee. Registrations shall expire on June 30th of each odd-numbered year. If the application for renewal is not made and the fee paid before September 1st of the odd-numbered year, the registration shall lapse and shall not be renewed. An application for a new registration shall be required.

(f) A registrant has a responsibility to update the Board with a change of home address and employment address within ten (10) days of such change.

Cite as Ga. Comp. R. & Regs. R. 480-15-.02
Authority: O.C.G.A. §§ 16-13-111, 26-4-5, 26-4-20, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-84, 26-4-85, 26-4-88, 26-4-110, 43-1-19.
History. Original Rule entitled "To Provide for the Revocation and Suspension of Licenses and Registration for Certain Causes" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Use of Pharmacy Technicians and Other Pharmacy Personnel" adopted. F. Nov. 14, 2007; eff. Dec. 4, 2007.
Repealed: New Rule entitled "Registration of Pharmacy Technicians" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.
Amended: F. Sept. 1, 2011; eff. Sept. 21, 2011.
Amended: F. June 29, 2015; eff. July 19, 2015.

Rule 480-15-.03. Use of Registered Pharmacy Technicians and Other Pharmacy Personnel.

(a) In dispensing drugs, no individual other than a licensed pharmacist, intern or extern working under direct supervision of a licensed pharmacist shall perform or conduct those duties or functions which require professional judgment. It shall be the responsibility of the supervising pharmacist to ensure that no other employee of the pharmacy, excluding pharmacy interns or externs, performs or conducts those duties or functions which require professional judgment.

(b) For all prescription drug orders, it shall be the responsibility of the Pharmacist on duty at a facility to ensure that only a pharmacist or a pharmacy intern and/or extern under the direct supervision of a registered pharmacist provides professional consultation and counseling with patients or other licensed health care professionals and that only a pharmacist or a pharmacy intern or an extern under the direct supervision of a registered pharmacist accepts telephoned oral prescription drug orders or provides or receives information in any manner relative to prescriptions or prescription drugs.

(c) Registered pharmacy technicians and other pharmacy personnel, i.e. clerks, cashiers, observers, etc., in the prescription department shall be easily identifiable by use of a name badge or other similar means which prominently displays their name and the job function in which the personnel are engaging at that time. Any pharmacy personnel or other person present in the pharmacy department must be under the direct supervision of a licensed pharmacist.

(d) In the dispensing of all prescription drug orders:

(1) The pharmacist shall be responsible for all activities of any registered pharmacy technician in the preparation of the drug for delivery to the patient.

(2) The pharmacist shall be present and personally supervising the activities of any registered pharmacy technician at all times.

(3) When electronic systems are employed within the pharmacy, registered pharmacy technicians may enter information into the system and prepare labels; provided, however, that it shall be the responsibility of the pharmacist to verify the accuracy if the information entered and the label produced in conjunction with the prescription drug order.

(4) When a prescription drug order is presented for filling or refilling, it shall be the responsibility of the pharmacist to review all appropriate information and make the determination as to whether to fill the prescription drug order, and

(5) Any other function deemed by the Board to require professional judgment.

(e) The pharmacist to registered pharmacy technician ratio shall not exceed one pharmacist providing direct supervision of three registered pharmacy technicians. One of the three technicians must:

(1) Have successfully passed a certification program approved by the Board of Pharmacy;

(2) Have successfully passed an employer's training and assessment program which has been approved by the Board of Pharmacy; or

(3) Have been certified by the Pharmacy technician Certification Board.

(f) In addition to the utilization of three (3) registered pharmacy technicians, if one is certified, a pharmacist may be assisted by and directly supervise at the same time one (1) pharmacy intern, as well as one (1) pharmacy extern, and one (1) pharmacy observer.

(g) The board may consider and approve an application to increase the ratio in a pharmacy located in a licensed hospital. Such application must be made in writing and may be submitted to the Board by the pharmacist in charge of a specific hospital pharmacy in this state.

(h) No completed prescription drug order shall be given to the patient requesting same unless the contents and the label thereof shall have been verified by a registered pharmacist.

(i) The Board of Pharmacy may revoke or suspend the registration of a pharmacy technician for any of the grounds set forth in O.C.G.A. Sections 43-1-19 or 26-40-60. The revocation or suspension of the registration of a pharmacy technician is not a contested case under the Georgia Administrative Procedures Act, O.C.G.A.T. 50, Ch.13, and the technician is not entitled to a hearing, but the technician may be entitled to an appearance before the Board.

Cite as Ga. Comp. R. & Regs. R. 480-15-.03
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-83, 26-4-84, 26-4-85, 26-488, 26-4-110, 26-4-111, 43-1-19.
History. Original Rule entitled "Substitution" adopted. F. Oct. 6, 1970; eff. Oct. 26, 1970.
Repealed: New Rule entitled "Duties or Functions Prohibited from Being Performed by a Pharmacy Technician" adopted. F. Nov. 14, 2007; eff. Dec. 4, 2007.
Repealed: New Rule entitled "Use of Registered Pharmacy Technicians and Other Pharmacy Personnel" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.
Amended: F. May 17, 2016; eff. June 6, 2016.

Rule 480-15-.04. Duties of the Pharmacist in Charge Related to Registered Pharmacy Technicians.

(a) The Pharmacist in Charge shall be responsible for:

(1) providing updated information to the Board in accordance with rules and regulations regarding the registered pharmacy technicians employed in the pharmacy for purposes maintaining the registry of registered pharmacy technicians established by the Board pursuant to paragraph (7) of subsection (a) of Code Section 26-4-28.

(2) Ensuring the reporting the separation of employment or termination of any Registered pharmacy technician for any suspected or confirmed criminal occupational-related activities committed or any drug-related reason, including but not limited to Adulteration, abuse, theft or diversion and shall include in the notice the reason for the termination.

(3) Assuring that all pharmacists and pharmacy interns and externs employed at the pharmacy are currently licensed and that registered pharmacy technicians employed at the pharmacy are currently registered with the Board of Pharmacy.

(4) Notifying the Board of any change in the employment status of all registered technicians in the pharmacy within 10 days of the technician's separation date from employment,

(5) Ensuring that registered pharmacy technicians in the prescription department shall be easily identifiable by use of a name badge or other similar means which prominently displays their name and job title. The Pharmacist-in-Charge is responsible for ensuring that such persons wear or display such identification at all times when they are working in the prescription department.

(6) Shall ensure that the current registration for each registered pharmacy technician is readily accessible for inspection by the Board or Drugs and Narcotics Agents.

(7) Ensuring that a pharmacist is responsible for the dispensing of all prescription drug orders and for all activities of any pharmacy technician in the preparation of the drug for delivery to the patient, and that a pharmacist shall be present and personally supervising the activities of any pharmacy technician at all times.

(b) The Board of Pharmacy can take disciplinary action against the license of a pharmacist in charge who violates the provisions of this rule as authorized by O.C.G.A. Sections 43-1-19 and 26-4-60.

Cite as Ga. Comp. R. & Regs. R. 480-15-.04
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-110, 43-1-19.
History. Original Rule entitled "Duties of the Pharmacist in Charge Related to Registered Pharmacy Technicians" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Rule 480-15-.05. Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician.

(a) In dispensing drugs, no individual other than a licensed pharmacist shall perform or conduct those duties or functions which require professional judgment. It shall be the responsibility of the supervising pharmacist to ensure to that no other employee of the pharmacy, excluding pharmacy interns or externs but including registered pharmacy technicians, performs, or conducts those duties or functions which require professional judgment. The following functions require the professional judgment of a pharmacist, or a pharmacy intern or extern, under the direct supervision of a pharmacist, and may not be performed by a registered pharmacy technician:

(1) Acceptance of telephoned or other oral prescriptions;

(2) Transfers of prescription drug orders from another pharmacy or transfers of a prescription drug order to another pharmacy;

(3) Patient counseling;

(4) Receiving information or providing information about a prescription drug order;

(5) Making the determination as to whether to refill the prescription drug order;

(6) Certification of a filled and finished prescription drug order;

(7) Weighing or measuring active ingredients without a mechanism of verification;

(8) Compounding of medication without a mechanism of verification;

(9) Giving a completed prescription to the patient requesting same without the label and contents and the label being verified by a pharmacist.

(10) Reconstitution of prefabricated medication without a mechanism of verification;

(11) Verification of the constituents of final IV admixtures for accuracy, efficacy, and patient utilization;

(12) Enter of order on patient medication profiles without verification by a pharmacist;

(13) Provision of drug information that has not been prepared or approved by the pharmacist;

(14) Review of the patient record for therapeutic appropriateness; and

(15) Any other act prohibited by Board rule, or law.

Cite as Ga. Comp. R. & Regs. R. 480-15-.05
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-60, 26-4-82, 26-4-84, 26-4-85, 26-4-88.
History. Original Rule entitled "Duties or Functions Prohibited from Being Performed by a Registered Pharmacy

Technician" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Rule 480-15-.06. Other Pharmacy Personnel.

(1) Effective June 1, 2016, a pharmacy may permit pharmacy observers to shadow licensed pharmacists for the limited and exclusive purpose of education about the practice of pharmacy.

(2) Requirements. In order to be pharmacy observer, an individual must:

   (a) Be at least seventeen (17) years old;

   (b) Be currently enrolled in high school or in general education diploma preparation courses; and

   (c) Not have been convicted of a felony and/or any offense that was related to drugs and have an attestation by the principal of his/her school or parent or guardian stating that the observer has neither been convicted of a felony or any offense that was related to drugs.

(3) Limitation of Duties. A pharmacy observer shall not perform any duties that require licensure as a pharmacist or pharmacy intern or registration as a pharmacy technician under the Georgia Pharmacy Practice Act (O.C.G.A. Title 26, Chapter 4) or the Rules of the Georgia Board of Pharmacy. It shall be the responsibility of the supervising pharmacist and the pharmacist-in-charge to ensure that no pharmacy observer performs or conducts those duties or functions that require licensure or registration under Georgia law or rules.

(4) Restriction of Access. A pharmacy observer shall not be present in the pharmacy for more than eight (8) hours per day and in no circumstance for more than forty (40) hours.

(5) Requirement of Direct Supervision. The supervising pharmacist shall be present and personally supervise the pharmacy observer at all times that the observer is in the pharmacy. The pharmacist to pharmacy observer ratio shall not exceed one pharmacist providing direct supervision of one pharmacy observer.

(6) Identification of Pharmacy Observers. The pharmacist-in-charge shall be responsible for ensuring that any pharmacy observer in the prescription department is easily identifiable by the use of a name badge or other similar means which prominently displays the observer's name and job title. The pharmacist-in-charge is responsible for ensuring that such a person wears or displays such identification at all times when the person is present in the prescription department.

(7) Professional Conduct. A pharmacy observer shall be subject to any confidentiality restrictions under state and/or federal law or regulation to which other pharmacy employees are subject. The pharmacist-in-charge shall conduct all training required to

ensure that the pharmacy observer understands and complies with his/her obligations of confidentiality under state and federal law or regulation.

Cite as Ga. Comp. R. & Regs. R. 480-15-.06
Authority: O.C.G.A. §§ 26-4-28, 26-4-110, 26-4-111.
History. Original Rule entitled "Other Pharmacy Personnel" adopted. F. May 17, 2016; eff. June 6, 2016.

Chapter 480-16. MISCELLANEOUS GUIDELINES FOR PHARMACISTS.

Rule 480-16-.01. Report of Unlicensed Dispensing or Impaired Pharmacist.

(1) Report of unlicensed dispensing. No licensed pharmacist of this state shall knowingly allow any unlicensed person to fill prescriptions (except as provided under the direct and personal supervision of a Georgia licensed pharmacist) or practice pharmacy while impaired in any place of business.

Any pharmacist having knowledge that a pharmacist or drug store owner allows or encourages any unlicensed person to illegally fill prescriptions or practice pharmacy while impaired shall report such action within ten (10) days to the Director of the Georgia Drugs and Narcotics Agency (GDNA) and upon his failure to report such acts to the director, which shall be grounds for sanctions on such licensed person's license.

Cite as Ga. Comp. R. & Regs. R. 480-16-.01
Authority: O.C.G.A. Secs. 26-4-37, 26-4-28, 26-4-60, 26-4-80, 26-4-112.
History. Original Rule was filed as Rule 480-7-.01 on June 30, 1965.
Amended: Filed October 6, 1970; effective October 26, 1970.
Amended: Filed March 20, 1975; effective April 9, 1975.
Amended: Rule repealed and a new Rule entitled "Rules and Regulations Concerning Additional Responsibilities of the Drugs and Narcotics Agency" adopted. Filed September 21, 1984; effective October 11, 1984.
Amended: Filed July 14, 1987; effective August 3, 1987.
Amended: Rule repealed and new Rule entitled "Report of Unlicensed Dispensing or Impaired Pharmacist" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-16-.02. Receipt of Prescription Drug Order by a Non-Pharmacy.

(1) No person or entity other than an establishment licensed under O.C.G.A. 26-4 shall engage in the practice of accepting and receiving prescriptions and forwarding same to a drug store or pharmacy to be filled and returned to the forwarding agency, which, in turn, delivers the filled prescriptions to the patient or agent of the patient and collects the charge there

(2) It shall be illegal for any person or entity to attempt to or to eliminate the patient/pharmacist contact, and for any such person or entity to prevent a pharmacist from properly supervising and controlling the dispensing of prescription drugs. Such pharmacist-patient contact is essential to the proper practice of pharmacy care.

(a) It shall be deemed detrimental to the health, safety, and welfare of the people of the State of Georgia for any firm, partnership, corporation, or business, other than a Pharmacy licensed by the Board under O.C.G.A. 26-4, to accept or receive any prescription drug order;

(b) Such practice is prohibited, and any such practice taking place shall be discontinued immediately upon verbal or written notice of the Board or the Georgia Drugs and Narcotics Agency.

(3) In order for a patient to authorize a licensed medical practitioner to hold, administer, or deliver the patient's prescription drug at his or her office location, and the drug was previously dispensed and delivered to the practitioner's office by a pharmacy, the patient must first provide the pharmacy with written authority to conduct such a delivery.

Cite as Ga. Comp. R. & Regs. R. 480-16-.02
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-60, 26-4-80.
History. Original Rule entitled "Receipt of Prescription Drug Order by a Non-Pharmacy" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.
Amended: F. Dec. 14, 2012; eff. Jan. 3, 2013.

Rule 480-16-.03. Return of Previously Dispensed Drugs or Devices.

(1) It shall be unlawful, and a violation of these rules, for any licensed pharmacist or pharmacy licensed under O.C.G.A. 26-4 to accept for refund purposes, or otherwise, any unused portion of a drug which has been previously dispensed via a prescription drug order and delivered to the patient or patient's caregiver, except where permitted under state and/or federal law or regulation.

(a) Such receipt is deemed detrimental to the public health due to the likelihood that such drugs, once out of the control of the pharmacy, could have been tampered with, been adulterated, or become contaminated with communicable diseases and/or contagious diseases under the holder thereof;

(b) In addition, such receipt would tend to create a health problem if placed in stock and could be reused by any licensed pharmacist or pharmacy.

(2) Nothing in this Rule shall be meant to be in conflict with Board Rule 480-10-. 17, which allow a pharmacy to receive unused, manufacturer's unit-dose packaged drugs from a Medicaid patient residing in a long term care facility.

(3) Nothing in this Rule shall prohibit an authorized collector from collecting controlled substances for the purposes of destruction as authorized in the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"), any regulations promulgated thereunder, and Ga. Comp. R. & Regs. c. 480-50.

Cite as Ga. Comp. R. & Regs. R. 480-16-.03
Authority: O.C.G.A. §§ 26-3-3, 26-4-27, 26-4-28, 26-4-60, 26-4-80, Pub. L. 111-273.
History. Original Rule entitled "Return of Previously Dispensed Drugs or Devices" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.
Amended: F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-16-.04. Damaged Pharmaceuticals and Other Items.

(1) Any drugs, poisons, narcotics, family remedies, grocers' drugs, flavoring extracts, essences, toilet articles, stock powders, veterinary supplies, proprietary preparations and any and all other and similar items intended for internal or external use of humans or animals which have been subjected to heat and/or water resulting from fire and/or water damage to a building or storage area in which said items were stored or retained is prohibited from being introduced into the stream of retail commerce without first causing an inspection of said items to determine their suitability for use as intended.

(a) Certain of the above classes of items when subjected to heat and/or water as a result of fire and/or water damage to a building or storage area in which said items are stored or retained are chemically altered or otherwise contaminated and therefore rendered unsafe and unfit for use of man or animal as intended.

(b) If certain of the above classes of items or units thereof are entered into the stream of retail commerce and sold for the internal or external use of humans or animals following their having been subjected to heat and/or water as a result of fire and/or water damage as aforesaid without first being inspected to determine their suitability for use as intended, they shall be considered adulterated or misbranded and will be subject to confiscation. Those persons placing them into the stream of retail commerce shall be subject to penalties and/or reprimands by the Board.

(2) Within three (3) days following any damage by fire and/or water to a building or storage area in which any of the above said items are stored or retained, written notice shall be forwarded to the Director of the Georgia Drugs and Narcotics Agency (GDNA) at his office, by the person or his agent with custody or control of the said items informing the Director of the GDNA of the circumstances and requesting an immediate inspection of said items.

(3) Within three (3) days from his receipt of such written notice the Director of the GDNA shall cause an inspection to be made of said items for the purpose of determining their suitability for use as intended and within a reasonable time after the completion of said inspection, the Director of the GDNA shall forward to the person from whom he received

such notice a report of the result of said inspection and an authorization to release said items for retail sale if the facts so indicate.

(4) The office of the Director of the GDNA is charged with the enforcement of the provisions of this regulation.

Cite as Ga. Comp. R. & Regs. R. 480-16-.04
Authority: O.G.C.A. Secs. 26-3-3, 26-3-16, 26-4-27, 26-4-28.
History. Original Rule entitled "Damaged Pharmaceuticals and Other Items" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-16-.05. Deceptive Advertising.

(1) No person or entity licensed under O.C.G.A. 26-4 shall engage in fraudulent or deceptive advertising or promotional procedures with respect to drugs, devices, cosmetics, poisons, or other substances subject to the provisions of O.C.G.A. Sections 16-13 or 26-3.

Cite as Ga. Comp. R. & Regs. R. 480-16-.05
Authority: O.C.G.A. Secs. 16-13-34, 26-3-16, 26-4-27, 26-4-28, 26-4-60.
History. Original Rule entitled "Deceptive Advertising" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-16-.06. Theft, Loss, or Unaccounted for Controlled Substances.

(1) The theft, loss, or unaccounted for controlled substances must, within three (3) days of its discovery, must be reported to the Drug Enforcement Administration and the GDNA.

(2) A written report must be made regarding any theft, loss or unaccounted for controlled substances by completing a DEA Form 106.

   (a) Within ten (10) days of receiving such DEA Form 106, the original and one copy of the report must be sent to the Drug Enforcement Administration; and

   (b) One copy must be sent to the GDNA.

(3) The report shall include the following information:

   (a) Full name and address of the pharmacy;(e) List of cost codes, or identification symbols on package stolen; and

   (b) Pharmacy DEA registration number;

   (c) Date of theft, loss, or discovery of missing controlled substance;

   (d) Type of incident, i.e. theft, loss, etc.;

(e) List of cost codes, or identification symbols on package stolen; and

(f) List of the controlled substances missing.

Cite as Ga. Comp. R. & Regs. R. 480-16-.06
Authority: O.C.G.A. Secs. 16-13-34, 26-4-27, 26-4-38.
History. Original Rule entitled "Theft, Loss, or Unaccounted for Controlled Substances" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-16-.07. Release of Confidential Prescription Drug Order Information.

Confidential prescription drug order information means information maintained by the pharmacist in the patient's records or which is communicated to the patient as part of patient counseling which is privileged and may be released only to the patient, to the patient's designee, or to those practitioners and other pharmacists where, in the pharmacist's professional judgement, such release is necessary to protect the patient's health and well being; and to such other persons or government agencies authorized by law to receive such confidential information.

(a) An electronically transmitted prescription drug order from a prescriber to a pharmacist shall be considered a highly confidential transaction and the said transmission shall not be compromised by interventions, control, change, altering, or manipulation by any other person or party in any manner whatsoever;

(b) Any pharmacist that transmits, receives, or maintains any prescription drug order or prescription drug order refill authorization either orally, in writing, or electronically shall ensure the security, integrity, and confidentiality of the prescription and any information contained therein;

(c) Information contained in the patient medication record or profile shall be considered confidential as defined by this Rule.

(d) Confidential information may be released to the following:

1. The patient;

2. The patient's authorized representative;

3. The prescriber, or other licensed health care practitioners then caring for the patient;

4. Another licensed pharmacist for purposes of transferring a prescription or as a part of a patient's drug utilization review, or other patient counseling requirements;

5. The Board, or its representative; or

6. Any law enforcement personnel duly authorized to receive such information such as a GDNA agent, DEA Agent, or Georgia Medicaid Agent.

(e) In accordance with O.C.G.A. 24-9-40(b), 26-4-80 and these rules, a pharmacist may release confidential information to such persons not mentioned in 480-16-. 08(d) only upon the receipt of the following:

1. A written authorization for release signed by the patient, or his or her parents or duly appointed guardian, such as in the case of a minor;

2. An subpoena issued and signed by an authorized government official; or

3. A court order issued and signed by a judge of an appropriate court.

(f) A letter from an attorney requesting confidential information without being accompanied by an official subpoena or court order is not considered a valid mechanism to cause a pharmacist to release such requested confidential information.

(g) Any pharmacist releasing information under written authorization or waiver of the patient, his or her parents or duly appointed guardian, such as in the case of a minor, or appropriate court order or subpoena shall not be liable to the patient or any other person; provided, further, that the privilege shall be waived to the extent that the patient places his or her care and treatment or the nature and extent of his or her injuries at issue in any administrative, civil, or criminal proceeding.

Cite as Ga. Comp. R. & Regs. R. 480-16-.07
Authority: O.C.G.A. Secs. 24-9-40, 26-4-27, 26-4-28, 26-4-80.
History. Original Rule entitled "Release of Confidential Prescription Drug Order Information" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-16-.08. Purchase or Receipt of Drugs by a Pharmacy.

All pharmacies are required to purchase or receive dangerous drugs and/or controlled substances from a firm licensed by this state as a drug wholesaler, distributor or manufacturer.

Cite as Ga. Comp. R. & Regs. R. 480-16-.08
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, and 26-4-113.
History. Original Rule entitled "Purchase or Receipt of Drugs by a Pharmacy" adopted. F. Apr. 4, 2014; eff. Apr. 24, 2014.

Chapter 480-17. ISSUANCE OF INTRAVENOUS MAINTENANCE DRUGS TO REGISTERED

PROFESSIONAL NURSES EMPLOYED OR CONTRACTED BY A HOME HEALTH AGENCY.

Rule 480-17-.01. Purpose.

According to O.C.G.A. 16-13-72(4.2), a registered professional nurse licensed under O.C.G.A. 43-26-6 who is employed or contracted by a licensed home health agency may possess sterile saline, sterile water and diluted heparin for use as intravenous maintenance for use in a home health setting, and such nurse may administer such items to patients of the home health agency upon the order of a licensed physician. The State Board of Pharmacy shall be authorized to adopt regulations governing the storage, quantity, use and administration of such items; provided however, nothing in this paragraph or in such regulations shall be construed to restrict any authority of nurses existing under other provisions of the law.

Cite as Ga. Comp. R. & Regs. R. 480-17-.01
Authority: O.C.G.A. Secs. 16-13-72(4.2), 26-4-27.
History. An Emergency Chapter 480-17-0 was filed on July 2, 1971; effective July 2, 1971 for not longer than 120 days.
Emergency Chapter repealed and original Rule 480-17-.01 entitled "Narcotic Drugs-Defined" adopted. Filed October 5, 1971; effective October 25, 1971.
Repealed: New Rule entitled "Purpose" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-17-.02. Definitions.

(1) Home Health Agency. Home Health Agency (HHA) means a public, non-profit, or proprietary organization which is licensed by the Georgia Department of Human Resources (DHR) to engage in providing home health services 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;

(2) Home Health Services. Home Health Services (HHS) means those items and services furnished to an individual according to a written plan of treatment signed by the patient's physician, by a home health agency on a visit or hourly basis, in place of temporary or permanent residence used as the individual's home;

(3) Hospital. Hospital means an institution which is primarily engaged in providing to inpatients and outpatients, 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, and other specialty hospitals.

(4) Issuing Pharmacy. Issuing Pharmacy means a pharmacy licensed as a retail pharmacy by the Georgia State Board of Pharmacy and which is authorized by this chapter to issue

Sterile Drug Intravenous (IV) Maintenance Kits (SDM Kits) for use in a home health setting by registered professional nurses employed or contracted by a licensed home health agency.

(5) Registered Professional Nurse. Registered Professional Nurse (RN) means a person who is authorized by a license issued under O.C.G.A. 43-26 to practice nursing as a registered professional nurse and is authorized to use the abbreviation "RN".

(6) Sterile Drug Intravenous Maintenance Kits. Sterile Drug Intravenous (IV) Maintenance Kits (SDM Kits) are sealed containers whose contents are strictly limited to the drugs sterile saline, sterile water, and diluted heparin, and which can only be distributed by an Issuing Pharmacy to professional registered nurses employed or contracted by a home health care agency.

Cite as Ga. Comp. R. & Regs. R. 480-17-.02
Authority: O.C.G.A. Secs. 16-13-72(4.2), 26-4-27.
History. Original Rule entitled "Definitions" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-17-.03. Issuance of Sterile Drug IV Maintenance Kits by an Issuing Pharmacy.

As set forth by this rule, pharmacies, hereafter known as Issuing Pharmacies, may issue sealed Sterile Drug IV Maintenance Kits (SDM Kits) to RNs who are employed or contracted by a HHA. The contents of such kits are strictly limited to the following IV maintenance drugs: sterile water, sterile saline, and diluted heparin. The manner of issuance of such SDM Kits is limited to procedures specified in written guidelines set forth by the Issuing Pharmacy and based on this rule. Pursuant to these guidelines, Home Health Agencies may authorize Registered Nurses employed or contracted by the Home Health Agency to carry and utilize such contingency kits for the purpose of IV maintenance for Home Health Agency patients. Nothing in this rule is to be interpreted to allow Home Health Agencies or registered professional nurses to independently possess dangerous drugs. Such SDM Kits and drugs contained therein, as described in this rule, will at all times be considered under the control of the Issuing Pharmacy described as follows:

(a) A written agreement, which has been signed by a pharmacist on behalf of the Issuing Pharmacy and by the medical director of the licensed Home Health Agency, will serve as a protocol, which establishes at a minimum, but not limited to: the contents of the kits and the manner in which sealed SDM kits will be issued, stored, handled, and restocked. Prior to any such agreement becoming effective, it must first be signed and dated by the medical director of the Home Health Agency and returned to the Issuing Pharmacy. This protocol will include at a minimum:

1. The manner in which a pharmacy initially labels and issues a SDM Kit;

2. The manner in which a pharmacy will restock or issue a replacement SDM Kit;

3. The manner in which sealed, SDM Kits are stored and kept secure at a licensed Home Health Agency (HHA);

4. The record keeping required of and the manner in which a HHA may issue on a daily basis the maximum number of SDM Kits necessary to authorized RNs. These issued kits may be carried by an R.N only during the nurse's daily, patient care duties, and such kits will be returned to the HHA after the completion of those duties;

5. The record keeping required of and the manner in which an authorized HHA RN may break the seal of and open a SDM Kit to utilize its' contents as necessary to perform necessary patient IV maintenance care duties. Such use requires the issuance of a prescriber's order prior to any drug being utilized;

6. The manner in which an Issuing Pharmacy will be notified within 72 hours of when such drug utilization occurs, with such notification to include a copy of the physician's order bearing the name of the prescriber, the name of the nurse administering the drug(s), the patient name, the name of the drug, the dosage form and directions for use, along with other pertinent information;

7. Once the seal on a SDM Kit has been broken and the SDM Kit has been opened, the kit shall be returned to the HHA. Upon being returned to the HHA, it cannot be reused or reissued until it has been restocked and resealed by a pharmacist from the Issuing Pharmacy.

(b) An Issuing Pharmacy will develop written guidelines in which, at a minimum, it establishes procedures for:

1. Maintaining a record of serial numbers on breakable seals utilized on individual.SD.M. Kits;

2. The record keeping of and manner of issuing or replacing the contents of SDM Kit;

3. The monthly inspection to include how SDM Kits are stored by a Home Health Agency, accountability for each issued kit, the condition of the drugs contained therein (including expiration date), and a method to handle the kits after their contents have expired;

4. How the authorized RN will possess kits in a manner which meets all Federal, State, and USP guidelines for the proper storage of the sterile dangerous drugs contained therein.

(c) Any retail pharmacy may enter into a SDM kit agreement with one or more Home Health Agencies. The pharmacist in charge of such pharmacy will be directly responsible for drafting a protocol which meets the requirements of this rule, and for the manner in which

these SDM Kits are utilized by a Home Health Agency and their authorized registered RNs.

1. Any and all records relating to a pharmacy issuing SDM Kits will be made available for inspection and copying by a representative of the Georgia Drugs and Narcotics Agency (GDNA).

2. The issuing pharmacy shall maintain a list with the name, address and the responsible person of each H. H. A. where SDM Kits are stored. Agents of the GDNA shall have unrestricted access to inspect Home Health Agencies in relation to SDM Kits and corresponding storage and distribution records, as set forth under O.G.C.A Title 26, Chapter 3.

3. The Issuing Pharmacy will maintain a list of any and all nurses authorized to possess such SDM kits.

4. During the inspection, the GDNA Agent may make recommendations as to any problems or discrepancies.

5. When any Issuing Pharmacy experiences discrepancies in the record keeping of a H. H. A., or any SDM Kits previously issued to a H. H. A. cannot be accounted for, the pharmacist in charge shall notify the GDNA.

Cite as Ga. Comp. R. & Regs. R. 480-17-.03
Authority: O.C.G.A. Secs. 16-13-72(4.2), 26-4-27.
History. Original Rule entitled "Issuance of Sterile Drug IV Maintenance Kits by an Issuing Pharmacy" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Chapter 480-18. OPIOID TREATMENT PROGRAM CLINIC PHARMACIES.

Rule 480-18-.01. Definitions.

For purposes of this chapter, the following definitions apply:

(a) Administer. The term administer means to give one, single dose of a pharmacy prepared narcotic controlled substance.

(b) Board. Board means the Georgia State Board of Pharmacy.

(c) Compound. The term compound means to mix, prepare, package or change the dosage form of a narcotic controlled substance for use in or by an opioid treatment program.

(d) CSAT. CSAT means the Center for Substance Abuse Treatment.

(e) DEA. DEA means the United States Drug Enforcement Administration.

(f) DHR. DHR means the Georgia Department of Human Resources.

(g) Dispense. The term dispense refers to the actions of a pharmacist when he/she fills a prescription drug order and prepares either a single dose or multiple doses in patient-specific take-home containers with narcotic controlled substances for an opioid treatment program.

(h) Director of Pharmacy Services. Director of Pharmacy Services shall be a pharmacist, licensed with the Board, who shall direct, oversee, establish protocols and be responsible for all pharmacy related transactions at an opioid treatment program clinic pharmacy.

(i) Emergency kit. An emergency kit is a kit containing drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source within the clinic in sufficient time to prevent risk of harm to patients;

(j) GDNA. GDNA means the Georgia Drugs & Narcotics Agency.

(k) Licensed medical personnel. The term licensed medical personnel is used to describe employees of an opioid treatment program clinic licensed by the State of Georgia as health care professionals, i.e. physicians, pharmacists, nurses.

(l) Medication dosing station. The term medication dosing station is used to describe the location where doses of medication are administered.

(m) Medication order. The term medication order is used to describe the manner in which a physician orders, via written, verbal or electronically transmitted means, the administration of a narcotic controlled substance to the ultimate user.

(n) Methadone clinic. Methadone clinic is defined the same as a narcotic treatment program clinic or an opioid treatment program clinic.

(o) Methadone treatment program. Methadone treatment program is defined the same as a narcotic treatment program or an opioid treatment program.

(p) Narcotic maintenance. The term narcotic maintenance means a treatment procedure in which individuals use an approved narcotic controlled substance over a period of time to relieve withdrawal symptoms and reduce narcotic craving in combination with rehabilitation services.

(q) Narcotic treatment program. Narcotic treatment program or NTP, also known as an opioid treatment program, is defined as a program licensed or otherwise authorized, by the State of Georgia Department of Human Resources (DHR), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Drug Enforcement Administration (DEA) to operate a narcotic substance abuse program using narcotic

replacement procedures for individuals dependant on opium, morphine, heroin or any derivative or synthetic drug in that group.

(r) Narcotic treatment program clinic pharmacy. Narcotic treatment program clinic pharmacy, is defined as a pharmacy licensed by the Board which is designated as an on-site pharmacy department of a narcotic treatment program.

(s) On-site pharmacy. On-site pharmacy (OSP) is a licensed opoid treatment program clinic pharmacy.

(t) Opioid replacement center. Opioid replacement center (ORC) is an opioid treatment program.

(u) Opioid treatment program. Opioid treatment program (OTP), is an opioid replacement program or a narcotic treatment program licensed, or otherwise authorized by the State of Georgia Department of Human Resources, the Substance Abuse and Mental Health Services Administration, and the U.S. Drug Enforcement Administration. This program operates as a narcotic substance abuse program using narcotic replacement procedures for individuals dependant on opium, morphine, heroin or any derivative or synthetic drug in that group.

(v) Opioid treatment program clinic pharmacy. Opioid treatment program clinic pharmacy is a licensed pharmacy which is designated as an on-site pharmacy department located in and operated by any opioid treatment program or opiate replacement treatment program.

(w) Opioid treatment program clinic pharmacy license. An opioid treatment program clinic pharmacy license is issued by the Georgia State Board of Pharmacy to an opioid treatment program clinic pharmacy.

(x) Outpatient. Outpatient shall mean an opioid treatment program patient who is treated on an outpatient basis.

(y) SAMHSA. SAMHSA means the Substance Abuse and Mental Health Services Administration.

(z) Take-home dose. The term take-home dose means a quantity of a physician ordered narcotic controlled substance dispensed by an opioid treatment program clinic pharmacy which an individual can take away from the OTP clinic, as set forth in the Georgia Department of Human Resources rules.

Cite as Ga. Comp. R. & Regs. R. 480-18-.01
Authority: O.C.G.A. 26-4-37.
History. Original Rule was filed Emergency Rule on October 1, 1974; effective October 1, 1974, for 120 days, or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule.
Amended: Permanent Rule filed November 13, 1974; effective December 3, 1974.
Amended: Filed November 2, 1987; effective November 22, 1987.
Repealed: New Rule entitled "Definitions" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-18-.02. Licensure and Registration.

(1) All opioid treatment program (OTP) clinics must have an on-site pharmacy. All such pharmacies shall obtain a license by registering with the Georgia State Board of Pharmacy (Board). Such license shall be renewed biennially with the Board. Before a Board license can be issued, an opioid treatment program clinic must meet all the requirements for licensure and registration as provided by both state and federal law and all Board rules.

(2) Licensure and Applications. Certificates of registration or licensure shall be issued only to those opioid treatment program clinic pharmacies who meet the following requirements:

(a) Submission of an application with the following information:

1. The name, full business address, and telephone number of the licensee;

2. All trade or business names used by the licensee;

3. Address, telephone number, and the name of the Director of Pharmacy

4. The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

5. The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of the partnership and the name of each partner;

(iii) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; or

(iv) If a corporation, the corporate name, the name and title of each corporate officer and director, the state of incorporation; and the name of the parent company, if any.

(v) If operations are conducted at more than one location by a single opioid treatment program clinic pharmacy, each such location shall be licensed by the Board.

(3) Payment of an application fee. Application fees shall not be refundable.

(4) Applicant must file a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.

(5) Licenses become null and void upon the sale, transfer or change of mode of operation or location of the pharmacy.

(6) Licenses are required to be renewed June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each pharmacy and the filing of an application for renewal. Said renewal is for a two year period. If the application for renewal is not filed with the Board and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

(7) Changes in any licensee information pertaining to this rule shall be submitted in writing to the Board prior to such change.

(8) The Board will consider the following factors in determining eligibility for licensure of applicants in charge of the facility who are applying for an opioid treatment program clinic pharmacy license:

(a) Convictions of the applicant under any Federal, State, or local laws relating to wholesale or illegal distribution of dangerous drugs or controlled substances;

(b) Any felony convictions of the applicant under Federal, State, or local laws;

(c) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(d) Suspension or revocation by Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;

(e) Compliance with licensing requirements under previously granted licenses, if any;

(f) Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by the opioid treatment program clinic pharmacies; and

(g) Other factors or qualifications the Board considers relevant to and consistent with the public health, safety and welfare.

(9) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

(10) The pharmacist's wall certificate issued by the Georgia State Board of Pharmacy (Board), along with the current renewal license of each full-time pharmacist, employed at the pharmacy, shall be displayed in a conspicuous place, near the prescription department where such pharmacist is actively engaged in the practice of pharmacy.

(a) While employed in a pharmacy on a full-time basis, if a pharmacist has not yet received his/her Board issued pharmacist wall certificate, in its place such pharmacist shall post a copy of his/her current Board issued pocket license card;

(b) Any pharmacist employed on a part-time basis at a pharmacy shall post a copy of his/her current Board issued pocket license instead of posting his/her pharmacist wall certificate; and

(c) Any pharmacist employed as a relief or "prn" pharmacist need not post any type of Board issued license, but such pharmacist must maintain and present upon request his/her current Board issued pocket license.

(11) Any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from this, or any other rule, must be posted and/or displayed next to the current Board of Pharmacy permit; and

(12) No pharmacist or intern/extern shall display his/ her license in any pharmacy where he or she is not employed or engaged in the practice of pharmacy, and shall not knowingly permit any other person to use his or her license for the purpose of misleading anyone to believe that such person is the holder or recipient of said license or intern certificate.

Cite as Ga. Comp. R. & Regs. R. 480-18-.02
Authority: O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-37, 26-4-5, 26-4-20, 26-4-27, 26-4-28, 26-4-60, 26-4-110, 26-4-111, 26-4-113, 43-1-19.
History. Original Rule was filed as an Emergency Rule on October 1, 1974; effective for 120 days, or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule.
Amended: Permanent Rule filed November 13, 1974; effective December 3, 1974.
Amended: Filed September 3, 1975; effective September 23, 1975.
Repealed: New Rule entitled "Licensure and Registration" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.
Amended: F. June 29, 2015; eff. July 19, 2015.

Rule 480-18-.03. Personnel.

The personnel shall be as follows:

(a) Director of Pharmacy Services. Each OTP clinic pharmacy shall be under the direction of a Director of Pharmacy Services, hereafter referred to as the Director. The Director shall:

1. Direct, oversee and be responsible for all activities related to pharmacy transactions at an opioid treatment program clinic pharmacy;

2. Be a pharmacist licensed by the Board to practice;

3. Be charged with meeting all of the requirements of applicable state and federal laws and rules;

4. Be employed on a full-time or part-time basis consistent with the need and objectives of the OTP clinic.

5. Shall have such other duties and responsibilities as set forth in this chapter.

(b) Supportive Personnel. The Director of an OTP clinic pharmacy shall be assisted by a sufficient number of licensed pharmacists and other personnel as may be required to operate such pharmacy competently, safely, and to meet the needs of the outpatients of the OTP clinic pharmacy.

(c) Secretary and clerical personnel shall be provided to assist with record keeping, report submission, and other administrative duties, provided such personnel do not perform any dispensing duties.

(d) Supervision. All of the activities and operations of each OTP clinic pharmacy shall be personally and directly supervised by the Director or his/her pharmacist designee.

1. All functions and activities of supportive personnel shall be supervised by an adequate number of registered pharmacists to insure that all such functions and activities are performed competently, safely, and without risk of harm to patients;

2. Personal supervision can only be accomplished by the physical presence of a licensed pharmacist in the OTP clinic pharmacy.

3. The Director of Pharmacy shall insure that all supportive personnel will be trained in the matters of an opioid treatment program clinic pharmacy.

4. The Director of Pharmacy shall develop and implement written policies and procedures to specify the duties to be performed by such supportive personnel. These policies and procedures shall, at a minimum, specify that supportive personnel are personally and directly supervised by a licensed pharmacist while on duty in the pharmacy, and that supportive personnel are not assigned duties which may be performed only by licensed pharmacists.

Cite as Ga. Comp. R. & Regs. R. 480-18-.03
Authority: O.C.G.A. Secs. 16-13-34, 26-4-27, 26-4-28, 26-4-80, 26-4-87, 26-4-110, 26-4-111.
History. Original Rule was filed as an Emergency Rule on October 1, 1974; effective October 1, 1974 for 120 days, or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule.
Amended: Permanent Rule F. Nov. 13, 1974; eff. Dec. 3, 1974.
Amended: Rule repealed, New Rule entitled "Personnel" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-18-.04. Absence of a Pharmacist.

The following regulations shall be followed in the absence of a pharmacist:

(1) General. Access to drugs in the absence of a licensed pharmacist shall be limited to specifically authorized licensed medical personnel consistent with policies and procedures of the Director. Such areas shall be sufficiently secure to deny access by unauthorized persons. The Director shall, in conjunction with the appropriate committee of the narcotic treatment program clinic, develop a list of the drugs to be accessible and shall ensure that:

(a) Such drugs available therein, are properly labeled, with drug name, strength, lot number and expiration date;

(b) Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(c) Whenever access to such area shall have been gained, written physician's orders and proof of use for controlled substances are provided;

(d) All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and

(2) Written policies and procedures are established to implement the requirements of this subsection.

(3) Emergency Kits. Drugs may be provided for use by authorized licensed health care personnel by emergency kits, provided such kits meet the following requirements:

(a) Drugs included. The Director and the medical staff of the clinic shall jointly determine the drugs, by identity and quantity, to be included in the emergency kits. Such drugs shall also be approved by the Board or its authorized agent;

(b) Storage. Emergency kits shall be stored in limited access areas and sealed to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them;

(c) Labeling-exterior. The exterior of emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of each drug shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by the Board upon a recommendation of the GDNA.

(d) Labeling-interior. All drugs contained in emergency kits shall be labeled in accordance with such state and federal laws and regulations which pertain thereto; and shall also be labeled with such other and further information as may be required by the medical staff of the clinic to prevent misunderstanding or risk of harm to the patients;

(e) Removal of drugs. Drugs shall be removed from emergency kits only pursuant to a valid physician's order, by authorized licensed clinic personnel, or by a pharmacist for the clinic pharmacy;

(f) Notification. Whenever an emergency kit is opened, the pharmacy shall be notified; and the pharmacy shall replace or re-stock and reseal the kit within a reasonable time so as to prevent risk of harm to patients. In the event the kit is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

(g) Inspections. Each emergency kit shall be opened and its contents inspected by the pharmacy at least once every ninety (90) days. Upon completion of inspection, the emergency kit shall be re-sealed.

(4) Access to pharmacy. Whenever any drugs are not available from an after hours safe or emergency kit(s), and such drugs are required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drugs may be obtained from the pharmacy pursuant to the physician's order and the requirements of this subsection.

(a) At any given time, there may be only one licensed health care professional who is designated in the policies and procedures, to have access to the pharmacy and to remove drugs therefrom.

(b) Such licensed health care professional shall be designated in writing by the Director of the OTP clinic pharmacy and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training by the Director or his or her designee in the proper methods of access, removal of drugs, and records and procedures required.

(c) Such licensed healthcare professional shall at a minimum record on a suitable form the name of any drug, the strength, amount, date and time removed from the pharmacy and his or her signature and title.

(d) Such licensed healthcare professional shall place the container from which the drug is removed in a conspicuous place in the pharmacy to be promptly reviewed and inspected by a pharmacist.

(e) Procedures. The Director, in conjunction with the medical staff of the clinic, shall develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

Cite as Ga. Comp. R. & Regs. R. 480-18-.04
Authority: O.C.G.A. Secs. 16-13-34, 26-4-27, 26-4-28, 26-4-87, 26-4-110, 26-4-111.
History. Original Rule entitled "Absence of a Pharmacist" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-18-.05. Physical Requirements and Equipment.

(1) Physical Area. An OTP clinic pharmacy shall have within the clinic which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed space, and which meet the other requirements of this section, the Georgia Pharmacy laws, and other applicable state and federal laws and rules. Such space shall be at a minimum 150 square feet. Such space shall include all areas which are assigned and under the direct control of the Director.

(2) Minimum equipment. No OTP clinic pharmacy licensed in accordance with O.C.G.A. Title 26, Ch. 4 shall engage in the practice of filling, compounding or dispensing prescription drugs for an OTP Clinic unless it shall possess the following items:

(a) Copies of and/or electronic access to current reference materials appropriate to the practice of pharmacy related to OTP. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(b) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be posted or readily available in areas both inside and outside of the pharmacy where drugs are stored or patients are being cared for.

(c) Current copies or electronic or computer access to the following:

1. The Georgia Pharmacy Practice Act/Drug and Cosmetic Act, O.C.G.A. §§ 26-4 and 26-3;

2. The Georgia Controlled Substances Act/Dangerous Drug Act, O.C.G.A. § 16-13;

3. The official rules of the Georgia State Board of Pharmacy.

(d) Equipment:

1. Sink in working condition with both hot and cold running water;

2. Two spatulas;

3. One oral solid counting tray;

4. Typewriter, word processor or computer with label printer;

5. A refrigerator in working order with a thermometer.

6. Any other equipment the Board may deem necessary for a specialized practice setting where such a specialized practice takes place.

(e) Weighing and labeling:

1. Appropriate prescription labels consistent with the requirements of O.C.G.A. §§ 16-13, 26-3 and 26-4; and

2. Appropriate auxiliary labels that should be used in the pharmacist's professional judgement.

3. If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance.

(f) An adequate supply of drugs used in an OTP Clinic setting.

(g) Assorted sizes and types of appropriate dispensing containers.

(3) The Director in an OTP clinic pharmacy may submit to the Board a typed request for a variance to the provisions relating to the minimum equipment requirements.

(a) The reason for requesting each variance must be included in the typed request;

(b) A variance shall be granted by the Board only when, in the judgement of the Board, there are sound reasons for doing so which relate to the necessary or efficient delivery of health care.

(c) Any variance granted by the Board shall be in writing, and the variance must be posted in the pharmacy next to the current Board issued license certificate.

Cite as Ga. Comp. R. & Regs. R. 480-18-.05
Authority: O.C.G.A. §§ 16-13-34, 26-4-27, 26-4-28, 26-4-110, 26-4-111.
History. Original Rule entitled "Physical Requirements and Equipment" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.
Amended: F. Apr. 13, 2021; eff. May 3, 2021.

Rule 480-18-.06. Drug Distribution and Control.

(1) General. A drug distribution system is the entirety of that mechanism by which a physician's drug order is executed, from the time the practitioner transmits the order either orally, in writing, or electronically to a licensed health care professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration. No drugs can be dispensed or administered without a physician's medication drug order.

(2) Responsibility. The Director shall be responsible for the safe and efficient distribution, control, and accountability for drugs. The other professional staff, including the

physicians, at the OTP clinic shall cooperate with the Director in meeting this responsibility and in ordering, administering, and accounting for the drugs and devices so as to achieve this purpose.

(a) The Director shall establish written policies and procedures for the distribution of medications including emergency kits, etc. to achieve this goal.

1. The drugs must be identified up to the point of administration;

2. The pharmacy must receive a direct, electronic (only for drugs to be administered on site) or mechanical copy of a physician's order before the first dose of medication is dispensed as defined by the clinic stat order policy.

3. At a minimum, the pharmacy must maintain a patient profile for each OTP clinic patient for use in prospective and retrospective drug reviews, for comparing with the central registry as required by the DHR and to report violators to the GDNA and DHR, for discharge from another OTP, and for urine or blood tests to check for drug positive test results.

4. Records of all transactions of the OTP clinic pharmacy, such as daily drug dosing summaries, daily drug inventory sheets, patient medication profiles, and bulk drug inventory records must be maintained by the clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all drugs and devices within the scope of the clinic practice.

5. All drug invoices must be attached to their accompanying DEA form 222 order form and must be filed separately from all other drug records. A biennial inventory of all controlled substances on hand must be taken every two years from the date of the pharmacy opening for business. This inventory must be an accurate count of all such drugs, signed in indelible ink by the pharmacist taking the inventory and dated on the date it is taken.

6. Any drug compounded by the pharmacy must be accounted for by use of a compounding log form. This form, at a minimum must display the date the drug was compounded, the name of the drug, the strength, quantity made, manufacturer's lot number, manufacturer's expiration date, and the signature of the pharmacist compounding the drug.

7. Nothing in this section shall prohibit the use of computerized records, where such records meet all other requirements of the law. An OTP clinic pharmacy may not dispense or administer prescription medications other than OTP program medications; and

8. The pharmacy must participate in those aspects of the OTP clinic patient care evaluation program which relate to drug and device utilization and effectiveness.

(b) All records must be maintained by the pharmacy for a minimum of two years and be readily retrievable upon request by an agent of the Board.

(3) Labeling:

(a) For use inside the clinic, all drugs dispensed by an OTP clinic pharmacy, including those for use in an after hours safe or emergency kit shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum:

1. Brand name or generic name of the drug;

2. Drug strength;

3. Lot number assigned by either the drug manufacturer or the clinic pharmacy; and

4. Expiration date assigned either by the drug manufacturer or the clinic pharmacy.

(b) Any drug container dispensed by the pharmacy for take-home use by an OTP clinic patient must display a label which contains at least the following:

1. Patient name;

2. Name of the prescribing physician;

3. Name, address and telephone number of the OTP clinic pharmacy;

4. Drug name (either brand or generic name);

5. Drug strength;

6. Date of dispensing;

7. Expiration date of the drug as determined by the pharmacy;

8. "Federal Caution" for controlled substances;

9. Clinic Pharmacy serial number for that specific prescription drug order;

10. Any other labeling or information as required by the DEA;

(c) All take-home medication dispensed by the pharmacy, including one-time use containers, must be in child-proof containers which meet the requirements of the U.S. Consumer Product Safety Commission.

(4) Discontinued drugs. The Director shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(5) Accountability of controlled substances.

(a) Nothing shall prohibit the use of controlled substance drugs issued via proof of use forms for general or emergency use for specific patients. Proof of use controlled substances forms shall be provided by the pharmacy.

(b) Each proof of use form shall display the name of the patient to or for which it has been issued and an indication that the drugs are for general or emergency use and a serial number. The form shall also show the date the form was issued and the signature of the pharmacist issuing the form and the signature of the licensed medical practitioner receiving the form for storage in the after-hour safe. A detachable receipt reflecting all the previous information must be returned and filed by the pharmacy as a safeguard to prevent drug diversion.

(c) Each proof of use sheet shall provide space to record the administration information necessary to account for each dose of medication. This information shall specify at a minimum:

1. Drug name, strength, and dosage form;

2. Dose administered;

3. Name of prescriber. This shall include, at a minimum, the first initial and complete last name of the prescriber;

4. First and last name of the patient;

5. Date and time of administration to patient;

6. Signature of individual administering the dose, which shall include at a minimum, the first and last name and title;

7. Documentation of destruction of all unused portions by two signature verifications of licensed healthcare professionals;

8. Proof of receipt of medication bearing identifying serial numbers;

9. Date the medication was issued and date the proof of use form was returned.

(6) Any OTP clinic pharmacy licensed by the Board may make on-premises destruction of small quantities of controlled substances prepared for oral administration provided:

(a) The controlled substance is the remainder of a single-dose unit; and,

(b) The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.

(7) Perpetual inventory of Schedule II controlled substances shall be required and accountability of said drugs shall be by an appropriate form indicating at a minimum the date used, name of shipper or drug recipient, corresponding serial number of a drug order, invoice or proof of use form, and quantity received or issued.

(8) Recall. The Director shall develop and implement a recall policy and procedure to assure that all drugs within the clinic included on the recall are returned to the pharmacy for proper disposition.

(9) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering physician, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's pharmacy profile shall also be made.

(10) Security. All areas occupied by an OTP clinic pharmacy shall be capable of being locked by key or combination, so as to prevent unauthorized personnel access except by force. Such areas shall meet the security requirements of all applicable Federal and State laws and rules. Only those persons so authorized shall be permitted to enter these areas.

(a) All drugs shall be stored in designated areas within the clinic pharmacy or all dispensing medications shall be stored in designated areas within the clinic which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage areas shall be locked or otherwise secured when licensed health care professionals are not present.

(b) Storage for Schedule II controlled substances shall be in an enclosed room or space with controlled limited access capable of showing forced entry is preferable. However, a safe or a lockable metal cabinet that is permanently affixed to the structure is acceptable.

(c) Whenever any area of an OTP clinic pharmacy is not under the personal and direct supervision of authorized licensed personnel, such areas shall be locked and secured.

(11) Reports and records. The Director shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board, the GDNA or its designated agents. All such records shall be maintained for a minimum of two years. These shall include, at a minimum, the following:

(a) Patient profile, chart or other appropriate record;

(b) Proof of use forms for controlled substances;

(c) Reports of suspected adverse drug reactions;

(d) Inventories of after hours safe(s) and emergency drug kits,

(e) All perpetual inventories maintained by the pharmacy, and all other records pertaining to controlled substances, including a biennial controlled substances inventory;

(f) Such other records and reports as may be required by Federal or State laws and/or rules;

(12) The compounding, labeling and quality control of large volumes of opioid treatment medication is the responsibility of a pharmacist and shall be prepared within the on-site pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-18-.06
Authority: O.C.G.A. Secs. 16-13-34, 16-13-41, 26-3-8, 26-4-27, 26-4-28, 26-4-80, 26-4-86, 26-4-87, 26-4-110, 26-4-111.
History. Original Rule entitled "Drug Distribution and Control" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-18-.07. Delivery of Drugs, General.

(1) 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 in an OTP.

(a) A licensed medical practitioner must write an initial dosing medication order for each patient prior to any medication being dispensed or prepared by the OTP clinic pharmacy.

(b) In emergency situations, a verbal order may be given by the physician and it must be signed by the physician within 72 hours, or such order would be considered a violation of these rules.

(c) Any adjustment to a patient's dosage regimen is considered to be a new medication order. Such orders shall be written per protocol developed by the clinic's medical director and signed by the ordering physician within 72 hours.

(2) Drugs shall be administered by authorized licensed personnel in accordance with policies and procedures specified by the Director of Pharmacy Services under applicable laws and rules and regulations, and by usual and customary standards of good medical practice

which protect the public health, safety and welfare. Only licensed personnel shall administer medications.

Cite as Ga. Comp. R. & Regs. R. 480-18-.07
Authority: O.C.G.A. Secs. 16-13-34, 16-13-41, 16-13-74, 26-4-27, 26-4-28, 26-4-80, 26-4-87, 26-4-110, 26-4-111.
History. Original Rule entitled "Delivery of Drugs, General" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-18-.08. Drugs From Outside Sources.

(1) The Director shall establish policies and procedures relating to drugs brought into the OTP clinic by outside sources. Such drugs shall not be administered unless they can be precisely identified. Administration shall be pursuant only to an authorized practitioner's prescription drug order. These medications shall be kept in the pharmacy. If such drugs are not to be administered, the medication shall be returned to an adult member of the patient's family or stored by the pharmacy and returned to the patient upon discharge. Nothing in this section shall prohibit another method of accomplishing the intent of this section provided such method is approved by the Board.

Cite as Ga. Comp. R. & Regs. R. 480-18-.08
Authority: O.C.G.A. Secs. 16-13-34, 16-13-41, 16-13-74, 26-4-27, 26-4-28, 26-4-80, 26-4-87, 26-4-110, 26-4-111.
History. Original Rule entitled "Drugs From Outside Sources" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-18-.09. Inspections.

(1) Board Inspection. The Board, through either the GDNA or by its qualified designee, shall, at a minimum, inspect each OTP clinic pharmacy once every two (2) years to verify compliance with the laws and these rules and regulations.

   (a) The Director shall maintain a copy of the inspection report in the OTP clinic pharmacy and shall submit a copy of the report to the DHR Methadone Authority.

   (b) Any discrepancies or deficiencies noted shall be corrected within thirty (30) days of the inspection.

   (c) Written notice of such corrections or a plan of action to correct deficiencies shall be filed with the GDNA within thirty (30) days after receipt of the inspection report.

(2) Director inspections. The Director shall no less than once each month, either personally or by qualified designee, inspect all matters within the jurisdiction and responsibility of the pharmacy and make appropriate written records of such inspections. Such inspections shall, at a minimum, verify that:

(a) Drugs are dispensed only by licensed pharmacists or licensed pharmacy interns/externs acting under the direct supervision of a licensed pharmacist;

(b) Non-licensed pharmacy personnel are properly directed and supervised;

(c) Drugs for external use are stored separately and apart from drugs for internal use or injection;

(d) Drugs requiring special storage conditions to insure their stability are properly stored;

(e) No outdated drugs are stocked in the OTP clinic pharmacy or the facility it serves;

(f) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;

Cite as Ga. Comp. R. & Regs. R. 480-18-.09
Authority: O.C.G.A. Secs. 16-13-34, 26-4-27, 26-4-28, 26-4-29, 26-4-80, 26-4-82, 26-4-87, 26-4-88, 26-4-110, 26-4-111.
History. Original Rule entitled "Inspections" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-18-.10. Notification Required by the Georgia Department of Human Resources.

Whenever the DHR central registry determines that a patient is improperly utilizing more than one OTP at the same time, and notifies the Director, the Director shall notify the Board and the GDNA.

Cite as Ga. Comp. R. & Regs. R. 480-18-.10
Authority: O.C.G.A. Secs. 16-13-34, 16-13-43, 26-4-27, 26-4-28, 26-4-29, 26-4-60, 26-4-82, 26-4-111.
History. Original Rule entitled "Notification Required by the Georgia Department of Human Resources" adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Chapter 480-19. EXEMPT OVER-THE-COUNTER (OTC) SCHEDULE V CONTROLLED SUBSTANCES.

Rule 480-19-.01. Excepted Sales of Non-Pseudoephedrine Schedule V Controlled Substances.

Excepted Sales of Non-Pseudoephedrine Schedule V Controlled Substances. No person shall obtain or attempt to obtain, sell, dispense or otherwise dispose of any non-pseudoephedrine substance included in Schedule V of the Georgia Controlled Substances Act, except as herein

provided, and as in compliance with all other applicable laws, rules and regulations. All terms used in this section shall have the same meaning as in O.C.G.A. T. 16, Ch. 14 and T. 26, Ch. 4, as amended.

(a) A physician or medical practitioner may dispense Schedule V substances for legitimate medical purposes in the normal course of his/her professional practice.

(b) A licensed pharmacist, or intern acting under the immediate and direct supervision of a licensed pharmacist, may sell, dispense or otherwise dispose of without prescription not more than 4 oz. or 32 dosage units of an exempted non-pseudoephedrine Schedule V controlled substance within any 48 hour period of time, but only:

1. After applying reasonable means or effort to determine that such is to be used for legitimate medical purposes; and

2. After the purchaser has written his/her signature, date of birth, address, city, state and zip code upon a register which records and reflects the date of such transaction, the name, kind, quantity and intended use of such Schedule V substance sold, dispensed, or otherwise disposed of, and such records shall be maintained as required by Schedule V records.

(c) No person shall obtain or attempt to obtain, in any 48-hour period of time, more than 4 oz. or 32 dosage units of a Schedule V controlled substance.

Cite as Ga. Comp. R. & Regs. R. 480-19-.01
Authority: O.C.G.A. Secs. 16-13-29.2, 26-4-27, 26-4-28.
History. Original Rule entitled "Excepted Sales of Schedule V Substances" adopted as ER. 480-19-0.4-.01. F. and eff. Oct. 1, 1974, as specified by the Agency.
Amended: Permanent Rule of same title adopted. F. Nov. 13, 1974; eff. Dec. 3, 1974.
Repealed: New Rule entitled "Excepted Sales of Schedule V Controlled Substances" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005..
Repealed: New Rule entitled "Excepted Sales of Non-Pseudoephedrine Schedule V Controlled Substances" adopted. F. Nov. 28, 2011; eff. Dec. 18, 2011.

Rule 480-19-.02. Exempt Non-Pseudoephedrine Schedule V Controlled Substances.

Before the sale of any non-pseudoephedrine Schedule V Controlled Substance without a prescription, a licensed pharmacist should first determine whether or not the product to be sold is packaged in a container with not more than 4 ounces or 32 dosage units of the drug, and whether the label provided by the product manufacturer contains a Federal Caution or Warning. If such Legend or Warning or Rx Only indication is present on the manufacturer's label, this product cannot be sold without a prescription.

Cite as Ga. Comp. R. & Regs. R. 480-19-.02
Authority: O.C.G.A. Secs. 16-13-22, 16-13-34, 26-4-27, 26-4-28.
History. Original Rule entitled "Exempt Schedule V Controlled Substances" adopted. F. Aug. 31, 2005; eff. Sept.

20, 2005.
Repealed: New Rule entitled "Exempt Non-Pseudoephedrine Schedule V Controlled Substances" adopted. F. Nov. 28; eff. Dec. 18.

Rule 480-19-.03. Over-thecounter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products Containing Pseudoephedrine.

(a) No person shall obtain or attempt to obtain, sell, dispense or otherwise distribute any exempt Schedule V controlled substance drug product containing pseudoephedrine as listed under O.C.G.A. 16-13-29(5), except as herein provided, and as in compliance with all other applicable state or federal laws, rules and regulations. All terms used in this section shall have the same meaning as in O.C.G.A. T.16, Ch. 13 and T. 26, Ch. 4.

1) All exempt Schedule V controlled substance pseudoephedrine containing drug products must be stored in a pharmacy's prescription department.

2) All pharmacy personnel who engage in the sale or distribution of exempt Schedule V controlled substance containing drug products must complete the DEA's self-certification training as required by the Combat Methamphetamine Epidemic Act of 2005, 21 U.S.C. 830.

(b) A registered pharmacist or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may sell, dispense or otherwise dispose of without prescription not more than 3.6 grams every 24 hours, or a maximum of 9 grams every 30 days, to each customer of a pseudoephedrine containing drug product, but only:

1) After applying reasonable means or effort to determine that such is to be used for legitimate medical purposes, following the proper record keeping procedures, and ensuring the required information has been properly recorded in a logbook which contains either a written or electronic list of sales.

2) For hand-written logbooks used to record patient information before the sale of an exempt Schedule V pseudoephedrine containing drug product can take place:

(A) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist, must approve all such sales or transactions. Approval means verifying the patient's identification and ensuring the patient has a valid reason for obtaining the pseudoephedrine. After approval, the registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may direct designated pharmacy personnel, to complete any sales transactions to a patient by writing in the logbook at a minimum the name of the pseudoephedrine containing drug product, strength, and quantity sold along with the name of the patient, their date of birth, address, zip code, data and time of sale; The pharmacy may require

additional patient information for the logbook as long as the required information is obtained.

(B) The patient must sign the logbook to acknowledge the sale and receipt of the pseudoephedrine containing drug product.

(C) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may personally, or may direct designated pharmacy to, ask the patient to produce a photo identification issued by a state or the federal government to use in verifying that the patient's name on the photo identification matches the name the patient wrote in the logbook; No exempt Schedule V pseudoephedrine containing drug product can be sold to a patient unless they present appropriate identification

(D) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist must or may direct designated pharmacy personnel to verify that the date and time of the sale and other information that has been entered in the logbook is correct by use of the patient's photo identification, and initial the logbook verifying the information for the sale as being correct.

3) For electronic logbooks used to record patient information for the sale of an exempt Schedule V pseudoephedrine containing drug product:

(A) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist, must approve all such sales or transactions. Approval means verifying the patient's identification and ensuring the patient has a valid reason for obtaining the pseudoephedrine. After approval, the registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may direct designated pharmacy personnel, to complete any sales transactions to a patient by entering, at a minimum, the name of the pseudoephedrine containing drug product, strength, and quantity sold; the patient's name, date of birth, address, and zip code, or entering this information may be accomplished through a point of sales system and bar code reader. The pharmacy may require additional patient information for the logbook as long as the required information is obtained.

(B) The computer for the electronic logbook can automatically enter the date and time of the sale,

(C) The patient's signature on the logbook must be captured using an electronic signature system of a type similar to or one used for credit card purchases

(D) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may personally, or may direct designated pharmacy personnel to, must ask the patient to produce a photo identification issued by a state or the federal government to use in verifying that the patient's name on the photo identification matches the name the patient wrote in the logbook; No exempt Schedule V pseudoephedrine containing drug product can be sold to a patient unless they present appropriate photo identification

(E) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist must, or may direct designated pharmacy personnel to, enter their name or pharmacist, pharmacy intern license number, or pharmacy personnel's identification in the logbook to indicate the information for the sale is correct.

(4) The quantities of different strength pseudoephedrine containing drug products that equals 3.6 grams is:

Tablets/capsules - Number of tablets/capsules that equal 3.6 grams

Ingredients	**Number of tablets = 3.6 grams**
30 mg Pseudoephedrine HCl	146 Tablets
60 mg Pseudoephedrine HCl	73 Tablets
120 mg Pseudoephedrine HCl	36 Tablets
30 mg Pseudoephedrine Sulfate	155 Tablets
60 mg Pseudoephedrine Sulfate	77 Tablets
120 mg Pseudoephedrine Sulfate	38 Tablets
240 mg Pseudoephedrine Sulfate	19 Tablets

Liquids -Number of milliliters that equal 3.6 grams

Ingredients	**Number of milliliters (ml) = 3.6 grams**
6.25 mg Ephedrine HCl/ 5 ml Liquid	3515 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	468 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	2929 ml

15 mg Pseudoephedrine HCl / 5 ml Liquid	1464 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	366 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	366 ml

(c) No registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist can knowingly sell more than 9 grams of pseudoephedrine to a patient in a 30 day period of time.

(1) The quantities of different strength pseudoephedrine containing drug products that equals 9 grams is:

Tablets/capsules - Number of tablets/capsules that equal 9 grams

Ingredients	Number of tablets = 9 grams
30 mg Pseudoephedrine HCl	366 Tablets
60 mg Pseudoephedrine HCl	183 Tablets
120 mg Pseudoephedrine HCl	91 Tablets
30 mg Pseudoephedrine Sulfate	389 Tablets
60 mg Pseudoephedrine Sulfate	194Tablets
120 mg Pseudoephedrine Sulfate	97 Tablets
240 mg Pseudoephedrine Sulfate	48 Tablets

Liquids -Number of milliliters in 9 grams

Ingredients	Number of milliliters (ml) = 9 grams
6.25 mg Ephedrine HCl / 5 ml Liquid	8788 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	1171 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	7323 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	3661 ml

15 mg Pseudoephedrine HCl / 2.5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	915 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	915 ml

(d) All logbooks must be retained for a minimum period of 2 years from the date of the last recorded sale.

(e) Logbooks must be kept in a secure location in the pharmacy and information contained in a logbook can be shared:

(A) To comply with state or federal laws and rules;

(B) For a product recall

(C) With local, state, and federal law enforcement officers, to allow logbook information to be inspected, copied.

(f) Nothing in this rule would prohibit pharmacies, or 3rd party information technology company acting on behalf of a pharmacy, to report or transmit sales data for exempt Schedule V controlled substance drug products containing pseudoephedrine to the state operated central registry, also known as the Georgia Methamphetamine Information System (GMIS). Without approval from GDNA, such data cannot be reported to any other central record keeping system. These sales may be reported to the registry either electronically, by means of transmitting a faxed copy of a handwritten logbook, or by sending copies of handwritten logbooks to the GDNA designated collection location for the registry via the U.S. mail or other similar means.

(g) Nothing in this rule requires a pharmacy to maintain a logbook that is separate and apart from the logbook required under the U.S. Combat Methamphetamine Epidemic Act of 2005, 21 U.S.C 830 and 844, other than drug products containing pseudoephedrine must be stored in the prescription department area of a pharmacy and the sales are made by a registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist.

Cite as Ga. Comp. R. & Regs. R. 480-19-.03
Authority: O.C.G.A. §§ 16-13-22, 16-13-29, 16-13-29.2, 16-13-34, 26-4-27, 26-4-28.
History. Original Rule entitled "Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine" adopted. F. Nov. 28, 2011; eff. Dec. 18, 2011.

Rule 480-19-.04. Record keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine.

(a) A record created this rule must be maintained in the pharmacy at which the transaction occurred, except that records may be kept either at a single, central location for the pharmacy or by a third party information technology company on behalf of the pharmacy only if the pharmacy has notified the GDNA of its intention to do so and received GDNA approval.

(1) Written notification must be submitted by registered or certified mail, return receipt requested, to the Director, Georgia Drugs and Narcotics Agency, 40 Pryor Street, SW, Suite 2000, Atlanta, Georgia 30303.

(2) This notification must include telephone and address contact information as well as a telephone number and email address for a point of contact person who is responsible for providing requested record for either the pharmacy's central record keeping location or any third party information technology company.

(3) The Director of the Georgia Drugs and Narcotics Agency shall issue written approval of any central record keeping location or third party information technology company prior to records being maintained in such a manner.

(b) The records required to be kept under this rule must be readily retrievable and available for inspection and copying by GDNA or other law enforcement officers as requested as provided for under the provisions of 21 U.S.C. 880, and the U.S. Combat Methamphetamine Epidemic Act of 2005.

(1) A record developed and maintained to comply with federal law may be used to meet the requirements of this rule if the record includes the information specified by this rule.

(2) Readily retrievable shall mean records must be produced by the pharmacy or the harmacy's third party information technology company in less than 6 hours for all electronically maintained records or 24 hours for any handwritten records.

(c) If a pharmacy fails to produce records or produce records in the required time is considered a violation of O.C.G.A. Sections 16-13-37, 16-13-39, and 16-13-42.

Cite as Ga. Comp. R. & Regs. R. 480-19-.04
Authority: O.C.G.A. §§. 16-13-22, 16-13-29, 16-13-29.2,16-13-34, 16-13-35, 26-4-27, 26-4-28, 26-4-60.
History. Original Rule entitled "Record keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine" adopted. F. Nov. 11, 2011; eff. Dec. 18, 2011.

Rule 480-19-.05. Exceptions to Exempt Schedule V Controlled Substance Drug Products Containing Pseudoephedrine Sales.

(a) Any drug product containing pseudoephedrine which comes in a container packaged by the its manufacturer with and its label contains a Federal Caution or Rx Only indication, this product is not an exempt narcotic under this rule and cannot be sold as an Exempt OTC Schedule V drug product and can only be dispensed by a pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist upon receipt of a prescription issued by a licensed practitioner.

(1) Such prescriptions should be filed and maintained in the manner set forth for Schedule III, IV or V controlled substance prescriptions.

(b) Any licensed practitioner who is authorized to dispense drugs by O.C.G.A. 26-4-130 may dispense drug products containing pseudoephedrine in accordance to state laws and board of pharmacy rule 480-28.

(1) Such prescriptions dispensed according to board of pharmacy rule 480-28 should be filed and maintained in the manner set forth for Schedule III, IV or V controlled substance prescriptions.

Cite as Ga. Comp. R. & Regs. R. 480-19-.05
Authority: O.C.G.A. §§ 16-13-22, 16-13-34, 26-4-27, 26-4-28, 26-4-130.
History. Original Rule entitled "Exceptions to Exempt Schedule V Controlled Substance Drug Products Containing Pseudoephedrine Sales" adopted. F. Nov. 28, 2011; eff. Dec. 18, 2011.

Chapter 480-20. REGISTRATION REQUIREMENTS UNDER GEORGIA CONTROLLED SUBSTANCES ACT.

Rule 480-20-.01. Registration of Retail Pharmacies, Hospital Pharmacies, Opioid Treatment Program Clinic Pharmacies, Clinic Pharmacies, Nuclear Pharmacies, Prison Clinic Pharmacies, Manufacturers, Drug Wholesalers and Distributors, Researchers, and Reverse Distributors.

A person or firm issued a license or a permit by the Georgia Board of Pharmacy as a pharmacist, pharmacy intern, retail pharmacy, hospital pharmacy, opioid treatment program clinic pharmacy, clinic pharmacy, nuclear pharmacy, prison clinic pharmacy, manufacturer, drug wholesale distributor, researcher, or reverse distributor under the provisions of O.C.G.A. 16-13-35 and registered with the Drug Enforcement Administration under the provisions of the Federal Controlled Substances Act are hereby registered likewise concerning the same schedules and substances under the Georgia Controlled Substances Act, and are exempt from the application and fee requirements of O.C.G.A. 16-13-34.

Cite as Ga. Comp. R. & Regs. R. 480-20-.01
Authority: O.C.G.A. Secs. 26-4-27, 16-13-34..
History. Original Rule was filed as an Emergency Rule on October 1, 1974; effective October 1, 1974 for 120 days, or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule.
Amended: Permanent Rule filed November 13, 1974: effective December 3, 1974.

Repealed: New Rule entitled "Registration of Retail Pharmacies, Hospital Pharmacies, Opioid Treatment Program Clinic Pharmacies, Clinic Pharmacies, Nuclear Pharmacies, Prison Clinic Pharmacies, Manufacturers, Drug Wholesalers and Distributors, Researchers, and Reverse Distributors" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-20-.02. Record-Keeping Requirements For Registrants.

(1) Each registrant shall maintain records of unusual orders of controlled substances received by the registrant and s hall inform the Off ice of the Director of the Georgia Drugs and Narcotics Agency (GDNA) of unusual orders when discovered by the registrant. For purposes of this section, an unusual order shall include orders of greatly increased quantity, orders deviating substantially from a normal pattern, and orders of highly abnormal frequency.

(2) Before distributing or transferring any controlled substance and/or a dangerous drug, without a prescription drug or der, to any customer, a registrant must ensure such customer is properly licensed or registered to purchase, receive, or possess such drug(s) by maintaining, on file, a copy of the current license or registration for any and all such customers. Any transfer, sale, distribution of a drug to an unlicensed or unregistered customer shall be deemed to be in violation of O.C.G.A. 26-4-115, 16-13-30 and/or 16-13-72.

Cite as Ga. Comp. R. & Regs. R. 480-20-.02
Authority: O.C.G.A. §§ 16-13-34, 26-4-27, 26-4-115.
History. Original Rule was filed on August 24, 1976; effective September 13, 1976.
Repealed: New Rule entitled "Record-Keeping Requirements for Registrants" adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.

Chapter 480-21. RETAIL PHARMACIES PROVIDING HOME HEALTH CARE SERVICES.

Rule 480-21-.01. Definitions.

For the purpose of these rules and regulations, the following definitions apply:

(a) Retail Pharmacy Providing Home Health Care Services. A retail pharmacy providing home health care services is defined as a licensed retail pharmacy that routinely prepares and dispenses compounded, sterile parenteral products to outpatients.

(b) Outpatient. An outpatient is defined as a patient in the home environment or an institutionalized patient that is receiving compounded, sterile parenteral products from a pharmacy outside the institution.

(c) Compounded, Sterile Parenteral Products. Compounded, sterile parenteral products are defined as those parenteral drug products that require preparation by the pharmacist and which must be sterile, stable, and effective when dispensed for patient use.

Cite as Ga. Comp. R. & Regs. R. 480-21-.01
Authority: O.C.G.A. Secs. 26-4-3726-4-27, 26-4-28, 26-4-110, 26-4-111.
History. Original Rule entitled "Fertile Seed of Marijuana, Cannabis or Cannabis Sativa L." was filed as an Emergency Rule on October 1, 1974; effective October 1, 1974 for 120 days or until the adoption of a permanent Rule covering the same subject matter superseding said Emergency Rule.
Amended: Permanent Rule of the same title filed November 13, 1974; effective December 3, 1974.
Amended: Rule repealed. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Original Rule entitled "Definitions" was filed on Aug. 30, 1985; eff. Sept. 19, 1985.
Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-21-.02. Registration.

All retail pharmacies providing home health care services must have a current retail pharmacy permit. Therefore, they must comply with all retail pharmacy laws and regulations as well as the special regulations contained in these rules.

Cite as Ga. Comp. R. & Regs. R. 480-21-.02
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110, and 26-4-111.
History. Original Rule entitled "Registration" was filed on August 30, 1985; effective September 19, 1985.
Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-21-.03. Personnel.

(1) Pharmacist-in-Charge. The pharmacist-in-charge at each retail pharmacy providing home health care services shall be knowledgeable in the specialized functions of preparing and dispensing compounded, sterile parenteral products, including the principles of aseptic technique and quality assurance. This knowledge is may be obtained through residency training programs, continuing education programs, or experience in an IV admixture facility. The pharmacist-in-charge shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all drugs and pharmaceuticals. The pharmacist-in-charge shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs. The pharmacist-in-charge may be assisted by additional pharmacists adequately trained in this area of practice.

(2) Supportive Personnel. The pharmacist-in-charge may be assisted by supportive personnel. These personnel shall have specialized training in this field, and shall work under the direct supervision of a licensed pharmacist. The training provided to these personnel shall be described in writing in a training manual. The duties and responsibilities of these personnel must be consistent with their training and experience.

(3) Secretarial Personnel. Secretarial and clerical support shall be provided as required to assist with record keeping and other administrative duties.

(4) Staffing. A licensed pharmacist shall be accessible at all times at each such licensed facility to respond to patients' and other health professionals questions and needs.

Cite as Ga. Comp. R. & Regs. R. 480-21-.03
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110, 26-4-111.
History. . Original Rule entitled "Personnel" was filed on August 30, 1985; effective September 19, 1985.
Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-21-.04. Physical Requirements.

The physical requirements are:

(a) Space. Each retail pharmacy providing home health care services shall have a designated area for preparing compounded, sterile parenteral products. This area shall be physically separate from other areas and should be designed to avoid unnecessary traffic and airflow disturbances. The minimum space shall be 150 square feet. It shall be used only for the preparation of specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) Equipment.

1. Laminar Airflow Hood; or Class 100 Clean Room;

2. Infusion Pumps, if appropriate;

3. Sink, in working condition, with hot and cold running water, which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

4. Equipment for light/dark field examination;

5. Appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapy agents;

6. A Class II, vertical flow biological safety cabinet, if chemotherapy agents are routinely prepared;

7. Refrigerator/Freezer with a thermometer and in working condition.

(c) Supplies.

1. Disposable needles, syringes and other supplies needed for aseptic admixture;

2. Disinfectant cleaning solutions;

3. Handwashing agent with bactericidal action;

4. Disposable, lint free paper towels;

5. Appropriate filters and filtration equipment;

6. Disposable masks and sterile, disposable gloves;

7. Gowns, if chemotherapy agents are routinely prepared;

8. An oncology drug spill kit, if chemotherapy agents are routinely prepared.

(d) References. In addition to references required of a retail pharmacy, current edition of an established reference on IV stability and incompatibility, such as, HANDBOOK ON INJECTABLE DRUGS, or KING'S GUIDE TO PARENTERAL ADMIXTURES.

(e) Variances.

1. The pharmacist-in-charge may submit to the Georgia State Board of Pharmacy a written request for a variance to these provisions relating to minimum equipment requirements. Stated reasons for application for variances must be included in the submitted request. A variance shall be granted by the Board only when, in the judgement of the Board, there are sound reasons for doing so that relate to the necessary or efficient delivery of health care. After consideration by the Board, the requestor will be notified in writing of the Board's decision.

2. If approved, said letter(s) will serve as the proof of the Board's approval for variances indicted in the letter, and must be posted next to the inspection report.

Cite as Ga. Comp. R. & Regs. R. 480-21-.04
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-110, 26-4-111.
History. Original Rule entitled "Physical Requirements" was filed on August 30, 1985; effective September 19, 1985.
Amended: F. Sept. 29, 1998; eff. Oct. 19, 1998.
Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-21-.05. Drug Distribution and Control.

Regulations are:

(a) General. A drug distribution system is the entirety of that mechanism by which a physician's prescription drug order is executed, from the time the drug is ordered and received in the pharmacy, to the time the prescribed drug is dispensed to the patient.

(b) Purchasing. All drugs and pharmaceutical products purchased and dispensed by a retail pharmacy providing home health care services shall meet national standards of quality (USP-NF standards) and shall be clearly and accurately labeled by the manufacturer or distributor as to contents.

(c) Policy and Procedure Manual. A policy and procedure manual shall be prepared and maintained at each retail pharmacy providing home health care services and be available for inspection by agents of the Georgia Drugs and Narcotics Agency. The policy and procedure manual shall set forth in detail the objectives and operational guidelines of the pharmacy. The manual shall be reviewed and revised at a minimum on an annual basis. A copy shall be provided to the Board of Pharmacy when applying for a permit or engaging in this specialized area of practice.

(d) Prescription Drug Order. The pharmacist or pharmacy intern/extern acting under the direct supervision of a licensed pharmacist must receive a written or verbal prescription drug order from a physician before dispensing any compounded, sterile parenteral product or other drug. Prescriptions drug orders may be filed by patient, assigned consecutive numbers, or any other system that assures a complete, retrievable and accurate record. A new prescription drug order is required every six (6) months if the physician does not specify a course of therapy. These prescriptions drug orders shall, at a minimum, contain the following:

1. Patient's full name;
2. Patient address for a controlled substance;
3. Drug name, strength, and dispensing quantity;
4. Patient directions for use;
5. Date of issuance;
6. Prescriber's signature;
7. Prescriber's address and drug enforcement administration identification code, if applicable;
8. Refill instructions.

(e) Patient Profile. A pharmacy generated patient profile that may be separate from the prescription file must be maintained for each patient. The patient profile shall be maintained under the control of the pharmacist-in-charge for a period of two years after the last dispensing activity. The patient profile shall contain, at a minimum:

1. Patient's full name;
2. Age;

3. Weight;
4. Sex;
5. Compounded, sterile parenteral products dispensed;
6. Date dispensed;
7. Drug content and quantity;
8. Patient directions;
9. Prescription serial number;
10. Identification of dispensing pharmacist(s);
11. Other drugs patient is receiving;
12. Patient's drug sensitivities and allergies to drugs and foods;
13. Primary diagnosis of the patient.

(f) Labeling. Each compounded, sterile parenteral product dispensed to outpatients shall be labeled with the following information with a permanent, non-removable label:

1. Name, address, and telephone number of the retail pharmacy providing home health care services;
2. Date and identifying prescription number;
3. Patient's full name;
4. Name of each drug (brand or generic), strength, and amount;
5. Directions for use to the patient, including infusion rate;
6. Prescriber's name;
7. Required precautionary information regarding controlled substances;
8. Date and time of compounding;
9. Expiration date and expiration time of the product; and
10. Identity of pharmacist compounding and dispensing the product.

(g) Records and Reports. The pharmacist-in-charge shall maintain appropriate records and reports as are required to ensure patient's health, safety, and welfare. Such records shall

be readily available, maintained for two years, and subject to inspections by the Board of Pharmacy or its agents. These records shall include, as a minimum, the following:

1. Patient profile;
2. Prescription record;
3. Inventories of the pharmacy;
4. Biennial controlled substances inventories;
5. Policy and procedures manual;
6. Training manuals;
7. Policies and procedures for cytotoxic waste, if applicable;
8. Such other records and reports as may be required by law and rules and regulations of the Board of Pharmacy.
9. Delivery Service. The pharmacist-in-charge is responsible for the environmental control of all products shipped or delivered, and must ensure that all drug products are shipped in compliance with O.C.G.A. 26-4-60(a)(11). Therefore, any compounded, sterile parenteral product that is frozen, or requires refrigeration, must be shipped or delivered to a patient in appropriate coolers and stored appropriately in the patient's home.

Cite as Ga. Comp. R. & Regs. R. 480-21-.05
Authority: O.C.G.A. Secs. 16-13-34, 16-13-35, 16-13-39, 16-13-41, 16-13-72, 16-13-73, 26-4-27, 26-4-28, 26-4-29, 26-4-60, 26-4-83, 26-4-85, 26-4-87, 26-4-110, 26-4-110.
History. Original Rule entitled "Drug Distribution and Control" was filed on August 30, 1985; effective September 19, 1985.
Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-21-.06. Cytotoxic Agents.

The following additional requirements are necessary for those retail pharmacies providing home health care services that routinely prepare chemotherapy agents to insure the protection of the personnel involved:

(a) All chemotherapy agents should be compounded in a vertical flow, Class II, biological safety cabinet. If possible, other products should not be compounded in this cabinet.

(b) Protective apparel shall be worn by personnel compounding chemotherapy drugs. This shall include disposable masks, gloves, and gowns with tight cuffs.

(c) Proper aseptic and safety techniques shall be used by personnel compounding chemotherapy agents. This shall include, at a minimum, utilizing syringes and sets with luer-lock fittings, and wrapping alcohol swabs around needle and neck of vials when withdrawing cytotoxic solutions from a vial.

(d) Appropriate disposal procedures for cytotoxic waste must be developed that comply with applicable state and federal regulations.

(e) Written policies and procedures for handling both major and minor spills of cytotoxic agents must be developed.

(f) Prepared doses of chemotherapy must be dispensed and shipped or delivered in a manner to minimize the risk of accidental rupture of the primary container.

Cite as Ga. Comp. R. & Regs. R. 480-21-.06
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-86, 26-4-87, 26-4-110, 26-4-111.
History. Original Rule entitled "Cytotoxic Agents" was filed on August 30, 1985; effective September 19, 1985.
Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-21-.07. Patient Care Guidelines.

(1) Primary Provider. There shall be a designated practitioner responsible for the patient's medical care. There shall be a clear understanding between the practitioner, the patient, and the pharmacist of the responsibilities of each in the areas of the delivery of care, the monitoring of the patient, and the reimbursement for services. The responsibilities of each person shall be documented in the patient's profile.

(2) Patient Counseling A pharmacist shall provide to the patient or patient's care-giver any information required for the use of the drugs, supplies and equipment being dispensed. The pharmacist must document the patient's counseling in the pharmacy's patient profile.

(3) Pharmacist-Patient Relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. The patient should be contacted by the pharmacist at least quarterly. This contact shall be documented in the patient's profile.

(4) Patient Monitoring. The pharmacist should have access to clinical and laboratory data concerning each patient and should monitor each patient's response to his drug therapy. Any unexpected or untoward response should be reported to the prescribing physician. In the absence of the pharmacist monitoring, it shall be documented in the patient's profile, which health care provider has assumed this responsibility.

Cite as Ga. Comp. R. & Regs. R. 480-21-.07
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-60, 26-4-83, 26-4-85, 26-4-110, 26-4-111, and 43-1-19.
History. Original Rule entitled "Patient Care Guidelines" was filed on August 30, 1985; effective September 19, 1985.

Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Rule 480-21-.08. Quality Control.

There shall be a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications.

(a) Hood Certification. All laminar flow hoods shall be certified by Federal Standard 209B for operational efficiency at least every 12 months. Appropriate records shall be maintained.

(b) Prefilters. Prefilters for the clean air source shall be replaced on a regular basis and these activities shall be documented.

(c) End Product Sampling. There shall be written documentation that the end product has been tested on a sampling basis for microbial contamination.

(d) Bulk Compounding. If bulk compounding of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine. This process must include testing for sterility and pyrogens.

(e) Expiration Dates. If the product is assigned a lengthy expiration date (anything exceeding 10 days) there must be in-house data or data in the literature to assure the sterility and stability of the product at the time it is used by the patient.

(f) Quality Control Audits. There shall be documentation of quality assurance audits at regular, planned intervals.

Cite as Ga. Comp. R. & Regs. R. 480-21-.08
Authority: O.C.G.A. Secs. 16-13-73, 26-3-80, 26-4-27, 26-4-28, 26-4-60, 26-4-86, 26-4-87, 26-4-110, 26-4-111.
History. Original Rule entitled "Quality Control" was filed on August 30, 1985; effective September 19, 1985.
Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.

Chapter 480-22. REQUIREMENTS OF A PRESCRIPTION UNDER ORDER.

Rule 480-22-.01. Definitions.

Except as noted herein, any term contained in this chapter shall have the same meaning as set forth in O.C.G.A. §§ 16-13-21, 26-3-2, 26-4-5, and Title 43, Chapter 34.

Cite as Ga. Comp. R. & Regs. R. 480-22-.01
Authority: O.C.G.A. Secs. 16-13-34, 16-13-74, 26-3-16, 26-4-27, 26-4-37, 26-4-53, 26-4-78, 43-34.
History. Original Rule entitled "Requirements of a Prescription" adopted. F. Mar. 20, 1975; eff. Apr. 9, 1975.
Amended: F. Apr. 8, 1988; eff. Apr. 28, 1988.
Repealed: New Rule entitled "Definitions" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Nov. 14, 2007; eff. Dec. 4, 2007.

Rule 480-22-.02. Purpose for Issuance of a Controlled Substance Prescription Drug Order.

(1) For a controlled substance prescription drug order to be legal, it must be issued for a legitimate medical purpose by an authorized individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of controlled substances is upon the prescribing practitioner, but the pharmacist is responsible for the proper filling of the prescription drug order. Any person knowingly filling a purported prescription drug order, as well as the person issuing it, shall be subject to disciplinary action.

(2) A controlled substance prescription drug order issued by an individual practitioner, in his or her name or written "For Office Use" to obtain a controlled substance for the purpose of general dispensing or administration to patients in his/her office shall not be filled by a pharmacist.

Cite as Ga. Comp. R. & Regs. R. 480-22-.02
Authority: O.C.G.A. Secs. 16-13-34, 16-13-41, 26-4-27, 26-4-60, 26-4-80.
History. Original Rule entitled "Purpose for Issuance of a Controlled Substance Prescription Drug Order" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-22-.03. Manner of Issuance of a Controlled Substance Prescription Drug Order.

(1) All controlled substance prescription drug orders issued by the authorized practitioner shall bear the prescribing practitioner's name, address, telephone number and the Drug Enforcement Administration (DEA) permit number assigned to the practitioner for that corresponding address, and each shall be signed and dated on the same day when issued. At the time of dispensing, at a minimum, each shall bear the name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and indications for any refills or zero for none.

(a) A practitioner shall sign a prescription in the same manner as he or she would sign a check or legal document, except as the rules allow regarding the issuance of electronic or facsimile prescriptions. Such controlled substance prescription drug orders shall be written with ink or indelible pencil, pen, typewriter, or printer and shall either be done manually or electronically via computer, as defined by the

Board, and signed by the practitioner. Such prescription drug orders may be prepared for the practitioner's signature by the practitioner's authorized agent, but the practitioner is responsible for ensuring that the prescription conforms to all essential respects to the laws and regulations.

(b) A hard copy prescription drug order for any Schedule II controlled substance must be on security paper.

1. If a hard copy of an electronic data prescription drug order for any Schedule II controlled substance is given directly to the patient, the manually signed order must be on security paper.

(2) If a practitioner gives a hard copy of an electronic visual image prescription drug order directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.

(3) Practitioners may electronically transmit prescription drug orders directly to the pharmacy of the patient's choice where the prescription meets the requirements of O.C.G.A. §§ 16-13-41, 26-4-80, 26-4-80.1, 21 C.F.R. 1306, 21 C.F.R. 1311 and any other applicable state or federal law or regulation for dispensing of a controlled substance prescription drug order transmitted via electronic means.

(4) Practitioners not registered with the DEA, but affiliated with hospitals or other institutions, shall include the registration number of the hospital or other institutions as well as the special internal code assigned to the authorized practitioner by the hospital or other institution, as provided for in federal regulations 21 CFR 1301.22(c), in lieu of a DEA registration when prescribing or issuing a controlled substance drug order.

(a) Each such hand written prescription drug order shall meet the requirements of Rule 480-22-.04(a) and shall have the name of the practitioner stamped, typed or hand printed on it, as well as the signature of the practitioner, along with the telephone number where the practitioner can be contacted for verification.

(b) Such prescription drug orders can only be issued by such practitioner for patients treated as a part of his/her duties at such hospital or other institution.

Cite as Ga. Comp. R. & Regs. R. 480-22-.03
Authority: O.C.G.A. §§ 16-13-34, 16-13-41, 26-4-27, 26-4-80, 26-4-80.1.
History. Original Rule entitled "Manner of Issuance of a Controlled Substance Prescription Drug Order" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: F. July 30, 2015; eff. Aug. 19, 2015.

Rule 480-22-.04. Requirements of a Schedule II (C-II) Controlled Substance Prescription Drug Order.

(1) A pharmacist or pharmacy intern/extern shall dispense a schedule II Controlled Substance (C-II), as defined by O.C.G.A. § 16-13-26, only pursuant to a prescription drug order on security paper, except as provided in subparagraphs (1)(a) and (1)(b) and paragraph (3) of this Rule.

(a) A C-II prescription drug order, meeting the requirements of Rule 480-22-.03(1)(a), may be transmitted by the practitioner or the practitioner's agent, to a pharmacy via facsimile machine or equipment. Prior to the practitioner's agent transmitting such schedule II (C-II) prescription via facsimile machine, the C-II prescription drug order, meeting the requirements of Rule 480-22-.03(1)(a), may be transmitted by the practitioner or the practitioner's agent, but not the patient or patient's agent, to a pharmacy via facsimile machine or equipment. The original written, signed prescription drug order must be presented to the pharmacist prior to the actual dispensing of the schedule II (C-II) drug, except as provided in paragraphs (4), (5) or (6) of this section.

(b) A pharmacist may dispense a C-II pursuant to an electronic data prescription drug order where the prescription is transmitted by the practitioner directly to the pharmacy and the prescription otherwise meets the requirements of O.C.G.A. §§ 16-13-41, 26-4-80, 26-4-80.1, 21 C.F.R. 1306, 21 C.F.R. 1311 or any other applicable state or federal law or regulation for dispensing of a C-II prescription drug order transmitted via electronic means.

(2) Upon dispensing a schedule II (C-II) drug, the pharmacist shall physically sign his or her name on either the face or rear of the schedule II (C-II) prescription drug order in such a manner that the signature does not cover any information required by this chapter. In addition, the pharmacist will ensure that the dispensing date and the serial number for the prescription drug order are indicated on either the face or the back of the C-II prescription drug order.

(3) In the case of an emergency situation, a pharmacist may dispense a schedule II (C-II) controlled substance only upon receiving oral authorization of the prescribing practitioner. For purposes of this paragraph, an emergency situation means a situation in which the prescribing practitioner determines that immediate administration of a schedule II (C-II) controlled drug is necessary, there is no appropriate alternative treatment or drug in a schedule less than CII, and it is not reasonably possible for the practitioner to provide a written prescription drug order for the pharmacist dispensing the drug prior to issuance. Such emergency prescription drug order is permissible provided that:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period must be pursuant to an additional written prescription drug order signed by the prescribing practitioner;

(b) The prescription drug order shall be immediately reduced to writing by the pharmacist or pharmacy intern/extern working under the direct supervision of a

licensed pharmacist and shall contain all information required in Rule 480-22-.03, except for the signature of the prescribing practitioner;

(c) If the prescribing practitioner is not known to the pharmacist, the pharmacist must make reasonable effort to determine that the oral authorization came from a licensed practitioner, such effort may include a callback to the prescribing individual using his or her telephone number and/or other good faith efforts to insure the practitioner's identity; and

(d) Within 7 days after authorizing an emergency oral prescription drug order, the prescribing practitioner shall cause a written prescription drug order to be delivered to the dispensing pharmacist for the emergency quantity prescribed. In addition to conforming to the requirements of Rule 480-22-.03, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order.

1. The written prescription drug order shall be delivered to the pharmacist in person or by other means, but if delivered by mail or common carrier it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription drug order to the emergency oral prescription drug order, which had earlier been reduced to writing. The pharmacist shall notify the Georgia Drugs and Narcotics Agency, if the prescribing practitioner fails to deliver a written prescription drug order to the dispensing pharmacist.

(4) A prescription drug order for a terminally ill patient, prepared in accordance with Rule 480- 22-.03 written for a Schedule II Controlled Substance as defined by O.C.G.A. § 16-13-26, may be transmitted directly by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile machine.

(a) Prior to the prescribing practitioner's agent transmitting such Schedule II Controlled Substance prescription via facsimile machine, the name of the agent and a telephone number for the prescribing practitioner must be included in the face of prescription. The information may be used for verification of the prescription.

(b) The facsimile serves as the original, written prescription drug order for purposes of this paragraph, and it shall be maintained in accordance with Rule 480-22-.04(7) and this chapter. After transmission of the original prescription, the pharmacist should suggest that the practitioner mark "VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical record chart.

(5) A prescription drug order prepared in accordance with Rule 480-22-.04 written for any C-II substance for a resident of Long Term Care Facility (LTCF) may be transmitted

directly by the prescribing practitioner or the practitioner's agent, but not the patient or the patient's agent, to the dispensing pharmacy by facsimile machine or equipment.

(a) The practitioner, practitioner's agent, or pharmacist will note on the prescription drug order that the patient is a LTCF patient by writing "LTCF" on the face of the prescription.

(b) In addition to the term LTCF being noted on the face of the prescription, whenever a practitioner's agent transmits or a pharmacist receives such a prescription, the name of the agent and the practitioner's telephone number or the name and license number of the pharmacist must be included on the face of the prescription. This information may be used for verification of the prescription drug order.

(c) The facsimile serves as the original, written prescription drug order for purposes of this paragraph (c), and it shall be maintained in accordance with Rule 480-22-.04(a) and this chapter. After transmission of the original prescription, the pharmacist should suggest that the practitioner mark "VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical record chart.

(6) A prescription drug order prepared in accordance with Rule 480-22-.03 written for any Schedule II Controlled Substance as defined by O.C.G.A. § 16-13-26, for a patient of a hospice program licensed by the State of Georgia Department of Community Health may be directly transmitted by the practitioner or the practitioner's agent, but not the patient or the patient's agent, to the dispensing pharmacy by facsimile machine or equipment.

(a) The practitioner or practitioner's agent will note on the prescription drug order that the patient is a hospice patient by writing "HOSPICE" on the face of the prescription.

(b) In addition to the term "HOSPICE" being noted on the face of the prescription, whenever a practitioner's agent transmits such prescription, the name of the agent and the practitioner's telephone number must be included on the face of the prescription. This information may be used for verification of the prescription drug order.

(c) The facsimile serves as the original, written prescription drug order for purposes of this paragraph, and it shall be maintained in accordance with Rule 480-22-.04(a) and this chapter. After transmission of the original prescription drug order, the pharmacist should suggest that the practitioner mark "VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical chart.

(7) Record keeping for Schedule II Controlled Substances shall be as follows:

(a) Original and all other hard copy schedule II (C-II) prescription drug orders shall be maintained in a separate file from all other prescription drug orders.

(b) Whenever a pharmacy utilizes a computerized record keeping system in addition to hard copies to record the dispensing of prescription drug orders for C-II drugs, such records shall be immediately retrievable without delay in a printout form by the prescribing practitioner's name, patient's name, drug name or date of dispensing upon a verbal request from a representative of the Georgia Drugs and Narcotics Agency (GDNA), and/or one of its agents.

(8) Whenever a pharmacist receives a prescription for a C-II controlled substance, and either the quantity of the drug to be dispensed or the strength of the drug to be dispensed has not been included by the prescribing practitioner, or when the strength of the prescribed drug is not immediately available, in order to dispense this drug, the pharmacist must perform the following:

(a) Contact and speak directly with the practitioner, not with an agent for the practitioner, and inform the practitioner of the missing information on the face of the prescription, or the problem with the prescription in question by:

1. Determining the quantity of the drug the practitioner intended to be dispensed; or

2. Determining the strength of the drug the practitioner intended to be dispensed; or

3. Informing the practitioner the drug in the strength prescribed is not immediately available, but another strength of the prescribed drug is available.

(b) Regarding the information provided by the practitioner, the pharmacist must write the missing quantity, the missing strength, or the changed quantity and strength of the prescribed drug on the face of the prescription along with the initials of the pharmacist.

(c) On the back of the prescription, the pharmacist must write the date and time the pharmacist spoke with the practitioner, along with a brief explanation of the situation and how it was resolved.

(d) Nothing in this rule is intended to require a pharmacist in a hospice or LTCF setting to obtain a new prescription drug order when changes are made to a patient's dosing requirements. This action may be taken as long as the pharmacist verifies the change(s) with the practitioner and makes a notation of the change(s) along with the date of the change(s) on the original hardcopy prescription drug order.

(9) A Schedule II narcotic controlled substance prescription prepared in accordance with Rule 480-22-.03 and as defined by O.C.G.A. § 16-13-26, to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with this rule and state and federal law.

Cite as Ga. Comp. R. & Regs. R. 480-22-.04
Authority: O.C.G.A. §§ 16-13-34, 16-13-39, 16-13-41, 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-60, 26-4-80.1, 26-4-82, and 26-4-111.
History. Original Rule entitled "Requirements of a Schedule II (C-II) Controlled Substance Prescription Drug Order" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: F. Dec. 14, 2012; eff. Jan. 3, 2013.
Amended: F. Sep. 17, 2014; eff. Oct. 7, 2014.
Amended: F. July 27, 2015; eff. Aug. 16, 2015.

Rule 480-22-.05. Refilling of a Schedule II (C-II) Controlled Substance Prescription Drug Order.

The refilling of a prescription for a schedule II (C-II) controlled substance is prohibited.

Cite as Ga. Comp. R. & Regs. R. 480-22-.05
Authority: O.C.G.A. Secs. 16-13-34, 16-13-41, 26-4-27.
History. Original Rule entitled "Refilling of a Schedule II (C-II) Controlled Substance Prescription Drug Order" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-22-.06. Partial Filling of a Schedule II (C-II) Controlled Substance Prescription Drug Order.

(1) The partial filling of a schedule II (C-II) prescription drug order is permissible, if the pharmacist is unable to supply the full quantity prescribed in a written or emergency oral prescription drug order, and the pharmacist makes a notation on the face of the written prescription drug order of the quantity supplied (dispensed).

(a) Except as provided for in paragraph (b), the remaining portion of the prescription drug order may be filled within 72 hours of the first partial filling.

(b) After this 72 hour period, the remaining quantity shall not be dispensed, thereby causing the remaining quantity to be void. No additional quantity may be dispensed without receipt of a new prescription drug order.

(2) A prescription drug order for a schedule II (C-II) controlled substance written for a patient in a Long Term Care Facility (LTCF), a hospice patient, or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities.

(a) If there is any question whether a patient may be classified as having a terminal illness (TI), the pharmacist must contact the prescribing practitioner prior to partially filling the prescription drug order. The pharmacist must record on the prescription drug order whether the patient is "terminally ill", a "hospice patient", or a "LTCF patient".

(b) A prescription drug order may not be partially filled unless it contains the notation "terminally ill","hospice patient", or "LTCF patient", or it shall be deemed an unlawful prescription drug order.

(c) For each partial filling, the dispensing pharmacist shall record on the back of the prescription drug order (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

(d) The total quantity of a schedule II (C-II) controlled substance dispensed in all partial fillings may not exceed the total quantity prescribed. Such C-II prescription drug orders may be partially filled for a period not to exceed 60 days from the dispensing date or sooner if the medication is discontinued.

(3) Information pertaining to current schedule II (C-II) prescription drug orders for patients in a LTCF, a hospice, or for terminally ill patients may also be maintained in a computerized system if this system has the capability to permit the following:

(a) Output (display or printout) of the original prescription drug order serial number, date of dispensing, identification by name of the prescribing practitioner, identification by name of the patient, address of the LTCF, hospice, the hospital, or residence of the patient, identification of the medication dispensed to include, dosage, form, strength, and quantity, listing of the partial fillings that have been dispensed under each prescription drug order, and the information required in this rule.

(b) Immediate updating of the prescription drug record each time a partial filling is conducted.

(c) Retrieval of partially filled C-II prescription drug order information is the same as required by Rule 480-22-.09 for Schedule III and IV prescription refill information.

Cite as Ga. Comp. R. & Regs. R. 480-22-.06
Authority: O.C.G.A. Secs. 16-13-34, 16-13-39, 16-13-41, 26-4-27, 26-4-80, 26-4-83.
History. Original Rule entitled "Partial Filling of a Schedule II (C-II) Controlled Substance Prescription Drug

Order" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-22-.07. Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders.

(1) A pharmacist or pharmacy intern/extern may dispense Schedule III, IV and V Controlled Substances (C-III, IV, V), as defined by O.C.G.A. §§ 16-13-27, 16-13-28, and 16-13-29, pursuant to:

(a) A written prescription drug order bearing the signature of a practitioner as permitted by this rule;

(b) A facsimile of a written, signed prescription drug order transmitted directly to the pharmacy with the requirements contained in O.C.G.A. § 26-4-80, by the practitioner of the practitioner's agent;

(c) An oral prescription drug order made by an individual practitioner and promptly reduced to writing by the pharmacist or pharmacy intern/extern to a hard copy; and

(d) A written prescription drug order transmitted via electronic means other than a facsimile, if it meets the requirements and limitations for electronically transmitted prescription drug orders set forth in O.C.G.A. § 26-4-80, and Rules as set forth by the Board. Such electronically received prescription drug orders must be promptly reduced to hard copy, except as follows:

(2) Permanent records of electronic prescriptions do not have to be reduced to hard copy provided the following requirements are met:

A). Electronic prescription data must be maintained in the original format received for a minimum of two years; and

B). Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1hr UL approved) container, stored in a secured offsite location or backed up to a documented offsite secure storage device within 48 hours following each work day.

(3) A pharmacy must either file the original prescription drug order or generate a hard copy prescription drug order to be filled, both of which are required to contain all of the information required by this chapt

(4) Upon dispensing a C-III, IV, or V controlled substance, the dispensing pharmacist shall ensure that his or her initials, the dispensing date, and the prescription serial number appear on the face of or the rear of each such prescription. Nothing shall prohibit the use of a computer-generated label to fulfill the requirements of this paragraph and/or the requirements of this Rule.

(a) All such information shall be placed on the prescription drug order in such a manner that it does not cover or veil any information required by this chapter or any other rule or law to appear on such prescription.

(5) Prescription drug orders for schedule C-III, IV, or V controlled substances shall be maintained either in a separate prescription drug order file for such C-III, IV, or V drug orders only or in such a form that they are readily retrievable from the other prescription drug orders of the pharmacy.

(a) A prescription drug order will be deemed readily retrievable if, at the time it is initially filled, the face of the prescription drug order is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed in the usual consecutively numbered prescription drug order file for dangerous drugs; or

(b) A pharmacy which utilizes a computerized record keeping system for prescription drug orders which permits identification of prescription drug orders by serial number and retrieval of documents by prescriber's name, patient's name, drug dispensed, and date filled, then there is no requirement to mark hard copy prescriptions with a red "C".

Cite as Ga. Comp. R. & Regs. R. 480-22-.07
Authority: O.C.G.A. Secs. 16-13-34, 16-13-39, 16-13-41, 26-4-27, 26-4-80, 26-4-83.
History. Original Rule entitled "Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Order" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: F. Dec. 14, 2012; eff. Jan. 3, 2013.

Rule 480-22-.08. Refilling of Schedule III, IV, and V (C-III, IV, V) Controlled Substance Prescription Drug Orders.

(1) No prescription drug order for a C-III, IV, or V controlled substance shall be filled or refilled more than six (6) months after the date on which such prescription drug order was issued by the prescribing practitioner and no such prescription drug order may be authorized to be refilled for the quantity prescribed more than five (5) times.

(a) Nothing shall prohibit the refilling of such a prescription drug order in amounts less than the quantity prescribed as long as the total number of dosage units authorized for dispensing both the original quantity plus the refill quantities does not exceed six (6) months.

(2) The date of each refilling of a prescription drug order shall be entered on the back of the prescription drug order or in a computerized record system, with which all documents must be uniformly maintained and readily retrievable.

(3) If the pharmacist initials and dates the back of the prescription drug order, it shall be deemed that the full face amount of the prescription has been dispensed. If an amount other than the full face amount is dispensed, the quantity shall be noted next to the initials of the pharmacist.

(4) The prescribing practitioner may authorize additional refills of the original C-III, IV or V controlled substance prescription drug order through an oral refill authorization transmitted directly to the pharmacist or pharmacy intern/extern working under the direct supervision of a licensed pharmacist provided the following conditions are met:

(a) The total quantity of refills authorized, including the quantity of refills indicated on the original prescription drug order does not exceed five (5) refills and does not extend beyond six (6) months from the date of issue of the original prescription drug order.

(b) The pharmacist or pharmacy intern/extern that receives the oral authorization shall record on the reverse side of the original prescription drug order the date, quantity of refill, number of additional refills authorized (for the quantity prescribed), and the initials showing who received the authorization from the prescribing practitioner that issued the original prescription drug order.

(c) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription drug order.

(d) The prescribing practitioner must execute or authorize a completely new and separate prescription drug order for any additional quantities beyond the five (5) refills and/or six (6) month limitation.

(e) If the authorization comes from a practitioner that is not the original prescriber, the authorization shall be treated as a new prescription drug order authorized by the new prescribing practitioner.

(5) An automated data processing (ADP) or computerized system may be used for the storage and retrieval of refill information for prescription drug orders for C-III, IV or V substances, subject to the requirements as set forth in Rule 480-27-.04.

Cite as Ga. Comp. R. & Regs. R. 480-22-.08
Authority: O.C.G.A. Secs. 16-13-34, 16-13-39, 16-13-41, 26-4-27, 26-4-80, 26-4-83.
History. Original Rule entitled "Refilling of Schedule III, IV, and V (C-III, IV, V) Controlled Substance Prescription Drug Orders" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-22-.09. Partial Filling of Schedule III, IV, and V (C-III, IV, V) Controlled Substance Prescription Drug Ord.

The partial filling of a C-III, IV, or V prescription drug order is permissible, subject to the following requirements:

(a) Each partial filling is recorded in the same manner as a refill;

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

(c) No dispensing occurs six (6) months after the date on which the prescription drug order was issued.

Cite as Ga. Comp. R. & Regs. R. 480-22-.09
Authority: O.C.G.A. Secs. 16-13-34, 16-13-39, 16-13-41, 26-4-27.
History. Original Rule entitled "Partial Filling of Schedule III, IV, and V (C-III, IV, V) Controlled Substance Prescription Drug Orders" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-22-.10. Labeling of Controlled Substance Prescription Drug Orders.

(1) A pharmacist filling a prescription drug order for a C-II, III, IV or V substance shall affix to the package a label showing the following:

(a) The name, address and telephone number of the pharmacy;

(b) The prescription drug order serial number;

(c) The date the prescription was initially filled or refilled;

(d) The name of the patient;

(e) The name of the prescribing practitioner;

(f) The directions for use;

(g) The expiration date of the dispensed drug; and

(h) Cautionary statements, if any, as required.

(2) All prescription drug orders for C-II, III, IV or V controlled substances shall be kept in accordance with this chapter.

Cite as Ga. Comp. R. & Regs. R. 480-22-.10
Authority: O.C.G.A. Secs. 16-13-34, 26-3-8, 26-3-16, 26-4-27.
History. Original Rule entitled "Labeling of Controlled Substance Prescription Drug Orders" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-22-.11. Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes.

(1) The transfer of original prescription drug order information for a C-III, IV, or V substance for the purpose of refill dispensing is permissible between pharmacies one time only.

(a) However, pharmacies electronically sharing a real-time, online computerized database may transfer the prescription drug order information as many times as there are authorized refills, up to the maximum of five (5) times, if it is within six (6) months from the date of issuance.

(2) A transfer is considered a communication between two licensed pharmacists and/or pharmacy interns/externs. Transfers are subject to the following requirements:

(a) The transferring pharmacist or pharmacy intern/extern shall record the following information in either real time or at the first opportunity after the transfer:

1. The word "VOID" must be written on the face of the original, hard copy, invalidated prescription drug order;

2. The following must be written on the back of the original, invalidated prescription drug order: the name, address, telephone number, and DEA number of the pharmacy to which it is transferred, and the name of the pharmacist receiving the prescription information; and

3. The date of the transfer and the name of the pharmacist transferring the information must be recorded on the back of the prescription drug order.

(b) The pharmacist or pharmacy intern/extern receiving the transferred prescription drug order information shall reduce it to writing and record the following information:

1. The word "TRANSFER" shall be written on the face of the transferred prescription drug order hard-copy;

2. All information required to be recorded on a prescript ion drug order pursuant to this chapter, which shall include:

(i) Date the prescription drug order was originally issued by the prescribing practitioner;

(ii) The number of refills authorized on the original prescription drug order.

(c) Date the prescription drug order was originally dispensed by the transferring pharmacy;

(d) Number of valid refills remaining, and date(s) and pharmacy location(s) where any previous refills were dispensed;

(e) The pharmacy's name, address, telephone number, DEA number, and prescription serial number from which the prescription information was transferred; and

(f) The name of the pharmacist who transferred the prescription drug order.

(3) The original and transferred prescription(s) must be maintained for a period of two yearsfrom the date of the last refill.

(4) Pharmacies electronically transferring a prescription drug order for the purpose of refills must maintain the same information and record keeping requirements as do pharmacies with manual, non-electronic record keeping systems.

Cite as Ga. Comp. R. & Regs. R. 480-22-.11
Authority: O.C.G.A. §§ 16-13-34, 16-13-39, 26-4-27, 26-4-28, 26-4-80, 26-4-82.
History. Original Rule entitled "Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: F. June 22, 2016; eff. July 12, 2016.

Rule 480-22-.12. Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia.

(1) Under O.C.G.A. § 43-34-103(e.1), a physician assistant (PA) licensed by the Georgia Composite Medical Board is permitted to issue a prescription drug order or orders for any dangerous drugs, as defined in O.C.G.A. § 16-13-71, or for any Schedule III, IV, or V controlled substance without the co-signature of a supervising physician under the following conditions:

(a) The supervising physician has delegated the authority to prescribe dangerous drugs and/or controlled substances in the PA's job description on file with the Georgia Composite Medical Board.

(b) If the prescription is for controlled substances, the PA has a DEA number.

(c) If the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.

(d) The prescription drug order must include the following:

(i) The name, address, and telephone number of the supervising physician and the PA;

(ii) The patient's name and address;

(iii) The drug name, strength and quantity prescribed;

(iv) The directions to the patient with regard to taking the drug;

(v) The number of authorized refills, if any;

(vi) A NPI number; and

(vii) If applicable, the DEA permit number of the PA.

(d) If the prescription is transmitted by facsimile or computer, the prescription shall include:

(i) The complete name and address of the supervising physician and the PA;

(ii) In the case of a prescription drug order for a controlled substance, the DEA registration number of the PA;

(iii) The telephone number of the PA for verbal confirmation;

(iv) The name and address of the patient;

(v) The time and date of the transmission;

(vi) The full name of the person transmitting the order; and

(vii) The drug name, strength and quantity prescribed;

(viii) The directions to the patient with regard to taking the drug;

(ix) The number of authorized refills, if any;

(x) A NPI number; and

(xi) The signature of the PA as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.

(e) No prescription drug order issued by a PA can be used to authorize refills more than twelve (12) months past the date of the original drug order.

(2) Under O.C.G.A. § 43-34-25, an advanced practice registered nurse (APRN) who is recognized by the Georgia Board of Nursing as having met the requirements to engage in advanced nursing practice, and whose registered nurse license and advanced practice

registered nurse license are in good standing with the Georgia Board of Nursing, is permitted to issue a prescription drug order or orders for any dangerous drugs, O.C.G.A. § 16-13-71 except for drugs intended to cause an abortion to occur pharmacologically, or for any Schedule III, IV, or V controlled substance without the co-signature of a delegating physician under the following conditions:

(a) The APRN has been delegated the authority to issue prescription for the dangerous drugs and controlled substances by a physician licensed by the Georgia Composite Medical Board in a nurse protocol agreement and that agreement has been filed with the Georgia Composite Medical Board.

(b) If the prescription is for controlled substances, the APRN has a DEA number.

(c) If the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.

(d) The prescription drug order must include the following:

(i) The name, address, and telephone number of the delegating physician and the APRN;

(ii) The patient's name and address;

(iii) The drug name, strength and quantity prescribed;

(iv) The directions to the patient with regard to taking the drug;

(v) The number of authorized refills, if any;

(vi) A NPI number; and

(vii) If applicable, the DEA permit number of the APRN.

(d) If the prescription is transmitted by facsimile or computer, the prescription shall include:

(i) The complete name and address of the delegating physician and the APRN;

(ii) In the case of a prescription drug order for a controlled substance, the DEA registration number of the APRN;

(iii) The telephone number of the APRN for verbal confirmation;

(iv) The name and address of the patient;

(v) The time and date of the transmission;

(vi) The full name of the person transmitting the order; and

(vii) The drug name, strength and quantity prescribed;

(viii) The directions to the patient with regard to taking the drug;

(ix) The number of authorized refills, if any;

(x) A NPI number; and

(xi) The signature of the APRN as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.

(e) No prescription drug order issued by an APRN can be used to authorize refills more than twelve (12) months past the date of the original drug order unless the prescription drug order is for oral contraceptives, hormone replacement, or prenatal vitamins. Oral contraceptives, hormone replacement and prenatal vitamins may be refilled up to twenty-four (24) months from the date of the original drug order.

(3) Nothing in this Rule, Title 16, Chapter 13 or Title 43, Chapter 34, shall be construed to create a presumption of liability, either civil or criminal, on the part of a pharmacist who in good faith fills a prescription drug order presented by a patient that had been issued by a PA or an APRN consistent with this Rule.

(a) A pharmacist shall presume that a prescription drug order issued by a PA or APRN was issued by a PA or APRN duly licensed and qualified under Title 43, Chapter 34 to prescribe pharmaceutical agents.

(b) A pharmacist shall presume that the drug prescribed by the PA is a drug approved by the supervising physician in the PA's job description and that the drug prescribed by an APRN is a drug authorized by the delegating physician in the APRN's nurse protocol agreement, unless the pharmacist has actual or constructive knowledge to the contrary.

(4) Any prescription drug order form containing less information than that described in this Rule shall not be offered to or accepted by any pharmacist.

Cite as Ga. Comp. R. & Regs. R. 480-22-.12
Authority: O.C.G.A. §§ 16-13-21, 16-13-41, 16-13-70.1, 16-13-72, 26-4-5, 26-4-27, 26-4-28, 26-4-80, 43-34-25, 43-34-103, 21 C.F.R. 1301.22, and 45 C.F.R. Part 162.
History. Original Rule entitled "Requirements of Controlled Substance and Dangerous Drug Prescription Drug Orders as Carried Out By a Physician's Assistant (PA) Licensed to Practice in the State of Georgia" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: Rule retitled "Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or an

Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia" adopted. F. Nov. 14, 2007; eff. Dec. 4, 2007.
Amended: F. Nov. 29, 2011; eff. Dec. 19, 2011.
Amended: F. July 27, 2015; eff. Aug. 16, 2015.

Rule 480-22-.13. Requirements of a Prescription Drug Order for Drugs that are Scheduled Under the Georgia Controlled Substances Act, but not Scheduled Under the Federal Controlled Substances Act.

(1) Any drug scheduled under the Georgia Controlled Substances Act (GCSA), but not scheduled under the Federal Controlled Substances Act (FCSA), must be purchased, stored, inventoried, recorded, distributed, or dispensed in the same manner as any other controlled substance, except:

(a) The manufacturer of the product is not required to indicate the schedule of the drug on the label of its commercial container; and

(b) The manufacturer of the product is not required to print the symbol designating the schedule of the drug on the label of its commercial container.

(2) A prescription drug order for any drug scheduled under the GCSA, but not scheduled under the Federal CSA, must be maintained in the same manner for the corresponding controlled substance prescription drug order as previously set forth in this chapter (480-22).

Cite as Ga. Comp. R. & Regs. R. 480-22-.13
Authority: O.C.G.A. Secs. 16-13-34, 16-13-72, 26-4-27, 43-34-103.
History. Original Rule entitled "Requirements of a Prescription Drug Order for Drugs That Are Scheduled Under the Georgia Controlled Substances Act, But Not Scheduled Under the Federal Controlled Substances Act" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-22-.14. Ordering and Receipt of Samples.

(1) For purposes of this rule, a practitioner means:

(a) A physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, with respect to, or to administer a controlled substance or dangerous drug in the course of professional practice in this state;

(b) An advanced practice registered nurse (APRN) acting pursuant to the authority of Code Section 43-34-26.3. For purposes of this chapter and Code Section 43-34-26.3, an advanced practice registered nurse (APRN) who is registered with the

Federal Drug Enforcement Administration (DEA) and appropriate state authorities; or

(c) A physician's assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103. For purposes of this chapter and subsection (e.1) of Code Section 43-34-103, a physician's assistant (PA) who is registered with the federal Drug Enforcement Administration (DEA) and appropriate state authorities.

(2) Only a practitioner which has been issued an individual permit number by the DEA and is licensed by its respective state licensing board is authorized to or any other type of container.

(3) Any practitioner receiving, maintaining, and dispensing professional drug samples shall maintain records of all drug samples requested and received, along with a complete list of the specific number and dosage of each professional drug sample and medication dispensed by the practitioner and the person to whom the drug samples were dispensed; Such records must be maintained for a minimum of two years by the practitioner at each facility or office location where professional drug samples are received, maintained, and dispensed.

(4) In addition to the requirements of this rule, practitioners shall maintain all professional drug samples as required by all applicable state and federal laws and regulations.

Cite as Ga. Comp. R. & Regs. R. 480-22-.14
Authority: O.C.G.A. Secs. 16-13-34, 16-13-72, 26-4-27.
History. Original Rule entitled "Ordering and Receipt of Samples" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Nov. 14, 2007; eff. Dec. 4, 2007.

Rule 480-22-.15. Refilling of Ophthalmic Topical Products.

Ophthalmic topical products may be refilled without authorization from a practitioner to prevent unintended interruptions in drug therapy provided that:

(1) The original prescription order contains valid refills;

(2) Refills occur at 70 percent or greater of the predicted days of use; and

(3) Refills are purchased through retail and/or mail order pharmacies.

Cite as Ga. Comp. R. & Regs. R. 480-22-.15
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-80.
History. Original Rule entitled "Refilling of Ophthalmic Topical Products" adopted. F. Sep. 18, 2015; eff. Oct. 8, 2015.

Chapter 480-23. PROCEDURAL RULES.

Rule 480-23-.01. Investigations and Hearings.

(1) Proceedings by the Board in the exercise of its authority to cancel, suspend, sanction, or revoke any license issued by the Board shall be conducted in accordance with O.C.G.A. Tit le 50 Chapter 13, the "Georgia Administrative Procedure Act." In all such proceedings, the Board shall have the authority to compel the attendance of witnesses and production of any book, writing, or document upon the issuance of a subpoena thereafter signed by the Executive Director for the Board or the Director of the Georgia Drugs and Narcotics Agency (GDNA).

(2) The Board shall have the authority to conduct investigative interviews or board hearing, with or without the necessity of utilizing the Office of the State Administrative Hearings, in respect thereto.

(3) The Vice President of the Board will be known as the investigative member of the Board and shall have the following duties:

   (a) Serve as the contact member, or liaison member, between the Board and the GDNA;

   (b) Receive findings from GDNA case reports and other investigations regarding possible violations of law and report same to the Board;

   (c) Conduct investigative interviews on behalf of the Board; and

   (d) Make various presentments, recommendations, and findings from investigative interviews and other miscellaneous sources to the Board.

Cite as Ga. Comp. R. & Regs. R. 480-23-.01
Authority: O.C.G.A. §§ 26-4-21, 26-4-24, 26-4-27, 26-4-28, 26-4-29.
History. Original Rule was filed on August 24, 1976; effective September 13, 1976.
Repealed: New Rule of same title adopted. F. Feb. 20, 2002; eff. Mar. 12, 2002.
Amended: New title "Investigations and Hearings." F. Dec. 22, 2014; eff. Jan. 11, 2015.

Chapter 480-24. NURSING HOMES, LONG TERM CARE FACILITIES AND HOSPICE EMERGENCY DRUG KITS.

Rule 480-24-.01. Definitions.

For purposes of these Rules and Regulations, the following definitions apply:

(a) Board. Board shall mean the Georgia State Board of Pharmacy.

(b) GDNA. GDNA shall mean the Georgia Drugs and Narcotics Agency.

(c) Hospice emergency drug kits. A hospice emergency drug kit shall mean an emergency drug kit placed by a provider pharmacy in a hospice licensed by the Department of Human Resources.

(d) Unit dose. A unit dose is a single dose of a medication(s), which is individually packaged, sealed, and properly labeled to maintain the integrity and the identity of the drug, and patient?ready at the time of dispensing by the pharmacist.

Cite as Ga. Comp. R. & Regs. R. 480-24-.01
Authority: O.C.G.A. Secs. 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-29, 26-4-110.
History. Original Rule entitled "Definitions" was filed on May 5, 1980; effective May 25, 1980.
Repealed: New Rule of same title adopted. F. Jun. 14, 1989; eff. Jul. 4, 1989.
Repealed: New Rule of same title adopted. F. Feb. 24, 2002; eff. Mar. 17, 2002.

Rule 480-24-.02. Personnel.

(1) Consultant Pharmacist. A consultant pharmacist is a pharmacist licensed to engage in the practice of pharmacy in this state who is responsible for developing, coordinating, and supervising pharmaceutical services in the nursing facility. These services shall include, at a minimum, review of each patient's drug regimen monthly and report of any irregularities to the Medical Director and Administrator of the nursing facility, written reports of pharmaceutical services, and monitoring of established policies and procedures for medication handling and storage.

(2) Vendor Pharmacist. A vendor pharmacist is a pharmacist licensed to engage in the practice of pharmacy in this state who is responsible for supervising the proper dispensing and delivery of drugs to a nursing facility. These services shall include, at a minimum, proper drug labeling, storage, transport, and record keeping in compliance with all federal, state and local laws and regulations.

Cite as Ga. Comp. R. & Regs. R. 480-24-.02
Authority: O.C.G.A. Secs. 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Personnel" was filed on May 5, 1980; effective May 25, 1980.
Repealed: New Rule of same title adopted. F. Jun. 14, 1989; eff. Jul. 4, 1989.
Repealed: New Rule of same titled adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-24-.03. Physical Requirements.

The vendor pharmacist shall establish standards to ensure that all drugs are stored in a manner sufficient to insure the proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

Cite as Ga. Comp. R. & Regs. R. 480-24-.03
Authority: O.C.G.A. Secs. 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Physical Requirements" was filed on May 5, 1980; effective May 25, 1980.
Repealed: New Rule of same title adopted. F. Jun. 14, 1989; eff. Jul. 4, 1989.
Repealed: New Rule of same titled adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-24-.04. Drug Distribution.

(1) Dispensing of all drugs to the facility shall be pursuant to a legal prescription drug order for an individual patients. Standing medication orders shall not be allowed. Policies may be established by the vendor pharmacist in conjunction with the appropriate committee of the facility. All drugs supplied to the facility must be obtained from a pharmacy having a retail pharmacy permit.

(2) For use inside the facility, all drugs dispensed shall be dispensed in appropriate containers, as defined by the Food and Drug Administration and the Consumer Protection Agency, and adequately labeled with the following information:

(a) Name, address, and telephone number of the pharmacy;

(b) Date of issuance and identifying serial number;

(c) Full name of patient;

(d) Brand and/or generic name of drug, strength, and quantity dispensed;

(e) Directions for use, which may be placed on the container label or on a Medication Administration Record available and consulted at the time of the administration of each dose, provided, however, that both methods may be utilized inside a single facility;

(f) Name of physician prescribing;

(g) Required precautionary information regarding controlled substances;

(h) Such other and further accessory cautionary information as may be required or desirable for proper use and absolute safety to the patient; and

(i) Expiration date.

(3) If a unit dose drug distribution system is utilized, the above information shall be readily available on the patient medication profile. A drug distribution system in a long term care facility may be regarded as a unit dose drug distribution system if:

(a) The pharmacist maintains medication profiles on each patient and refers to these files each time a medication is filled;

(b) Doses of solid oral medications dispensed are pharmacy-prepared or manufacturer-prepared in individually packaged and sealed doses which are identifiable and properly labeled to include, at a minimum:

1. Brand and/or generic name of the drug;

2. Strength;

3. Lot number; and

4. Expiration date.

(c) Doses of medication for individual patients are placed into individual patient containers, bins, compartments, or drawers and whenever possible, are subdivided by dose and administration time and not to exceed a 72-hour supply. Drug distribution systems which exceed a 72-hour supply must follow labeling requirements of 480-24-.04(2).

(4) Partial filling of Schedule II drugs will be allowed but limited to 60 days only.

(5) Drugs added to parenteral, enteral, or irrigation solutions. Whenever any drugs are added to such solutions, whether within or outside the direct and personal supervision of a registered pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and identity of the person so adding.

(6) Prescription drug orders.

(a) Drugs may be dispensed or administered only upon orders of an authorized prescriber. For schedule II drugs refer to the Georgia Controlled Substances Act, Code Section 16-13-41, and Chapter 480-22 of the Board rules and regulations. For other drugs orders may be received by the pharmacy by fax or delivery of:

1. A direct copy of a prescription drug order;

2. Obtaining a signed prescription drug order from the prescriber; or

3. A verbal or telephone order from an authorized prescriber or duly authorized agent.

(b) The consultant pharmacist will verify orders as required by current state and federal laws, rules and regulations.

(c) For purposes of recordkeeping under this chapter, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the retail pharmacy and must be filed by the usually consecutively serial numbered prescription file or by patient name or by any other means that assures a complete, retrievable and accurate record. Any refill information subsequently authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(3).

(7) Emergency kits. Emergency kits may be placed in licensed nursing homes by the pharmacy of the consultant or vendor pharmacist provided the following guidelines are met:

(a) A record of the drugs to be kept in an emergency drug kit be kept in the nursing home and the provider pharmacy;

(b) Drugs shall not be accessed for use from the emergency drug kit in an emergency situation without a new prescription drug order from a licensed practitioner. A valid, signed prescription drug order for any such drug must be issued to the vendor pharmacy, supplying the emergency drug kit, within 72 hours of the drug being taken from the kit.

(c) Emergency drug kits shall be stored in limited access areas and sealed to prevent unauthorized access and to insure a proper environment for preservation of the drugs therein. The provider pharmacy shall develop a method to readily determine if an emergency drug kit has been accessed without authorization;

(d) An emergency drug kit must be inventoried at least once a month by a pharmacist from the provider pharmacy and sign a card attached to the kit indicating the date it was inspected. The provider pharmacy must maintain an adequate record of such inspections.

(e) Special Agents of the GDNA shall have the authority to check emergency drug kits as well as the records in the provider pharmacy to determine that drugs and records are accurate and the emergency drug kit is being properly used;

(f) The provider pharmacy must apply on an individual basis to the Board, in care of the GDNA Director, for approval to place an emergency drug kit in each individual nursing home and a copy of this approval will be kept on file in both the nursing home and the provider pharmacy. Upon recommendation by the GDNA Director, the Board may revoke the approval for an emergency drug kit in any nursing home where abuse or misuse of drugs from the emergency drug kit is used for any purpose other than emergency purposes;

(g) The Board shall have the authority to approve on an individual basis the drugs and the amounts of each individual drug allowed to be kept in an emergency drug kit. Any change in the drugs and amounts kept in a kit must be submitted in writing to the GDNA Director who shall make recommendations to the Board. After Board approval, a copy of this approval will be maintained in the GDNA provider pharmacy file and by the nursing home. Any emergency drug kit approval becomes null and void once the approved pharmacy ceases to provide that kit.

(h) Each solid oral dosage form placed in an emergency drug kit must be individually labeled with the name and strength of the drug, lot number, expiration date, and other appropriate cautionary information; and

(i) The exterior of an emergency drug kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for "EMERGENCY USE ONLY", and the label shall be physically signed and dated by the pharmacist who sealed the kit. In addition, a listing of the drugs contained therein, including the name, address, and telephone number(s) of the provider pharmacy shall be attached to both the exterior and the interior of an emergency drug kit.

(8) Accountability of scheduled drugs and other specified drugs.

(a) Proof of use. Proof of use of Schedule II, III, IV and V controlled substances and such other drugs as may be specified by the appropriate committee of the facility, shall be upon proof of use forms which shall specify at a minimum:

1. Name and strength of the drug;

2. Dose and route of administration for the drug;

3. Name of ordering prescriber;

4. Name of patient;

5. Date and time of administration to patient;

6. Signature and title of individual administering, the medication; and 7. Documentation of destruction of all unused portions of single doses shall include signature verifications of two licensed authorized personnel.

(b) Container requirement. Any medication that has to be counted and accounted for with proof of use forms must be dispensed in a container that allows verification of individual doses. Containers for solid oral doses must allow identification of individual doses and individual accountability.

(9) Medications brought by patients. When patients bring drugs into the facility, such drugs shall be sent to the vendor pharmacist who shall handle these drugs in accordance with guidelines established by the appropriate committee within the facility.

Cite as Ga. Comp. R. & Regs. R. 480-24-.04
Authority: O.C.G.A. Secs. 16-13-21(23), 16-13-34, 16-13-35, 16-13-39, 16-13-41, 16-13-45, 16-13-72, 16-13-77, 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-80, 26-4-110.
History. Original Rule entitled "Drug Distribution" was filed on May 5, 1980; effective May 25, 1980.
Amended: Filed February 15, 1982; effective March 7, 1982.
Amended: Filed March 26, 1982; effective April 15, 1982.
Amended: Filed August 7, 1984; effective August 27, 1984.
Amended: Filed July 21, 1988; effective August 10, 1988.
Repealed: New Rule of same title adopted. F. Jun. 14, 1989; eff. Jul. 4, 1989.
Repealed: New Rule of same title adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.
Amended: F. May 15, 2009; eff. June 4, 2009.

Rule 480-24-.05. Duties of Consultant Pharmacist.

(1) A pharmacist serving as a consultant to a facility must contract with the facility in writing for those services. Notification must also be made to the Board in writing when a pharmacist becomes a consultant to a facility. The pharmacist must also notify the Board when the consultant services are terminated with a facility. When providing contracted services the consultant pharmacist is held to the same professional standards for a licensed pharmacist as set forth in state law and by the rules and regulations of the Board.

(2) The pharmacist, through the appropriate committee within the facility, shall establish policies and procedures for safe and effective drug therapy, distribution, use, and control. At a minimum, the pharmacist shall:

(a) Make periodic inspections, which shall occur at least every 30 days, of drugs and medication records kept within the facility. A written report of inspection shall be maintained at the facility; and,

(b) Remove for proper disposal any drugs or narcotics which are in a deteriorated condition, expired, discontinued for use, or the patient for whom they are ordered is no longer a patient These drugs shall be the responsibility of the vendor pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-24-.05
Authority: O.C.G.A. Secs. 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Duties of Registered Pharmacist" was filed on May 5, 1980; effective May 25, 1980.
Repealed: New Rule of same title adopted. F. Jun. 14, 1989; eff. Jul. 4, 1989.
Repealed: New Rule of same title adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-24-.06. Destruction of Drugs.

(1) The following methods of destruction of non-controlled substances are approved by the Board for medications dispensed to patients residing in long term care facilities (nursing home or skilled nursing facility) or other facility where a consultant pharmacist's services are required under state or federal regulations:

(a) When non-controlled drugs are expired, discontinued from use or the patient for whom they were ordered is no longer a patient, the drugs shall be immediately removed from the active stock and inventoried by two people who shall be licensed either as a pharmacists, a nurses, or a licensed practical nurses. The completed inventory record shall be signed and dated by these two individuals. The original inventory record shall be maintained by the facility for two years, and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs can either be:

1. Placed in a secure storage area at the facility separated from medications with active orders. The drugs can be destroyed at the facility by the consultant pharmacist and another pharmacist, nurse, or licensed practical nurse designated by the facility. However, before the destruction can take place it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction along with the inventory record for two years. This record shall include at a minimum the date, time, personnel involved with the destruction and the method of destruction; or

2. Removed from the facility and kept by the consultant pharmacist until they are returned to the vendor pharmacist for destruction. The consultant pharmacist shall make a receipt for the drugs removed, and the original receipt to be kept by the facility and a copy of the receipt kept by the pharmacist. The receipt shall reflect: the date the drugs were removed from the facility, the name of the person removing the drugs, the name and address of the pharmacy to which the drugs have been removed. Both the receipt and its copy must be maintained for two years. Before any drugs can be removed for destruction, their inventory must be verified by at least one pharmacist and one other licensed health care practitioner. Once taken to the vendor pharmacy, the drugs must be stored in a secure, location, separate from active inventory, within the pharmacy. When the drugs are destroyed, a record of the manner of disposal of the drugs must be maintained by the vendor pharmacy for two years. The disposal record shall include at a minimum, whether:

(i) The drugs are destroyed at the pharmacy, and

(I) Manner of destruction;

(II) Date and time of destruction;

(III) Names of at least one pharmacist and one other licensed health care practitioner witnessing the destruction; or

(2) The drugs for destruction are removed from the pharmacy by transfer to a reverse distributor with a current permit issued by the Board; and

(I) The date and time the drugs were taken from the pharmacy;

(II) The name, Board permit number, address, and telephone number of the reverse distributor removing the drugs;

(III) The name and signature of the responsible person representing the reverse distributor physically removing the drugs;

(IV) The name and signature of the pharmacist transferring the drugs to the reverse distributor.

(2) The following methods of on-site destruction of controlled substances are approved by the Board:

(a) When controlled drugs are expired, discontinued from use or the patient for whom they are ordered is no longer a patient, the medication shall be removed from the active stock immediately and inventoried and verified by two people who shall be licensed either as a pharmacist, a nurse, or a licensed practical nurse. The completed inventory record shall be signed and dated by those two individuals. An inventory form will be established by the pharmacist, which must include the following data:

1. Date of discontinuance or inventory date;

2. Name of patient;

3. Name of issuing pharmacy;

4. Identifying serial numbers of the prescriptions;

5. Name and strength of drug; and

6. Quantities of drugs in containers when inventoried.

(b) After being removed from active stock, controlled substances to be destroyed must be placed in a secure cabinet or area as identified by the consultant or vendor pharmacist.

(c) On-site destruction can be as follows:

1. The consultant or vendor pharmacist will notify the GDNA as to the date and time the destruction will take place at least two weeks prior to destruction at the facility. (Please note that the consultant may set up a specific schedule of destruction - an example would be the first Tuesday in each month at 10:00 a.m.)

2. Three licensed professionals or law enforcement officers, one of whom must be a pharmacist, must witness the destruction of these drugs.

3. Destruction must take place within the facility.

4. Inventory of final destruction must be taken in duplicate, one copy shall be retained by the facility, and one copy shall be retained by the consultant pharmacist. The inventory shall be certified by all three witnesses present at the destruction in the following format:

   "We, whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____(location) on _____(date) at _____o'clock."

   _____(Signature)

   _____(Signature)

   _____(Signature)

5. The Board and/or the GDNA, or the DEA, may prohibit any consultant pharmacist or facility from utilizing this method.

(3) Methods of off site destruction as follows:

(a) When controlled substances are expired, discontinued from use or the patient for whom they are ordered is no longer a patient, the medication shall be removed from the active stock immediately and inventoried and verified by two people who shall be licensed either as a pharmacist, a nurse, or a licensed practical nurse. The completed inventory record shall be signed and dated by those two individuals. An inventory form will be established by the pharmacist, which must include the following data:

1. Date of discontinuance or inventory date;

2. Full name of patient;

3. Name of issuing pharmacy;

4. Identifying serial numbers of the prescriptions;

5. Name and strength of drug; and

6. Quantities of drugs in containers when inventoried.

(b) After being removed from active stock, controlled substances to be destroyed must be placed in a secure cabinet or area as identified by the consultant or vendor pharmacist.

(c) The drugs, along with a copy of the permanent record, can then be transferred to the vendor pharmacy by the consultant pharmacist to hold for disposal by a Board licensed reverse drug distributor or by a GDNA Agent. The consultant pharmacist shall make a receipt for the drugs removed, and the original receipt is to be kept by the facility and a copy of the receipt kept by the consultant pharmacist, both for two years. The receipt shall reflect at a minimum:

1. The date the drugs were removed from the facility;

2. The name and signature of the consultant pharmacist removing the drugs;

3. The name and signature of the Director of Nursing witnessing the drug removal;

4. The name and address of the pharmacy to which the drugs are being removed.

(d) Once received by the pharmacy, the drugs for disposal must be stored in a secure location within the pharmacy. When disposal of the drugs takes place, a record of the disposal will be maintained by the pharmacy for two years. The type of disposal record shall be, either:

1. On a separate receipt showing the drugs for destruction were removed from the pharmacy by transfer to a Board licensed reverse distributor, showing:

   (i) The date and time the drugs were taken from the pharmacy;

   (ii) The name, address, telephone number and Board permit number of the reverse distribution firm taking possession of the drug;

   (iii) The name and signature of the responsible person representing the reverse distributor firm and physically removing the drugs;

(iv) The name and signature of the pharmacy representative transferring possession of the drugs; and

(v) A copy of the permanent drug inventory destruction record from the facility; or

2. On the permanent record showing the drugs were destroyed by a GDNA Agent with:

(i) The signature of the GDNA Agent;

(ii) The signature of the pharmacy manager as listed on the pharmacy license; and

(iii) The date and time of the drug destruction.

Cite as Ga. Comp. R. & Regs. R. 480-24-.06
Authority: O.C.G.A. Secs. 16-13-34, 16-13-35, 16-13-39, 16-13-72, 26-4-27, 26-4-28, 26-4-110, 26-4-113, 26-4-115.
History. Original Rule entitled "Destruction of Drugs" was filed on May 5, 1980; effective May 25, 1980.
Amended: Rule repealed and a new Rule of the same title adopted. Filed February 15, 1983; effective March 7, 1983.
Repealed: New Rule of same title adopted. F. Jun. 14, 1989; eff. Jul. 4, 1989.
Amended: F. May 21, 1997; eff. June 10, 1997.
Amended: F. Aug. 17, 1998; eff. Sept. 6, 1998.
Repealed: New Rule of same title adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-24-.07. Hospice Emergency Drug Kits.

Emergency Drug Kits may be placed in licensed hospices by the pharmacy of the consultant or vendor pharmacist provided the following guidelines are met:

(1) A record of the drugs to be kept in an emergency drug kit to be kept in the hospice and the provider pharmacy;

(2) Drugs shall not be accessed for use from the emergency drug kit in an emergency situation without a new prescription drug order from a licensed practitioner. A valid, signed prescription drug order for any such drug must be issued to the vendor pharmacy, supplying the emergency drug kit, within 72 hours of the drug being taken from the kit.

(3) Emergency drug kits shall be stored in limited access areas and sealed to prevent unauthorized access and to insure a proper environment for preservation of the drugs

therein. The provider pharmacy shall develop a method to readily determine if an emergency drug kit has been accessed without authorization;

(4) An emergency drug kit must be inventoried once a month by a pharmacist from the provider pharmacy and sign a card attached to the kit indicating the date it was inspected. The provider pharmacy must maintain an adequate record of such inspections.

(5) Special Agents of the GDNA shall have the authority to check emergency drug kits as well as the records in the provider pharmacy to determine that drugs and records are accurate and the emergency drug kit is being properly used;

(6) The provider pharmacy must apply on an individual basis to the Board, in care of the GDNA Director, for approval to place an emergency drug kit in each individual hospice and a copy of this approval will be kept on file in both the hospice and the provider pharmacy. Upon recommendation by the GDNA Director, the Board may revoke the approval for an emergency drug kit in any hospice where abuse or misuse of drugs from the emergency drug kit is used for any purpose other than emergency purposes;

(7) The Board shall have the authority to approve on an individual basis the drugs and the amounts of each individual drug allowed to be kept in an emergency drug kit. Any change in the drugs and amounts kept in a kit must be submitted in writing to the GDNA Director who shall make recommendations to the Board. After Board approval, a copy of this approval will be maintained in the GDNA provider pharmacy file and by the nursing home. Any emergency drug kit approval becomes null and void once the approved pharmacy ceases to provide that kit.

(8) Each solid oral dosage form placed in an emergency drug kit must be individually labeled with the name and strength of the drug, lot number, expiration date, and other appropriate cautionary information; and

(9) The exterior of an emergency drug kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for "EMERGENCY USE ONLY", and the label shall be physically signed and dated by the pharmacist who sealed the kit. In addition, a listing of the drugs contained therein, including the name, address, and telephone number(s) of the provider pharmacy shall be attached to both the exterior and the interior of an emergency drug kit.

Cite as Ga. Comp. R. & Regs. R. 480-24-.07
Authority: O.C.G.A. Secs. 16-13-34, 16-13-35, 16-13-36, 16-13-21(23), 16-13-39, 16-13-41, 16-13-72, 16-13-77, 24-4-53, 26-4-27, 26-4-28, 26-4-29, 26-4-100, .
History. Original Ruler entitled "Hospice Emergency Drug Kits" adopted. F. Apr. 8, 1998; eff. Apr. 28, 1998.
Repealed: New Rule of same title adopted. F. Feb. 25, 2002; eff. Mar. 17, 2002.

Rule 480-24-.08. Crisis Stabilization Unit (CSU) Emergency Drug Kits.

Emergency drug kits may be placed in licensed Crisis Stabilization Units (CSU) by the pharmacy of the consultant or vendor pharmacist provided the following conditions are met:

(1) A record of the drugs to be kept in an emergency drug kit must be kept in the CSU and the provider pharmacy;

(2) Drugs shall not be accessed for use from the emergency drug kit in an emergency situation without a prescription drug order from a licensed practitioner. A valid, signed prescription drug order for any such drug must be issued to the vendor pharmacy, supplying the emergency drug kit, within 72 hours of the drug being taken from the kit;

    (a) Whenever an emergency drug kit is accessed and a drug is removed, personnel shall immediately reseal the kit with a tamper-proof, serial-numbered seal, with the seal serial number to be recorded in a log along with the name of the person removing the drug and resealing the kit and date the kit was opened;

(3) Emergency drug kits shall be stored in limited access areas and sealed to prevent unauthorized access and to insure a proper environment for preservation of the drugs therein. The provider pharmacy shall develop a method to readily determine if an emergency drug kit has been accessed without authorization;

(4) An emergency drug kit must be inventoried once a month by a pharmacist from the provider pharmacy and sign a card attached to the kit indicating the date it was inspected. The provider pharmacy must maintain an adequate record of such inspections;

(5) Special Agents of the GDNA shall have the authority to check emergency drug kits as well as the records in the provider pharmacy to determine that drugs and records are accurate and the emergency drug kit is being properly used;

(6) The provider pharmacy must apply on an individual basis to the Board, in care of the GDNA Director, for approval to place an emergency drug kit in each individual CSU and a copy of this approval will be kept on file in both the CSU and the provider pharmacy. Upon recommendation by the GDNA Director, the Board may revoke the approval for an emergency drug kit in any CSU where abuse or misuse of drugs from the emergency drug kit is noted;

(7) The Board shall have the authority to approve on an individual basis the drugs and the amounts of each individual drug allowed to be kept in an emergency drug kit. Any change in the drugs and amounts kept in a kit must be submitted in writing to the GDNA Director who shall make recommendations to the Board. After Board approval, a copy of this approval will be maintained in the GDNA provider pharmacy file and by the CSU. Any emergency drug kit approval becomes null and void once the approved pharmacy ceases to provide that kit;

(8) Each solid oral dosage form placed in an emergency drug kit must be individually labeled with the name and strength of the drug, lot number, expiration date, and other appropriate cautionary information; and

(9) The exterior of an emergency drug kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for "EMERGENCY USE ONLY", and the label shall be physically signed and dated by the pharmacist who sealed the kit. In addition, a listing of the drugs contained therein, including the name, address, and telephone number(s) of the provider pharmacy shall be attached to both the exterior and the interior of an emergency drug kit.

Cite as Ga. Comp. R. & Regs. R. 480-24-.08
Authority: O.C.G.A. §§ 16-13-34, 16-13-35, 16-13-36, 16-13-39, 16-13-41, 16-13-72, 26-4-27, 26-4-28, 26-4-29, 26-4-110, 26-4-111.
History. Original Rule entitled "Crisis Stabilization Unit (CSU) Emergency Drug Kits" adopted. F. Feb. 22, 2018; eff. Mar. 14, 2018.

Chapter 480-25. NUCLEAR PHARMACIES AND PHARMACISTS.

Rule 480-25-.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) "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

(b) "Board" means the State Board of Pharmacy.

(c) "Compounding of radiopharmaceuticals" means the addition of a radioactive substance to nonradioactive substances or the use of a radioactive substance in preparation for single or multidose dispensation upon the prescription order of a physician who is licensed to use radioactive materials. Compounding of radiopharmaceuticals may include: loading and eluting of radionuclide generators; using manufactured reagents; preparing reagent kits; a liquoting reagents; formulation and quality assurance testing of radiochemicals for use as radiopharmaceuticals, and radiolabeling of compounds or products, including biological products, for use as radiopharmaceuticals.

(d) "Department" means the Department of Natural Resources.

(e) "Governing Body" or "Management" means the board of directors, trustees, partnership, corporation, association, person or group of persons who maintain and control the operation of the nuclear pharmacy, and who are legally responsible for its operation.

(f) "Internal Test Assessment" means, but is not limited to conducting those tests of a quality assurance necessary to ensure the integrity of the test.

(g) "Licensed Nuclear Pharmacist" means an authorization granted by the Board to a pharmacist to practice as a nuclear pharmacist.

(h) "Manufacturing of radiopharmaceuticals" means the preparation, derivation, or production of a product to which a radioactive substance is or will be added to provide a radiopharmaceutical for sale, resale, redistribution, or reconstitution.

(i) "Nuclear pharmacist" means a pharmacist who compounds and dispenses radiopharmaceuticals in the course of his/her pharmacy practice.

(j) "Nuclear Pharmacy" means a pharmacy providing radiopharmaceutical services.

(k) "Nuclear Pharmacy Permit" means an authorization granted by the Board to the governing body of a facility to operate a nuclear pharmacy.

(l) "Pharmacist" means an individual who is currently licensed to practice pharmacy under the provisions of O.C.G.A. Title 26, Chapter 4, Article 3.

(m) "Pharmacy Intern" means an individual who is currently licensed to practice as a pharmacy intern under the provisions of O.C.G.A. Title 26, Chapter 4, Article 3.

(n) "Physician" means an individual who is currently licensed to practice medicine under the provisions of O.C.G.A. Title 43, Chapter 34.

(o) "Radiopharmaceutical" means radioactive drugs and chemical products used for diagnostic and therapeutic purposes and includes the terms radioactive pharmaceuticals, radioisotopes, and radioactive tracers.

(p) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on radiopharmaceuticals and their component materials and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

(q) "Radiopharmaceutical service" means, but is not limited to, the compounding, dispensing, labeling, and delivering of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization review; the maintenance of radiopharmaceutical quality assurance; and the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy.

(r) "Unit dose transport container" (a/k/a "lead pig") means a lead lined container designed to transport doses of radiopharmaceutical agents and prevent the emission of radiation or radioactive materials during the process. The terms "unit dose transport container" and "lead pig" may be used interchangeably.

Cite as Ga. Comp. R. & Regs. R. 480-25-.01
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-110, 26-4-130, 26-4-171, 26-5-178.
History. Original Rule entitled "Dangerous Drugs Identified" adopted as ER. 480-25-0.6-.01 F. June 17, 1980; eff. June 12, 1980, the date of adoption.
Amended: ER. 480-25-0.7-.01 of same title adopted. F. Sept. 25, 1980; eff. Sept. 22, 1980, the date of adoption.
Amended: Permanent Rule of same title adopted. F. Dec. 30, 1980; eff. Jan. 19, 1981.
Repealed: New Rule entitled "Definitions" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.
Amended: F. Apr. 20, 2015; eff. May 10, 2015.

Rule 480-25-.02. Applicability of Regulations.

(1) All persons who manufacture, possess, transport, or otherwise handle pharmaceuticals or radioactive materials intended for radiopharmaceutical use prior to their arrival at a nuclear pharmacy shall comply with the requirements of the Department's Rules and Regulations for Radioactive Materials, and the requirements of the Rules and Regulations of the Board.

(2) The requirements of these Rules and Regulations are in addition to, and not in substitution of, other applicable Rules and Regulations by the Department for radioactive materials and applicable Rules and Regulations promulgated by the Board for pharmacists and pharmacies.

(3) Nothing in these Rules and Regulations shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when his/her use of radiopharmaceuticals is limited to the diagnosis and treatment of his/her own patients.

(4) Nothing in these Rules and Regulations shall be construed so as to require a licensed clinical laboratory which is also licensed by the Department to handle radioactive materials to obtain the services of a nuclear pharmacist, or to have a nuclear pharmacy license, unless the laboratory is engaged in the commercial sale or resale of radiopharmaceuticals.

(5) Nothing in these Rules and Regulations shall be construed to require a department of nuclear medicine which is located in a hospital of 250 beds or less, which has a board certified radiologist in the practice of nuclear medicine, and which is licensed by the Department to handle radioactive materials to obtain the services of a nuclear pharmacist or to have a nuclear pharmacy license.

Cite as Ga. Comp. R. & Regs. R. 480-25-.02
Authority: O.C.G.A. Secs. 26-4-130, 26-4-138, 26-4-172, 26-4-178.
History. Original Rule entitled "Applicability of Regulations" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.03. Licensure of Nuclear Pharmacists.

(1) Except as provided for in Rule 480-25-.02, all acts of compounding and dispensing radiopharmaceuticals in the State of Georgia shall be performed by persons licensed as nuclear pharmacists; provided, however, that licensed pharmacists and licensed pharmacy interns/externs under the direct supervision and control of a nuclear pharmacist may compound and dispense radiopharmaceuticals without being separately licensed as nuclear pharmacists.

(2) An applicant for a license as a nuclear pharmacist shall:

(a) Be a currently licensed pharmacist in the State of Georgia, and

(b) Submit to the Board a completed application and the appropriate fee, on forms to be provided by the Board, and an affidavit of training and experience which indicates that the applicant:

1. Meets the minimum requirements to use radioactive materials as required by the Department's Rules and Regulations for Radioactive Materials, and either

(i) Is certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties of the American Pharmaceutical Association; or

(ii) Has completed a minimum of 200 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy, and, completed a minimum of 500 hours of clinical nuclear pharmacy training:

(I) Under the direct supervision of a licensed nuclear pharmacist in a licensed nuclear pharmacy providing nuclear pharmacy service; or

(II) In a certified nuclear pharmacy residency program approved by the American Society of Hospital Pharmacists or the Board; or

(III) In a structured nuclear pharmacy training program of an accredited college of pharmacy.

(3) Pharmacists engaged in the practice of nuclear pharmacy in the State of Georgia prior to March 18, 1983 shall be exempt from the requirements listed in subsection (2)(b)1. (i) and (2)(b)1. (ii).

(4) A license as a nuclear pharmacist may be issued to any pharmacist who makes application to the Board, together with a required fee, and meets the requirements of these Rules and Regulations. The Board may refuse to issue a license for any of the grounds set forth in O.C.G.A. Section 26-4-60, and may also refuse to issue a license to an applicant

who makes any false statement in the application or cheats in any manner upon any examination administered pursuant to these Rules and Regulations.

(5) Licenses shall be renewed biennially on odd numbered years by application to the Board for renewal.

(6) The Board may limit, suspend, or revoke licenses issued under the provisions of these Rules and Regulations, or impose any other reasonable sanctions upon holders of such licenses upon violation of these Rules and Regulations or violation of O.C.G.A. Section 26-4-60.

Cite as Ga. Comp. R. & Regs. R. 480-25-.03
Authority: O.C.G.A. Secs. 26-4-28, 26-4-37, 26-4-117, 26-4-130, 26-4-138, 26-4-173, 26-4-176, 26-4-178, 43-1-4.
History. Original Rule entitled "Licensure of Nuclear Pharmacists" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Amended: F. Jan. 13, 1986; eff. Feb. 2, 1986.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.04. Licensure of Nuclear Pharmacies.

(1) No nuclear pharmacy shall be operated in the State of Georgia without a valid permit.

(2) The governing body of the facility shall submit a completed application with the required fee to the Board for a permit using forms provided by the Board.

(3) Separate applications and permits are required for nuclear pharmacies maintained on 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 trade name.

(4) Permits are not transferable or assignable.

(5) The applicant shall comply with additional application requirements as may be required by the Board.

(6) Following inspection and evidence of compliance with these Rules and Regulations, the Board may issue a nuclear pharmacy permit to the applicant(s). The Board may refuse to issue a permit to any applicant for any of the grounds set forth in O.C.G.A. Section 26-4-113, and may also refuse to issue or revoke a permit if an applicant makes any false statements in the application.

(7) Permits shall be renewed biennially on even numbered years by application to the Board for renewal.

(8) The Board may limit, suspend, or revoke permits issued under the provisions of these Rules and Regulations, or impose any other reasonable sanctions upon holders of such

permits upon violation of these Rules and Regulations or violation of O.C.G.A. Section 26-4-113.

Cite as Ga. Comp. R. & Regs. R. 480-25-.04
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-130, 26-4-138, 26-4-170, 26-4-172, 26-4-174, 26-4-176 to 26-4-178, 43-1-4.
History. Original Rule entitled "Licensure of Nuclear Pharmacies" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Amended: F. Jan. 13, 1986; eff. Feb. 2, 1986.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.05. Inspections.

(1) Any nuclear pharmacy shall be open during all business hours for observation and examination by properly identified representatives of the Board and the Department.

(2) All nuclear pharmacies shall be inspected by the Board prior to licensure and may be inspected at the discretion of the Board or the Department to determine whether it continues to meet these requirements.

Cite as Ga. Comp. R. & Regs. R. 480-25-.05
Authority: O.C.G.A. Secs. 26-4-27 to 26-4-29, 26-4-130, 26-4-138, 26-4-174, 26-4-178.
History. Original Rule entitled "Inspections" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.06. Nuclear Pharmacy General Requirements.

(1) In addition to complying with these Rules and Regulations, nuclear pharmacies shall comply with the Rules and Regulations of the Board and with all applicable Federal and State laws and regulations pertaining to nonradioactive drugs and pharmaceuticals.

(2) The pharmacist in charge at a nuclear pharmacy shall be a licensed nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a licensed nuclear pharmacist. All acts of compounding and dispensing of radiopharmaceuticals shall be performed by the nuclear pharmacist or by a pharmacist or pharmacy intern, under the direct supervision and control of a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the nuclear pharmacy and shall be in personal attendance at all times when the acts of compounding and dispensing are performed and the pharmacy is open for business.

(3) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(4) Radiopharmaceuticals are to be dispensed only upon prescription drug order by a practitioner who is authorized by the Department to possess, use, and administer radioactive materials.

(5) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with the Department Rules and Regulations for Radioactive Materials. A nuclear pharmacy may also furnish radioactive materials for use to practitioners, for individual patient use in accordance with subsection (4) of this regulation.

(6) The amount of radioactivity dispensed in each individual preparation shall be determined by the nuclear pharmacist through radiometric methods immediately prior to dispensing.

(7) Nuclear pharmacies may redistribute Federal Food and Drug Administration approved radiopharmaceuticals if the pharmacy does not possess the radiopharmaceuticals in any manner or violate the product packaging. Such redistribution may only be made to another nuclear pharmacy or other authorized person or institution.

Cite as Ga. Comp. R. & Regs. R. 480-25-.06
Authority: O.C.G.A. Secs. 16-13-71, 26-4-110, 26-4-130, 26-4-138, 26-4-174, 26-4-178.
History. Original Rule entitled "Nuclear Pharmacy General Requirements" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.07. Space Requirements.

(1) Nuclear pharmacies shall have adequate space, commensurate with the scope of service required and provided and meet the minimal space requirements of all pharmacies in the State.

(2) Nuclear pharmacies shall have a minimum area, secured from unauthorized personnel, which comprise at least 600 square feet designed for the compounding and dispensing and quality assurance of radiopharmaceuticals.

(3) The foregoing nuclear pharmacy areas shall be exclusive from other pharmacy areas such as those for nonradioactive drugs and office space.

(4) Detailed floor plans shall be submitted to the Board before the permit is granted.

Cite as Ga. Comp. R. & Regs. R. 480-25-.07
Authority: O.C.G.A. Secs. 26-4-110, 26-4-130, 26-4-138, 26-4-174, 26-4-178.
History. Original Rule entitled "Space Requirements" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.08. Equipment.

(1) In addition to other articles and equipment required by the Board for all pharmacies in the State, the nuclear pharmacy shall have:

(a) dose calibrator;

(b) vertical laminar flow hood;

(c) single or multiple channel scintillation analyzer;

(d) microscope and hemocytometer;

(e) adequate glassware, utensils, and gloves;

(f) calculator;

(g) laboratory incubator;

(h) water or oil bath;

(i) aluminum ion test kit; and

(j) adequate apparatus and supplies for performing chromatography.

(2) Nuclear pharmacies shall also have equipment required for the safe handling and storage of radioactive materials, as required by the Department's Rules and Regulations for radioactive materials.

(3) Each nuclear pharmacy shall utilize unit dose transport containers, a/k/a lead pigs,

(a) Unit dose transport containers, a/k/a lead pigs, for radioactive doses shall include:

1. an effective tamper-evident seal;

2. an effective mechanism to avoid radioactive contamination; and

3. an effective system to prevent contamination of the transport container with blood, bodily fluids, or other biohazardous substances.

(b) No nuclear pharmacist or nuclear pharmacy shall re-use a unit dose transport container or lead pig that has been contaminated with blood, bodily fluids, or other hazardous substances.

(c) Any unit dose transport container or lead pig returned to a nuclear pharmacy with the tamper-evident seal broken and containing an exposed unit dose syringe shall be considered contaminated.

(d) Section 3 of this Rule shall not apply to:

1. an individual prescriber preparing radiopharmaceuticals for administration to his or her own patients;

2. transfer of radioactive material, not intended for use as a drug, to other legally authorized persons; and

3. the occasional transfer of bulk radiopharmaceuticals to other authorized entities or persons to meet shortages.

(e) Biohazardous prevention systems containing a barrier that if used properly eliminates or substantially reduces the potential for contamination of the unit dose transport container, or lead pig, would meet the requirements of these regulations. Improper use of such system resulting in ineffective sanitation of the unit dose transport container, or lead pig, would require that such containers be effectively sanitized prior to subsequent use or discarding of that container.

Cite as Ga. Comp. R. & Regs. R. 480-25-.08
Authority: O.C.G.A. §§ 26-3-7, 26-3-17, 26-4-27, 26-4-28, 26-4-110, 26-4-130, 26-4-170, 26-4-172, 26-4-174, 26-4-178.
History. Original Rule entitled "Equipment" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Amended: F. Sept. 29, 1998; eff. Oct. 19, 1998.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.
Amended: F. Apr. 20, 2015; eff. May 10, 2015.

Rule 480-25-.09. Labeling.

All radiopharmaceuticals dispensed from a nuclear pharmacy shall be dispensed in appropriate containers and labeled in accordance with the following:

(a) The immediate inner container shall be labeled with:

1. the identifying prescription number; and

2. the name of the radioactive drug.

(b) In addition to any labeling standards established by law the immediate outer container shall be labeled with:

1. the name of the radionuclide;

2. the chemical form;

3. the amount of radioactive material contained, in millicuries (mCi) or microcuries (uCi);
4. if a liquid, the volume expressed in cubiccentimeters (cc) or milliliters (ml);
5. the requested calibration time and date;
6. the words "For Physician Use Only" in the absence of the name of the patient;
7. the name and address of the institution where the radiopharmaceutical will be administered;
8. the expiration date and time of the radioactive drug;
9. auxillary instructions for use, if applicable;
10. name of the procedure for which drug is intended;
11. name of prescribing practitioner;
12. The standard radiation symbol; and
13. The words "**Caution - Radioactive Material**".

Cite as Ga. Comp. R. & Regs. R. 480-25-.09
Authority: O.C.G.A. Secs. 16-13-73, 26-3-7, 26-3-8, 26-3-17, 26-4-87, 26-4-130, 26-4-138, 26-4-174, 26-4-178.
History. Original Rule entitled "Labeling" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.10. Library.

In addition to any reference material required by the Board of all pharmacies in the State, a nuclear pharmacy shall maintain a reference library which shall include the following:

(a) Current U.S. Pharmacopoeia/National Formulary with supplements or computer or electronic access to same;

(b) Computer or electronic access to Federal and State Laws and Regulations relating to pharmacy practice in Georgia;

(c) A minimum of three texts dealing with nuclear medicine;

(d) Current Department of Human Resources Rules and Regulations for Radioactive Materials.

Cite as Ga. Comp. R. & Regs. R. 480-25-.10
Authority: O.C.G.A. Secs. 26-4-37, 26-4-110, 26-4-111, 26-4-130, 26-4-138, 26-4-174, 26-4-178.
History. Original Rule entitled "Library" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Amended: F. Jan. 13, 1986; eff. Feb. 2, 1986.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.11. Records.

The nuclear pharmacy shall maintain acquisition and disposition records as required by the Board of all pharmacies in the State.

Cite as Ga. Comp. R. & Regs. R. 480-25-.11
Authority: O.C.G.A. Secs. 26-4-130, 26-4-138, 26-4-170, 26-4-178.
History. Original Rule entitled "Records" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-25-.12. Enforcement.

The enforcement and administration of these Rules and Regulations shall be as prescribed in the Georgia Administrative Procedure Act, O.C.G.A., Title 50, Chapter 13, Title 26, Chapter 4, and Title 43, Chapter 1.

Cite as Ga. Comp. R. & Regs. R. 480-25-.12
Authority: O.C.G.A. §§ 26-4-130, 26-4-138, 26-4-170, 26-4-178, 43-1-19.
History. Original Rule entitled "Enforcement" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 480-25-.13. Severability.

In the event that any rule, sentence, clause or phrase or 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 Pharmacy 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. 480-25-.13
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-130, 26-4-138, 26-4-178.
History. Original Rule entitled "Severability" adopted. F. Mar. 9, 1984; eff. Mar. 29, 1984.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Chapter 480-26. FEES.

Rule 480-26-.01. Fees.

(1) All fees for applications for pharmacist license, examinations, application and examination fee for reciprocity, wall certificates, duplicate wall certificates, renewals, late renewals, reinstatements, and all other fees which may be authorized by law shall be established by the Board periodically as set forth on a fee schedule and may be obtained from the Board office. Such fees must be paid directly to the Board office.

(2) Fees for the North American Pharmacist Licensing Examination (NAPLEX) portion of any examination or the fee for National Association of Boards of Pharmacy (NABP) electronic license score transfer process are separate from and not included in the Georgia State Board of Pharmacy fee schedule. Such fees must be paid directly to NABP.

(3) All fees for applications for pharmacies and other licenses, renewals, late renewals, and all other fees which may be authorized by law shall be established by the Board periodically as set forth on a fee schedule and may be obtained from the Board office.

(4) Pharmacist license reactivation and reinstatement is considered at the discretion of the Board once thirty (30) hours of approved pharmacy continuing education along with the required fee, and any other requirements as set forth by Board policy is received.

Cite as Ga. Comp. R. & Regs. R. 480-26-.01
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-41, 26-4-42, 26-4-44, 26-4-6, 26-4-49, 26-4-110, 26-4-115, 26-4-170.
History. Original Rule entitled "Fees" was filed on March 26, 1982; effective April 15, 1982.
Amended: Rule repealed and a new Rule of same title adopted. Filed June 17, 1985: effective July 7, 1985.
Amended: Filed January 13, 1986; effective February 2, 1986.
Amended: Filed September 4, 1986; effective September 24, 1986.
Amended: Filed July 21, 1988; effective August 10, 1988.
Amended: F. Sept. 19, 1989; eff. Oct. 9, 1989.
Amended: F. Sept. 4, 1992: eff. Sept. 24, 1992.
Amended: F. May 10, 1993; eff. May 30, 1993.
Amended: Rule repealed, new Rule of same titled adopted. F. Feb. 19, 2002; eff. Mar. 11, 2002.

Chapter 480-27. REQUIREMENTS OF A PRESCRIPTION DRUG ORDER WHEN UTILIZING A COMPUTER OR OTHER ELECTRONIC MEANS.

Rule 480-27-.01. Definitions.

For purposes of these Rules and Regulations, the following definitions apply:

(a) Authentication. Any process by which the identities of the parties sending and receiving electronic prescription data are verified.

(b) Automated Electronic Data Processing System. A system utilizing computer software and hardware for the purpose of record-keeping and/or receiving prescription drug orders. Any and all such systems that are compatible and capable of interacting with, and electronically transferring prescription drug data with any other system must be in compliance with the rules of the Board for use in electronic prescription monitoring.

(c) Board. The Georgia State Board of Pharmacy.

(d) Computer. Programmable electronic device capable of multifunctions including but not limited to storage, retrieval and processing of information.

(e) Controlled Substances. Those drug items regulated by federal law and/or the Georgia Controlled Substances Act.

(f) Dangerous Drugs. Those drug items and devices regulated by the Georgia Dangerous Drug Act.

(g) Digital ID. An authenticated identifiable signature than can be attached to an electronic e-mail and is tamper proof.

(h) Downtime. That period of time when a computer is not operable.

(i) Electronic Means. An electronic device used to send, receive, and/or store prescription drug order information, including computers, facsimile machines, etc.

(j) Electronic Signature. An electronically reproduced visual image signature or an electronic data signature of a practitioner, which appears on, is attached to or is logically associated with an electronic prescription drug order.

(k) Facsimile. A hard copy prescription drug order sent via a facsimile machine.

(l) Hard Copy. A fileable prescription drug order which is written or printed via electronic means.

(m) Hardware. The fixed component parts of a computer.

(n) HIPPA. The Health Insurance and Portability and Accountability Act and the associated security standards for the protection of electronic protected health information.

(o) Intervening Electronic Formatter. An entity that is not prohibited under O.C.G.A. Section 26-4-80(c)(1) and (5), and that provides the infrastructure that connects a computer or automated electronic data processing system or other electronic device used by a prescribing practitioner with a computer or automated electronic data processing system or another electronic device used by the pharmacy to facilitate the secure transmission of:

1. An electronic prescription drug order;
2. A refill authorization request;
3. A communication; and
4. Other patient care information between a practitioner and pharmacy.

(p) NPI. National Provider Standard Identifier.

(q) Practitioner Drug Order. A drug order written in an institutional practice/setting in a patient's chart for a specific patient. It is not necessary to reduce to writing as required for a prescription drug order.

(r) Prescriber. A practitioner authorized to prescribe and acting within the scope of this authorization.

(s) Prescription Drug Order. A lawful order from a practitioner, acting within the scope of his or her license to practice, for a drug or device for a specific patient. Such order includes a written order from the practitioner, a telephone order reduced to writing by the pharmacist, and electronic image prescription drug order and an electronic data prescription drug order.

(t) Print-out. A hard copy document generated by computer or other electronic means that is readable without the aid of any special device.

(u) Regulatory Agency. Any federal or state agency charged with enforcement of pharmacy or drug laws and regulations, i.e., the Georgia Drugs and Narcotics Agency (GDNA), the Drug Enforcement Administration (DEA), or the Georgia Department of Medical Assistance (Medicaid).

(v) Security Paper. Paper with security features on which the electronic visual image prescription drug order of a practitioner is printed and presented to a patient so as to ensure that a prescription drug order is not subject to any form of copying, reproduction, or alteration, and may include a watermark produced by the electronic digital process when a prescription is printed that clearly shows if a prescription has been reproduced or copied in an unauthorized manner. Such security paper shall include, at a minimum, but not limited to, the following security features:

1. A latent, repetitive pattern shall be visible across the entire front of the prescription blank if the prescription is scanned or photocopied; and
2. A chemical void protection that prevents alteration by chemical washing.

(w) Software. Programs, procedures and systems for receipt and/or storage of required information data.

(x) Stop Date. In institutional settings, the practitioner normally indicates on his/her drug order, the length of time to administer the medication. In absence of such a notation, a committee will have determined by policy, the length of time to administer the medication by category.

Cite as Ga. Comp. R. & Regs. R. 480-27-.01
Authority: O.C.G.A. Secs. 26-4-5, 26-4-27 to 26-4-29, 26-4-37, 26-4-80, 26-4-83.
History. Original Rule entitled "Definitions" adopted. F. Nov. 26, 1986; eff. Dec. 16, 1986.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Aug. 18, 2006; eff. Sept. 7, 2006.
Amended: F. Jan. 23, 2009; eff. Feb. 12, 2009.

Rule 480-27-.02. Prescription Drug Order Requirements.

(1) Prescription drug orders shall include, but not be limited to, the following information:

(a) Date of issue;

(b) Name and address of patient (or patient location if in an institution):

(c) Name and address of prescriber, telephone number, and NPI as assigned under federal law;

(d) DEA registration number of the prescriber in the case of controlled substances;

(e) Name, strength, dosage form and quantity of drug prescribed;

(f) Number of authorized refills;

(g) Directions for use by patient;

(h) If a written prescription drug order, the signature of the prescribing practitioner; and

(i) Any cautionary statements as may be required or necessary.

(2) Electronically transmitted prescription drug orders shall contain all information required for written prescriptions above and required by state and federal law including the prescriber's name, address, and phone number, except the signature may be an electronic signature as provided below and the electronically transmitted prescription must include the time and date of transmission.

(a) Electronically transmitted prescription drug orders transmitted from the practitioner and received by a pharmacy via facsimile must contain either an electronically reproduced visual image signature or original signature of the practitioner.

(b) Electronically generated prescription drug orders transmitted from the practitioner and received by a pharmacy as e-mails must contain an electronic data signature of the practitioner.

(c) All electronic prescription drug orders generated by a practitioner containing an electronically reproduced visual image signature or an electronic data signature must bear wording that appears on the face of the prescription which indicates the signature was electronically generated.

(3) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists are entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from an intervening electronic for matter that comply with this rule.

(4) An electronic visual image prescription drug order that bears an electronic reproduction of the visual image of the practitioner's signature and is given directly to the patient must be printed on security paper with the wording that indicates the signature was electronically generated.

(a) Every hard copy prescription drug order for any Schedule II controlled substance written in this state by a practitioner shall be written on security paper. If a hard copy of an electronic data prescription drug order for any Schedule II controlled substance is given directly to the patient, the manually signed hard copy prescription drug order must be on security paper.

(5) Pharmacies are prohibited from receiving electronic data from intervening electronic for matters that do not meet all of the following requirements:

(a) Utilize recognized encrypted technology and secure servers.

(b) Maintain HIPAA compliance.

(c) Maintain a combination of technical and administrative security measures, such as, but not limited to those listed in Security Standards for the Protection of Electronic Protected Health Information (HIPAA), to ensure a reasonable and appropriate level of:

1. Practitioner and dispenser authentication;

2. Content integrity; and

3. Confidentiality.

(d) Refrain from collecting and disseminating patient and/or prescriber data to sources other than the originating prescriber and the receiving pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-27-.02
Authority: O.C.G.A. §§ 16-13-41, 16-13-73, 16-13-74, 26-4-5, 26-4-27, 26-4-28, 26-4-37, 26-4-80, 26-4-80.1, 26-4-83, 42 C.F.R. Part 423.
History. Original Rule entitled "Prescription Requirements" adopted. F. Nov. 26, 1986; eff. Dec. 16, 1986.
Repealed: New Rule entitled "Prescription Drug Order Requirements" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Aug. 18, 2006; eff. Sept. 7, 2006.
Amended: F. Jan. 23, 2009; eff. Feb. 12, 2009.
Amended: F. July 27, 2015; eff. Aug. 16, 2015.

Rule 480-27-.03. Records of Dispensing.

Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for two years and shall include, but not be limited to:

(a) Quantities dispensed;

(b) Date of dispensing;

(c) Serial number (or equivalent if an institution);

(d) The identification of the pharmacist responsible for dispensing;

(e) Documentation of satisfaction of state requirements for drug product selection;

(f) Records of refills to date to include date(s) of refills, and identification of pharmacist(s) dispensing refills.

Cite as Ga. Comp. R. & Regs. R. 480-27-.03
Authority: O.C.G.A. Secs. 16-13-39, 26-4-27, 26-4-28, 26-4-37, 26-4-50, 26-4-80, 26-4-81, 26-4-83, 43-34-26.2.
History. Original Rule entitled "Records of Dispensing" adopted. F. Nov. 26, 1986; eff. Dec. 16, 1986.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-27-.04. Use of Facsimile Machine to Transmit or Recieve Prescription Drug Order.

(1) All prescription drug orders sent via facsimile or other electronic means must meet the requirements of O.C.G.A. § 26-4-80 and Chapter 480-22 of the Board Rules and the requirements for electronically transmitted prescriptions or drug orders.

(2) All persons engaged in the practice of pharmacy in this state, which includes accepting or receiving a prescription drug order, must be licensed by the Board.

(3) All dangerous drugs and controlled substances must be dispensed pursuant only to a valid prescription drug order. A pharmacist shall not dispense a prescription drug order which the pharmacist knows or should know is not a valid prescription drug order.

(4) A prescription drug order may be accepted by a licensed pharmacist, a pharmacy intern or extern, acting under the direct supervision of a registered pharmacist, in written form, orally, via facsimile, or electronically as set forth in O.C.G.A. § 26-4-80 and the Rules of the Board. Provisions for accepting a prescription drug order for a schedule II controlled substance are set forth in Chapter 480-22.

(5) Prescription drug orders transmitted either electronically or via facsimile shall include the following requirements:

(a) Electronically transmitted prescription drug orders shall be transmitted directly by the prescribing practitioner or indirectly utilizing intervening electronic formatters as permitted under Georgia law, except in the case of a prescription drug order sent via facsimile equipment by the practitioner or the practitioner's agent acting under the direct supervision of the practitioner, to the pharmacy of the patient's choice with no other intervening person or intermediary having access to or retaining information contained in the prescription drug order. No patient or agent for a patient may transmit a prescription drug order to a pharmacy.

(b) Prescription drug orders transmitted or received by facsimile or other electronic means shall include:

1. In the case of a prescription drug order for a dangerous drug, the complete name, address and telephone number of the prescribing practitioner;

2. In the case of a prescription drug order for a controlled substance when authorized by federal law, the complete name, address, telephone number, and DEA registration number of the prescribing practitioner;

3. The complete name and address of the patient;

4. The time and date of transmission;

5. The complete name of the person transmitting the prescription drug order and a telephone number for verbal confirmation; and

6. The NPI for the prescriber as assigned under federal law; and

7. The practitioner's signature in the manner required in 480-27-.02(2).

(c) An electronically transmitted prescription drug order which meets the requirements of this Chapter shall be deemed sufficient to serve as the original prescription drug order for the pharmacy;

(d) Electronically generated prescriptions may be transmitted directly or indirectly thru one or more Intervening Electronic Formatters to a pharmacy's computer or other similar electronic device;

(e) Intervening electronic formatters not compliant with the requirements of this chapter will be considered an invalid source and are prohibited;

(f) Electronically generated prescriptions as e-mails directly from the prescriber to a pharmacy of the patient's choice shall be encrypted and accompanied by a digital ID for authentication purposes. The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists is entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions. E-mail prescriptions should comply with the following:

1. E-mails shall be reduced to hard copy and maintained as a prescription order record and maintained as required by rules and statute for all other prescription orders; and

2. The prescription may not be for a controlled substance unless allowed by federal law.

(6) The pharmacist or pharmacy intern or extern acting under the direct supervision of a licensed pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the transmitted prescription drug order consistent with Federal and State Laws and rules and regulations adopted pursuant to same.

(7) A prescription drug order electronically transmitted from a prescriber or a prescriber's agent acting under the direct supervision of the prescriber, shall be considered a highly confidential transaction and said transmission shall not be compromised by interventions, control, change, altering, or manipulation by any other person or party in any manner whatsoever except by an intervening electronic formatter as permitted by law and these rules.

(8) Any pharmacist or pharmacy intern or extern acting under the direct supervision of a licensed pharmacist that transmits, receives, or maintains any prescription or prescription refill either orally, in writing, or electronically shall ensure the security, integrity, and confidentiality of the prescription drug order and any information contained therein.

(9) The Board may provide exceptions to this Rule by establishing policies for institutional settings such as hospital pharmacies, nursing home pharmacies, outpatient clinic

pharmacies, opioid treatment program clinic pharmacies, or pharmacies owned and operated directly by health maintenance organizations.

(10) Receiving computers or other similar electronic devices used to view the prescription shall be located within the pharmacy or pharmacy department with only authorized personnel having access.

(11) Transmission of prescriptions to answering machines and electronic voice recording devices by an authorized practitioner or approved agent shall be retrieved by a licensed pharmacist, intern, or extern and is considered to be a direct transmission of a prescription order.

Cite as Ga. Comp. R. & Regs. R. 480-27-.04
Authority: O.C.G.A. Secs. 16-13-41, 16-13-72, 26-4-5, 26-4-27, 26-4-28, 26-4-37, 26-4-40, 26-4-78, 26-4-80, 26-4-82, 26-4-83, 43-34-26.1.
History. Original Rule entitled "Automated Data Processing Systems" adopted. F. Nov. 26, 1986; eff. Dec. 16, 1986.
Amended: F. July 31, 1992; eff. Aug. 20, 1992.
Amended: F. July 8, 1996; eff. July 28, 1996.
Repealed: New Rule entitled "Use of Facsimile Machine or Other Electronic Means to Transmit or Receive Prescription Drug Orders" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Aug. 18, 2006; eff. Sept. 7, 2006.
Amended: Rule retitled "Use of Facsimile Machine to Transmit or Receive Prescription Drug Orders". F. Jan. 23, 2009; eff. Feb. 12, 2009.

Rule 480-27-.05. Record-Keeping When Utilizing an Automated Data Processing System.

In order to comply with the record keeping requirements of this Chapter, an automated electronic data processing system may be utilized for the record keeping system if the following conditions have been met:

(a) Except as otherwise provided herein, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the usual consecutively serial numbered prescription file. Any refill information subsequently authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(e).

(b) The system shall at a minimum produce sight-readable records for all dangerous drug and controlled substance prescriptions filled or refilled during each 24 hour period. The term "sight-readable" means that a representative of the Board or GDNA shall be able to immediately retrieve and examine the record and read the information during any on-site visit to the pharmacy. For purposes of off-site audits and review, a separate copy of any sight-readable hard-copy printout or electronic readable file (such as a PDF file) of each

daily record shall be made available to a representative of the Board of GDNA upon verbal request by that representative. These daily prescription records can:

1. Be generated as hard-copy print-outs at least once weekly, separated into each 24 hour period, by the pharmacy and maintained for at least two years after the last date on which the prescription was filled or refilled. If a hard-copy printout of each day's filled and refilled prescription is generated, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date; or

2. Be maintained electronically. The computers on which the records are maintained may be located at another location, but the records must be immediately retrievable as hard-copy print-outs or viewing on a computer monitor set aside for such viewing at each individually registered pharmacy upon a verbal request by a representative from the Board or GDNA. The computer software must be capable of printing out or transferring the prescription records in a format that is readily understandable to the representative for the Board or GDNA at the registered location. Prescription records must also be sortable and retrievable by prescriber name, patient name, drug dispensed, and date filled. When utilizing electronic daily prescription fill and refill records, each pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the prescription information entered by him or her into the computer that day has been reviewed by him or her and is correct as shown. Such a book or file must be maintained at the pharmacy employing such software for a period of two years after the date of dispensing the appropriately authorized refill.

(c) The information maintained by the automated electronic data processing system shall include, but not be limited to the following:

1. Date of dispensing;

2. Prescription number;

3. Patient's name;

4. Patient's address;

5. Drug name, strength and dosage form;

6. Quantity prescribed, and if the quantity dispensed is different from the quantity prescribed, the quantity dispensed;

7. Prescriber's name;

8. Identification of dispensing pharmacist;

9. Indication whether drugs are being dispensed pursuant to a new prescription or for a refill order;

10. In case of a controlled substance as allowed by federal law, the name, address and DEA registration of the practitioner and the schedule of the drug;

11. Directions for administration of the prescription to the patient;

12. Total number of refills authorized; and

13. NPI of the prescriber as assigned under federal law.

(d) Permanent records of electronic prescriptions for dangerous drugs and controlled substances do not have to be reduced to hard copy provided the following requirements are met:

1. Electronic prescription data must be maintained in the original format received for a minimum of two years; and

2. Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1 hr UL approved) container, stored in a secured offsite location or backed up to a documented offsite secure storage device within 48 hours following each work day.

(e) The individual pharmacist responsible for completeness and accuracy of the entries to the system must provide documentation that prescription information entered into the computer is correct, by dating and signing the print-out in the same manner as signing a check or legal document (e.g., Mary A. Smith or M. A. Smith).

(f) An auxiliary record-keeping system shall be established for the documentation of filling new prescriptions, refills, and transfers if the automated electronic data processing system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When this automated electronic data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated electronic data processing system as soon as possible. However, nothing in this section shall preclude the pharmacist from using his/her professional judgment for the benefit of a patient's health and safety.

(g) Any pharmacy using an automated electronic data processing system must comply with all applicable State and Federal laws and regulations.

(h) A pharmacy shall make arrangements with the supplier of data processing services or materials to insure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall insure continuity in the maintenance of records.

Cite as Ga. Comp. R. & Regs. R. 480-27-.05
Authority: O.C.G.A. §§ 16-13-39, 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-80, 26-4-83, and 26-4-111.
History. Original Rule entitled "Security" adopted. F. Nov. 26, 1986; eff. Dec. 16, 1986.
Repealed: New Rule entitled "Record-Keeping When Utilizing an Automated Data Processing System" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Aug. 18, 2006; eff. Sept. 7, 2006.
Amended: F. Dec. 14, 2012; eff. Jan. 3, 2013.
Amended: F. Sep. 17, 2014; eff. Oct. 7, 2014.

Rule 480-27-.06. Security.

The computerized information provided by the system shall be used only by the pharmacy in which the data has been entered or a pharmacy sharing a common database. To maintain the confidentiality of patients' prescriptions, there must exist adequate safeguards or security of the records.

Cite as Ga. Comp. R. & Regs. R. 480-27-.06
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-80.
History. Original Rule entitled "Prescription Transferal" adopted. F. Nov. 26, 1986; eff. Dec. 16, 1986.
Repealed: New Rule entitled "Security" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-27-.07. Dangerous Prescription Drug Order Transfer.

A pharmacy utilizing an automated electronic data processing system must satisfy all the information requirements as that used in a manual mode when transferring an original dangerous drug prescription drug order. The transfer of original prescription drug information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) The prescription drug order is transmitted directly to the pharmacy of the patient's choice.

(b) The transfer is communicated directly between licensed pharmacists or licensed interns or externs under the direct supervision of a licensed pharmacist and the transferring pharmacist or intern or extern records the following information:

1. The word "VOID" is written on the face of the invalidated prescription drug order, and/or indicate in the pharmacy's electronic data system this prescription is void;

2. Record on the reverse of the invalidated prescription drug order the name and address of the pharmacy to which it was transferred and the name of the pharmacist

or intern or extern under the direct supervision of a licensed pharmacist receiving the prescription drug order information, or have the electronic data system reflect the fact that the prescription drug order has been transferred, the name and address of the pharmacy to which it was transferred and the name of the pharmacist or intern or extern under the direct supervision of a licensed pharmacist to which it was transferred, and the date of the transfer; and

3. Record the date of the transfer and the name of the pharmacist or intern or extern under direct supervision of a licensed pharmacist transferring the information.

(c) The pharmacist or intern or extern under the direct supervision of a licensed pharmacist receiving the transferred prescription drug order shall reduce to writing, or cause the computer to reduce to writing, the following information which shall be filed as required by O.C.G.A. Title 16, Chapter 13 and Title 25, Chapter 4:

1. The word "TRANSFER" shall be written on the face of the transferred prescription and/or indicate in the pharmacy's electronic data system this prescription was a transfer;

2. All information required to be included on the prescription drug order pursuant to all State and Federal laws and regulations shall be provided which shall include at a minimum the following:

   (i) Date of issuance of the original prescription drug order;

   (ii) Original number of refills authorized on the original prescription drug order;

   (iii) Date of original dispensing;

   (iv) Number of valid refills remaining and date of last refill;

   (v) The pharmacy's name, address, and original prescription serial number from which the prescription drug order information was transferred; and

   (vi) Name of transferring pharmacist.

3. Both the original and transferred prescription must be maintained for a period of two years from the date of last refill.

(d) Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to record on the original hard copy prescription drug order any information when transferring or refilling prescription drug orders as required for pharmacies not utilizing a common electronic file as noted in this Chapter. However, a hard copy of the prescription drug order must be generated and maintained by the pharmacist refilling or receiving the electronically transferred prescription drug order

information. The common database must contain complete records of each prescription drug order transferred.

Cite as Ga. Comp. R. & Regs. R. 480-27-.07
Authority: O.C.G.A. Secs. 16-13-39, 26-4-5, 26-4-27, 26-4-28, 26-4-37, 26-4-80, 26-4-83.
History. Original Rule entitled "Controlled Substances Prescription Transferal" adopted. F. Nov. 26, 1986; eff. Dec. 16, 1986.
Amended: F. Feb. 10, 1993; eff. Mar. 2, 1993.
Repealed: New Rule entitled "Dangerous Prescription Drug Order Transfer" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Aug. 18, 2006; eff. Sept. 7, 2006.

Rule 480-27-.08. Controlled Substance Prescription Drug Order Transfer.

Pharmacies utilizing automated data processing systems must satisfy all information requirements of a manual mode for prescription transferal. The transfer of original prescription information for a controlled substance list in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. Transfers are subject to the following requirements:

(a) The transfer is communicated directly between licensed pharmacists or intern or extern under the direct supervision of a licensed pharmacist, and the transferring pharmacist or intern or extern records the following information:

1. The word "VOID" is written on the face of the invalidated prescription drug order;

2. Record on the reverse side of the invalidated prescription drug order the name and address of the pharmacy to which it was transferred and the name of the pharmacist or intern or extern receiving the prescription drug order;

3. The date of the transfer and the name of the pharmacist or intern or extern transferring the information is recorded;

4. The computer record shall reflect the fact that the prescription drug order has been transferred, the name of the pharmacy to which it was transferred, and the date of the transfer, except as otherwise set forth in this Chapter relating to pharmacies utilizing common databases.

(b) The pharmacist or intern or extern receiving the transferred prescription information shall reduce to writing the following:

1. The word "TRANSFER" is written on the face of the transferred prescription drug order;

2. All information required to be on a prescription drug order pursuant to State and Federal laws and regulations shall be provided to the receiving pharmacist which shall include at a minimum the following:

   (i) Date of issuance of the original prescription drug order;

   (ii) Original number of refills authorized on the original prescription drug order;

   (iii) Date of original dispensing;

   (iv) Number of valid refills remaining and date of last refill;

   (v) Pharmacy's name, address, DEA registration number, telephone number and original prescription drug order serial number from which the prescription information was transferred;

   (vi) Name of transferring pharmacist or intern or extern.

(c) Both the original and transferred prescription drug order must be maintained for a period of two years from the date of last refill.

(d) Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to record on the original prescription drug order any information when transferring or refilling prescription drug orders as required for pharmacies not utilizing a common electronic file as noted in this Chapter. A hard copy of the prescription drug order must be generated and maintained by the pharmacist refilling the electronically transferred prescription drug order. The common database must contain complete records of each prescription drug order transferred.

Cite as Ga. Comp. R. & Regs. R. 480-27-.08
Authority: O.C.G.A. Secs. 16-13-39, 26-4-27, 26-4-28, 26-4-80.
History. Original Rule entitled "Controlled Substance Prescription Drug Order Transfer" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-27-.09. Patient Records.

(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for filling or dispensing. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

   (a) Full name of the patient for whom the drug is intended;

(b) Street address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) The patient's gender;

(e) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug, prescription number, name and strength of the drug, the quantity and date received, and the name of the practitioner; and

(f) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs or devices currently being used by the patient which may relate to prospective drug review.

(3) A patient record shall be maintained for a period of not less than five years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

Cite as Ga. Comp. R. & Regs. R. 480-27-.09
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-83.
History. Original Rule entitled "Patient Records" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-27-.10. Other Considerations.

(1) All prescription drug orders lawfully authorized to be received via facsimile or other electronic means are allowed to serve as the original prescription drug order for the receiving pharmacy.

(2) No person or firm licensed under O.C.G.A. Title 26, Chapter 4 (the Georgia Pharmacy Practice Act) nor any other entity shall be permitted to provide facsimile machines or equipment, computer software, technology hardware, digital or electronic prescription drug order systems or supplies related to the transmission of prescription drug orders by electronic means to any practitioner which restricts such practitioner from issuing prescription drug orders for certain prescription drugs or restricts a patient from choosing the retail pharmacy to which an electronic prescription drug order maybe transmitted.

(3) A pharmacist or a pharmacy owner and/or manager that participates in any process which restricts the patient's freedom of choice is considered to have engaged in unprofessional conduct as defined by the Board's Rules.

(4) In compliance with O.C.G.A. Title 26, Chapter 4, no pharmacy or pharmacist may surrender copies of any patient's prescription drug order information or patient profile except under the following conditions:

(a) Written authority from the patient, the patient's caretaker, or a person with power of attorney for the patient;

(b) A subpoena or court order signed and issued by a government official or court;

(c) Any other person as authorized by O.C.G.A. § 26-4-80(d) to have access to the prescription; or

(d) A forged prescription drug order. Such forged prescription is considered evidence of a crime and should be surrendered to the proper law enforcement authority investigating such forgery. When turning over a forged prescription drug order to law enforcement officers, the officer should provide the pharmacy with a signed photocopy of the forged prescription drug order along with the name of the officer, his/her agency and telephone number.

(5) The receipt of, maintenance of, and dispensing pursuant to digital and electronic prescription drug orders in any manner other than as set forth in this chapter shall be considered a violation of the Board rules and regulations.

(6) Nothing in this rule is meant to supercede any U.S. Drug Enforcement Administration (DEA) laws or rules concerning the legality of transmission of or dispensing of controlled substance prescription drug orders bearing electronic or digital signatures.

(7) Nothing in this rule is meant to restrict compliance with e-prescribing as permitted under the Medicare Prescription Drug Improvement and Modernization Act of 2003.

Cite as Ga. Comp. R. & Regs. R. 480-27-.10
Authority: O.C.G.A. Secs. 16-13-34, 16-13-39, 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 43-1-19, 42 C.F.R. Part 423.
History. Original Rule entitled "Other Considerations" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Repealed: New Rule of same title adopted. F. Aug. 18, 2006; eff. Sept. 7, 2006.

Chapter 480-28. PRACTITIONER DISPENSING OF DRUGS.

Rule 480-28-.01. Definitions.

For purpose of these Rules and Regulations, the following definitions apply:

(a) Drugs. Drugs shall mean drugs as defined in O.C.G.A. Section 26-4-5.

(b) Practitioner or Dispensing Practitioner. Practitioner or dispensing practitioner means a person licensed as a dentist, physician, podiatrist or veterinarian under Chapters 11, 34, 35 or 50, respectively of Title 43 of the Official Code of Georgia Annotated.

Cite as Ga. Comp. R. & Regs. R. 480-28-.01
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130.
History. Original Rule entitled "Definitions" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.02. General Requirements.

All practitioners who dispense drugs shall comply with all record-keeping, labeling, packaging, and storage requirements imposed upon pharmacists and pharmacies with regard to such drugs and those regulations contained in this Chapter.

(a) Nothing in this Rule is meant to prohibit veterinarians from meeting the prescription drug order record keeping requirements of this Chapter by utilizing a record keeping system in which a patient's prescription drug order is maintained in the patient's chart. However, nothing in such a system shall relieve a veterinarian from meeting the other requirements of this Chapter.

Cite as Ga. Comp. R. & Regs. R. 480-28-.02
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130.
History. Original Rule entitled "General Requirements" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.03. Notification of Intent to Dispense.

(1) Any practitioner who intends for his/her agent to dispense drugs shall notify, at the time of the renewal of that practitioner's license to operate, that practitioner's respective licensing board of that practitioner's intention to dispense drugs. The licensing board shall notify the Georgia State Board of Pharmacy regarding each practitioner whom that Board has received a notification of intention to dispense drugs. The licensing board's notification shall include the following information:

(a) The name and address of the practitioner;

(b) The state professional license number of the practitioner;

(c) The practitioner's Drug Enforcement Administration license number; and

(d) The complete name and address of the office or facility from which drugs shall be dispensed and the complete address where all records pertaining to such drugs shall be maintained.

Cite as Ga. Comp. R. & Regs. R. 480-28-.03
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-130.
History. Original Rule entitled "Notification of Intent to Dispense" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.04. Record-keeping and Filing.

(1) Requirements of a prescription drug order. A practitioner shall write a prescription drug order for each drug dispensed. The prescription drug order shall contain the following information:

(a) The name and address of the person for whom the drug is prescribed;

(b) The name, quantity, and strength of such drug;

(c) The directions for taking or giving;

(d) The signature of the practitioner and the date the prescription was written; and

(e) For controlled substance drugs, the name, address, and Drug Enforcement Administration number of the dispensing practitioner.

(2) Documentation required for filling or refilling a prescription drug order. A practitioner who fills or refills a prescription drug order shall write on the prescription itself the date it was filled or refilled and the signature of the practitioner who fills or refills the prescription drug order.

(3) Prescription drug orders dispensed by a practitioner cannot be transferred to another practitioner or pharmacist for subsequent filling.

(4) Retention of records. Prescription drug orders shall be maintained on file by a practitioner for a period of two years from the date the prescription is filled and shall be accessible for inspection by the Board and/or its agents from the Georgia Drugs and Narcotics Agency and its inspectors.

(5) Special requirements for record-keeping and filing of controlled substance prescription drug orders.

(a) Invoices. A record of all controlled substance drugs received and disposed of by a dispensing practitioner must be maintained. All invoices of Schedule II controlled substances must be kept or maintained in a separate file. All invoices for Schedule III, IV or V controlled substances must be kept in or maintained in a separate file, provided that these invoices may be filed with other invoices only if the letter "C" in red ink is stamped on each invoice of Schedule III, IV or V controlled substances so that such invoice shall be easily accessible and retrievable.

(b) Inventory. An inventory of all controlled substances must be maintained separately and taken biennially on May 1st, or two (2) years from the day of the last inventory, of every odd-numbered year.

(c) Files. A prescription drug order for a controlled substance must be filed in one of the following ways:

1. A practitioner can maintain three separate files; one for all Schedule II controlled substances dispensed, one for all Schedule III, IV and V controlled substances dispensed, and one for all dangerous drugs dispensed, or

2. A practitioner can maintain two files, one for Schedule II controlled substances dispensed and one for all other drugs dispensed. If this method is utilized, the prescriptions for Schedule III, IV and V controlled substances must be stamped with the letter "C" in red ink, not less than one inch high, in the lower right-hand corner, so that such records are easily accessible and retrievable, or

3. A practitioner can maintain two files; one for all controlled substance drugs dispensed and one for all dangerous drugs dispensed. If this method is utilized, the prescriptions for Schedule III, IV and V controlled substances must be stamped with the letter "C" in red ink, not less than one inch high, in the lower right-hand corner so that such records are easily accessible and retrievable.

Cite as Ga. Comp. R. & Regs. R. 480-28-.04
Authority: O.C.G.A. Secs. 16-13-34, 16-13-39, 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130.
History. Original Rule entitled "Record-keeping and Filing" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.05. Labeling.

All drugs dispensed by a practitioner must be labeled with the following information:

(a) Date and identifying serial number;

(b) Name of patient;

(c) Name of practitioner prescribing;

(d) Name, address and telephone number of the dispensing practitioner;

(e) Name of drug and strength;

(f) Directions for use to the patient;

(g) The expiration date of the drug; and

(h) Any other information required by the Drug Enforcement Administration or the Food and Drug Administration.

Cite as Ga. Comp. R. & Regs. R. 480-28-.05
Authority: O.C.G.A. Secs. 16-13-34, 26-3-8, 26-4-4, 26-4-28, 26-4-37, 26-4-130.
History. Original Rule entitled "Labeling" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.06. Packaging.

All drugs dispensed by a practitioner must be dispensed in containers which meet the requirements of the Food and Drug Administration and the Consumer Protection Agency, including the use of child-proof and moisture-proof containers.

Cite as Ga. Comp. R. & Regs. R. 480-28-.06
Authority: O.C.G.A. Secs. 16-13-34, 26-3-8, 26-3-16, 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130.
History. Original Rule entitled "Packaging" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.07. Storage.

(1) All practitioners shall exercise diligent care in protecting controlled substance drugs and records possessed from loss or theft. Agents of the Board shall have the responsibility of offering to practitioners written recommendations concerning the satisfactory storage, keeping, handling, and security of such controlled substances and records. When not in actual use, all controlled substance drugs shall be maintained in a place which is secured.

(2) All drugs which bear, or are required to bear, upon the package, the words "Caution, Federal Law Prohibits Dispensing Without Prescription", or "RX only" or words of like import, shall be stored in a secured area by a practitioner possessing such drugs. All drugs shall be stored beyond the normal reach of small children.

(3) There shall be provided within each practitioner's office sufficient space for the neat and orderly storage of all drugs. In addition, there shall be clear floor space within such office to permit a practitioner and his/her assistant employed therein to adequately, safely, and accurately fulfill his/her duties related to prescriptions and drugs.

(4) There shall be provided within each dispensing practitioner's office adequate facilities for the proper storage of drugs which require refrigeration, and such drugs shall be stored therein in such manner as to preserve their therapeutic activity.

(5) No dispensing practitioner shall operate in any manner or dispense any drugs under unclean, unsanitary, overcrowded, or unhealthy conditions, or under any condition which endangers the health, safety, or welfare of the public.

(6) A practitioner shall cause to be removed from stock all outdated and deteriorated drugs, at regular intervals of not more than six months duration, and under no circumstances will any practitioner permit any drug to be dispensed which bears a date of expiration which has been reached, or which is in a deteriorated condition.

Cite as Ga. Comp. R. & Regs. R. 480-28-.07
Authority: O.C.G.A. Secs. 16-13-34, 26-3-16, 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-87, 26-4-130.
History. Original Rule entitled "Storage" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.08. Practitioner's Assistants.

Nothing in these rules shall prohibit any person from assisting any duly licensed practitioner in the measuring of quantities of medication and the typing of labels therefore, but excluding the dispensing, compounding, or mixing of drugs, provided that such practitioner shall be physically present and personally supervising the actions of such person in doing such measuring and typing, and provided, further, that no prescription shall be given to the person requesting the same unless the contents and the label thereof shall have been verified by a licensed practitioner. No practitioner shall be assisted by more than one such person at any one time.

Cite as Ga. Comp. R. & Regs. R. 480-28-.08
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-60, 26-4-85, 26-4-130.
History. Original Rule entitled "Practitioner's Assistants" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.09. Practitioner in Charge of Common Inventory.

Whenever more than one practitioner dispenses drugs from a common inventory, one of the practitioners shall be designated "practitioner in charge" of said inventory. All practitioners in charge shall insure that a complete and accurate record of all controlled substances on hand, received, manufactured, sold, dispensed, or otherwise disposed of has been kept in accordance with the record-keeping requirements of federal law, state law, and the rules of the Board.

Cite as Ga. Comp. R. & Regs. R. 480-28-.09
Authority: O.C.G.A. Secs. 16-13-34, 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-60, 26-4-78, 26-4-130.
History. Original Rule entitled "Practitioner in Charge of Common Inventory" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.10. Loss or Theft of Controlled Substances.

(1) A loss or theft of any controlled substance drugs must, within 48 hours of discovery, be reported to the Board, Drug Enforcement Administration and the GDNA. A written report on DEA Form 106 must be made regarding any theft or loss of any controlled substances. The original and one copy of the report must be sent to the Board, Drug Enforcement Administration and one copy must be sent to the GDNA (40 Pryor Street, #2000, Atlanta, GA 30303) within ten (10) days of the initial receipt of DEA Form 106. The report shall include the following information:

(a) Full name and address of practitioner;

(b) The practitioner's DEA registration number;

(c) The date of theft;

(d) The type of theft;

(e) A list of cost codes, or identification symbols on package(s) stolen; and

(f) A list of controlled substances missing.

Cite as Ga. Comp. R. & Regs. R. 480-28-.10
Authority: O.C.G.A. Secs. 16-13-34, 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-112, 26-4-130.
History. Original Rule entitled "Loss or Theft of Controlled Substances" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-28-.11. Inspection of Records.

The Board, GDNA and their representatives shall have the authority to conduct inspections or audits of all records of drugs received and/or disposed of by any practitioner. The Board or GDNA personnel shall have the authority to examine and copy all such records, and to examine and inventory all controlled substances. It shall be the responsibility of all practitioners possessing such drugs or records to make the same available for such inspection, copying, examination, or inventorying by said Board or GDNA representatives. Any practitioner possessing controlled substances or records may request that such an inspection be made, and upon receipt of such written request, the GDNA Director shall make, or cause to be made, without unreasonable delay, an inspection in compliance with said request.

(a) Every dispensing practitioner shall ensure that all controlled substances and/or dangerous drugs are purchased from and returned to firms that have a current permit issued by the Georgia State Board of Pharmacy. The practitioner shall obtain and maintain a copy of each such firm's current Georgia State Board of Pharmacy permit which shall be made available during any GDNA inspection.

Cite as Ga. Comp. R. & Regs. R. 480-28-.11
Authority: O.C.G.A. Secs. 16-13-34, 26-4-4, 26-4-27 to 26-4-29, 26-4-50, 26-4-115, 26-4-130.
History. Original Rule entitled "Inspection of Records" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Chapter 480-29. PHARMACY PERMITS FOR COLLEGES OF PHARMACY.

Rule 480-29-.01. Definitions.

For purposes of these Rules and Regulations, the following definitions apply:

(a) College of Pharmacy. A school or college of pharmacy located in the State of Georgia and accredited by the American Council on Pharmaceutical Education.

(b) Pharmacy Permit. A permit which is issued by the Georgia State Board of Pharmacy to a pharmacy located within and owned and operated by a college of pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-29-.01
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-114, 26-4-120.1.
History. Original Rule entitled "Definitions" adopted. F. Sept. 19, 1989; eff. Oct. 9, 1989.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-29-.02. Permits Issued to Pharmacies Operated by Colleges of Pharmacy.

(1) A pharmacy located within and owned and operated by a college of pharmacy may apply to the Board for a pharmacy permit in order to purchase, receive, possess, and dispose of drugs utilized solely for educational and research purposes.

(2) An applicant for a pharmacy permit for a college of pharmacy shall complete an application on forms to be provided by the Board. The application shall include the name of a Director of Pharmacy, who shall be responsible for maintaining accurate records regarding the purchase, receipt, possession, and disposal of drugs utilized for educational and research purposes. Applications must be filed with the Board with the required fee every two years.

(3) A pharmacy owned and operated by a college of pharmacy shall be inspected by the Board or its designated agent prior to the issuance of a permit.

Cite as Ga. Comp. R. & Regs. R. 480-29-.02
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-114, 26-4-120.1.
History. Original Rule entitled "Licensure of Pharmacies Operated by Colleges of Pharmacy" adopted. F. Sept. 19, 1989; eff. Oct. 9, 1989.
Repealed: New Rule entitled "Permits Issued to Pharmacies Operated by Colleges of Pharmacy" adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-29-.03. Director of Pharmacy.

Each pharmacy owned and operated by a college of pharmacy shall be directed by a pharmacist, hereinafter referred to as the Director of Pharmacy, who is licensed to engage in the practice of pharmacy in this state and who is knowledgeable and thoroughly familiar with the specialized functions of a pharmacy owned and operated by the college of pharmacy for educational and research purposes. The Director of Pharmacy shall be responsible for maintaining accurate records regarding the purchase, receipt, possession, and disposal of drugs for educational or research purposes.

Cite as Ga. Comp. R. & Regs. R. 480-29-.03
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-114, 26-4-120.1.
History. Original Rule entitled "Director of Pharmacy" adopted. F. Sept. 19, 1989; eff. Oct. 9, 1989.
Repealed: New Rule of same title adopted. F. June 13, 2002; eff. July 3, 2002.

Rule 480-29-.04. Requirements of Holders of Pharmacy Permits for a College of Pharmacy.

(1) Except as provided herein, the holder of a pharmacy permit for a college of pharmacy shall be exempt from requirements otherwise applicable to pharmacies, including but not limited to those contained in Chapter 480-10 of these Rules and Regulations.

(2) The holder of a pharmacy permit for a college of pharmacy shall not engage in the sale or dispensing of drugs.

(3) The Director of Pharmacy shall be responsible for the security and proper storage of all controlled substances and dangerous drugs and shall exercise diligent care in protecting such drugs from loss or theft.

(4) The holder of a pharmacy permit for a college of pharmacy shall comply with all applicable federal laws and regulations regarding the handling of controlled substances.

(5) The Director of Pharmacy shall prepare a policy and procedure manual with respect to the purchase, receipt, possession, and disposal of drugs and their proper security. The

Director of Pharmacy shall make the manual, as well as any other records maintained by the pharmacy owned and operated by the college of pharmacy, available for inspection, copying, or examination by agents of the Board.

(6) A pharmacy owned and operated by a college of pharmacy may be inspected at the discretion of the Board to ensure the continued compliance with applicable law and these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 480-29-.04
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-114, 26-4-120.1.
History. Original Rule entitled "Requirements of Holders of Special Pharmacy Permits" adopted. F. Sept. 19, 1989; eff. Oct. 9, 1989.
Repealed: New Rule entitled "Requirements of Holders of Pharmacy Permits for a College of Pharmacy" adopted. F. June 13, 2002; eff. July 3, 2002.

Chapter 480-30. DISPENSING OF DRUGS UNDER AUTHORITY OF JOB DESCRIPTION OR NURSE PROTOCOL.

Rule 480-30-.01. Definitions.

For purpose of these Rules and Regulations, the following definitions apply:

(a) "Dispensing procedure" means a written document signed by a licensed pharmacist and a licensed practitioner which document establishes the appropriate manner under which drugs may be dispensed under authority of a nurse protocol or job description.

(b) "Drugs" shall mean any dangerous drug under O.C.G.A. §§ 16-13-71, *et seq.*, or, where applicable, any controlled substance under O.C.G.A. §§ 16-13-21, *et seq.*

(c) "Job description" means a document signed by a licensed practitioner that describes the duties which may be performed by a physician's assistant, by which document the physician delegates to that physician's assistant the authority to perform certain medical acts pursuant to O.C.G.A. § 43-34-26.1.

(d) "Nurse protocol" means a document mutually agreed upon and signed by a nurse and licensed physician by which document the physician delegates to that nurse the authority to perform certain medical acts pursuant to O.C.G.A. § 43-34-26.1(b).

Cite as Ga. Comp. R. & Regs. R. 480-30-.01
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-130, 43-34-26.1.
History. Original Rule entitled "Definitions" adopted. F. Mar. 23, 1990; eff. Apr. 12, 1990.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-30-.02. General Requirements.

Any person who dispenses drugs in accordance with a dispensing procedure and under the authority of a job description or nurse protocol shall comply with all record keeping, labeling, packaging, and storage requirements imposed upon pharmacists and pharmacies with regard to such drugs pursuant to O.C.G.A. Title 26, Chapter 4, Title 16, Chapter 13, and those regulations contained in this Chapter.

Cite as Ga. Comp. R. & Regs. R. 480-30-.02
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130, 43-34-26.1.
History. Original Rule entitled "General Requirements" adopted. F. Mar. 23, 1990; eff. Apr. 12, 1990.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-30-.03. Labeling.

All drugs dispensed in accordance with a dispensing procedure and under authority of a job description or nurse protocol must be labeled with the following information:

(a) Date and identifying serial number;

(b) Name of patient;

(c) Name of practitioner prescribing;

(d) The name, address and telephone number of the facility where the drugs are dispensed in accordance with a dispensing procedure and under the authority of a job description or nurse protocol;

(e) Name of drug and strength;

(f) Directions for use to the patient;

(g) The expiration date of the drug; and

(h) Any information required by the Drug Enforcement Administration or the Food and Drug Administration.

Cite as Ga. Comp. R. & Regs. R. 480-30-.03
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130, 43-34-26.1.
History. Original Rule entitled "Labeling" adopted. F. Mar. 23, 1990; eff. Apr. 12, 1990.
Amended: F. Oct. 17, 1990; eff. Nov. 6, 1990.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-30-.04. Packaging.

All drugs dispensed in accordance with a dispensing procedure or under authority of a job description or nurse protocol must be dispensed in containers meeting the requirements of the Food and Drug Administration and the Consumer Protection Agency, including the use of child-proof and moisture-proof containers.

Cite as Ga. Comp. R. & Regs. R. 480-30-.04
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130, 43-34-26.1.
History. Original Rule entitled "Packaging" adopted. F. Mar. 23, 1990; eff. Apr. 12, 1990.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-30-.05. Storage.

(1) Any person dispensing drugs in accordance with a dispensing procedure and under authority of a job description or nurse protocol shall exercise diligent care in protecting drugs and records possessed from loss or theft. Agents of the Georgia Drugs and Narcotics Agency (GDNA) shall have the responsibility of offering to such persons written recommendations concerning the satisfactory storage, keeping, handling, and security of such drugs and records. When not in actual use, all drugs shall be stored in a place which is secured.

(2) All drugs which bear or are required to bear, upon the package, the words,"Caution, Federal Law Prohibits Dispensing Without a Prescription" or words of like import, shall be stored in a secured area. All drugs shall be stored beyond the normal reach of small children.

(3) No person dispensing drugs in accordance with a dispensing procedure and under authority of a job description or nurse protocol shall operate in any manner or dispense any drugs under unclean, unsanitary, overcrowded, or unhealthy conditions, or under any condition which endangers the health, safety, or welfare of the public.

(4) All outdated and deteriorated drugs shall be removed from stock at regular intervals of not more than six months duration, and under no circumstances will any drug be dispensed which bears a date of expiration which has been reached, or is in a deteriorated condition.

Cite as Ga. Comp. R. & Regs. R. 480-30-.05
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130, 43-34-26.1.
History. Original Rule entitled "Storage" adopted. F. Mar. 23, 1990; eff. Apr. 12, 1990.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-30-.06. Inspection of Records.

GDNA agents shall have the authority to conduct inspections or audits of all records of drugs received and/or disposed of by any person dispensing drugs in accordance with a dispensing procedure and under authority of a job description or nurse protocol. GDNA agents shall have

the authority to examine and copy all such records, and to examine and inventory all prescription drug orders.

Cite as Ga. Comp. R. & Regs. R. 480-30-.06
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130, 43-34-26.1.
History. Original Rule entitled "Inspection of Records" adopted. F. Mar. 23, 1990; eff. Apr. 12, 1990.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-30-.07. Submission of Dispensing Procedure for Board Review.

All licensed pharmacists who sign a dispensing procedure must submit such document to the Georgia State Board of Pharmacy for review. Any such dispensing procedure must be in conformity with this Chapter and O.C.G.A. § 43-34-26.1, and shall include the names of all persons dispensing drugs pursuant to such dispensing procedure.

Cite as Ga. Comp. R. & Regs. R. 480-30-.07
Authority: O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-37, 26-4-130, 43-34-26.1.
History. Original Rule entitled "Submission of Dispensing Procedure for Board Review" adopted. F. Mar. 23, 1990; eff. Apr. 12, 1990.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Chapter 480-31. PATIENT COUNSELING.

Rule 480-31-.01. Patient Counseling.

Purpose: The purpose of the regulations issued in this part is to comply with the requirements of the Omnibus Budget Reconciliation Act of 1990 and to enhance the public health and welfare by providing that pharmacists shall offer consultation to patients regarding their medications and various conditions which could affect or be affected by the use of those medications.

(a) Patient Records.

1. A patient record system shall be maintained by all pharmacies for patients for whom Prescription Drug Orders are dispensed. For purposes of the regulations under this part,"Prescription Drug Order" is defined to mean the lawful order of a Practitioner for a Drug or Device for a specific patient. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The Pharmacist or his designee shall make a reasonable effort to obtain, record, and maintain the following information:

   (i) full name of the patient for whom the Drug is intended.

(ii) address and telephone number of the patient;

(iii) date of birth; and

(iv) patients gender.

2. The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs, or devices currently being used by the patient which may relate to Prospective Drug Review unless the patient or the patient's agent refuses such information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

   (i) A list of all Prescription Drug Orders obtained by the patient at the Pharmacy where the Prescription Drug Order is being filled within the preceding two years, showing prescription number, name and strength of the Drug, the quantity and date dispensed, the name of the Practitioner; and

   (ii) comments from the Pharmacist relevant to the individual's drug therapy, including any other information peculiar to the specific patient or Drug.

3. A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(b) Prospective Drug Review.

1. A pharmacist shall review the patient record and each Prescription presented for Dispensing for purposes of promoting therapeutic appropriateness by identifying:

   (i) over-utilization or under-utilization;

   (ii) therapeutic duplications;

   (iii) drug-disease contraindications;

   (iv) Drug-Drug interactions;

   (v) incorrect Drug dosage or duration of Drug treatment;

   (vi) Drug-allergy interactions;

   (vii) clinical abuse/misuse.

2. Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(c) Patient Counseling.

1. Upon receipt of a Prescription Drug Order and following a review of the patient's record, the dispensing Pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling, based on the professional judgment of the pharmacist. Such elements may include but are not limited to the following:

   (i) the name and description of the Drug;

   (ii) the dosage form, dose, route of Administration, and duration of drug therapy;

   (iii) intended use of the Drug and expected action;

   (iv) special directions and precautions for preparation, Administration, and use by the patient;

   (v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

   (vi) techniques for self-monitoring drug therapy;

   (vii) proper storage;

   (viii) prescription refill information;

   (ix) action to be taken in the event of a missed dose; and

   (x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

2. Additional forms of patient information shall be used to supplement Patient Counseling when appropriate.

3. Patient Counseling, as described above and defined in the Act, shall not be required for:

   (i) in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(ii) inmates of correctional institutions where pharmacy services are provided by the Georgia Department of Corrections or by county or municipal political subdivisions either directly or by a subcontractor of the above; or

(iii) patients receiving drugs from the Georgia Department of Human Resources Division of Public Health; provided however, that pharmacists who provide medications to patients in accordance with Section 43-34-26.1 of the Official Code of Georgia Annotated shall include in all dispensing procedures a written process whereby the patient or the caregiver of such patient is provided with the information contained in Chapter 480-31 of the Rules of the Georgia State Board of Pharmacy.

(iv) refills of prescription drug orders for which, in the professional judgment of the Pharmacist, appropriate counseling has taken place or has been declined. The need for counseling on refills resides in the professional judgment of the dispensing Pharmacist.

4. A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

5. These rules will become effective January 1, 1993.

(d) Nothing in these rules shall be interpreted so as to prohibit the pharmacist from being remunerated for said professional services.

Cite as Ga. Comp. R. & Regs. R. 480-31-.01
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-80, 26-4-85.
History. Original Rule entitled "Patient Counseling" adopted. F. Nov. 24, 1992; eff. Jan. 1, 1993, as specified by the Agency.
Amended: F. Nov. 6, 1995; eff. Nov. 26, 1995.
Amended: F. Jan. 23, 2009; eff. Feb. 12, 2009.

Chapter 480-32. REPEALED.

Rule 480-32-.01. Repealed.

Cite as Ga. Comp. R. & Regs. R. 480-32-.01
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 50-13-2.
History. Original Rule entitled "Electronic Transfer of Prescriptions" adopted. F. Feb. 10, 1993; eff. Mar. 2, 1993.
Amended: F. July 6, 1995; eff. July 26, 1995.
Repealed: F. Aug. 18, 2006; eff. Sept. 7, 2006.

Chapter 480-33. OUTPATIENT CLINIC PHARMACIES.

Rule 480-33-.01. Definitions.

For purposes of these Rules and Regulations, the following definitions apply:

(1) Outpatient Clinic. An outpatient clinic shall be defined as a health care facility or location, other than a medical practitioner's office, providing outpatient treatment or case such as, but not limited to, an outpatient surgery center, outpatient urgent care center, infusion treatment center, or ambulatory care center.

(b) Outpatient Clinic Pharmacy. An outpatient clinic pharmacy shall be defined as that part of an outpatient clinic health care facility engaged in the practice of pharmacy.

(c) Outpatient Clinic Pharmacy License. An outpatient clinic pharmacy license shall be defined as a pharmacy license issued by the Georgia State Board of Pharmacy to Clinic pharmacies, pursuant to the provisions of O.C.G.A. Title 26, Chapter 4, whereas the licensee shall be subject to special outpatient clinic pharmacy regulations as set forth herein, but exempt from other certain regulations and requirements.

(d) Outpatient. An outpatient shall be defined as an ambulatory patient who comes to an outpatient clinic to receive health care services related to the objectives of the outpatient clinic and departs within 24 hours.

(e) Standard Ward Inventory. The pharmacist-in-charge of the outpatient clinic pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of drugs to be kept at one or more locations at all times within the outpatient clinic and such stocks of drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the pharmacist-in-charge or his/her pharmacist designee.

(f) Outpatient Prescription. An outpatient prescription shall be defined as a prescription drug order prescribed by a medical practitioner engaged in the practice of that clinic and prescribed for services received in that clinic in conjunction with health care services related to the objectives of that clinic.

Cite as Ga. Comp. R. & Regs. R. 480-33-.01
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-100, 26-4-110.
History. Original Rule entitled "Definitions" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-33-.02. Licensure and Registration.

(1) All outpatient clinic pharmacies shall renew biennially by June 30th of each odd numbered year with the Georgia State Board of Pharmacy. Certificates of registration shall be issued to outpatient clinic pharmacies which meet the requirements for licensure and which comply with Chapter 480-33 of the Rules of the Georgia State Board of Pharmacy.

(2) Minimum Required Information for Licensure. The Board requires the following information from each outpatient clinic pharmacy as part of the initial licensing procedure and as part of each renewal of such license. The name, complete street address for the business (i.e., geographic location), and telephone number of the applicant/ licensee. All trade or business names used by the applicant/licensee. Address, telephone numbers, and the name(s) of the clinic administrator;

(a) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(b) The name(s) of the owner and/or operator of the applicant/licensee, including:

1. If a sole proprietorship, the complete name of the proprietor;

2. If a partnership, the complete name of each partner, and the name of the partnership;

3. If a corporation, the name and title of each corporate officer and director, the corporate name and the state of incorporation, and the name of the parent company, if any.

(i) Where operations are conducted at more than one location by a single outpatient clinic pharmacy, each such location shall be licensed by the Board.

(ii) Applications for Licensure.

(I) Registration of an outpatient clinic pharmacy shall be considered filed with the Board when an application is received by the Board, a fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying that the applicant possesses the necessary qualifications for a license.

(II) Application fees shall not be refundable.

(III) Licenses shall become null and void upon the sale, transfer or change of mode of operation or location of the business.

(IV) Licenses are renewed for two year periods and expire on June 30th of each odd numbered year and may be renewed

upon the payment of the required fee for each place of business and the filing of an application for renewal. If the application for renewal is not filed with the Board and the fee paid before September 1st, of each odd numbered year, the license shall lapse and may not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

(V) Changes in any information in this section shall be submitted to the Board prior to such change.

(iii) Minimum Qualifications.

(I) To obtain an outpatient clinic pharmacy license, the outpatient clinic pharmacy must employ a pharmacist-in-charge.

(II) The Board shall consider the following factors in determining eligibility for licensure for each person(s) in charge of the facility when considering an application for an outpatient clinic pharmacy license:

I. Any convictions of the applicant under any Federal, State, or local laws relating to drugs, wholesale or retail drug distribution, or distribution of controlled substances;

II. Any felony convictions of the applicant under any Federal, State, or local laws;

III. The furnishing by the applicant of false or fraudulent material or information in any application;

IV. Suspension or revocation of Federal, State, or local government of any pharmacist, pharmacy or other healthcare license currently or previously held by the applicant;

V. Failure to comply with any licensing requirements under a previously held license, if any;

VI. Failure to comply with any requirements to maintain and/or make available to the state licensing authority

or to Federal, State, or local law enforcement officials, any records required to be maintained by outpatient clinic pharmacies;

VII. Other factors or qualifications the Board considers relevant to and consistent with the public's health and safety; and

VIII. The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

(3) An outpatient clinic pharmacy registered with the Board shall not be authorized to dispense refills on prescription drug orders.

(4) Nothing in these regulations shall be construed to prohibit an outpatient clinic from applying for a retail pharmacy license as provided for in O.C.G.A. §§ 26-4-110 and Rule 480-6-.01. Any retail pharmacy located in an outpatient clinic holding a retail pharmacy license, shall comply with all the laws, rules and regulations applicable to such licensed retail pharmacy.

(5) Nothing herein shall be construed to interfere with a practitioner of the healing arts practicing as authorized by law.

Cite as Ga. Comp. R. & Regs. R. 480-33-.02
Authority: O.C.G.A. §§ 26-4-20, 26-4-27, 26-4-28, 26-4-37, 26-4-60, 26-4-100, 26-4-110, 26-4-111, 43-1-4, 43-1-7, 43-1-19.
History. Original Rule entitled "Registration" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule entitled "Licensure and Registration" adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: F. June 29, 2015; eff. July 19, 2015.

Rule 480-33-.03. Personnel.

The Personnel shall be as follows:

(a) Pharmacist-in-charge. Each outpatient clinic pharmacy shall be directed by a pharmacist, hereinafter referred to as the pharmacist- in-charge, who is licensed to engage in the practice of pharmacy in this State, and who is knowledgeable in and thoroughly familiar with the specialize functions of outpatient clinic pharmacies. The pharmacist-in-charge shall be responsible for all activities of the outpatient clinic pharmacy, and for meeting

the requirements of the Georgia Pharmacy Laws and Rules and Regulations of the Georgia State Board of Pharmacy. The pharmacist-in-charge shall be employed on a full-time or part-time basis consistent with the needs and objections of the outpatient clinic.

(b) Supportive personnel. The pharmacist-in-charge of an outpatient clinic pharmacy shall be assisted by a sufficient number of additional pharmacists and non-licensed personnel, in ratios consistent with state law and Board Rules as may be required to operate such pharmacy competently, safely, and to meet the needs of the patients of the clinic facility.

1. The pharmacist-in-charge shall insure that non-licensed personnel shall be adequately trained. The pharmacist-in-charge shall develop and implement written policies and procedures to specify the duties to be performed by such non-licensed personnel. These policies and procedures shall, at a minimum, specify that non-licensed personnel are personally and directly supervised by a licensed pharmacist and that non-licensed personnel are not assigned duties which may be performed only by licensed pharmacists.

2. Secretarial and clerical personnel shall be provided as required to assist with record-keeping, report submission, and other administrative duties, provided such personnel do not perform any dispensing duties.

3. Supervision. All of the activities and operations of each outpatient clinic pharmacy shall be personally and directly supervised by the pharmacist-in-charge or his/her pharmacist designee. All functions and activities of non-licensed personnel shall be personally and directly supervised by an adequate number of licensed pharmacists to insure that all such functions and activities are performed competently, safely, and without risk of harm to patients. Personal supervision can only be accomplished by the physical presence of a licensed pharmacist in the clinic pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-33-.03
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-82, 26-4-100, 26-4-110.
History. Original Rule entitled "Personnel" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-33-.04. Absence of Pharmacist.

The following regulations shall be followed in the absence of a pharmacist:

(a) General. When a licensed pharmacist is not physically present in the clinic pharmacy, written policies and procedures shall be prepared in advance by the pharmacist-in-charge for the provision of drugs to the medical staff and other authorized licensed personnel of the clinic by use of after hours cabinets or containers and/or by access to the pharmacy.

(b) After hours cabinets or containers. Access to drugs, in the absence of a licensed pharmacist, shall be by locked cabinet(s) or other enclosure(s) or container(s) constructed and located outside of the pharmacy area to which only specifically authorized licensed clinic personnel as indicated by written policies and procedures may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the outpatient clinic facility, develop inventory listings of those drugs to be included in such cabinet(s), enclosure(s) or container(s) and shall insure that:

1. Such drugs available are properly labeled, with drug name, strength, lot number and expiration date;

2. Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

3. Whenever access to such cabinet(s), enclosure(s) or container(s) shall have been gained, written practitioner's orders and proof of use for controlled substances are provided;

4. All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and

5. Written policies and procedures are established to implement the requirements of this subsection.

(c) Access to pharmacy. Whenever any drug is not available from standard ward inventories or after hours cabinet(s), container(s) or enclosure(s) and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy pursuant to the practitioner's order and the requirements of this subsection. One licensed health care professional as designated in the policies and procedures may have access to the pharmacy and may remove drugs therefrom. Such licensed health care professional shall be designated in writing by the pharmacist-in-charge of the outpatient clinic pharmacy and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be given by the pharmacist-in-charge who shall require, at a minimum, the following records and procedures:

1. Removal of any drug from the pharmacy by an authorized licensed health care professional must be recorded on a suitable form showing name of drug, strength, amount, date, time and signature of the designated licensed health care professional;

2. The container from which the drug is removed shall be placed conspicuously in the pharmacy to be promptly reviewed and inspected by a pharmacist.

(d) Emergency kits. Drugs may be provided for use by authorized health care personnel by emergency kits, provided such kits meet the following requirements:

1. Emergency kit drugs defined. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source within the clinic in sufficient time to prevent risk of harm to patients;

2. Drugs included. The pharmacist-in-charge and the medical staff of the clinic shall jointly determine the drugs, by identity and quantity, to be included in emergency kits;

3. Storage. Emergency kits shall be locked and stored in limited access areas to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them;

4. Labeling - exterior. The exterior of emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by the Board, the GDNA or one of their agents;

5. Labeling - interior. All drugs contained in emergency kits shall be labeled in accordance with such State and Federal Laws and Regulations which pertain thereto; and shall also be labeled with such other and further information as may be required by the medical staff of the clinic to prevent misunderstanding or risk of harm to the patients;

6. Removal of drugs. Drugs shall be removed from emergency kits only pursuant to a valid prescription drug order of an authorized prescribing practitioner, by authorized clinic personnel, or by a pharmacist of the clinic facility;

7. Notification. Whenever an emergency kit is opened, the pharmacy shall be notified; and the pharmacy shall replace or re-stock and re-seal the kit within a reasonable time so as to prevent risk of harm to patients. In the event the kit is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

8. Inspections. Each emergency kit shall be opened and its contents inspected by the pharmacy at least once every ninety (90) days. Upon completion of inspection, the emergency kit shall be resealed.

9. Procedures. The pharmacist-in-charge shall, in conjunction with the medical staff of the clinic, develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

(e) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be posted or readily available in areas outside the pharmacy where these drugs are stored or patients are being cared for.

Cite as Ga. Comp. R. & Regs. R. 480-33-.04
Authority: O.C.G.A. Secs. 26-3-16, 26-4-27, 26-4-28, 26-4-37, 26-4-100, 26-4-110.
History. Original Rule entitled "Absence of Pharmacist" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-33-.05. Physical Requirements.

(1) Area. An outpatient clinic pharmacy shall have within the clinic which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this section and the Georgia Pharmacy Laws. The outpatient clinic pharmacy space requirements shall be a minimum of 150 square feet. Such space shall include all areas which are assigned and under the direct control of the pharmacist-in-charge.

(2) Minimum Equipment. No outpatient clinic pharmacy licensed in accordance with Title 26, Chapter 4 of the Official Code of Georgia Annotated shall engage in the practice of filing, compounding or dispensing prescription drugs unless it shall possess the following items:

(a) Copies of and/or electronic access to current reference materials appropriate to the individual pharmacy practice. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(b) The telephone number of a poison control center. This number shall be conspicuously posted within the pharmacy and at other locations within the clinic facility.

(c) Current copies of or computer or electronic access to the following:

1. The Georgia Pharmacy Practice Act, O.C.G.A. Title 26, Chapter 4;

2. The Georgia Controlled Substances Act/Dangerous Drug Act, O.C.G.A. Title 16, Chapter 13;

3. Official Rules of the Georgia State Board of Pharmacy.

(d) Equipment (appliances):

1. Refrigerator in operating condition and a thermometer; and

2. Sink in working condition with both hot and cold running water.

(e) Weighing and labeling:

1. If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance;

2. Appropriate prescription labels consistent with the requirements of the Georgia Drug and Cosmetic Act, O.C.G.A. Title 26, Chapter 3; and

3. Appropriate auxiliary labels that should be used in the pharmacist's professional judgment.

(f) Other equipment;

1. Graduates of assorted sizes;

2. Two mortars and pestles of assorted sizes;

3. Two spatulas;

4. One oral solid counting tray;

5. Ointment slab, tile or ointment paper pad;

6. Typewriter, word processor or computer with label printer; and

7. Any other equipment necessary for a specialized practice setting where such a specialized practice takes place.

(g) Adequate supply of drugs most commonly prescribed.

(h) Assorted sizes and types of appropriate dispensing containers.

(3) Variances.

(a) The pharmacist-in-charge in an outpatient clinic facility may submit to the Georgia State Board of Pharmacy a typed request for a variance to these provisions relating to minimum equipment requirements. The reasons for the request for the variance must be included in the submitted request. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for doing so that relate to the necessary or efficient delivery of health care. After consideration by the Board, the requester will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as the proof of the Board's approval for the variances indicated in the letter, and must be posted next to the facility's inspection report.

(4) The compounding, admixture, and quality control of large volume parenterals is the responsibility of a pharmacist and shall be prepared under a laminar flow hood within the pharmacy. Other licensed healthcare professionals who are authorized by law to prepare or administer large volume parenterals must have special training to do so. These functions of compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas, emergency situations, and during unattended hours of the pharmacy department. The pharmacist-in-charge shall be responsible for providing written guidelines and for approving the procedure to assure that all pharmaceutical requirements are met when any part of the above functions (preparing, sterilizing and labeling parenteral medications and solutions) is performed within the clinic by other licensed healthcare professionals who are authorized by law to prepare parenteral medications and solutions.

(5) Storage. All drugs shall be stored in designated areas within the clinic pharmacy which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage areas shall be locked or otherwise secured when health care professionals are not present.

(6) Controlled drug storage for Schedule II drugs. An enclosed controlled room or space with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet that can be locked and that is permanently affixed to the structure is acceptable.

(7) Unattended areas. Whenever any area of a clinic pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.

(8) Security. All areas occupied by a clinic pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel by force. The director of pharmacy shall designate in writing, the name and specific area, of persons who shall have access to particular areas within the pharmacy. These areas shall meet the security requirements of Federal and State Laws and Regulations. Only those persons so authorized shall be permitted to enter these areas.

Cite as Ga. Comp. R. & Regs. R. 480-33-.05
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-37, 26-4-100, 26-4-110, 26-4-111, 50-13-9.1.
History. Original Rule entitled "Physical Requirements" adopted. F. June 7, 1995; eff. June 27, 1995.
Amended: F. Sept. 19, 1998; eff. Oct. 19, 1998.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.
Amended: F. Apr. 13, 2021; eff. May 3, 2021.

Rule 480-33-.06. Drug Distribution and Control.

(1) General. A drug distribution system is the entirety of that mechanism by which a prescription drug order is executed, from the time the practitioner transmits the order either orally, in writing, or electronically to an authorized health professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration.

(2) Responsibility. The pharmacist-in-charge shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the clinic shall cooperate with the pharmacist-in-charge in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials so as to achieve this purpose. The pharmacist-in-charge shall establish written procedures for the distribution of medications including standard ward inventory, emergency kits, etc. to achieve this goal.

(a) The drugs must be identified up to the point of administration;

(b) The pharmacy must receive a direct, electronic (only for drugs to be administered on site) or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by the clinic stat order policy;

(c) Records of all transactions of the clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials within the scope of the clinic practice. Nothing in this section shall prohibit the use of computerized records, where such records meet all other requirements of the law. If an outpatient clinic pharmacy elects to dispense prescription medications other than outpatient prescriptions as defined herein, the pharmacy must meet all applicable State and Federal Laws and regulations and must also obtain a retail pharmacy permit; and

(d) Participation in those aspects of the clinic patient care evaluation program which relate to pharmaceutical material utilization and effectiveness.

(3) Labeling.

(a) For use inside the clinic, all drugs dispensed by a clinic pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.

(b) Drugs added to parenteral admixtures. Wherever any drugs are added to parenteral admixtures, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time, if applicable, and identity of person preparing the admixture.

(4) Discontinued drugs. The pharmacist-in-charge shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(5) Accountability of controlled drugs.

(a) Proof of use of controlled drugs on standard ward inventory and/or those issued for a specific patient. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the clinic, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:

1. Drug name, strength, and dosage form;

2. Dose;

3. Name of prescriber. This shall include, at a minimum, the given and last name;

4. Given and last name of patient;

5. Date and time of administration to patient;

6. Signature of individual administering, which shall include at a minimum, the initial, last name and title;

7. Documentation by two signature verifications of destruction of all unused portions;

8. Proof of receipt of medications that bears identifying serial numbers; and

9. Date medication was issued and the date that the proof of use form was returned.

(b) Anesthesia, surgical, diagnostic and treatment departments that obtain controlled drugs from the clinic pharmacy must show accountability of the controlled drugs by proof of use as defined above.

(c) Use of computer hard copy is permitted where such copy meets all other requirements of the law.

(d) Any outpatient clinic pharmacy licensed by the Georgia State Board of Pharmacy in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:

1. The controlled substance is the remainder of a single-dose unit; and

2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.

(e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.

(f) Recall. The pharmacist-in-charge shall develop and implement a recall policy and procedure to assure that all drugs within the clinic included on the recall are returned to the pharmacy for proper disposition.

(g) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering practitioner, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's record shall also be made.

(h) Records and reports. The pharmacist-in-charge shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board or its agents. These shall include, at a minimum, the following:

1. Patient profile, chart or other appropriate record;

2. Proof of use forms for controlled substances;

3. Reports of suspected adverse drug reactions;

4. Inventories of night cabinets, cabinets or enclosures; emergency drug kits; and standard ward inventories;

5. Inventories of the pharmacy;

6. Biennial controlled substances inventories;

7. Alcohol and flammables reports; and

8. Such other records and reports as may be required by law and the rules and regulations of the Georgia State Board of Pharmacy.

(i) Standard Ward Inventory. The outpatient clinic pharmacy may distribute drugs within a clinic for the purpose of establishing and/ or maintaining a standard ward inventory. Such drugs may be supplied only upon a signed requisition from an authorized licensed health care professional of said clinic or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order and shall be documented in the patient's record. A record of drugs administered to patients in ancillary areas such as surgical suite, treatment

rooms, anesthesiology and diagnostic areas will become a part of the patient's record and shall be retrievable by the pharmacy. A survey of usage trends of each standard ward inventory shall be made monthly. Such records shall be maintained for a period of two years.

(j) Security of controlled substances. Controlled drugs that are maintained as authorized standard ward inventory in patient care/ treatment areas outside the pharmacy shall be stored in secured cabinets or areas that provide a double lock system.

Cite as Ga. Comp. R. & Regs. R. 480-33-.06
Authority: O.C.G.A. Secs. 16-13-39, 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-37, 26-4-82, 26-4-100, 26-4-110.
History. Original Rule entitled "Drug Distribution and Control" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-33-.07. Administration of Drugs. General.

Drugs shall be administered only upon the orders of those members of the medical staff who have been granted staff privileges. Drugs shall be administered by authorized licensed personnel in accordance with policies and procedures specified by the appropriate committee of the facility, under applicable laws and rules and regulations, and by usual and customary standards of good medical practice.

Cite as Ga. Comp. R. & Regs. R. 480-33-.07
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-100.
History. Original Rule entitled "Administration of Drugs" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule entitled "Administration of Drugs, General" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-33-.08. Medications from Outside Sources Brought by Patients.

The pharmacist-in-charge shall establish procedures relating to medications brought into the clinic. Such drugs shall not be administered unless they can be precisely identified. Administration shall be pursuant to an authorized practitioner's prescription drug order only. If such medications are not to be administered, the medication shall be returned to an adult member of the patient's immediate family or stored by the pharmacy and returned to the patient at the time of his/her departure from the clinic. Nothing in this section shall prohibit another method of accomplishing the intent of this section provided such method is approved by an agent of the Georgia State Board of Pharmacy. These medications shall not be maintained in any of the ancillary areas of the clinic.

Cite as Ga. Comp. R. & Regs. R. 480-33-.08
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-100, 26-4-110.
History. Original Rule entitled "Medications from Outside Sources" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule entitled "Medications from Outside Sources Brought by Patients" adopted. F. July 24, 2002;

eff. Aug. 13, 2002.

Rule 480-33-.09. Investigational Drugs.

Investigational drugs shall be properly labeled. Investigational drugs shall be dispensed and administered by the pharmacist in accordance with an approved protocol that includes any requirements for a patient's appropriate informed consent. Nurses may administer such drugs only after they have been educated by the practitioner or the pharmacist. A central unit shall be maintained by the pharmacy wherein essential information regarding such drugs may be obtained. Investigational drugs in use shall be properly stored, distributed, and controlled maintaining the confidentiality of patient-medical staff information. The pharmacist-in-charge shall be responsible for policies and procedures concerning the use of investigational drugs.

Cite as Ga. Comp. R. & Regs. R. 480-33-.09
Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-37, 26-4-100, 26-4-110.
History. Original Rule entitled "Investigational Drugs" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Rule 480-33-.10. Inspections.

(1) Monthly. The pharmacist-in-charge shall no less than once per month, personally or by qualified designee, inspect all matters within his/her jurisdiction and responsibility and make appropriate written records of such inspections. Such inspections shall, at a minimum, verify that:

(a) Drugs are dispensed only by licensed pharmacists;

(b) Pharmacy personnel are properly directed and supervised;

(c) Drugs for external use are stored separately and apart from drugs for oral internal use or injection;

(d) Drugs requiring special storage conditions to insure their stability are properly stored;

(e) No outdated drugs are stocked in the outpatient clinic pharmacy or the facility it serves;

(f) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and medical personnel;

(g) Standard Ward Inventory. Verification of standard ward inventory lists and accountability, including such updating if applicable are maintained;

(h) All necessary and required security and storage standards are met;

(i) Metric-apothecary weight and measure conversion tables and charts and compatibility charts are available;

(j) All policies and procedures of the director of pharmacy and of appropriate committees of the clinic relevant to the pharmacy are being followed;

(k) All discontinued and out-dated medications are returned to the pharmacy for proper disposition; and

(l) Disinfectants and other similar supplies intended for external use are stored separately and apart from drugs for oral internal use or for parenteral injection.

(2) Board Inspection. The agents of the Georgia Drugs and Narcotics Agency (GDNA) will conduct inspections on behalf of the Georgia State Board of Pharmacy. Such inspections shall be conducted no less than once every two years and cover all aspects of the management and operation of all outpatient clinic pharmacies in this State to verify compliance with the law, these rules and regulations of the Georgia State Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety, and welfare of patients of the clinic serviced by the pharmacy are protected. A written report shall be filed with the GDNA, the pharmacist- in-charge, and the clinic administrator. Any discrepancies or deficiencies noted shall be corrected within a reasonable time. Written notice of such corrections or a plan of action to correct deficiencies shall be filed with the Georgia State Board of Pharmacy and GDNA within thirty (30) days after receipt of the inspection report.

(a) Every registrant should ensure that all controlled substances and/or dangerous drugs are purchased from and returned to firms currently licensed by the Georgia State Board of Pharmacy. This requirement shall be met by obtaining and maintaining a copy of each such firm's current Georgia Board permit.

Cite as Ga. Comp. R. & Regs. R. 480-33-.10
Authority: O.C.G.A. Secs. 26-3-16, 26-4-27, 26-4-28, 26-4-37, 26-4-100, 26-4-110, 26-4-115.
History. Original Rule entitled "Inspection" adopted. F. June 7, 1995; eff. June 27, 1995.
Repealed: New Rule entitled "Inspections" adopted. F. July 24, 2002; eff. Aug. 13, 2002.

Chapter 480-34. CONTROLLED SUBSTANCES.

Rule 480-34-.01. Carisoprodol.

This rule was adopted to protect the health, safety, and welfare of the public. This rule places Carisoprodol (known as Soma) under Schedule IV, of the Georgia Controlled Substances Act, Code Section 16-13-28(a)(2-25). The Board finds that:

(a) Carisoprodol has a high potential for abuse;

(b) It appears to have an addictive effect on the human body;

(c) It is regarded as a threat to public health and safety by other states, as well as the U.S. Drug Enforcement Administration;

(d) It has a history of increasing abuse;

(e) The abuse and need to obtain the drug results in multiple uses and combinations, and multiple violations of the law;

(f) It has the same risk the public health of the citizens of the state of Georgia as any substance already contained in the Controlled Substances Act;

(g) It has shown great potential for physiological dependence;

(h) It is not a precursor of a substance already scheduled in Georgia;

(i) It is about to be placed under Schedule IV of the federal Controlled Substances Act.

Cite as Ga. Comp. R. & Regs. R. 480-34-.01
Authority: O.C.G.A. Sec. 16-13-22.
History. Original Rule entitled "Carisoprodol" adopted. F. Jul. 8, 1996; eff. Jul. 28, 1996.

Rule 480-34-.02. Ketamine.

This rule was adopted to protect the health, safety, and welfare of the public. This rule places Ketamine under Schedule III of the Georgia Controlled Substances Act, Code Section 16-13-27(8). The Board finds:

(a) that Ketamine has an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of Ketamine demonstrate that the public would be at risk if it is not regulated as a controlled substance;

(c) that the pattern of abuse of Ketamine and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of Ketamine;

(e) that Ketamine has the same risk to the public health of citizens of the State of Georgia as any substance already contained in the Controlled Substances Act;

(f) that Ketamine has no known precursor already scheduled under the Act; and

(g) that the DEA has filed the intent to add Ketamine to the Federal Controlled Substances Act under Schedule III.

Cite as Ga. Comp. R. & Regs. R. 480-34-.02
Authority: O.C.G.A. Secs. 26-4-37, 16-13-22, 50-13-4.
History. Original Rule entitled "Ketamine" adopted. F. Sept. 26, 1997; eff. Oct. 16, 1997.

Rule 480-34-.03. Sodium Oxybate.

This Chapter was adopted to protect the health, safety, and welfare of the public. This Chapter places Sodium Oxybate (known as Xyrem) that is contained in a drug product for which an application has been approved under Section 505 of the Federal Food, Drug and Cosmetic Act under Schedule III, of the Georgia Controlled Substances Act, Code Section 16-13-28(a)(2-25). The Board finds that:

(a) Sodium Oxybate has a high potential for abuse;

(b) It appears to have an addictive effect on the human body;

(c) It is regarded as a threat to public health and safety by other states, as well as the U.S. Drug Enforcement Administration;

(d) It has a history of increasing abuse;

(e) The abuse and need to obtain the drug results in multiple uses and combinations, and multiple violations of the law;

(f) It has the same risk to the public health of the citizens of the state of Georgia as any substance already contained in the Controlled Substances Act;

(g) It has shown great potential for physiological dependence;

(h) It is not a precursor of a substance already scheduled in Georgia;

(i) It is about to be placed under Schedule III of the federal Controlled Substances Act.

Cite as Ga. Comp. R. & Regs. R. 480-34-.03
Authority: O.C.G.A. Secs. 16-13-22, 26-4-27, 26-4-28.
History. Original Rule entitled "Sodium Oxybate" adopted. F. Jan. 3, 2003; eff. Jan. 23, 2003.

Rule 480-34-.04. Synthetic Cannabinoids.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places newly identified compounds, including any material, compound, mixture, or preparation which contains these substances or their derivatives, salts, isomers, or salts of isomers, halogen analogues, and/or homologues, collectively known as Synthetic Cannabinoids, under Schedule I, of the Georgia Controlled Substances Act, Code Section 16-13-25(12)as follows:

(M) (1-Pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl) methanone (UR-144)

(N) [1-(5-fluoropentyl)indole-3yl]-(2,2,3,3-tetramethylcyclopropyl) methanone (XLR11)

(O) [1,1'-biphenyl]-3-yl-carbamic acid, cyclohexyl ester (URB602)

(P) [1-(2-morpholin-4-ylethyl)-1H-indol-3-yl]-(2,2,3,3-tetramethylcyclopropyl) methanone (A-796,260)

(Q) [3-(3-carbamoylphenyl)phenyl] N-cyclohexylcarbamate (URB597).

(R) 6-methyl-2-[(4-methylphenyl)amino]-1-benzoxazin-4-one (URB754)

(S) 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide (AKB48)

(T) 1-pentyl-3-(1-adamantylamido)indole (2NE1)

(U) 1-(5-fluoropentyl)-N-tricyclo[3.31.13,7]dec-1-yl-1H-indole-3-carboxamide (STS-135)

(V) 1-naphthalenyl[4-(pentylox)-1-naphthalenyl]-methanone (CB-13)

(W) (1-(5-chloropentyl)indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (5-Chloro-UR-144)

(X) (1-(5-bromopentyl)indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (5-Bromo-UR- 144)

(Y) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indole-3-carboxamide (ADBICA)

(Z) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5-Fluoro-ADBICA)

(aa) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5fluoro-ABICA)

(bb) (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (FUB-144)

(cc) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5-fluoro-ABICA);

(dd) 1-naphthalenyl(1-pentyl-1H-indazol-3-yl)-methanone (THJ 018);

(ee) 1-(cyclohexylmethyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (BB-22);

(ff) Naphthalene-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (NM2201).

(2) This rule is based on the following findings of the Board:

(a) that Synthetic Cannabinoids have an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act;

(f) that these compounds have no known precursor already scheduled under the Act; and

(g) that the DEA encourages all states to add these compounds to their respective Controlled Substances Acts while DEA follows its procedures to add such compounds to the Federal Controlled Substances Act under Schedule I.

Cite as Ga. Comp. R. & Regs. R. 480-34-.04
Authority: O.C.G.A §§ 16-13-22, 26-4-28, 50-13-4.
History. Emergency Rule adopted. F. Jun. 12, 2012; eff. Jun. 11, 2012. Original Permanent Rule entitled "Synthetic Cannabinoids" adopted. F. Aug. 16, 2012; eff. Sep. 5, 2012.
Repealed: New rule with same title adopted. F. Nov. 16, 2012; eff. Dec. 6, 2012.
Amended: F. Oct. 15, 2013; eff. Nov. 4, 2013.
Amended: F. Dec. 19, 2013; eff. Jan. 8, 2014.
Amended: F. Jul. 17, 2014; eff. Aug. 6, 2014.
Amended: F. Nov. 26, 2014; eff. Dec. 16, 2014.
Amended: F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-34-.05. Synthetic Cathinones.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places an additional newly identified compound, including any material, compound, mixture, or preparation which contains these substances or their derivatives, salts, isomers, or salts of isomers, halogen analogues, or homologues, collectively known as a Synthetic Cathinone, under Schedule I, of the Georgia Controlled Substances Act, Code Section 16-13-25(12)as follows:

(aa) N-acetyl-3,4-methylenedioxymethcathinone

(2) This rule is based on the following findings of the Board:

(a) that Synthetic Cathinones have an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act;

(f) that these compounds have no known precursor already scheduled under the Act; and

(g) that the DEA encourages all states to add these compounds to their respective Controlled Substances Acts while DEA follows its procedures to add such compounds to the Federal Controlled Substances Act under Schedule I.

Cite as Ga. Comp. R. & Regs. R. 480-34-.05
Authority: O.C.G.A. §§ 16-13-22, 16-13-25, 26-4-27 and 26-4-28.
History. Original Rule entitled "Synthetic Cathinones" adopted. F. Dec. 19, 2013; eff. Jan. 8, 2014.

Rule 480-34-.06. Hydrocodone Combination Products.

(1) Effective October 6, 2014, Official Code of Georgia Annotated (O.C.G.A.) §§ 16-13-27(4)(C), 16-13-27(4)(D) are hereby removed from Schedule III of the Georgia Controlled Substances Act, O.C.G.A. 16-13-25, et. seq. The following language shall be deleted from O.C.G.A. §§ 16-13-27(4): "(C) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than

15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; (D) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts."

(2) Effective October 6, 2014, all Hydrocodone Combination Products (HCPs) in the State of Georgia are Schedule II controlled substances.

(a) Each registrant possessing HCPs must make an actual count inventory of all HCPs as of October 6, 2014 and maintain it with the registrant's biennial DEA inventory.

(b) All HCPs products must be treated as any other Schedule II controlled substance. There can be no oral prescriptions except in the case of an emergency, and all hard-copy HCP prescriptions must be issued on security paper.

(c) For any HCP prescription written and filled before October 6, 2014 with authorized refills, the prescription can be refilled only for the authorized number of refills prior to April 8, 2015.

(3) This rule is based on the following findings of the Board:

(a) that as Schedule III controlled substances, HCPs have an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of HCPs demonstrate that the public is at extreme risk if HCPs are not regulated as Schedule II controlled substances;

(c) that the history and pattern of abuse of HCPs as a Schedule III controlled substance and the scope and significance of that abuse support stricter regulation;

(d) that as a Schedule III controlled substance, there exists an imminent peril to the public health and welfare with regard to the abuse of HCPs;

(e) that HCPs have the same risk to the public health of citizens of the State of Georgia as other Schedule II controlled substances already contained in the Georgia Controlled Substances Act;

(f) that as of October 6, 2014, the U.S. Drug Enforcement Administration has removed all reference to HCPs from Schedule III of 21 CFR 1308.13, which places all HCPs under Schedule II of 21 CFR 1308.12.

Cite as Ga. Comp. R. & Regs. R. 480-34-.06
Authority: O.C.G.A. §§ 16-13-22, 26-4-28, and 50-13-4.
History. Original Rule entitled "Hydrocodone Combination Products" adopted. F. Nov. 26, 2014; eff. Dec. 16, 2014.

Amended: F. Jan. 23, 2015; eff. Feb. 12, 2015.

Rule 480-34-.07. Hallucinogens.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains any quantity of the following substances, their salts, isomers (whether optical, position, or geometrics), and salts of isomers under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(3)as follows:

(BBBB) Methoxyphencyclidine (MeO-PCP)

(CCCC) 4-hydroxy-N-methyl-N-isopropyltryptamine (4-OH-MiPT)

(DDDD) N,[ALPHA]-dimethyl-5-benzofuranethanamine (5-MAPB)

(EEEE) 1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (SDB-006)

(FFFF) methyl (S)-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (MDMB-CHMICA)

(2) This rule is based on the following findings of the Board:

(a) that hallucinogens have an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act; and

(f) that these compounds have no known precursor already scheduled under the Act.

Cite as Ga. Comp. R. & Regs. R. 480-34-.07
Authority: O.C.G.A. §§ 16-13-22, 26-4-27, 26-4-28, 50-13-4.
History. Original Rule filed as Emergency Rule 480-34-0.23-.07 entitled "Hallucinogens" on May 14, 2015; effective May 13, 2015, the date of adoption, to remain in effect for a period of 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.

Adopted: Emergency Rule 480-34-0.25-.07. F. and eff. June 30, 2015, the date of adoption, to remain in effect for a period of 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.
Adopted: Emergency Rule 480-34-0.26-.07. F. and eff. July 21, 2015, the date of adoption, to remain in effect for a period of 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.
Adopted: Permanent Rule of the same title. F. July 27, 2015; eff. Aug. 16, 2015.
Amended: F. Sep. 18, 2015; eff. Oct. 8, 2015.
Amended: F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-34-.08. Lidocaine.

(1) This rule was adopted to protect the health, safety, and welfare of the public. Lidocaine topical, 40 mg/gm. or less (4.0%) is deleted from Official Code of Georgia Annotated (O.C.G.A.) § 16-13-71(b)(520).

(2) This rule is based on the following findings of the Board:

   (a) that lidocaine topical, 40 mg/gm. or less (4.0%) does not have a high potential for abuse;

   (b) that the Board has considered the scientific evidence of its pharmacological effects, the state of current scientific knowledge regarding the drug, the history and current pattern of abuse, the scope, duration, and significance of abuse, the potential of the drug to produce psychic or physiological dependence liability; and

   (c) that the drug is no longer included as a prescription drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301, et. seq., as amended.

Cite as Ga. Comp. R. & Regs. R. 480-34-.08
Authority: §§ 16-13-71, 26-4-27, 50-13-4.
History. Original Rule filed as Emergency Rule 480-34-0.24-.08 entitled "Lidocaine" on May 14, 2015; effective May 13, 2015, the date of adoption, to remain in effect for a period of 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.
Adopted: Permanent Rule of the same title. F. Sep. 18, 2015; eff. Oct. 8, 2015.

Rule 480-34-.09. Additional Compounds under Schedule IV.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains any quantity of the following substances, their salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specified chemical designation, including as having a stimulant or depressant effect on the central nervous system or a hallucinogenic effect,

under Schedule IV of the Georgia Controlled Substances Act, Section 16-13-28 as follows:

(14.3) Flubromazepam

(30.07) Pyrazolam

(2) This rule is based on the following findings of the Board:

(a) that benzodiazepines have a high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule IV under the Controlled Substances Act; and

(f) that these compounds have no known precursor already scheduled under the Act.

Cite as Ga. Comp. R. & Regs. R. 480-34-.09
Authority: O.C.G.A. §§ 16-13-22, 26-4-28, 50-13-4.
History. Original Rule filed as Emergency Rule 480-34-0.24-.08 entitled "Additional Compounds under Schedule IV" on July 21, 2015; effective July 21, 2015, the date of adoption, to remain in effect for a period of 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.
Adopted: Permanent Rule of the same title. F. Sep. 18, 2015; eff. Oct. 8, 2015.

Rule 480-34-.10. Synthetic Opiates.

This rule was adopted to protect the health, safety, and welfare of the public. This rule places newly identified compounds, including their isomers, esters, ethers, salts and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers, or salts is possible within the specific chemical designation under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(1)as follows:

(RR) *trans*-3,4-dichloro-*N*-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(b) This rule is based on the following findings of the Board:

(1) that Synthetic Opiates have an extremely high potential for abuse;

(2) that scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;

(3) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(4) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(5) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act; and

(6) that these compounds have no known precursor already scheduled under the Act.

Cite as Ga. Comp. R. & Regs. R. 480-34-.10
Authority: O.C.G.A. §§ 16-13-22, 26-4-28, 50-13-4.
History. Original Rule entitled "Synthetic Opiates" adopted as ER. 480-34-0.30-.10. F. and eff. April 22, 2016, the date of adoption.
Adopted: Permanent Rule of the same title. F. June 22, 2016; eff. July 12, 2016.

Rule 480-34-.11. Levocetirizine Dihydrochloride.

(1) This rule was adopted to protect the health, safety, and welfare of the public. Levocetirizine dihydrochloride in 5 mg tablets or an oral solution of 2.5 mg per 5 mL (.05 mg per mL), as identified in Official Code of Georgia Annotated (O.C.G.A.) § 16-13-71(b)(516.75), is hereby removed from the list of dangerous drugs of the Georgia Dangerous Drugs Act.

(2) This rule is based on the following findings of the Board:

(a) that levocetirizine dihydrochloride does not have a high potential for abuse;

(b) that the Board has considered the scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; the potential of the drug to produce psychic or physiological dependence liability; and

(c) that the drug, when in 5 mg tablets or an oral solution of 2.5 mg per 5 mL (.05 mg per mL), has been approved for non-prescription status by the Federal Food and Drug Administration.

Cite as Ga. Comp. R. & Regs. R. 480-34-.11
Authority: O.C.G.A. §§ 16-13-71, 26-4-27.
History. Original Rule entitled "Levocetirizine Dihydrochloride" adopted. F. Oct. 3, 2017; eff. Oct. 23, 2017.

Rule 480-34-.12. Synthetic Fentanyl.

(a) This rule was adopted to protect the health, safety, and welfare of the public. This rule places newly identified compounds, including any derivatives, their salts, isomers, or salts of isomers, unless specifically utilized as part of the manufacturing process by a commercial industry of a substance or material not intended for human ingestion or consumption, as a prescription administered under medical supervision, or for research at a recognized institution, whenever the existence of these salts, isomers, or salts of isomers is possible within the specific chemical designation or unless specifically excepted or listed in this or another schedule, structurally derived from fentanyl, and whether or not further modified in any of the following ways under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(13)as follows:

(H) Tetrahydrofuran fentanyl (N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]oxolane-2-carboxamide)

(b) This rule is based on the following findings of the Board:

(1) That synthetic fentanyls have an extremely high potential for abuse;

(2) That scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;

(3) That the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(4) That there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(5) That these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act; and

(6) That these compounds have no known precursor already scheduled under the Act.

Cite as Ga. Comp. R. & Regs. R. 480-34-.12
Authority: O.C.G.A. §§ 16-13-22, 16-13-25, 26-4-28, 50-13-4.
History. Original Rule entitled "Synthetic Fentanyl" adopted. F. Feb. 22, 2018; eff. Mar. 14, 2018.

Rule 480-34-.13. Triamcinolone Acetonide Nasal Spray.

(1) This rule was adopted to protect the health, safety, and welfare of the public. Triamcinolone acetonide nasal spray 55mcg per spray or less, is hereby deleted from the dangerous drug list as referenced in the Official Code of Georgia Annotated (O.C.G.A.) § 16-13-71(b)(976).

(2) This rule is based on the following findings of the Board:

(a) that triamcinolone acetonide nasal spray 55mcg per spray or less does not have a high potential for abuse;

(b) that the Board has considered the scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; the potential of the drug to produce psychic or physiological dependence liability; and

(c) that the drug, when in nasal spray form of 55mcg per spray or less has been approved for non-prescription status by the Federal Food and Drug Administration.

Cite as Ga. Comp. R. & Regs. R. 480-34-.13
Authority: O.C.G.A. §§ 16-13-71, 26-4-5, 26-4-27, 26-4-28.
History. Original Rule entitled "Triamcinolone Acetonide Nasal Spray" adopted. F. Nov. 19, 2018; eff. Dec. 9, 2018.

Rule 480-34-.14. Sodium Chloride Injection for Catheter Flush.

(1) This rule was adopted to protect the health, safety, and welfare of the public. Sodium chloride injection in quantities of 10cc or less, when used as a catheter flush solution to act by physically occupying space within a catheter and exerting pressure on the patient's circulating blood, is hereby deleted from the dangerous drug list as referenced in Official Code of Georgia Annotated (O.C.G.A.) § 16-13-71(b)(867).

(2) This rule is based on the following findings of the Board:

(a) that sodium chloride injection in quantities of 10cc or less does not have a high potential for abuse;

(b) that the Board has considered the scientific evidence of its pharmacological effects, the state of current scientific knowledge regarding the drug, the history and current pattern of abuse, the scope, duration, and significance of abuse, the potential of the drug to produce psychic or physiological dependence liability; and

(c) that the Federal Food and Drug Administration concluded that sodium chloride injection (saline injection or flush), when used as a catheter flush solution and acting in this manner, this solution meets the definition of a device in that it affects

the structure or function of the body, and does not achieve its primary intended purposes through chemical or metabolic action.

Cite as Ga. Comp. R. & Regs. R. 480-34-.14
Authority: O.C.G.A. §§ 16-13-71, 26-4-5, 26-4-27, 26-4-28.
History. Original Rule entitled "Sodium Chloride Injection for Catheter Flush" adopted. F. Nov. 19, 2018; eff. Dec. 9, 2018.

Rule 480-34-.15. Additional Compounds under Schedule V.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places an additional compound as specifically identified here under Schedule V of the Georgia Controlled Substances Act, Section 16-13-29 as follows:

(1.5) Epidiolex: A drug product in finished dosage formulation in its original container that has been approved by and labelled in compliance with the U.S. Food and Drug Administration (FDA) that contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

(2) This rule is based on the following findings of the Board:

(a) that the FDA approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is an oral solution that contains CBD extracted from the cannabis plant.

(b) that the U.S. Drug Enforcement Administration (DEA) did seek a medical and scientific evaluation or scheduling recommendation from the U.S. Department of Health and Human Services (HHS) with respect to the Epidiolex formulation. In responding to that request, HHS advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and therefore, recommended that if DEA concluded that control of the drug was required under the Single Convention, Epidiolex should be placed in Schedule V of the Federal Controlled Substance Act (CSA).

(c) that the Board has considered, based on available information, the potential for abuse; scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; and the potential of the drug to produce psychic or physiological dependence liability.

Cite as Ga. Comp. R. & Regs. R. 480-34-.15
Authority: O.C.G.A. §§ 16-13-22, 16-13-29, 26-4-5, 26-4-27, 26-4-28.
History. Original Rule entitled "Additional Compounds under Schedule V" filed as Emergency Rule 480-34-0.35-.12 on Nov. 5, 2018; effective Nov. 5, 2018, to remain in effect for a period of 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 Board.
Adopted: Permanent Rule of the same title. F. May 9, 2019, eff. May 29, 2019.

Chapter 480-35. PHARMACIST MODIFICATION OF DRUG THERAPY.

Rule 480-35-.01. Definitions.

(1) Board. Board means the Georgia State Board of Pharmacy.

(2) Drug Therapy Modification. Drug Therapy Modification means the adjustment of dosages, dosage schedules, and/or medications by a pharmacist under authority delegated and supervised by a physician. Such medications need not be pharmaceutically or therapeutically equivalent to the initial prescription issued to the patient by the prescribing physician.

(3) Pharmacist. Pharmacist means a person holding a current license to practice pharmacy in the State of Georgia.

(4) Physician. Physician means a person holding a current license to practice medicine in the State of Georgia.

(5) Supervision by a Physician. Supervision by a physician means the pharmacist has a means available to communicate with the physician for consultation, assistance, and direction in regards to drug therapy modification.

Cite as Ga. Comp. R. & Regs. R. 480-35-.01
Authority: O.C.G.A. Secs. 16-13-41, 16-13-74, 26-4-6, 26-4-27, 26-4-28, 26-4-50, 26-4-81, 43-1-7, 43-34-26.2.
History. Original Rule entitled "Definitions" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-35-.02. Pharmacist Certification.

(1) A pharmacist may apply to the Board for a certification which will allow the pharmacist to enter into a protocol or agreement with a physician for drug therapy modification. Each application shall be reviewed by the Board for completeness and authenticity before certification can be issued. Such application shall include, but is not limited to:

(a) Completion of an application form approved by the Board to include at a minimum:

(i) Name, home address, telephone number, and email address (if applicable);

(ii) Georgia pharmacist license number, including any previous sanctions by the Board or any other actions by a licensing or criminal authority; and

(iii) Current place of practice setting, including name, address, and telephone number and place where the protocol and patient records will be maintained.

(b) Submission of an application fee approved by the Board;

(c) Submission of evidence of completion of a course of study, approved by the Board, related to drug therapy modification; and

(d) Submission of evidence of 0.3 continuing education units (CEUs) or 3.0 contact hours in courses related to drug therapy modification. Such CEUs must be obtained during the 12 months prior to submitting the application.

(2) The Board will review the completed application. If the pharmacist has a current license in good standing, the completed course of study is approved, and the continuing education hours are acceptable, the Board may issue a certification, renewable on an annual basis.

(3) A certification authorizing drug therapy modification must be renewed by December 31st of each year. A certification authorizing drug therapy modification not renewed by December 31st shall expire.

(4) In order to renew a certification, a pharmacist must apply to the Board on an application form approved by the Board, submit a renewal fee, and submit evidence of 0.3 CEUs or 3 contact hours in continuing education courses obtained annually and approved by the Board or the Accreditation Council for Pharmacy Education (ACPE).

(5) The current certification must be posted with the pharmacist's license.

Cite as Ga. Comp. R. & Regs. R. 480-35-.02
Authority: O.C.G.A. §§ 16-13-41, 16-13-74, 26-4-6, 26-4-27, 26-4-28, 26-4-50, 26-4-81, 43-1-7, 43-34-24.
History. Original Rule entitled "Pharmacist Certification" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.
Amended: F. Apr. 20, 2015; eff. May 10, 2015.

Rule 480-35-.03. Continuing Education.

In order to renew a certification under this chapter, the continuing education must:

(1) Be from a provider approved by the Board pursuant to Rule 480-3-.03 or a provider approved by ACPE.

(2) Have been taken and credit received for the continuing education during the 12 months preceding the application for renewal.

(3) Have been from a live program at least 1.0 contact hour (0.1 CEU) in length.

(4) Have been on the topic of the therapy area in which the Pharmacist seeks to make drug therapy modifications.

Cite as Ga. Comp. R. & Regs. R. 480-35-.03
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-50.
History. Original Rule entitled "Continuing Education" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.
Amended: F. Nov. 19, 2018; eff. Dec. 9, 2018.

Rule 480-35-.04. Requirements for a Protocol.

(1) A physician may delegate authority to a pharmacist certified under this chapter to modify drug therapy through a protocol for a patient under the physician's direct medical care and supervision. The protocol shall meet the applicable requirements for the issuance of prescriptions provided in O.C.G.A. Section 16-13-41 or 16-13-74, which ever is applicable.

(2) A protocol shall be in writing and must contain the following:

(a) The printed name and signature of the physician, along with the license number issued to the physician by the Georgia Composite Board of Medical Examiners;

(b) The printed name and signature of the pharmacist, along with the license number issued to the pharmacist by the Board;

(c) The date the protocol was established, and the date the protocol becomes effective;

(d) The length of time the protocol shall be in effect;

(e) The identity of each patient covered by the protocol, and a mechanism to inform the patient the physician has authorized the pharmacist to modify the patient's drug therapy pursuant to this protocol, including information as to how the patient may opt out of the protocol;

(f) The physician's diagnosis of condition or disease state for each patient identified in the protocol, along with a listing of the initial drug therapy prescribed by the physician for each patient;

(g) A description of the parameters and responsibilities for drug therapy modification;

(h) Description of the monitoring required by the pharmacist and physician for each patient identified in the protocol;

(i) The procedures the pharmacist must follow when modifying drug therapy including, but not limited to, the method and frequency of notification to the physician of any drug therapy modification;

(j) For each patient's drug therapy modification, the identification of types and categories of medications allowed to be utilized, and the maximum/minimum dosage levels within each type and category of medication; and

(k) Identification of the documentation required by the pharmacist when drug therapy has been modified, including, but not limited to, a record of any problems or complications encountered, a list of recommendations, and a list of all drug modifications.

(3) No protocol can be longer than two (2) years. Protocols shall terminate immediately when the pharmacist's or physician's license and/or certificate has lapsed, been revoked, or has not been renewed.

Cite as Ga. Comp. R. & Regs. R. 480-35-.04
Authority: O.C.G.A. Secs. 16-13-41, 16-13-74, 26-4-6, 26-4-27, 26-4-28, 26-4-50, 26-4-81, 43-1-7, 43-34-26.2.
History. Original Rule entitled "Requirements for a Protocol" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-35-.05. Recordkeeping.

(1) Each pharmacist certified for drug therapy modification, who enters into a drug therapy modification protocol with a physician, shall establish and maintain a separate record system which shall include, but not limited to, the following:

(a) A patient medical record for each patient named in the protocol;

(b) Documentation of any action taken regarding drug therapy, including counseling of the patient in regard to the new medication;

(c) Documentation of any prescription drug order initiated by the pharmacist on behalf of the physician pursuant to the protocol;

(d) Documentation of any test results supporting drug therapy modification;

(e) Documentation of any notification to the physician regarding drug therapy modification;

(f) Documentation of any problems or adverse effects encountered due to the initial drug order or any drug therapy modification; and

(g) Other pertinent patient information;

(2) All such patient records must be maintained for a period of ten (10) years following the date the protocol is terminated;

(3) Nothing in this rule shall prohibit a pharmacist who is practicing outside a licensed pharmacy from documenting the patient information required in this rule in the patient's medical record established by the physician, clinic, or other medical facility, and such documentation shall meet the requirements of this rule.

(4) All patient records required by this rule must be available for inspection and copying by the Georgia Drugs and Narcotics Agency upon request.

Cite as Ga. Comp. R. & Regs. R. 480-35-.05
Authority: O.C.G.A. Secs. 16-13-41, 16-13-74, 26-4-6, 26-4-27, 26-4-28, 26-4-50, 26-4-81, 43-1-7, 43-34-26.2.
History. Original Rule entitled "Recordkeeping" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-35-.06. Financial Remuneration for Professional Services.

Nothing in this rule shall be construed to prohibit the pharmacist from being remunerated for the professional services rendered.

Cite as Ga. Comp. R. & Regs. R. 480-35-.06
Authority: O.C.G.A. Secs. 16-13-41, 16-13-74, 26-4-6, 26-4-27, 26-4-28, 26-4-50, 26-4-81, 43-1-7, 43-34-26.2.
History. Original Rule entitled "Financial Remuneration for Professional Services" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-35-.07. Authority to Initiate Modification of Drug Therapy.

Nothing in this chapter shall be construed to limit or restrict the authority of a pharmacist to substitute a drug as provided in O.C.G.A. Section 26-4-81.

Cite as Ga. Comp. R. & Regs. R. 480-35-.07
Authority: O.C.G.A. Secs. 16-13-41, 16-13-74, 26-4-6, 26-4-27, 26-4-28, 26-4-50, 26-4-81, 43-1-7, 43-34-26.2.
History. Original Rule entitled "Authority to Initiate Modification of Drug Therapy" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Rule 480-35-.08. Exception.

Nothing in this chapter shall be construed to limit hospital pharmacists from participating in medication therapy management by protocol or other legal authority established or approved by a member of the hospital medical staff for the care and treatment of hospital patients.

Cite as Ga. Comp. R. & Regs. R. 480-35-.08
Authority: O.C.G.A. Secs. 16-13-41, 16-13-74, 26-4-6, 26-4-27, 26-4-28, 26-4-50, 26-4-81, 43-1-7, 43-34-26.2.

History. Original Rule entitled "Exception" adopted. F. Aug. 31, 2005; eff. Sept. 20, 2005.

Chapter 480-36. RETAIL PHARMACY REQUIREMENTS FOR REMOTE PRESCRIPTION DRUG ORDER PROCESSING.

Rule 480-36-.01. Definitions.

As used in this chapter, the following terms:

(1) "Board" shall mean the Georgia Board of Pharmacy.

(2) "Remote prescription drug order processing" shall mean the processing of prescription or patient information from a location other than the location from which the prescription medication is received and dispensed. It shall not include the dispensing of a drug, but may include:

(a) Receiving the prescription order from the primary dispensing pharmacy

(b) Interpreting, analyzing, or clarifying prescriptions;

(c) Entering prescription or patient data into a data processing system;

(d) Transferring prescription information;

(e) Performing a drug regimen review;

(f) Performing a drug allergy review;

(g) Performing therapeutic interventions; or

(h) Any combination of these order processing functions.

(3) Primary dispensing pharmacy. A primary dispensing pharmacy shall be defined as the retail pharmacy from which a prescription is physically received and dispensed to the patient or the patient's caregiver.

(4) Secondary remote entry pharmacy. A secondary remote entry pharmacy shall be defined as the retail pharmacy which performs remote prescription drug order processing but does not dispense the medication to the patient or the patient's caregiver. There shall only be one secondary pharmacy to assist the primary dispensing pharmacy with remote prescription drug order processing per prescription.

Cite as Ga. Comp. R. & Regs. R. 480-36-.01
Authority: O.C.G.A. Secs. 26-4-5, 26-4-27, 26-4-28.

History. Original Rule entitled "Definitions" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Rule 480-36-.02. Licensing.

(1) Pharmacies which perform remote prescription drug order processing shall be independently licensed as a retail pharmacy by the Board and physically located within the State of Georgia.

(2) Remote prescription drug processing from any location other than a retail pharmacy licensed in this State is prohibited.

(3) Pharmacies which perform remote prescription drug order processing shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy. Such contract shall be available for review by the Board or its representative.

Cite as Ga. Comp. R. & Regs. R. 480-36-.02
Authority: O.C.G.A. Secs. 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-110.
History. Original Rule entitled "Licensing" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Rule 480-36-.03. Personnel and Supervision.

(1) The primary dispensing pharmacy shall have a licensed pharmacist on site during business hours and his/her shall duties shall include the verification of the validity of all prescriptions. Such pharmacist shall be responsible for obtaining and recording all information needed. This shall include but not be limited to the following patient information: biographical information, medication history, drug allergies, and other information as required. Pharmacy technicians and pharmacy interns/externs may assist a pharmacist located at the primary dispensing pharmacy with remote prescription drug order processing. Such pharmacies shall comply with Georgia laws and rules set forth pertaining to ratios and the supervision of pharmacy technicians and pharmacy interns/externs.

(2) The secondary remote entry pharmacy shall have a pharmacist on duty, licensed in this State, who is physically present and personally supervising all pharmacy activities. Remote prescription drug order processing in a retail pharmacy without the direct supervision of a pharmacist is prohibited.

(3) Pharmacy technicians and pharmacy interns/externs may assist a pharmacist located at the secondary remote entry pharmacy with remote prescription drug order processing. Such pharmacies shall comply with Georgia laws and rules set forth pertaining to ratios and the supervision of pharmacy technicians and pharmacy interns/externs.

(4) The pharmacist on duty at the secondary remote entry pharmacy shall be responsible for assuring the accuracy of prescriptions for which he/she performed or supervised remote prescription drug order processing. This responsibility shall exclude the compounding, preparation, dispensing, and counseling for prescriptions for which he/she has performed remote prescription drug order processing. The pharmacist shall verify the data entered into the computer system is consistent with the prescription. The pharmacist shall conduct a drug regimen review for each prescription. Any activity requiring the exercise of professional judgment shall be performed by the pharmacist on duty and shall not be delegated to pharmacy technicians. The pharmacist on duty at the secondary remote entry pharmacy shall be responsible for verification of all activities performed by pharmacy technicians, or pharmacy interns/externs.

Cite as Ga. Comp. R. & Regs. R. 480-36-.03
Authority: O.C.G.A. §§ 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-83, 26-4-110.
History. Original Rule entitled "Personnel and Supervision" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.
Amended: F. Apr. 13, 2021; eff. May 3, 2021.

Rule 480-36-.04. Policy and Procedures.

The primary dispensing pharmacy and the secondary remote entry pharmacy shall have a written policy and procedure that relates to the remote processing at each pharmacy involved in the processing of a prescription and available for inspection by the Board or its representative. The policy shall at a minimum include the following:

(a) The responsibilities of each pharmacy;

(b) A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;

(c) Procedures for protecting the confidentiality and integrity of patient information;

(d) Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

(e) Procedures for maintaining required records;

(f) Procedures for complying with all applicable laws and regulations to include counseling.

Cite as Ga. Comp. R. & Regs. R. 480-36-.04
Authority: O.C.G.A. Secs. 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-83, 26-4-110.
History. Original Rule entitled "Policy and Procedure" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Rule 480-36-.05. Record Keeping.

(1) The primary dispensing pharmacy and the secondary remote entry pharmacy shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.

(2) In addition to any other required records, the primary dispensing pharmacy and the secondary remote entry pharmacy shall maintain retrievable records which show, for each prescription remotely processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function.

(3) The primary dispensing pharmacy and the secondary remote entry pharmacy may maintain records separately at each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.

(4) These records maintained by the primary dispensing pharmacy and the secondary remote entry pharmacy shall be readily retrievable for at least two years through the primary dispensing pharmacy, and shall be available for inspection by the Board or its representative.

(5) The record keeping required by this rule is in addition to the record keeping required under Rule Chapter 480-10 and any other Board rules and state and federal laws.

Cite as Ga. Comp. R. & Regs. R. 480-36-.05
Authority: O.C.G.A. Secs. 16-13-34, 16-3-39, 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-83, 26-4-85, 26-4-110.
History. Original Rule entitled "Record Keeping" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Rule 480-36-.06. Patient Counseling.

(1) It shall be the responsibility of the pharmacist on duty at the primary dispensing pharmacy to perform patient counseling of all prescriptions, as required, including those assisted by remote processing.

(2) The secondary remote entry pharmacy shall not perform patient counseling on behalf of the primary dispensing pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-36-.06
Authority: O.C.G.A. Secs. 26-4-4, 26-4-5, 26-4-27, 26-4-28, 26-4-85.
History. Original Rule entitled "Patient Counseling" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Rule 480-36-.07. Notification to Patients.

(1) Prior to utilizing remote prescription drug order processing, the primary dispensing pharmacy shall:

(a) Notify patients their prescription drug order may be processed by another pharmacy. Such notification may be provided through a one time written consent from the patient or the patient's authorized representative and through use of a sign in the pharmacy which states: "Remote Order Processing Utilized Here."Such sign must be clear and legible with letters at least three (3) inches in size, and the sign shall be free from obstruction and visible to patients at the time the prescription is presented to the pharmacy.

(b) Give the name of that pharmacy, or if the pharmacy is part of a network of pharmacies under a common ownership and any of the network pharmacies may process the prescription order, the patient shall be notified of this fact. Such notification may be provided through a one time written consent from the patient or the patient's authorized representative and through use of a sign in the pharmacy which states: "Remote Order Processing Utilized Here." Such sign must be clear and legible with letters at least three (3) inches in size, and the sign shall be free from obstruction and visible to patients at the time the prescription is presented to the pharmacy.

(2) Prior to utilizing remote prescription drug order processing, written consent from the patient or the patient's authorized representative shall be obtained by the primary dispensing pharmacy when the primary dispensing pharmacy and the secondary remote entry pharmacy do not share the same owner.

Cite as Ga. Comp. R. & Regs. R. 480-36-.07
Authority: O.C.G.A. Secs. 24-9-40, 26-4-5, 26-4-27, 26-4-28, 26-4-80.
History. Original Rule entitled "Notification to Patients" adopted. F. Feb. 21, 2011; eff. Mar. 13, 2011.

Chapter 480-37. REMOTE AUTOMATED MEDICATION SYSTEMS.

Rule 480-37-.01. Definitions.

For purposes of this Chapter, the following words shall mean:

(a) "Board" means the Georgia Board of Pharmacy

(b) "GDNA" means the Georgia Drugs and Narcotics Agency.

(c) "Remote automated medication system" or "RAMS" means an automated mechanical system in which medication is stored and retrieved for a specific patient pursuant to a practitioner's prescription medication order.

Cite as Ga. Comp. R. & Regs. R. 480-37-.01
Authority: O.C.G.A. Secs. 26-4-5, 26-4-28.
History. Original Rule entitled "Definitions" adopted. F. Feb. 24, 2012; eff. Mar. 15, 2012.

Rule 480-37-.02. Licensure.

(a) In order to install or operate a RAMS, a Georgia licensed pharmacy must make application for licensure to the Board on a form approved by the Board, and pay a fee. No person other than an approved licensed pharmacy may install or operate a RAMS. Each location having a RAMS must have a separate license from the Board. If more than one licensed pharmacy operates a RAMS at the same skilled nursing facility or hospice, each licensed pharmacy must maintain a registration at the skilled nursing facility or hospice. A Georgia licensed pharmacy that has paid a fee for one RAMS location will be required to pay fees for the additional locations.

(b) Licenses are renewed for two years and expire on June 30th of each odd-numbered year. Renewals are contingent upon the renewal of the pharmacy facility license. If the application for renewal is not made and the fee paid before September 1st of the odd-numbered year, the license shall lapse, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.

(c) A Georgia licensed pharmacy may only use the RAMS at a skilled nursing facility or hospice licensed as such pursuant to O.C.G.A. T. 31, Ch. 7, that does not have an on-site licensed pharmacy.

(d) The Pharmacist-in-Charge (PIC) for a licensed pharmacy shall be considered the PIC for each separate license to operate a RAMS at a skilled nursing facility or hospice.

(e) The RAMS must collect, control, and maintain all transaction information.

Cite as Ga. Comp. R. & Regs. R. 480-37-.02
Authority: O.C.G.A. §§ 26-4-5, 26-4-28, 26-4-110.
History. Original Rule entitled "Licensure" adopted. F. Feb. 24, 2012; eff. Mar. 15, 2012.
Amended: F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-37-.03. Minimum Requirements.

Minimum Requirements. A pharmacy may use a RAMS provided that:

(a) The pharmacy has a policy and procedure manual at the skilled nursing facilty or hospice that includes:

1) The type or name of each RAMS including a serial number or other identifying nomenclature.

2) A method to ensure security of a RAMS to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.

3) A process of filling and stocking a RAMS with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.

4) Documentation of inventory procedures including removal of any discontinued/out-dated medications.

5) Compliance with a Continuous Quality Improvement Program.

6) A method to ensure that patient confidentiality is maintained.

(b) No more than a 30 day supply of each individual medication may be stocked in a RAMS at one time.

(c) All drugs in a RAMS must inventoried no less than once every 30 days and documentation must be maintained of the inventories including the removal of any discontinued/out of date medications.

(d) All the registered pharmacists, licensed pharmacy interns or registered pharmacy technicians involved in the process of stocking, entering information into RAMS, or inventorying the RAMS must be identified. No person shall be permitted to perform a function related to the machine that they are not authorized to do in the pharmacy. Specifically, where direct supervision is required in the pharmacy, such supervision must occur in duties related to the RAMS.

(e) Patient confidentiality must be maintained.

(f) The PIC, or a pharmacist designated by the PIC, must be ablet to revoke, add, or change access to RAMS at any time.

(g) Only a Georgia registered nurses or a Georgia licensed practical nurse may be assigned access to and remove dangerous drugs from a RAMS.

(h) Only a Georgia registered nurse may access and remove a controlled substances from a RAMS

(i) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.

(j) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, or registered pharmacy technicians involved in the processing of the prescription order.

(k) A RAMS shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(l) The stocking or restocking of a dangerous drug or controlled substances shall only be completed by a Georgia pharmacist or a pharmacy intern/extern under the direct on-site supervision of a Georgia licensed pharmacist.

(m) A RAMS must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from a RAMS.

(o) All medication shall be packaged and labeled in compliance with Board rules and laws for patient specific labeled medication and/or unit of use medication.

(p) The licensed pharmacist responsible for filling, verifying, or loading the RAMS shall be responsible for their individual action.

(q) A prescription drug dispensed by the RAM pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

(r) A licensed pharmacist may remove discontinued and/or out-dated medications from the RAMS and return such medications to the licensed pharmacy for proper disposition. A registered or licensed practical nurse may remove discontinued and/or out-dated medications and place them in the designated secured return bin in a RAMS.

Cite as Ga. Comp. R. & Regs. R. 480-37-.03
Authority: O.C.G.A. Secs. 26-4-5, 26-4-28, 26-4-80, 26-4-110.
History. Original Rule entitled "Minimum Requirements" adopted. F. Feb. 24, 2012; eff. Mar. 15, 2012.

Rule 480-37-.04. Dispensing Drugs.

Drugs shall only be dispensed by the RAMS pursuant to prescription drug orders of practitioners authorized under the laws of this state to prescribe drugs.

Cite as Ga. Comp. R. & Regs. R. 480-37-.04
Authority: O.C.G.A. Secs. 16-13-41, 16-13-74, 26-4-5, 26-4-28.
History. Original Rule entitled "Dispensing Drugs" adopted. F. Feb. 24, 2012; eff. Mar. 15, 2012.

Rule 480-37-.05. Inspections.

(1) The Pharmacist in Charge, personally or by licensed pharmacist designee, shall inspect all RAMS within his/her jurisdiction and responsibility and make appropriate written records of such inspections. Such inspections, at a minimum, shall verify that:

(a) All drugs in a RAMS must inventoried no less than once every 30 days. All controlled substances drugs in a RAMS must inventoried no less than once every 7 days. A system of accountability must exist for all drugs contained in a RAMS.

(b) Drugs requiring special storage conditions are properly stored to insure their stability;

(c) No outdated drugs are stocked in a RAMS;

(d) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;

(e) Only medications may be stored in a RAMS and all medications stored in the RAMS must be on the RAMS inventory list.

(f) All necessary and required security and storage standards are met;

(g) A licensed pharmacist will empty the return bin at least every 30 days. Discontinued/out-dated return transactions shall be documented by the RAMS.

(2) Board of Pharmacy shall be conducted by representatives of the GDNA. Such inspections shall include all aspects of the management and operation of all RAMS in this State to verify compliance with the Pharmacy Laws, the Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety, and welfare of patients of the skilled nursing facility and/or hospice are protected. A written report shall be filed with the GDNA, the licensed pharmacy, and skilled nursing facility or hospice. Any discrepancies or deficiencies noted shall be corrected and written notice filed with GDNA within 30 days after receipt of the inspection notice.

Cite as Ga. Comp. R. & Regs. R. 480-37-.05
Authority: O.C.G.A. Secs. 26-4-5, 26-4-28, 26-4-29.
History. Original Rule entitled "Licensure" adopted. F. Feb. 24, 2012; eff. Mar. 15, 2012.

Chapter 480-38. GENERAL INFORMATION.

Rule 480-38-.01. Application of These Rules.

The following Rules govern procedure in "contested cases" as that term is defined in the Georgia Administrative Procedure Act (O.C.G.A. 50-13-2(2)) and which are conducted before the Board of Pharmacy. Additional Rules in subsequent chapters may also apply.

Cite as Ga. Comp. R. & Regs. R. 480-38-.01
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, 50-13-2, and 50-13-3.

History. Original Rule entitled "Scope and Application of These Rules" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.

Rule 480-38-.02. Docket.

(1) The Executive Director shall keep a book known as a docket, which shall be arranged by a sequential numbering system for each case or other matter and shall show for each case of matter, as permitted by law, all proceedings, actions and filings.

(2) The Executive Director shall keep a docket index by both docket number and alphabetical list of the names of the respondents in all proceedings.

Cite as Ga. Comp. R. & Regs. R. 480-38-.02
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, and 50-13-3.
History. Original Rule entitled "Docket" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014

Rule 480-38-.03. Office Hours.

The offices of the Board of Pharmacy shall be open from 8:00 a.m. to 5:00 p.m. each weekday, except State legal holidays.

Cite as Ga. Comp. R. & Regs. R. 480-38-.03
Authority: O.C.G.A. §§ 26-4-27 and 26-4-28.
History. Original Rule entitled "Office Hours" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.

Rule 480-38-.04. Communications.

All communications, including correspondence, motions, and pleadings, shall be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, 6th Floor, Atlanta, GA 30303. Copies shall be furnished to all parties of record, including the attorney representing the State. An original of all correspondence, motions, and pleadings shall be filed with the Executive Director and shall comply in all respects with Rule 480-41-.04.

Cite as Ga. Comp. R. & Regs. R. 480-38-.04
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, 50-13-3, and 50-13-13.
History. Original Rule entitled "Communications" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 480-38-.05. Date of Filing.

All communications, correspondence, motions and pleadings in any proceedings shall be deemed to be filed or received on the date on which they are actually received by the Executive Director.

Cite as Ga. Comp. R. & Regs. R. 480-38-.05
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, 50-13-3, and 50-13-13.
History. Original Rule entitled "Date of Filing" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.

Rule 480-38-.06. Computation of Time.

Computation of any period of time referred to in these rules shall begin with the first day following that on which the act which initiates such period of time occurs. When the last day of the period so computed is a day on which the office of the Board of Pharmacy is closed, the period shall run until the end of the following business day. When such period of time, with the intervening Saturdays, Sundays and legal holidays counted, is seven (7) days or less, the said Saturdays, Sundays and legal holidays shall be excluded from the computation; or otherwise such days shall be included in the computation.

Cite as Ga. Comp. R. & Regs. R. 480-38-.06
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, and 50-13-3.
History. Original Rule entitled "Computation of Time" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.

Rule 480-38-.07. Extension of Times.

It shall be within the discretion of the Board or its designee to extend, for good cause shown, any time limit prescribed or allowed by these rules. All requests for an extension should be made by a motion in accordance with 480-40-.01 and shall indicate therein whether all parties concur. The Board or its designee shall notify all parties of its action upon the motion. Extension shall be granted only when the Board or its designee is satisfied that good cause has been shown and not otherwise.

Cite as Ga. Comp. R. & Regs. R. 480-38-.07
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, and 50-13-3.
History. Original Rule entitled "Extension of Times" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.

Rule 480-38-.08. Signatures.

Every notice, pleading, petition, motion or other document filed by a party, represented by an attorney, shall be signed by at least one attorney of record in his/her individual name. His/her address, e-mail address, telephone number, and representative capacity shall be stated. A party who is not represented by an attorney shall sign his pleading and state his address, e-mail address, and telephone number. Except when otherwise specifically provided by rule or statute, pleadings need not be verified or accompanied by affidavit. The signature of an attorney constitutes a certificate by him/her that s/he has read the pleading, and that it is not interposed for delay.

Cite as Ga. Comp. R. & Regs. R. 480-38-.08
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, and 50-13-3.

History. Original Rule entitled "Signatures" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.

Rule 480-38-.09. Ex-parte Communication.

No person not employed by the Board of Pharmacy shall communicate *ex-parte* with any member of the Board of Pharmacy involved in the decisional process with respect to the merits of a contested case. If any *ex-parte* communication is directed to any person in violation of these rules, the Board or its designee and all other parties shall be immediately informed of the substance of the communication and the circumstances of its receipt; provided, that a request for information with respect to the status of a proceeding shall not be prohibited by this section.

Cite as Ga. Comp. R. & Regs. R. 480-38-.09
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, and 50-13-3.
History. Original Rule entitled "Ex-parte Communication" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.

Rule 480-38-.10. Petition for Promulgation, Amendment, or Repeal of Rules.

(1) Form of Petition. Each petition for promulgation, amendment or repeal of rules made pursuant to the Georgia Administrative Procedure Act shall be filed with the Board of Pharmacy. The petition shall be in writing and shall state:

   (a) The name and address of the petitioner;

   (b) The full text of the rule requested to be amended or repealed, or the full text of the rule desired to be promulgated;

   (c) A statement of the reason such rule should be amended, repealed, or promulgated including a statement of all pertinent existing facts which relate to petitioner's interest in the matter;

   (d) Citations of legal authority, if any, which authorize, support, or require the action requested by petition. The petition shall be verified under oath by or in proper behalf of the petitioner.

(2) Proceeding on Petition. Upon receipt of the petition, the Board of Pharmacy shall decide upon the action to be taken. Within thirty days after receipt of the petition, the Board either shall deny the petition in writing (stating its reasons for the denial) or shall initiate rule-making or rule-changing proceedings in accordance with the Georgia Administrative Procedure Act.

Cite as Ga. Comp. R. & Regs. R. 480-38-.10
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-3, and 50-13-9.
History. Original Rule entitled "Petition for Promulgation, Amendment, or Repeal of Rules" adopted. F. Jun. 1, 2014; eff. Jul. 10, 2014.

Chapter 480-39. PLEADINGS.

Rule 480-39-.01. Initial Pleading.

(1) The hearing in a contested case shall be commenced by the Board's filing of a notice of hearing directed to the respondent or respondents.

(2) Every pleading or other paper submitted for filing in a contested case, to the extent possible, shall contain the following:

   (a) A title which indicates the nature of the proceeding and the parties involved therein;

   (b) The name of the Board;

   (c) A short and plain statement of the nature of the pleading (e.g. Answer, Motion for Continuance, etc.);

   (d) In addition, the notice of hearing shall, to the extent possible, contain the following:

      1. A short and plain statement of the matters asserted or the issues involved;

      2. A clear and concise statement of the laws involved;

      3. A notice of the rights of the person to whom the notice of hearing is directed;

      4. A statement that an answer to the matters asserted is required; and

      5. Any other information required by law or deemed appropriate by the Board.

Cite as Ga. Comp. R. & Regs. R. 480-39-.01
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, 50-13-3, 50-13-13.
History. Original Rule entitled "Initial Pleading" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-39-.02. Answer.

The party to whom a notice of hearing is directed must file with the Board an answer within fourteen (14) days after service of the notice of hearing. All allegations contained in the notice of hearing which are not specifically admitted are deemed denied.

Cite as Ga. Comp. R. & Regs. R. 480-39-.02
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-3, 50-13-13.
History. Original Rule entitled "Answer" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-39-.03. Replies.

A reply to the answer shall not be permitted and any new matters asserted in the answer shall be deemed denied.

Cite as Ga. Comp. R. & Regs. R. 480-39-.03
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-3, 50-13-13.
History. Original Rule entitled "Replies" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-39-.04. Amendments.

Any party, including the Board, may amend any pleading or notice without leave until the eighth day prior to the date set for the hearing on the matter. Thereafter a party may amend his pleadings only by leave of the Board or its designee and leave shall be freely given when justice so requires. If an amendment is made to a notice of hearing, the answer to said amended notice shall be filed within seven (7) days after service of the amended notice, unless otherwise ordered by the Board or its designee.

Cite as Ga. Comp. R. & Regs. R. 480-39-.04
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-3, 50-13-13.
History. Original Rule entitled "Amendments" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-40. MOTIONS AND PRE-HEARING PROCEDURES.

Rule 480-40-.01. Motions: Written and Oral.

(1) An application to the Board for an order to take any action or to enter any order shall be made by motion which, unless made during the hearing, shall be made in writing, shall state specifically the grounds therefor, and shall set forth the action or order sought. A copy of all written motions shall be served upon the parties in accordance with Chapter 480-42.

(2) A motion for a continuance or an extension of time shall be ruled upon by the Board or its designee forthwith. All other motions shall be ruled upon by the Board or its designee at the outset of the hearing, after an opportunity for argument by the parties; provided, however, that the Board or its designee may establish a hearing schedule and dispose of motions. The Board or its designee may request briefs in support of or in opposition to any motion.

Cite as Ga. Comp. R. & Regs. R. 480-40-.01
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, 50-13-3, 50-13-13, 50-13-18.

History. Original Rule entitled "Motions: Written and Oral" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-40-.02. More Definite Statement.

A motion for more definite statement shall be filed and ruled upon pursuant to 480-40-.01.

Cite as Ga. Comp. R. & Regs. R. 480-40-.02
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-13.
History. Original Rule entitled "More Definite Statement" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-40-.03. General Procedures.

Proceedings before the Board shall be conducted as expeditiously as possible, with due regard to the rights of the parties. In contested cases before the Board of Pharmacy upon issuance of a notice of hearing, the procedures set forth in this chapter and Chapters 480-38 through Chapter 480-47 shall enable the parties to obtain relevant information needed for preparation of the case, to the extent that such disclosure is authorized by law.

Cite as Ga. Comp. R. & Regs. R. 480-40-.03
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-3, 50-13-13, 50-13-15.
History. Original Rule entitled "General Procedures" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014

Rule 480-40-.04. Witness Lists and Respondent Statements.

(1) Should a party seek a list of the names of witnesses, including experts, whom another party expects to call or may call on its behalf, the party seeking the list must communicate the request in writing (by mail, personal service, or electronically) to the other party at least fourteen (14) days prior to the hearing. Such a request must also be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, 6th Floor, Atlanta, GA 30303. The party of whom the information is requested shall, within a reasonable time prior to the commencement of the hearing but at least ten (10) days prior to the hearing, provide such a list to the requester.

(2) The parties may also, within a reasonable period of time prior to the hearing, exchange copies of documents and designate documents already in the possession of the other party which are intended to be introduced as evidence at the hearing. Upon request, the parties shall make available to each other for inspection, copying, testing or sampling any tangible item intended to be introduced as evidence, within a reasonable period of time prior to the hearing. Where a party seeks documents or other evidence already in the possession of the other party which are intended to be introduced as evidence at the hearing, the party seeking the documents must communicate a request for the evidence in writing (by mail, personal service, or electronically) to the other party at least fourteen (14) days prior to the hearing. Such a request must also be filed with the Executive

Director, Board of Pharmacy, 2 Peachtree Street, 6th Floor, Atlanta, GA 30303. The party of whom the information is requested shall, within a reasonable time prior to the commencement of the hearing but at least ten (10) days prior to the hearing, provide such evidence to the requester or file a motion seeking an order to quash the request.

(3) If a licensee makes a general or specific written request to the Board for exculpatory, favorable, or arguably favorable evidence that is relative to pending allegations concerning the licensee, the Board must furnish the requested information, indicate that no such information exists, or refuse to furnish the information requested prior to a hearing.

(a) The Board is not required to furnish information made confidential by state or federal law, until such requested information has been determined to be exculpatory, favorable, or arguably favorable pursuant to the *in camera* procedure specified in part (b) of this subsection.

(b) Once the Board has furnished exculpatory, favorable, or arguably favorable information, has indicated that no such information exists, or has refused to furnish such information, a licensee may request a prehearing *in camera* inspection of the remainder of the investigative file by the Board or its designee. The Board or its designee shall furnish the licensee with all material that would aid in the licensee's defense that is exculpatory, favorable, or arguably favorable. The Board or its designee shall seal a copy of the entire investigative file in order to preserve it in the event of an appeal.

(4) If a party refuses to or neglects to produce documents, evidence, witness lists or statements in accordance with a request pursuant to 480-40-.04(1) or 480-40-.04(2), the Board or its designee may issue an order compelling production by motion of the requester or on its own motion. Where the party of whom information is requested has filed a motion to quash the request for production pursuant to 480-40-.01 and 480-40-.04(2), the Board or its designee may issue an order to quash the request for production upon good cause shown by the party requesting such an order. If a party subsequently refuses to or neglects to produce the requested materials in spite of an order compelling it to do so, the Board or its designee shall have the same rights and powers given the court under the Georgia Civil Practice Act. The Board or its designee may certify the facts to the Superior Court of Fulton County or any county where the offense is committed for appropriate action, including a finding of contempt. The Board or its designee shall have the power to issue writs of *fieri facias* in order to collect fines imposed for violation of a lawful order of the Board or its designee.

(5) The parties shall be required to confer either in person or by telephone, in reasonable advance of a scheduled hearing date but at least seven (7) days prior to the hearing, in a good-faith attempt to reach an agreement as to the admissibility of any documents or tangible items intended to be offered in evidence for either side. The parties may stipulate as to any matter of fact and such stipulation will satisfy a party's burden of proving the fact alleged. The parties shall be encouraged to reach pre-hearing stipulations which

could facilitate adjudication of the case. The Board or its designee, upon its own motion or upon the request of either party, may schedule a pre-hearing conference to hear and rule on motions or other preliminary matters, or otherwise facilitate adjudication of the case.

Cite as Ga. Comp. R. & Regs. R. 480-40-.04
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-13.
History. Original Rule entitled "Witness Lists and Respondent Statements" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.
Amended: F. Dec. 18, 2014; eff. Jan. 7, 2015.

Rule 480-40-.05. Pre-Hearing Discovery.

Except as may be expressly authorized by these Rules or by statute, no other forms of prehearing discovery shall be authorized or permitted including, but not limited to, interrogatories and requests for production of documents and other materials

Cite as Ga. Comp. R. & Regs. R. 480-40-.05
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-13.
History. Original Rule entitled "Pre-Hearing Discovery" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-41. SERVICE.

Rule 480-41-.01. By the Board.

(1) Service of the notice of hearing, initial decision and final order shall be served personally upon the licensee or applicant or served by certified mail or statutory overnight delivery, return receipt requested, to the last known address of record with the Board.

(2) All other notices, pleadings, orders, motions and other documents shall be personally upon the licensee or applicant or served by certified mail or statutory overnight delivery, return receipt requested, to the last known address of record with the Board.

(3) If such materials are served by certified mail or statutory overnight delivery and are returned marked "unclaimed" or "refused" or is otherwise undeliverable, and if the licensee or applicant cannot, after diligent effort, be located, the Executive Director or his or her designee, shall be deemed the agent of service for such licensee or applicant, and service upon the Executive Director or his or her designee shall be deemed service upon the licensee or applicant.

Cite as Ga. Comp. R. & Regs. R. 480-41-.01
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, 26-4-60, 50-13-3, 50-13-13, 50-13-18.
History. Original Rule entitled "By the Board" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-41-.02. Service on All Parties.

A copy of the answer and all other pleadings, notices, motions, briefs, memoranda and other documents filed by any party with the Executive Director shall be served upon all other parties to the proceeding, including counsel for the Board, by personal delivery or by certified mail, return receipt requested.

Cite as Ga. Comp. R. & Regs. R. 480-41-.02
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, 50-13-13.
History. Original Rule entitled "Service on All Parties" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-41-.03. To Party's Attorney.

Service upon a party's attorney shall be deemed service upon the party.

Cite as Ga. Comp. R. & Regs. R. 480-41-.03
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 50-13-13, 50-13-18.
History. Original Rule entitled "To Party's Attorney" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-41-.04. Filing of Pleading.

(1) A party filing a document or other submission with the Board shall simultaneously serve a copy of the document or submission on each party of record. Service shall be by personal delivery, e-mail as an attachment, first-class mail, certified mail, or statutory overnight delivery, return receipt requested.

(2) A pleading subsequent to the Notice of Hearing shall not be entitled to filing unless accompanied by an Acknowledgement of Service from the person served, by his or her authorized agent for service, or by a certificate of service stating the date, place, and manner or service, as well as the name and address of the person(s) served.

Cite as Ga. Comp. R. & Regs. R. 480-41-.04
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, 26-4-60, 50-13-3, 50-13-13, 50-13-18.
History. Original Rule entitled "Filing of Pleading" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-42. INTERVENTION.

Rule 480-42-.01. Intervention.

(1) Any person desiring to intervene pursuant to O.C.G.A. § 50-13-14 shall file a motion in accordance with Rule 480-40-.01 and 480-41-.04.

(a) Such a motion can be made where a statute grants the movant an unconditional right to intervene or when representation of the movant's interest is or may be inadequate to protect that interest.

(b) Such a motion can also be made where a statute grants the person a conditional right to intervene or where the movant's claim or defense and the main action have a question of law or fact in common.

(2) The motion shall state therein the specific grounds for seeking intervention. The Board and any other parties shall have fourteen (14) days from the date of service to file a response to such request.

(3) In considering the motion, the Board or its designee shall consider whether the intervention will unduly delay or prejudice the rights of existing parties.

Cite as Ga. Comp. R. & Regs. R. 480-42-.01
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-28.1, 50-13-13, 50-13-14.
History. Original Rule entitled "Intervention" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-43. EVIDENCE; SUBPOENAS.

Rule 480-43-.01. Evidence on Hearings.

Unless otherwise provided by these rules, in all hearings, the testimony of witnesses shall be taken orally before the Board or its designee and presentation of all documentary and other evidence shall be done before the Board or its designee.

Cite as Ga. Comp. R. & Regs. R. 480-43-.01
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 50-13-13, 50-13-15.
History. Original Rule entitled "Evidence on Hearings" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-43-.02. Evidence on Motions.

When a motion is based on facts not appearing of record, the Board or its designee may hear the matter on affidavits presented by the respective parties, but the Board or its designee may direct that the matter by heard wholly or partly on oral testimony.

Cite as Ga. Comp. R. & Regs. R. 480-43-.02
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 50-13-13, 50-13-15.
History. Original Rule entitled "Evidence on Motions" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-43-.03. Objections and Exceptions.

Any objections and exceptions must be made on the record, and at a minimum, must make clear to the Board or its designee the action which s/he desires taken and the grounds therefor.

Cite as Ga. Comp. R. & Regs. R. 480-43-.03
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 50-13-13, 50-13-15.
History. Original Rule entitled "Objections and Exceptions" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-43-.04. Subpoenas.

(1) In contested cases, subpoenas shall be issued without discrimination between public and private parties. At any time after issuance of the Notice of Hearing, and prior to the scheduled date for the hearing, the parties may request the issuance of subpoenas by filing a written request with the Executive Director, in accordance with Rule 480-38-.04, with appropriate service on the opposing party or counsel. Subpoena requests shall state the name and complete address of the person to whom it is directed.

(2) Subpoenas issued pursuant to a request in accordance with Rule 480-43-.04(1) shall not be issued in blank. Every subpoena issued by the Executive Director shall state the name of the Board of Pharmacy and the title of the action, and shall command each person to whom it is directed to attend and give testimony at the hearing at a time and place therein specified, or to produce documents for examination at the hearing, or both.

(3) If such a subpoena is directed to any member, investigator, employee, or other agent or representative of the Board, including experts retained by the Board for purposes of the particular case, production of documentary evidence from the Board or investigative file of the applicant or licensee and the taking of testimony at the hearing from such person or persons shall be governed by applicable provisions in the Pharmacy Practice Act, and by O.C.G.A. §§ 16-13-60, 26-4-28, 26-4-28.1, and 26-4-60.

(3) The party requesting the issuance of the subpoena shall be responsible for serving the same and paying the cost of securing the attendance of witnesses, in the same manner as prescribed by law in civil cases in superior court.

Cite as Ga. Comp. R. & Regs. R. 480-43-.04
Authority: O.C.G.A. §§ 16-13-60, 26-4-26, 26-4-27, 26-4-28, 26-4-28.1, 50-13-13, 50-13-15.
History. Original Rule entitled "Subpoenas" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-44. TAKING OF TESTIMONY BY DEPOSITION OR INTERROGATORY.

Rule 480-44-.01. Taking of Testimony by Deposition.

(1) At any time during the course of the proceeding, the Board or its designee may, in his discretion, permit the testimony of a witness to be taken by deposition. Application to take testimony by deposition shall be made in writing and shall be filed with the Executive Director of the Board and served upon all parties to the proceedings, including counsel for the Board.

(2) The application shall state the name and address of the witness, the subject matter concerning which the witness is expected to testify, the date, time and place of the proposed deposition, and the reason why the witness cannot appear and testify before the Board. The Board or its designee may, in his, her or its discretion, allow the application where the circumstances are such that the witness to be deposed cannot appear before the Board without substantial hardship to the deponent or to the parties to the case or that testimony by any other method will unduly delay expeditious completion of the proceedings. An application for the taking of testimony by deposition shall not be allowed if the deposition would result in any undue burden to another party or any undue delay of the proceedings. If the application is allowed, the Board or its designee should give notice of the taking of the testimony by deposition to all parties.

Cite as Ga. Comp. R. & Regs. R. 480-44-.01
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-28.1, 50-13-13, 50-13-15.
History. Original Rule entitled "Taking of Testimony by Deposition" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-44-.02. Conduct of the Deposition.

(1) Examination and cross-examination of the witness shall proceed as would be permitted at the hearing and under those rules of evidence applicable to proceedings conducted pursuant to the Georgia Administrative Procedure Act. The officer before whom the deposition is to be taken shall put the witness on oath and shall personally record the testimony of the witness. The testimony shall either be taken stenographically and shall be transcribed or shall be taken by video deposition. All objections made at the time of examination to the qualifications of the officer taking the deposition, or to the manner of taking it, or to the evidence presented, or to the conduct of any party, and any other objections to the proceedings, shall be noted by the officer upon the deposition. Evidence objected to shall be taken subject to the objection.

(2) All errors and irregularities in the notice of taking testimony by deposition shall be deemed waived unless written objection thereto is served upon the Board prior to the deposition. Objections to taking testimony by depositions because of disqualification of the officer before whom it is to be taken shall be deemed waived unless made before the deposition begins or as soon thereafter as the disqualification becomes known or could be discovered with reasonable diligence.

(3) Objections to the competency of a witness are not waived by failure to make them before or during the deposition, unless the ground of the objection is one which might have been

obviated or removed if presented at that time. Errors and irregularities occurring at the taking of the testimony in the manner of taking the deposition, in the form that the questions are answered, in the oath of affirmation, or in the conduct of the parties, and errors of any kind which might be obviated, removed or cured if properly presented, shall be deemed waived unless reasonable objection thereto is made at the deposition.

(4) Errors and irregularities in the manner in which the testimony is transcribed or the deposition is prepared, certified, sealed, endorsed, transmitted, filed, or otherwise dealt with by the officer taking the testimony are waived unless a motion to suppress the deposition or some part thereof is made with reasonable promptness after such defect is, or with due diligence might have been, ascertained.

(5) The transcript of the deposition or the video deposition must be certified by a court reporter in order to be accepted as evidence upon filing with the Board or its designee.

Cite as Ga. Comp. R. & Regs. R. 480-44-.02
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-28.1, 50-13-13, 50-13-15.
History. Original Rule entitled "Conduct of the Deposition" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-44-.03. Taking of Testimony by Interrogatory.

Application to take testimony by interrogatory shall be made and allowed in the same manner as prescribed in Rule 480-44-.01.

Cite as Ga. Comp. R. & Regs. R. 480-44-.03
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-28.1, 50-13-13, 50-13-15.
History. Original Rule entitled "Taking of Testimony by Interrogatory" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-44-.04. Taking of Testimony by Telephone.

Application to take testimony by telephone shall be made and allowed in the same manner as prescribed in Rule 480-44-.01.

Cite as Ga. Comp. R. & Regs. R. 480-44-.04
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 50-13-13, 50-13-15.
History. Original Rule entitled "Taking of Testimony by Telephone" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-45. HEARINGS.

Rule 480-45-.01. Notice of Hearing.

For a hearing held directly before the Board, the Board shall notify all parties of record of the date, time and place of the hearing in the manner as provided by law and these Rules.

Cite as Ga. Comp. R. & Regs. R. 480-45-.01
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-28.1, 50-13-13.
History. Original Rule entitled "Notice of Hearing" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-45-.02. Conduct of the Hearing.

(1) The hearing shall be conducted by the Board or an administrative law judge (ALJ) appointed by the Office of State Administrative Hearings (OSAH).

(2) Duties of the Board or its designee. The Board or its designee shall have the authority to do the following: to administer oaths and affirmations; rule upon offers of proofs; regulate the course of the hearing; set the time and place for continued hearings; fix the time for filing briefs and memoranda; dispose of motions; and reprimand or exclude from the hearing any person for any indecorous or improper conduct committed in the presence of the Board or its designee.

(3) Sworn Testimony. All testimony given at the hearing shall be under oath administered by the Board or any person designated by the Board.

(4) Order of Presentation. The State, or in a proper case a moving or complaining party, shall present its evidence or testimony first. Where there is more than one moving or complaining party, the order of presentation shall be at the discretion of the Board. After all of the evidence and testimony of the State, or the moving or complaining party, has been received, all other parties shall be allowed to present their evidence or testimony. All parties, other than the party introducing the testimony, shall be allowed to cross-examine any witness immediately after his testimony has been received. The State, or the moving or complaining party, shall be allowed to present rebuttal testimony or evidence if it so desires.

Cite as Ga. Comp. R. & Regs. R. 480-45-.02
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-28.1, 50-13-13, 50-13-15, 50-13-41.
History. Original Rule entitled "Conduct of the Hearing" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-46. CONSOLIDATION.

Rule 480-46-.01. Consolidation.

The Board or its designee upon its own motion, or upon motion by a party or other person joined in the proceeding, may order proceedings involving a common question of law or fact to be consolidated for hearing on any or all of the matters at issue in such proceedings.

Cite as Ga. Comp. R. & Regs. R. 480-46-.01
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-28.1, 50-13-13.

History. Original Rule entitled "Consolidation" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-47. BRIEFS AND POST-HEARING PROCEDURE.

Rule 480-47-.01. Briefs.

Briefs may be filed by a party or any interested person either before or during the course of the hearing, or within such time thereafter as the Board or its designee shall designate. Failure to file a brief shall in no way prejudice the rights of any party.

Cite as Ga. Comp. R. & Regs. R. 480-47-.01
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-60, 50-13-3, 50-13-13, 50-13-15.
History. Original Rule entitled "Briefs" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-47-.02. Filing of Documents Subsequent to Hearing.

(1) Upon request, the Board or its designee may, for good cause shown, allow the parties to file evidentiary documents of any kind, or exhibits, at a time subsequent to the completion of the hearing, such time to be determined by the Board or its designee. If a request for such subsequent filing is granted, the requesting party shall, on or before the date set for filing, send copies of all documents or exhibits which are the subject of the request to all other parties.

(2) Prior to the admission into evidence of any documents or exhibits filed subsequent to the hearing, the opposing party shall have ten (10) days from the date of service of copies of such proposed documents or exhibits to file any objections to the admission of such evidence.

Cite as Ga. Comp. R. & Regs. R. 480-47-.02
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-60, 50-13-3, 50-13-13, 50-13-15, 50-13-17.
History. Original Rule entitled "Filing of Documents Subsequent to Hearing" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-47-.03. Motion to Reopen Hearing.

A party may, at any time prior to the rendering of a final decision by the Board, move that the hearing be reopened for the purpose of receiving new evidence. Such motions shall be filed in accordance with the provisions of Rule 480-40-.01 and shall be granted only for good cause shown. The Board shall notify all parties of its action upon the motion. Notwithstanding the above, the Board may at any time prior to the rendering of a decision, reopen the hearing on its own motion.

Cite as Ga. Comp. R. & Regs. R. 480-47-.03
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-60, 50-13-3, 50-13-13, 50-13-15, 50-13-17.
History. Original Rule entitled "Motion to Reopen Hearing" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-47-.04. Review of Initial Decision.

(1) Either the responding party or the Board may seek review of the initial decision of the administrative law judge (ALJ) pursuant to O.C.G.A. §§ 50-13-17(a), 50-13-41(d). If the responding party files a timely motion for review of the initial decision of the ALJ, the responding party may include therein a statement of the reasons for seeking review and alleged errors made by the ALJ in the initial decision. If the Board files a timely order for review of the initial decision on its own motion, it may include in its order the issues to be considered by the Board at the review hearing.

(2) Upon the filing of a timely motion by the responding party seeking review of the initial decision of the ALJ, or upon the filing of a timely order by the Board for review of an initial decision on its own motion, notice of the date and time for the review shall be served on the responding party or counsel for the responding party and counsel for the Board.

(3) The Board may appoint a hearing officer for review, who shall preside over the review proceedings and control the conduct of the review hearing. In acting as the presiding officer, the hearing officer for review shall rule on all procedural and evidentiary questions that arise during the course of the review. At the direction of the Board, the hearing officer for review shall draft the final decision for the Board.

(4) On review, the Board shall have all the powers it would have in making the initial decision, and in its discretion, shall have the power to take additional testimony or remand the case to the ALJ for such purpose, as provided in the Administrative Procedure Act, O.C.G.A. § 50-13-17 and in accordance with this Rule. Motions, including motions to present additional evidence, shall be filed in accordance with 480-40-.01 and 480-47-.03 and shall be ruled upon within the time period set by the Board but not to exceed thirty (30) days.

   (a) Motions to present additional evidence or to remand the case to the ALJ for such purpose shall be granted only if the additional evidence is material, and there was good cause for failing to present such evidence before the ALJ. All motions, including motions for the presentation of additional evidence, shall be ruled on by the Board, prior to oral arguments during the review hearing.

(5) Oral argument up to 30 minutes per side is permitted in the review hearing. Additional time for argument must be requested in writing and docketed at least fourteen (14) days before the date set for the review hearing.

(6) Once the review hearing is concluded, the Board shall deliberate as to the final decision. Neither the hearing officer for review nor the parties nor their counsel shall be present

during or participate in the deliberations or voting on the final decision. Provided, however, that during the course of the deliberations the Board may seek or obtain legal advice of its counsel or make an inquiry on the record concerning either procedure or the merits of the case in the presence of all parties.

(a) At the conclusion of the deliberations, the vote and decision of the Board shall be announced in open session, unless the sanction imposed by the decision is made confidential by statute, in which case it shall be announced *in camera* to the responding party and counsel for the parties. The Board may take the matter under advisement and continue the deliberations until a date certain if deemed necessary due to the Board's agenda or the complexity of the issues.

Cite as Ga. Comp. R. & Regs. R. 480-47-.04
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-28.1, 26-4-60, 26-4-61, 43-1-19, 50-13-3, 50-13-13, 50-13-15, 50-13-17, 50-13-18, 50-13-41.
History. Original Rule entitled "Review of Initial Decision" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-47-.05. Rehearing.

A responding party may file a motion for rehearing of a final decision of the Board within ten (10) days after the date of actual service of such final decision on the responding party or responding party's counsel. Such motion shall be in accordance with Rule 480-40-.01 and, in addition, shall include a statement of all matters alleged to have been erroneously decided and, if applicable, a statement as to any newly discovered matters or circumstances that have arisen subsequent to the final decision. The filing of said motion shall not operate as a stay of the final decision of the Board unless so ordered by the Board.

Cite as Ga. Comp. R. & Regs. R. 480-47-.05
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-60, 50-13-3, 50-13-13, 50-13-15, 50-13-17, 50-13-18, 50-13-19.
History. Original Rule entitled "Rehearing" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Rule 480-47-.06. Appeals of Final Decisions.

All appeals shall be filed in accordance with the Georgia Administrative Procedure Act and must be filed in the Superior Court of Fulton County or superior court of the county of the residence of the petitioner.

Cite as Ga. Comp. R. & Regs. R. 480-47-.06
Authority: O.C.G.A. §§ 26-4-26, 26-4-27, 26-4-28, 26-4-60, 26-4-61, 50-13-3, 50-13-17, 50-13-18, 50-13-19.
History. Original Rule entitled "Appeals of Final Decisions" adopted. F. Jun. 20, 2014; eff. Jul. 10, 2014.

Chapter 480-48. DELIVERY BY MAIL.

Rule 480-48-.01. Definitions.

For purposes of this chapter of the Rules and Regulations, the following definitions apply:

(a) "Board" shall mean the Georgia Board of Pharmacy.

(b) "Delivery by Mail" or "delivered by mail" or "delivery by mail" shall mean delivery to a patient or the patient's designee by the United States Postal Service or by a commercial common carrier from the pharmacy which fills the prescription.

(c) "Delivery by Pharmacy" shall mean delivery directly to a patient or patient's designee from the pharmacy by contract or private carrier or by an employee of the pharmacy.

(d) "Mail order pharmacy" shall mean a pharmacy that uses delivery by mail as a means of delivery of a prescription drug to a patient or the patient's designee.

(e) "Pharmacy" means a pharmacy holding a current Board issued license to operate a pharmacy in Georgia, including pharmacy benefit managers required to be licensed pursuant under O.C.G.A. § 26-4-110.1, and nonresident pharmacy permit holders.

Cite as Ga. Comp. R. & Regs. R. 480-48-.01
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-85, 26-4-110, 26-4-110.1, 26-4-114.1.
History. Original Rule entitled "Definitions" adopted. F. Sep. 22, 2014; eff. Oct. 12, 2014.
Amended: F. May 14, 2015; eff. June 3, 2015.

Rule 480-48-.02. Conditions for Use of Delivery by Mail.

(1) Any pharmacy can regularly employ the U.S. Postal Service or a common commercial carrier to deliver a drug which requires a prescription to a patient only after the patient has requested that a pharmacy deliver by mail his/her filled prescription drugs. Any pharmacy providing delivery by mail to its patients is required to follow applicable Georgia laws and rules.

(2) A mail order pharmacy located outside this state is required to follow all applicable pharmacy and drug rules and laws of the state in which the pharmacy is physically located.

(3) A mail order pharmacy shall ensure that all prescription medications are delivered to the patient in accordance with standards of the manufacturer, United States Pharmacopeia, Federal Food and Drug Administration and other recognized standards. A pharmacy shall ensure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by mail order and provide a notification to the patient of the timeliness in addressing the proper storage of the medication.

(a) The shipping method may include the use of temperature tags, time temperature strips, insulated packaging, or a combination of these.

(b) The notification method may be by verbal, written, electronic, or other technological means. If verbal, then the pharmacy must document the notification and maintain such documentation.

(4) Any pharmacy using delivery by mail to deliver dispensed prescription drugs shall comply with the following conditions:

(a) Any pharmacy that uses delivery by mail is accountable to the Board to arrange for the appropriate mailing/shipping process.

(b) A mail order pharmacy shall provide a method by which a patient or patient's caregiver can notify the mail order pharmacy as to any irregularity in the delivery of their medication to include but not be limited to:

1. Timeliness of delivery;

2. Condition on the prescription drug upon delivery; and

3. Failure to receive the proper prescription drug.

(c) Medications designated as requiring special handling by this rule must be signed for upon delivery by the patient or patient's designee. In the event that the medication cannot be delivered, the package will not be left behind and shall be returned to the mailing or shipping service to be held for pickup until signed for by the patient or the patient's designee, or redelivered to the patient if so requested by the patient or the patient's caregiver. The Board has designated the following drugs as requiring special handling:

1. All Schedule II, III, IV, and V controlled substances

(d) A mail order pharmacy shall provide a process by which, if the delivery of a prescription medication is in any way compromised, the pharmacy will replace the patient's medication, to be delivered by next-day delivery or the mail order pharmacy will immediately contact the patient's prescriber to arrange for a prescription for a minimum seven (7) day supply of the medication to be dispensed to the patient by a licensed pharmacy of the patient's choice.

(e) A pharmacy that employs delivery by mail must provide written information, set forth in Board Rule 480-31-.01, for each drug that is delivered, and a method of electronic or telephonic communications for a pharmacist or a Georgia-licensed pharmacy intern under direct supervision of the pharmacist to provide consultation or counseling in accordance with the obligations of O.C.G.A. § 26-4-85. All such counseling will be documented in the pharmacy's patient records. It is sufficient

proof to show counseling was refused if a patient or patient's caregiver does not contact the pharmacy.

(f) The pharmacy shall provide information to the patient on the procedure that the patient should follow if any prescription drug does not arrive in a timely manner, or if the integrity of the packaging or medication has been compromised during shipment and delivery by mail.

(g) A pharmacy using delivery by mail shall document in its records when the prescription drug was sent to the patient.

(h) A pharmacy using delivery by mail shall document the instances when prescription drugs have been compromised during shipment and delivery by mail or when drugs do not arrive in a timely manner, and shall maintain such documentation for two (2) years. In addition, the mail order pharmacy shall maintain reports of patient complaints and internal/external audits about timeliness of deliveries, condition of the medication when received by patient including medication that was compromised in delivery, misfills of prescriptions, and the failure of a patient to receive medication. Such records shall be provided to the Board, upon request.

(i) A pharmacy or a pharmacist shall refuse to deliver by mail a prescription drug which, in the professional opinion of the pharmacy or pharmacist may be clinically compromised by delivery by mail.

(j) A mail order pharmacy shall make available to the patient or the patient's caregiver contact information of the Board of Pharmacy.

Cite as Ga. Comp. R. & Regs. R. 480-48-.02
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-85, 26-4-110, 26-4-110.1, 26-4-114.1.
History. Original Rule entitled "Conditions for Use of Delivery by Mail" adopted. F. Sep. 22, 2014; eff. Oct. 12, 2014.
Amended: F. May 14, 2015; eff. June 3, 2015.
Amended: F. May 24, 2017; eff. June 13, 2017.

Rule 480-48-.03. Delivery by Pharmacy.

Any pharmacy may provide for delivery by pharmacy upon the request of the patient or the patient's designee. The Board will hold the pharmacy responsible for any problems in the service of delivery by pharmacy. In order for a delivery to be considered delivery by pharmacy, the delivery must be on a continuous route from the pharmacy to the patient or the patient's designee. All medications shall be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed. All deliveries of controlled substances must be signed for upon delivery by the patient or patient's designee.

Cite as Ga. Comp. R. & Regs. R. 480-48-.03
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-110.
History. Original Rule entitled "Delivery by Pharmacy" adopted. F. May 14, 2015; eff. June 3, 2015.

Chapter 480-49. DEFAULT ON OBLIGATIONS.

Rule 480-49-.01. Federal Student Loan Default.

(1) A person holding a current license issued by the Georgia Board of Pharmacy ("Board") may have his/her license indefinitely suspended if s/he is found to be in nonpayment status or default or breach of a repayment or service obligation under any federal educational loan, service conditional loan repayment program, or service conditional scholarship program in accordance with the procedures set forth herein.

(2) After receiving a certification from a federal agency that the licensee is in nonpayment status or default or breach of a repayment or service obligation under any federal educational loan, service conditional loan repayment program, or service conditional scholarship program, the Board shall provide written notice to the licensee via certified or registered mail at the licensee's address of record. The notice shall contain the following:

(a) The Board's intended action to suspend the license;

(b) The licensee's right to request an appearance before the Board;

(c) Notification that the request for an appearance must be in writing and must be received by the board within thirty (30) days of service of notice; and

(d) The address and telephone number of the Board.

(3) If the licensee does not request an appearance before the Board within thirty (30) days, the licensee waives the right for an appearance before the Board, and the license shall be suspended.

(4) If a request to appear is timely received by the Board, the suspension of the license shall be stayed pending the licensee's appearance before the Board.

(5) Upon receipt of the request for an appearance before the Board, the Board shall notify the licensee in writing of the date and time of the appearance via certified or registered mail sent to the licensee's address of record. At this appearance, the licensee may present evidence only on the following issues:

(a) Whether the licensee is a party named in a federal educational loan agreement, service conditional loan repayment agreement, or service conditional scholarship agreement;

(b) Whether the licensee is in default of the loan obligation, service conditional loan repayment or scholarship obligation;

(c) Whether the licensee is repaying the loan obligation, service conditional loan repayment or scholarship obligation, in a manner satisfactory to the federal agency involved.

(6) Within fourteen (14) working days after the licensee's appearance before the Board, the Board will issue its decision. The Board will mail a copy of its decision to the licensee by certified mail or registered mail to the licensee's address of record.

(7) If the license is suspended, the licensee shall not practice during the period of suspension.

(8) A person whose license was suspended for being in nonpayment status or default or breach of a repayment or service obligation under any federal educational loan, service conditional loan repayment program, or service conditional scholarship program may apply to have the suspension lifted. In order to have the suspension lifted, the licensee must:

(a) Request in writing to the Board that the suspension be lifted;

(b) Provide the Board a written release from the federal agency originally certifying that the licensee is in nonpayment status or default or breach of a repayment or service obligation under any federal educational loan, service conditional loan repayment program, or service conditional scholarship program;

1. The release must indicate that the licensee is making payments on the loan or satisfying the payment or service requirements in accordance with an agreement approved by the federal agency.

(c) Demonstrate to the satisfaction of the Board that the license has been timely renewed, where applicable, and, other than the suspension provided by this rule, is otherwise in good standing; and

(d) Submit a notarized declaration that all continuing education requirements, if any, for the entire suspension period have been met.

(9) Upon compliance with paragraph (8), the Board shall lift the suspension on the license. However, the Board may impose any conditions on the lifting of the suspension that it deems necessary to protect the public.

(10) If the licensee fails to timely renew his/her license during the period of suspension, the license shall be considered to be revoked by operation of law and subject to reinstatement in the sole discretion of the Board. The person who held the lapsed suspended license must comply with the Board's rules for reinstatement, pay any reinstatement fee, and provide the Board with a written release from the federal agency

originally certifying that the licensee is in nonpayment status or default or breach of a repayment or service obligation under any federal educational loan service conditional loan repayment program or service conditional scholarship program. The release must indicate that the licensee is making payments on the loan or satisfying the payment or service requirements in accordance with an agreement approved by the federal agency. It will be within the discretion of the Board whether to reinstate the license.

Cite as Ga. Comp. R. & Regs. R. 480-49-.01
Authority: O.C.G.A. §§ 26-4-20, 26-4-27, 26-4-28, 26-4-44, 26-4-60, 26-4-61, 43-1-19, and 43-1-29.
History. Original Rule entitled "Federal Student Loan Default" adopted. F. June 29, 2015; eff. July 19, 2015.

Rule 480-49-.02. Non-Compliance with an Order for Child Support.

(1) A person holding a current license issued by the Georgia Board of Pharmacy ("Board") may have his/her license indefinitely suspended if s/he is a person for whom an order for child support has been rendered and s/he is not in compliance with that order.

(2) After receiving notice of non-compliance with a child support order from the Department of Human Services, the Board shall suspend the license and shall provide written notice to the licensee via certified or registered mail at the licensee's address of record. If the license is suspended, the licensee shall not practice during the period of suspension.

(3) A person whose license was suspended for being non-compliant with an order for child support may apply to have the suspension lifted. In order to have the suspension lifted, the licensee must:

(a) Request in writing to the Board that the suspension be lifted;

(b) Ensure that the Department of Human Services provides a written notice of compliance and request for release indicating:

1. That the licensee has made satisfactory arrangements to pay the arrearage; or

2. That the licensee is now in compliance with his/her obligation to pay child support.

(c) Demonstrate to the satisfaction of the Board that the license has been timely renewed, where applicable, and other than the suspension provided by this rule, is otherwise in good standing; and

(d) Submit a notarized declaration that all continuing education requirements, if any, for the entire suspension period have been met.

(4) Upon compliance with paragraph (3), the Board shall lift the suspension on the license. However, the Board may impose any conditions on the lifting of the suspension that it deems necessary to protect the public.

(5) If the licensee fails to timely renew his/her license during the period of suspension, the license shall be considered to be revoked by operation of law and subject to reinstatement in the sole discretion of the Board. The person who held the lapsed suspended license must comply with the Board's rules for reinstatement, pay any reinstatement fee, and provide the Board with a written notice of compliance and request for release from the Department of Human Services. The release must indicate that the licensee has made satisfactory arrangements to pay the arrearage or that the licensee is now in compliance with his/her obligation to pay child support. It will be within the discretion of the Board whether to reinstate the license.

Cite as Ga. Comp. R. & Regs. R. 480-49-.02
Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60.
History. Original Rule entitled "Non-Compliance with an Order for Child Support" adopted. F. Sep. 18, 2015; eff. Oct. 8, 2015.

Rule 480-49-.03. Bad Checks and Reversals.

(1) It is the policy of the Board of Pharmacy to pursue its legal remedies under O.C.G.A. § 16-9-20 when a bad check is issued in payment of examination, license or renewal fees, application fees, or similar fees, and to take such other action as outlined herein. Any person issuing a bad check will be subject to the service charge as provided in O.C.G.A. § 16-9-20(a)(2).

(2) Bad Checks.

(a) If an applicant for licensure by examination or reciprocity issues a bad check to cover required licensure or examination fees, such applicant shall not be issued a license until the applicant has paid the appropriate fees and the service charge. If a license is issued prior to determining that the applicant issued a bad check, such license will be deemed to have been issued in error and deemed not current unless the applicant pays the licensure or examination fees and service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The applicant must pay the licensure fees and the service charge by cashier's check or money order.

(b) If an applicant for registration or permit issues a bad check to cover required application fees, such applicant shall not be issued a registration or permit until the applicant has paid the appropriate fees and the service charge. If a registration or permit is issued prior to determining that the applicant issued a bad check, such registration or permit will be deemed to have been issued in error and deemed not current unless the applicant pays the appropriate fees and service charge within ten

(10) days of the Board mailing the notice by certified or registered mail. The applicant must pay the application fees and the service charge by cashier's check or money order.

(c) If a licensee, permit-holder, or registrant attempts to renew a license, permit, or registration by the issuance of a bad check, the license, permit, or registration will not be renewed until the licensee, permit-holder, or registrant pays all fees due including any applicable late renewal fees plus the service charge. If the license, permit, or registration is renewed and reissued to the licensee, permit-holder, or registrant prior to determination that the licensee, permit-holder, or registrant issued a bad check, the licensee, permit-holder, or registrant will be notified by certified or registered mail that the renewed license, permit, or registration will be deemed not current unless the licensee, permit-holder, or registrant remits all fees due for renewal plus the service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The licensee, permit-holder, or registrant must pay the fees and service charge by cashier's check or money order.

(3) Reversals or chargebacks.

(a) If a license by examination or reciprocity is issued and the licensee initiates a chargeback, such license will be deemed to have been issued in error and deemed not current unless the applicant pays the licensure or examination fees and service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The applicant must pay the licensure fees and the service charge by cashier's check or money order.

(b) If a registration or permit is issued and the applicant initiates a chargeback, such registration or permit will be deemed to have been issued in error and deemed not current unless the applicant pays the licensure or examination fees and service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The applicant must pay the application fees and the service charge by cashier's check or money order.

(c) If the license, permit, or registration is renewed and reissued to the licensee, permit-holder, or registrant and the licensee, permit-holder, or registrant initiates a chargeback, the licensee, permit-holder, or registrant will be notified by certified or registered mail that the renewed license, permit, or registration will be deemed not current unless the licensee, permit-holder, or registrant remits all fees due for renewal plus the service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The licensee, permit-holder, or registrant must pay the fees and service charge by cashier's check or money order.

Cite as Ga. Comp. R. & Regs. R. 480-49-.03
Authority: O.C.G.A. §§ 16-9-20, 26-4-27, 26-4-28, 43-1-3, 43-1-7, 50-13-3.
History. Original Rule entitled "Bad Checks and Reversals" adopted. F. May 24, 2017; eff. June 13, 2017.

Chapter 480-50. DRUG DISPOSAL AND AUTHORIZED COLLECTORS.

Rule 480-50-.01. Definitions.

(1) "Authorized Collectors" or "Collectors" means retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment programs, manufacturers, distributors, and reverse distributors which have registered with the DEA to become authorized collectors of drugs for disposal, are authorized to handle controlled substances, and are currently licensed by the Georgia Board of Pharmacy.

(2) "Authorized Employees" means employees of authorized collectors that have met the DEA employment standards and are pharmacists licensed by the Georgia Board of Pharmacy.

(3) "Collection Receptacle" means a lockable and sturdy container with a permanent outer container and a removable numbered inner-liner with a small opening that allows contents to be added but not removed and which container is securely fastened to a permanent structure in a secure area.

(4) "Drugs" means controlled substances and dangerous drugs (non-controlled substances) as those terms are defined in O.C.G.A. Title 16, Chapter 13.

(5) "Mail-back Packages" means pre-paid postage packages provided by authorized collectors at a price or at no cost to the patient or patient's family

(6) "Mail-back Programs" means programs that utilize mail-back packages provided by authorized collectors in which the packages are mailed directly to a reverse distributor and can never be mailed back to the authorized collector.

(7) "Numbered Inner-liner" means a removable, tamper-evident, and tear-resistant liner that bears a unique identification number that is used inside a collection receptacle and which can be securely sealed for transfer to a reverse distributor for transportation to a drug destruction site.

(8) "Ultimate user" means a person who has lawfully obtained and who possesses a drug for his/her own use or for the use of a member of his/her household or for an animal owned by him/her or a member of his/her household.

(9) "Unique Identification Number" means a number traceable to a specific authorized collector.

Cite as Ga. Comp. R. & Regs. R. 480-50-.01
Authority: O.C.G.A. §§ 16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112, Pub. L. 111-273.

History. Original Rule entitled "Definitions" adopted. F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-50-.02. Collection Receptacles Located at Authorized Collectors.

(1) Authorized collectors may place, utilize, and maintain collection receptacles at their DEA registered location. Receptacles can only be available to receive drugs when the collector is open for business and only when an authorized employee is present.

(a) An authorized collector may only begin receiving drugs for disposal at the facility after providing thirty (30) days of advance notification to the Board and the Georgia Drugs and Narcotics Agency of its qualification for and intention to serve as an authorized collector.

(2) Collection receptacles must be lockable, sturdy, securely fixed within the collector's location. If the authorized collector is in a pharmacy, then the collection receptacle must be in the immediate vicinity of and can be observed from the prescription department areas where controlled substances are stored by registrants and where an authorized employee is present, and display a sign stating that non-controlled and controlled drugs in Schedule II, III, IV, or V can be accepted and placed in the receptacle. If the collection receptacle is in a hospital/clinic, it must be in an area monitored by employees, but shall not be in an area where emergency or urgent care is provided. If the collection receptacle is in an opioid treatment facility, it must be located in a room that does not contain other controlled substances and is securely locked with controlled access.

(3) Each receptacle must also be capable of holding a removable, tamper-evident, and tear-resistant inner-liner bearing a unique identification number to receive the drugs.

(a) To dispose of the contents of a receptacle, the sealed liners may be promptly delivered or transferred to a representative for a licensed reverse distributor for destruction. No on-site disposal of any drug is permitted. Only authorized employees can remove and seal an inner-liner and maintain records required by this rule.

(b) Authorized collectors may store inner-liners that have been sealed upon removal from a collection receptacle in a securely locked, substantially constructed cabinet or a securely locked room with controlled access for up to three business days until the liners can be transferred for destruction, and then transferred to a representative for a licensed reverse distributor for destruction.

(c) Collectors are encouraged to schedule inner-liner removals and installations as frequently as necessary.

(d) Drugs placed in the authorized receptacle and stored in secure inner-liners can only be removed from the authorized collector location for destruction by transfer

to a reverse distributor with a current permit issued by the Board and authorized by the DEA as a collector.

(e) The date and time that the numbered inner-liners were taken from the collector and the numbers of the inner-liners must be recorded in logs: one maintained by the collector for two years and one maintained by the reverse distributor for each facility for two years.

(f) The name, Board permit/license number, address, and telephone number of the reverse distributor removing the drugs must be recorded in logs maintained by the collector and by the reverse distributor for a period of at least two years; and

(g) The name and signature of the responsible person representing the reverse distributor physically removing the inner-liners must be recorded in logs maintained by the collector and by the reverse distributor for a period of at least two years. Nothing in this rule shall prevent a DEA authorized common carrier from serving as the authorized representative of the reverse distributor.

Cite as Ga. Comp. R. & Regs. R. 480-50-.02
Authority: O.C.G.A. §§ 16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112, Pub. L. 111-273.
History. Original Rule entitled "Collection Receptacles Located at Authorized Collectors" adopted. F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-50-.03. Collection Receptacles Located at Long Term Care Facilities (LTCF).

(1) Collection receptacles in long-term care facilities ("LTCF") must be located in a secured area monitored by long-term care facility employees. Collection receptacles can only be used in facilities where a consultant pharmacist's services are required.

(a) A LTCF may only begin receiving drugs for disposal at the facility after providing thirty (30) days of advance notification to the Board and the Georgia Drugs and Narcotics Agency of its qualification for and intention to set up a collection receptacle.

(2) A LTCF may dispose of drugs on behalf of an ultimate user who resides, or has resided, at such LTCF by transferring those drugs into an authorized collection receptacle located at such LTCF. When using this method of destruction, the drugs must be transferred into the collection receptacle within three (3) business days after discontinuation of use by the ultimate user. This provision applied to drugs that are expired, discontinued from use, or when the patient for whom they were ordered is no longer a patient.

(3) When the drugs are expired, discontinued from use, or the patient for whom they were ordered is no longer a patient, the drugs shall be immediately removed from the active stock and inventoried by two people who shall be licensed either as a pharmacists, a nurses, or a licensed practical nurses. The completed inventory record shall be signed and dated by these two individuals. The original inventory record shall be maintained by the facility for two years by one supervisor-level employee, and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs must be placed in a collection receptacle at the facility containing a numbered secure Inner-liner which has been provided by an authorized collector (retail pharmacy).

(a) If the numbered inner-liner becomes full prior to collection by a reverse distributor, one supervisor-level employee of the LTCF (e.g., charge nurse or supervisor) and one authorized employee designated by the authorized collector or two authorized employees of the authorized collector pharmacy may change the collection receptacle inner-liner. Upon removal, sealed inner-liners may be stored at the LTCF for up to three (3) business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.

(4) The drugs placed in the authorized receptacle and stored in secure inner-liner and those secured inner-liners stored by the LTCF can only be removed from the LTCF for disposal for destruction by transfer to a representative for a reverse distributor with a current permit issued by the Board and authorized by the DEA as a collector.

(a) The date and time that the numbered inner-liners were taken from the facility and the numbers of the inner-liners recorded in logs, one maintained by the facility for two years and one maintained by the reverse distributor for each facility for two years;

(b) The name, Board permit/license number, address, and telephone number of the reverse distributor removing the drugs;

(c) The name and signature of the responsible person representing the reverse distributor physically removing the Inner-liners; and

(d) The name and signature of the persons transferring the drugs Inner-liners to the reverse distributor.

(5) Authorized collectors may not transfer sealed inner-liners from LTCFs to their primary registered location (i.e., the hospital/clinic or retail pharmacy location). Instead, collectors should deliver sealed inner-liners to a reverse distributor or distributor's registered location by common or contract carrier pick-up or by reverse distributor or distributor pick-up at the LTCF.

Cite as Ga. Comp. R. & Regs. R. 480-50-.03
Authority: O.C.G.A. §§ 16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112, Pub. L. 111-273.
History. Original Rule entitled "Collection Receptacles Located at Long Term Care Facilities (LTCF)" adopted. F.

Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-50-.04. Numbered Inner-Liner Requirements.

(1) A numbered inner-liner shall meet the following requirements:

(a) The inner-liner shall be waterproof, tamper-evident, and tear-resistant;

(b) The inner-liner shall be removable and sealable immediately upon removal without emptying or touching the contents;

(c) The contents of the inner-liner shall not be viewable from the outside when sealed;

(d) The size of the inner-liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and

(e) The inner-liner shall bear a permanent, unique identification number that enables the inner-liner to be tracked.

(2) Access to the inner-liner shall be restricted to authorized employees for the collector.

(3) The inner-liner shall be sealed by two authorized employees immediately upon removal from the permanent outer container, and the sealed inner-liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.

(4) The authorized collector shall maintain a sequential log of all numbered inner-liners. The log shall indicate, at a minimum:

(a) If the Inner-liner has been placed in a receptacle;

(b) If the Inner-liner has been damaged and rendered not usable;

(c) If the Inner-liner has been sealed and removed from the receptacle;

(d) The names of the collector employees sealing and removing the inner-liner from the collector; and

(e) The date and name of the reverse distributor, and authorized representative, by which the inner-liner was removed from the collector's facility.

Cite as Ga. Comp. R. & Regs. R. 480-50-.04
Authority: O.C.G.A. §§ 16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112, Pub. L. 111-273.
History. Original Rule entitled "Numbered Inner-Liner Requirements" adopted. F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-50-.05. Mail-back Programs.

(1) Pre-paid mail-back packages may be provided by authorized collectors to patients and their families for a price or at no cost to the patient.

(2) In Georgia, mail-back packages cannot be returned or mailed back to the authorized collector, unless that collector is a licensed reverse distributor. Collectors that are pharmacies cannot receive or dispose of mail back packages. All such mail-back packages must be shipped directly to a licensed reverse distributor for disposal.

Cite as Ga. Comp. R. & Regs. R. 480-50-.05
Authority: O.C.G.A. §§ 16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112, Pub. L. 111-273.
History. Original Rule entitled "Mail-back Programs" adopted. F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-50-.06. Reverse Distributors.

(1) Any person that reverse distributes a controlled substance shall be registered with the United States Drug Enforcement Administration as a reverse distributor and actively licensed by the Georgia Board of Pharmacy as a reverse distributor.

(2) A reverse distributor shall acquire controlled substances and non-controlled drugs from a collector in the following manner:

(a) Pick-up of sealed inner liner from a collector at the collector's licensed location or authorized receptacle collection site such as a LTCF; or

(b) Receive a sealed inner-liner delivered by common or contract carrier or delivered directly by a registrant or a LTCF to the reverse distributor.

(i) Delivery to the reverse distributor by common or contract carrier may only be made to the reverse distributor at the reverse distributor's registered location. Once *en route*, such deliveries may not be re-routed to any other location or person, regardless of registration status.

(ii) All controlled substance and non-controlled drug deliveries to a reverse distributor shall be personally received by an employee of the reverse distributor at the registered location.

(3) Upon acquisition of a drug by delivery or pick-up, a reverse distributor shall:

(a) Immediately store the controlled substance, in accordance with the security controls in accordance with DEA rules at the reverse distributor's registered location or immediately transfer the drugs to the reverse distributor's registered location for secure storage, in accordance with the security controls in DEA rules, until timely destruction.

(4) A reverse distributor shall destroy or cause the destruction of any drug received for the purpose of destruction no later than 30 calendar days after receipt.

Cite as Ga. Comp. R. & Regs. R. 480-50-.06
Authority: O.C.G.A. §§ 16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112, Pub. L. 111-273.
History. Original Rule entitled "Reverse Distributors" adopted. F. Jan. 20, 2016; eff. Feb. 9, 2016.

Rule 480-50-.07. Inspections.

(1) The Georgia Drugs and Narcotics Agency (GDNA) shall have the authority to conduct inspections of any place, premises, or receptacle utilized by any authorized collector in relation to collection, retention, and disposal of drugs.

(2) GDNA shall have the authority to examine, copy, or remove all records required by this rule, and to examine, remove, or inventory all numbered inner-liners.

(3) It shall be the responsibility of any authorized collector to make same available for such inspection, copying, examination, or inventorying by said GDNA.

(4) Following any such examination, inventory, or inspection of records or receptacles, GDNA shall provide to the authorized collector a copy of any written inspection report produced on which any deficiencies or violations are made along with any recommendations, if any, concerning the satisfactory storage, record-keeping, handling, and security of drugs for disposal.

(5) The Pharmacist-in-Charge of each authorized collector shall obtain a copy of the current Board permit of every reverse distributor to which inner-liners are returned. Such copies shall be made available during the GDNA's inspection.

(6) The Pharmacist-in-Charge of each authorized collector shall respond in a written report addressing any discrepancies or deficiencies noted in a GDNA inspection report within two weeks after receipt of the inspection notice. The deficiencies shall be corrected within ten (10) business days.

Cite as Ga. Comp. R. & Regs. R. 480-50-.07
Authority: O.C.G.A. §§ 16-13-45, 26-3-7, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-87, 26-4-112, Pub. L. 111-273.
History. Original Rule entitled "Inspections" adopted. F. Jan. 20, 2016; eff. Feb. 9, 2016.

Chapter 480-51. INTERCHANGEABLE BIOLOGICAL PRODUCTS.

Rule 480-51-.01. Definitions.

(1) "Biological product" means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act, 42 U.S.C. Section 262.

(2) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in subsection (k)(4) of 42 U.S.C. 262 or has been deemed therapeutically equivalent by the federal Food and Drug Administration.

Cite as Ga. Comp. R. & Regs. R. 480-51-.01
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-81.
History. Original Rule entitled "Definitions" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.

Rule 480-51-.02. Substituting Interchangeable Biological Products.

(1) If a practitioner of the healing arts prescribes a biological product by its nonproprietary name, the pharmacist may substitute the biological product with an interchangeable biological product, but shall dispense the lowest retail-priced interchangeable biological product, which is in stock.

(2) Substitutions as provided in this rule are authorized for the express purpose of making available to the consumer the lowest retail priced interchangeable biological product which is in stock.

(3) Whenever a substitution is made:

(a) The pharmacist shall record on the original prescription the fact that there has been a substitution and the identity of the dispensed interchangeable biological product and its manufacturer. Such prescription shall be maintained for two years and shall be available for inspection by the board or its representative.

(b) The pharmacist shall affix to the prescription label or container or an auxiliary label, the name of the interchangeable biological product, with an explanation of "interchangeable biological product for (insert name of prescribed biological product)" or similar language to indicate substitution has occurred, unless the prescribing practitioner indicated that the name of the biological product may not appear upon the prescription label.

1. This labeling requirement does not apply to biological products dispensed for in-patient hospital services, to hospital-administered biological products for outpatients, or to biological products in specialty packaging for dosing purposes. This labeling requirement does apply to hospital retail pharmacies and to any biological products dispensed by a hospital for a patient's use or administration at home.

(4) The substitution of any biological product by a registered pharmacist pursuant to this rule section does not constitute the practice of medicine.

(5) A patient for whom a prescription biological product order is intended may instruct a pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product.

(6) A practitioner of the healing arts may instruct the pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product by including the words "brand necessary" in the body of the prescription.

(a) When a prescription is a hard copy biological product order, such indication of brand necessary must be in the practitioner's own handwriting and shall not be printed, applied by rubber stamp, or any such similar means.

(b) When the prescription is an electronic prescription drug or biological product order, the words "brand necessary" are not required to be in the practitioner's own handwriting and may be included on the prescription in any manner or by any method.

(c) When a practitioner has designated "brand necessary" on an electronic biological product order, an interchangeable biological product shall not be substituted without the practitioner's express consent, which shall be documented by the pharmacist on the prescription and by the practitioner in the patient's medical record.

(7) Within forty-eight (48) hours, excluding weekends and holidays, following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the biological product and the manufacturer.

(a) The communication shall be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber by using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

1. There is no interchangeable biological product approved by the federal Food and Drug Administration for the prescribed product; or

2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(8) A link for the current list of all biological products determined by the federal Food and Drug Administration to be interchangeable with a specific biological products is available on the Board's website.

Cite as Ga. Comp. R. & Regs. R. 480-51-.02
Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-81.
History. Original Rule entitled "Substituting Interchangeable Biological Products" adopted. F. Mar. 21, 2018; eff. Apr. 10, 2018.