

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 1. GENERAL PROVISIONS

§ 26-4-2. Liberal construction of chapter

The practice of pharmacy in this state is declared to be a learned profession and the practice of pharmacy affects the public health, safety, and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy in this state as a learned profession, as defined in this chapter, should merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy to ensure the quality of drugs and related devices distributed in this state. This chapter shall be liberally construed to carry out these objectives and purposes.

HISTORY: Code 1981, § 26-4-2, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-3. Legislative intent

It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; the licensure, control, and regulation of all sites or persons, in or out of this state that distribute, manufacture, or sell drugs or devices used in the dispensing and administration of drugs within this state; and the regulation and control of such other materials as may be used in the diagnosis, treatment, and prevention of injury, illness, and disease of a patient or other individual.

HISTORY: Code 1981, § 26-4-3, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-4. Definition of "practice of pharmacy."

The "practice of pharmacy" means the interpretation, evaluation, or dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care; performing capillary blood tests and interpreting the results as a means to screen for or monitor disease risk factors and facilitate patient education, and a pharmacist performing such functions shall report the results obtained from such blood tests to the patient's physician of choice; and the responsibility for compounding and labeling of drugs and devices.

HISTORY: Code 1981, § 26-4-4, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 277, § 1.

§ 26-4-5. Definitions

As used in this chapter the term:

(1) "Administer" or "administration" means the provision of a unit dose of medication to an individual patient as a result of the order of an authorized practitioner of the healing arts.

(2) "Board of pharmacy" or "board" means the Georgia State Board of Pharmacy.

(3) "Brand name drug" means the proprietary, specialty, or trade name used by a drug manufacturer for a generic drug and placed upon the drug, its container, label, or wrapping at the time of packaging.

(4) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device 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.

(5) "Confidential 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 or, as the patient directs, to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being; and to such other persons or governmental agencies authorized by law to receive such confidential information.

(6) "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29, Schedules I through V of 21 C.F.R. Part 1308, or both.

(7) "Dangerous drug" means any drug, substance, medicine, or medication as defined in Code Section 16-13-71.

(8) "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.

(9) "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."

(10) "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.

(11) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(11.1) "Division director" means the division director of the professional licensing boards division, as provided in Chapter 1 of Title 43.

(12) "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.

(13) "Drug regimen review" includes but is not limited to the following activities:

(A) Evaluation of any prescription drug order and patient record for:

(i) Known allergies;

(ii) Rational therapy-contraindications;

(iii) Reasonable dose and route of administration; and

(iv) 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:

(i) Drug-drug;

(ii) Drug-food;

(iii) Drug-disease; and

(iv) Adverse drug reactions; and

(D) Evaluation of any prescription drug order and patient record for proper utilization, including overutilization or underutilization, and optimum therapeutic outcomes.

(14) "Drug researcher" means a person, firm, corporation, agency, department, or other entity which handles, possesses, or utilizes controlled substances or dangerous drugs, as defined in Chapter 13 of Title 16, for purposes of conducting research, drug analysis, animal training, or drug education, as such purposes may be further defined by the board, and is not otherwise registered as a pharmacist, pharmacy, drug wholesaler, distributor, supplier, or medical practitioner.

(14.1) "Electronic data prescription drug order" means any digitalized prescription drug order transmitted to a pharmacy, other than by facsimile, which contains the secure, personalized digital key, code, number, or other identifier used to identify and authenticate the prescribing practitioner in a manner required by state laws and board regulations and includes all other information required by state laws and board regulations.

(14.2) "Electronic data signature" means:

(A) A secure, personalized digital key, code, number, or other identifier used for secure electronic data transmissions which identifies and authenticates the prescribing practitioner as a part of an electronic data prescription drug order transmitted to a pharmacy; or

(B) An electronic symbol or process attached to or logically associated with a record and executed or adopted by a prescribing practitioner with the intent to sign an electronic data prescription drug order, which identifies the prescribing practitioner, as a part of an electronic data prescription drug order transmitted to a pharmacy.

(14.3) "Electronic signature" means an electronic visual image signature or an electronic data signature of a practitioner which appears on an electronic prescription drug order.

(14.4) "Electronic visual image prescription drug order" means any exact visual image of a prescription drug order issued by a practitioner electronically and which bears an electronic reproduction of the visual image of the practitioner's signature, is either printed on security paper and presented as a hard copy to the patient or transmitted by the practitioner via facsimile machine or equipment to a pharmacy, and contains all information required by state law and regulations of the board.

(14.5) "Electronic visual image signature" means any exact visual image of a practitioner's signature reproduced electronically on a hard copy prescription drug order presented to the patient by the practitioner or is a prescription drug order transmitted to a

pharmacy by a practitioner via facsimile machine or equipment.

(15) "Emergency service provider" means licensed ambulance services, first responder services or neonatal services, or any combination thereof.

(16) "Extern" or "pharmacy extern" means 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 to a licensed pharmacy for the purposes of obtaining practical experience and completing a degree in pharmacy. For the purposes of this chapter, a pharmacy extern may engage in any activity or perform any function which a pharmacy intern may perform under the direct supervision of a licensed pharmacist.

(17) "Federal act" or "Federal Food, Drug, and Cosmetic Act" means the Federal Food, Drug, and Cosmetic Act of the United States of America, approved June 25, 1938, officially cited as Public Document 717, 75th Congress (Chapter 675-3rd Sess.) and all amendments thereto, and all regulations promulgated thereunder by the commissioner of the Federal Food and Drug Administration.

(18) "Generic name" means a chemical name, a common or public name, or an official name used in an official compendium recognized by the Federal Food, Drug, and Cosmetic Act, as amended.

(18.05) "Hard copy prescription drug order" means a written, typed, reproduced, or printed prescription drug order prepared on a piece of paper.

(18.1) "Institution" means any licensed hospital, nursing home, personal care home, hospice, health clinic, or prison clinic.

(19) "Intern" or "pharmacy intern" means an individual who is:

(A) A student who is currently enrolled in an approved school or college of pharmacy, has registered with the board, and has been licensed as a pharmacy intern;

(B) 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

(C) An individual who does not otherwise meet the requirements of subparagraph (A) or (B) of this paragraph and 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.

(20) Reserved.

(21) "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, state, or federal and state law or rule.

(22) "Manufacturer" means a person engaged in the manufacturing of drugs or devices.

(23) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of any substance or labeling or relabeling of its container and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

(23.5) "Narcotic treatment program clinic pharmacy" means a pharmacy which is attached to, located in, or otherwise a part of and operated by a narcotic treatment program which provides an opiate replacement treatment program, as designated or defined by the Department of Human Resources or such other state agency as may be designated as the state authority for the purposes of implementing the narcotic treatment program authorized by federal and state laws and regulations.

(24) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

(25) "Patient counseling" means the oral communication by the pharmacist of information, as defined in 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.

(26) "Person" means an individual, corporation, partnership, or association.

(27) "Pharmaceutically equivalent" means drug products that contain identical amounts of the identical active ingredient, in identical dosage forms, but not necessarily containing the same inactive ingredients.

(28) "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.

(29) "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.

(30) "Pharmacy" means:

(A) The profession, art, and science that deals with pharmacy care, drugs, or both, medicines, and medications, their nature, preparation, administration, dispensing, or effect; or

(B) Any place licensed in accordance with this chapter 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.

(31) "Pharmacy care" means 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.

(32) "Pharmacy technician" means those support persons utilized in pharmacies 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.

(33) "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.

(34) "Preceptor" means an individual who is currently licensed as a pharmacist by the board, meets the qualifications as a preceptor under the rules of the board, and participates in the instructional training of pharmacy interns.

(35) "Prescription drug" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with either of the following statements: "Caution: federal law prohibits dispensing without prescription" or "Caution: federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only; or a controlled substance, as defined in paragraph (6) of this Code section or a dangerous drug as defined in paragraph (7) of this Code section.

(36) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient; such order includes an electronic visual image prescription drug order and an electronic data prescription drug order.

(37) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the rules of the board, prior to dispensing the drug as part of a drug regimen review.

(38) "Reverse drug distributor" means a person, firm, or corporation which receives and handles drugs from within this state which are expired, discontinued, adulterated, or misbranded, under the provisions of Chapter 3 of this title, the "Georgia Drug and Cosmetic Act," from a pharmacy, drug distributor, or manufacturer for the purposes of destruction or other final disposition or for return to the original manufacturer of a drug.

(38.5) "Security paper" means paper utilizing 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 the prescription drug order is not subject to any form of copying, reproduction, or alteration, or any combination of copying, reproduction, or alteration, and may include a watermark produced by the electronic digital process when a prescription is printed to clearly show if a prescription has been reproduced or copied in an unauthorized manner.

(39) "Significant adverse drug reaction" means a drug related incident that may result in serious harm, injury, or death to the patient.

(40) "Substitution" means to dispense pharmaceutically equivalent and therapeutically equivalent drug products as regulated by the board in place of the drug prescribed.

(41) "Wholesale distributor" means any person engaged in wholesale distribution of drugs, including but not limited to manufacturers; repackagers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail and hospital pharmacies that conduct wholesale distributions.

HISTORY: Code 1981, § 26-4-5, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26; Ga. L. 1999, p. 277, § 1.1; Ga. L. 2000, p. 1706, § 22; Ga. L. 2004, p. 738, §§ 2, 3.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 2. STATE BOARD OF PHARMACY

§ 26-4-20. State Board of Pharmacy continued; enforcement of provisions of chapter vested in board

(a) The Georgia State Board of Pharmacy existing immediately preceding July 1, 1998, is continued in existence, and members serving on the board immediately preceding that date shall continue to serve out their terms of office and until their respective successors are appointed and qualified.

(b) The responsibility for enforcement of the provisions of this chapter shall be vested in the Georgia State Board of Pharmacy. The board shall have all of the duties, powers, and authority specifically granted by or necessary for the enforcement of this chapter, as well as such other duties, powers, and authority as it may be granted from time to time by applicable law.

HISTORY: Code 1981, § 26-4-20, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-21. Eligibility requirements for board members; oath of office

(a) Each of the seven pharmacist members of the board shall, at the time of appointment:

(1) Be a resident of this state for not less than six months;

(2) Be currently licensed and in good standing to engage in the practice of pharmacy in this state;

(3) Be actively engaged in the practice of pharmacy in this state;

(4) Have five years of experience in the practice of pharmacy in this state after licensure; and

(5) Not be officially employed as a full-time faculty member by any school or college of pharmacy.

(b) The one consumer member of the board shall be a resident of Georgia who has attained the age of majority and shall not have any connection whatsoever with the pharmaceutical industry.

(c) Appointees to the board shall immediately after their appointment take and subscribe to an oath or affirmation before a qualified officer that they will faithfully and impartially

perform the duties of the office, which oath shall be filed with the Secretary of State, whereupon the Secretary of State shall issue to each appointee a certificate of appointment.

HISTORY: Code 1981, § 26-4-21, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-22. Number and terms of members; appointment; vacancies

(a) The board shall consist of seven members possessing the qualification specified in subsection (a) of Code Section 26-4-21 and one additional member possessing the qualifications specified in subsection (b) of Code Section 26-4-21 who shall be appointed by the Governor for a term of five years or until their successors are appointed and qualified. Pharmacist members shall represent a diversity of practice settings and geographic dispersion of practitioners across the state.

(b) At the annual meeting of the Georgia Pharmacy Association, there may be nominated by such licensed pharmacists as may be present three practicing registered pharmacists who shall meet the qualifications imposed by subsection (a) of Code Section 26-4-21 to fill the next vacancy occurring on the board, except a vacancy in the consumer member position on said board, by reason of expiration of term. The secretary of said association may regularly submit to the Governor the names of the three pharmacists so nominated and the Governor may make the appointment to fill such vacancy from the names so submitted. Should any vacancy occur upon the board, other than in the consumer member position on the board and other than by reason of expiration of term, such vacancy may be filled by appointment by the Governor for the unexpired term from a group of three practicing registered pharmacists nominated as provided in this subsection at any regular or special meeting of the Georgia Pharmacy Association.

(c) The consumer member of the board shall also be appointed by the Governor. Such member shall vote only on matters relating to administration and policy which do not directly relate to practical and scientific examination of pharmacists for licensing in Georgia. Vacancies occurring in the membership of the board occupied by a consumer shall be filled by the Governor for the unexpired term of office.

HISTORY: Code 1981, § 26-4-22, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-23. Removal of board members

Any member who has failed to attend three consecutive regular monthly meetings of the board for any reason other than illness of such member shall be subject to removal by the Governor upon request of the board. The president of the board shall notify the Governor in writing when any such member has failed to attend three consecutive regular monthly meetings. Any member of the board may be removed by the Governor as provided in Code Section 43-1-17.

HISTORY: Code 1981, § 26-4-23, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-24. Meetings and organization; appeals; serving of notices and legal process

The board shall meet at least annually to organize and elect a president and a vice-president from its members. The division director shall be the secretary of the board and shall have all the power, duties, and authority with reference to such board as shall be prescribed by Chapter 1 of Title 43 and shall perform such other duties as may be prescribed by the board. All appeals from the decision of the board, all documents or applications required by law to be filed with the board, and any notice or legal process to be served upon the board may be filed with or served upon the division director at his or her office in the county of domicile of the professional licensing boards division.

HISTORY: Code 1981, § 26-4-24, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2000, p. 1706, § 23.

§ 26-4-25. Compensation of members

Each member of the board shall be reimbursed as provided for in subsection (f) of Code Section 43-1-2.

HISTORY: Code 1981, § 26-4-25, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-26. Meetings; notice; quorum; open meetings

(a) The board shall meet on a regular basis to transact its business. The board shall meet at such additional times as it may determine. Such additional meetings may be called by the president of the board or by at least two-thirds of the members of the board.

(b) Notice of all meetings of the board shall be given in the manner and pursuant to requirements prescribed by Chapter 14 of Title 50 relating to open meetings.

(c) A majority of the members of the board shall constitute a quorum for the conduct of a board meeting and, except where a greater number is required by this chapter or by any rule of the board, all actions of the board shall be by a majority of a quorum.

(d) All board meetings and hearings shall be open to the public. The board may, in its discretion and according to law, conduct any portion of its meeting in executive session closed to the public.

HISTORY: Code 1981, § 26-4-26, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-27. Authority to establish rules and regulations

The board may establish such rules and regulations not inconsistent with this chapter and as in its judgment will best carry out the requirements thereof.

HISTORY: Code 1981, § 26-4-27, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-28. Powers, duties, and authority

(a) The board shall have the power, duty, and authority for the control and regulation of the practice of pharmacy in the State of Georgia including, but not limited to, the following:

(1) The licensing by examination or by license transfer of applicants who are qualified to engage in the practice of pharmacy under the provisions of this chapter;

(2) The renewal of licenses to engage in the practice of pharmacy;

(3) The establishment and enforcement of compliance with professional standards and rules of conduct of pharmacists engaged in the practice of pharmacy;

(4) The determination and issuance of standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, and the specification and enforcement of requirements for practical training including internship;

(5) The enforcement of those provisions of this chapter relating to the conduct or competence of pharmacists practicing in this state and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy;

(6) The licensure and regulation of pharmacies and pharmacy interns;

(7) The regulation of other employees in the prescription or pharmacy department;

(8) The collection of professional demographic data;

(9) The right to seize any such drugs and devices found by the board to constitute an imminent danger to the public health and welfare;

(10) The establishment of minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding, and dispensing of such drugs or devices utilized within the practice of pharmacy;

(11) The establishment of minimum standards for the purity and quality of such drugs utilized within the practice of pharmacy;

(12) The establishment of minimum standards for the purity and quality of such devices and other materials utilized within the practice of pharmacy;

(13) The issuance and renewal of licenses of all persons engaged in the manufacture and distribution of drugs;

(14) The issuance and renewal of licenses of all persons engaged in the manufacture and distribution of devices utilized within the practice of pharmacy;

(15) The inspection of any licensed person at all reasonable hours for the purpose of determining if any provisions of the laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The board and its officers, agents, and designees shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to drugs, devices, and the practice of pharmacy;

(16) The investigation of alleged violations of this chapter or any other law in this state pertaining to, or in connection with, persons or firms licensed by the board or otherwise authorized by the laws of this state to manufacture, sell, distribute, dispense, or possess drugs, medicines, poisons, cosmetics, or devices, as related to misbranded or counterfeit drugs, or any rules and regulations promulgated by the board under this chapter; the conducting of investigative interviews or full board hearings, with or without the necessity of utilizing the Office of State Administrative Hearings, in respect thereto when in its discretion it appears to be necessary; and the bringing of such violations to the notice of the Attorney General;

(17) The listing at any time upon either a list under Article 3 of Chapter 13 of Title 16, the "Dangerous Drug Act," or upon a schedule under Article 2 of Chapter 13 of Title 16, the "Georgia Controlled Substances Act," of any drug found to be potentially dangerous to public safety if dispensed without prescription;

(18) The expunging of the pharmacy related practice record of any pharmacist whose record consists of a sole sanction resulting from alcohol impairment and whose pharmacy related practice record during a five-year time period dating from the time of the sanction has incurred no additional charges or infractions;

(19) Restricting the inspection or examination of records or access to any area licensed and under the control of any registrant, which has been issued a permit by the board, to members of the board, agents for the Georgia Drugs and Narcotics Agency, the United States Drug Enforcement Administration, the Georgia Department of Medical Assistance, or other federal agencies or agencies of this state otherwise entitled to such inspections or examinations by law, subpoena, or court order. This paragraph specifically prohibits inspections or examinations of board registrants or any requirement which forces board registrants to allow inspection or examination, or both, of their records by representatives for any nongovernment affiliated, private organization for any purpose since the access of

patient prescription records is restricted by this chapter and access by such private organizations is unnecessary in that this access only duplicates existing record-keeping and inspection requirements already addressed by the laws and regulations of the board and other government organizations. This restriction shall also prohibit a private, nongovernment affiliated organization from examining or copying continuing education certificates maintained by individual registrants. Nothing in this paragraph shall prohibit the pharmacist in charge from voluntarily allowing appropriate agencies and organizations to inspect or examine the records and pharmacy area under the control of the pharmacist in charge provided such inspections or examinations are for the purposes of ensuring the quality of care provided to patients; and

(20) Serving as the sole governmental or other authority which shall have the authority to approve or recognize accreditation or certification programs for specialty pharmacy practice or to determine the acceptability of entities which may accredit pharmacies or certify pharmacists in a specialty of pharmacy practice, and the board may require such accreditation or certification as a prerequisite for specialty or advanced pharmacy practice. Such accreditation and certification standards for specialties shall be set forth in rules promulgated by the board with such rules to contain the required qualifications or limitations. Any accreditation or certification for specialty pharmacy practice approved or recognized by the board shall be deemed sufficient to meet any and all standards, licensure, or requirements, or any combination thereof, otherwise set forth by any private entity or other government agency to satisfy its stated goals and standards for such accreditation or certification. Nothing in this paragraph shall prohibit private entities, government agencies, professional organizations, or educational institutions from submitting accreditation or certification programs for the review and potential approval or recognition by the board. Accreditation and certification for specialty pharmacy practice under this paragraph shall be subject to the following conditions:

(A) Applications shall be submitted as set forth in rules promulgated or approved by the board for accreditation or certification;

(B) Only a pharmacist registered by this state and maintaining an active license in good standing is eligible for certification in a specialty pharmacy practice by the board;

(C) Only a pharmacy registered by this state and maintaining an active license in good standing is eligible for accreditation for specialty pharmacy practice by the board;

(D) Any board approved or recognized accreditation for a specialty pharmacy practice of a pharmacy is to be deemed sufficient and shall satisfy any standards or qualifications required for payment of services rendered as set forth by any insurance company, carrier, or similar third-party payor plan in any policy or contract issued, issued for delivery, delivered, or renewed on or after July 1, 1999;

(E) Any board approved or recognized specialty certification issued to a pharmacist is deemed sufficient and shall satisfy any standards or qualifications required for payment of services rendered as set forth by any insurance company, carrier, or similar third-party

payor plan in any policy or contract issued, issued for delivery, delivered, or renewed on or after July 1, 1999; and

(F) The board may deny, revoke, limit, suspend, probate, or fail to renew the accreditation or specialty certification of a pharmacy, pharmacist, or both for cause as set forth in Code Section 26-4-60 or for a violation of Chapter 13 of Title 16 or if the board determines that a pharmacy, pharmacist, or both, no longer meet the accreditation or certification requirements of the board. Before such action, the board shall serve upon the pharmacist in charge of a pharmacy or pharmacist an order to show cause why accreditation or certification should not be denied, revoked, limited, suspended, or probated or why the renewal should not be refused. The order to show cause shall contain a statement for the basis therefor and shall call upon the pharmacist in charge of a pharmacy, the pharmacist, or both, to appear before the board at a time and place not more than 60 days after the date of the service of the order.

(b) Proceedings by the board in the exercise of its authority to cancel, suspend, or revoke any license issued under the terms of this chapter shall be conducted in accordance with Chapter 13 of Title 50, the "Georgia Administrative Procedure Act." In all such proceedings the board shall have authority to compel the attendance of witnesses and the production of any book, writing, or document upon the issuance of a subpoena therefor signed by the secretary of the board. In any hearing in which the fitness of a licensee or applicant to practice pharmacy is in question, the board may exclude all persons from its deliberation of the appropriate action to be taken and may, when it deems it necessary, speak to a licensee or applicant in private.

(c) The board shall have such other duties, powers, and authority as may be necessary to the enforcement of this chapter and to the enforcement of board rules made pursuant thereto which shall include, but are not limited to, the following:

(1) The board may join such professional organizations and associations organized exclusively to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board;

(2) The board may place under seal all drugs or devices that are owned by or in the possession, custody, or control of a licensee at the time his or her license is suspended or revoked or at the time the board refuses to renew his or her license. Except as otherwise provided in this Code section, drugs or devices so sealed shall not be disposed of until appeal rights under Chapter 13 of Title 50, the "Georgia Administrative Procedure Act," have expired, or an appeal filed pursuant to such chapter has been determined. The court involved in an appeal filed pursuant to such chapter may order the board, during the pendency of the appeal, to sell sealed drugs that are perishable. The proceeds of such a sale shall be deposited with that court;

(3) Except as otherwise provided to the contrary, the board shall exercise all of its duties, powers, and authority in accordance with Chapter 13 of Title 50, the "Georgia

Administrative Procedure Act";

(4) In addition to the fees specifically provided for in this chapter, the board may assess additional reasonable fees for services rendered to carry out its duties and responsibilities as required or authorized by this chapter or the rules and regulations promulgated by the board. Such services rendered shall include but not be limited to the following:

- (A) Issuance of duplicate certificates or identification cards;
- (B) Certification of documents;
- (C) License transfer;
- (D) Examination administration to a licensure applicant; and
- (E) Examination materials; and

(5) Cost recovery.

(A) 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 costs 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 treasury; and

(B) In the case of a pharmacy or wholesale distributor, the order issued may be made to the corporate owner, if any, and to any pharmacist, officer, owner, or partner of the pharmacy or wholesale distributor who is found to have had knowledge of or have participated knowingly in one or more of the violations set forth in this Code section.

Where an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for payment in the court in the county where the administrative hearing was held. This right of enforcement shall be in addition to any other rights the board may have as to any person directed to pay costs. In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

HISTORY: Code 1981, § 26-4-28, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26; Ga. L. 1999, p. 277, §§ 2, 3.

§ 26-4-29. Georgia Drugs and Narcotics Agency; continuance; appointment, requirements, and duties of director; power to make arrests; report of violations of drug laws; dangerous drug list

(a) The agency created in 1908 as the Office of the Chief Drug Inspector and known as the Georgia Drugs and Narcotics Agency since 1976 is continued in existence as the

Georgia Drugs and Narcotics Agency. This agency shall be a budget unit as defined under Code Section 45-12-7; provided, however, that the agency shall be assigned for administrative purposes only, as defined in Code Section 50-4-3, to the office of the Secretary of State. The Georgia Drugs and Narcotics Agency is authorized by this Code section to enforce the drug laws of this state. The board shall appoint a director who shall be charged with supervision and control of such agency. The agency shall employ the number of personnel deemed necessary to properly protect the health, safety, and welfare of the citizens of this state. Such personnel shall be pharmacists registered in this state when employed as either special agents or the deputy director.

(b) The director shall hold office at the pleasure of the board, and should any vacancy occur in said office for any cause whatsoever, said board shall appoint a successor at a regular or called meeting. The director shall be a pharmacist registered in this state. The salary of the director shall be fixed by the board. The whole time of the director shall be at the disposal of the board. The director, or agency personnel acting on behalf of the director, shall have the duty and the power to:

(1) Visit and inspect factories, warehouses, wholesaling establishments, retailing establishments, chemical laboratories, and such other establishments in which any drugs, devices, cosmetics, and such articles known as family remedies, grocer's drugs, and toilet articles are manufactured, processed, packaged, sold at wholesale, sold at retail, or otherwise held for introduction into commerce;

(2) Enter and inspect any vehicle used to transport or hold any drugs, devices, cosmetics, or any of the articles listed in paragraph (1) of this subsection;

(3) Investigate alleged violations of laws and regulations regarding drugs, devices, cosmetics, or any of the articles listed in paragraph (1) of this subsection;

(4) Take up samples of the articles listed in paragraph (1) of this subsection from any of the said establishments for examination and analysis by the state chemist, or under such person's direction and supervision, as provided by Code Section 26-4-131;

(5) Seize and take possession of all articles which are declared to be contraband under Chapter 13 of Title 16 and Chapter 3 of this title and this chapter and deliver such articles to the agency;

(6) Compel the attendance of witnesses and the production of evidence on behalf of the board via a subpoena issued by the director, when there is reason to believe any violations of laws or regulations concerning drugs, devices, cosmetics, or any of the articles listed in paragraph (1) of this subsection have occurred; and

(7) Perform such other duties as may be directed by the board.

(c)(1) The director, deputy director, and special agents of the Georgia Drugs and Narcotics Agency shall have the authority and power that sheriffs possess to make arrests of any persons violating or charged with violating Chapter 13 of Title 16 and Chapter 3

of this title and this chapter. The deputy director and special agents shall be required to be P.O.S.T. certified peace officers under Chapter 8 of Title 35, the "Georgia Peace Officer Standards and Training Act."

(2) In case of such arrest, the director, deputy director, or any of the special agents shall immediately deliver the person so arrested to the custody of the sheriff of the county wherein the offense is alleged to have been committed. The duty of the sheriff in regard to the person delivered to the sheriff by any such person arrested under power of this Code section shall be the same as if the sheriff had made the original arrest.

(c.1) When the deputy director or a special agent employed by the Georgia Drugs and Narcotics Agency leaves the agency under honorable conditions after accumulating 25 years of service in the agency, as a result of a disability arising in the line of duty, or pursuant to approval by the State Board of Pharmacy, such director or agent shall be entitled to retain his or her weapon and badge pursuant to approval by the State Board of Pharmacy, and, upon leaving the agency, the director of the Georgia Drugs and Narcotics Agency shall retain his or her weapon and badge pursuant to approval by the State Board of Pharmacy.

(d) Except as otherwise provided in this chapter, upon receiving a summary report from agency personnel, the director shall report to the board what have been determined to be violations of the drug laws and rules over which the board has authority. After such reports have been made to the board, the board can instruct the director to:

(1) Cite any such person or establishment to appear before the cognizant member of the board for an investigative interview;

(2) Forward such reports to the Attorney General's office for action decided on by the board; or

(3) Take whatever other action the board deems necessary.

(e) The Georgia Drugs and Narcotics Agency shall compile and submit to the General Assembly during each annual legislative session a list of known dangerous drugs as defined in subsection (a) of Code Section 16-13-71 and any other drugs or devices which the board has determined may be dangerous or detrimental to the public health and safety and should require a prescription, and the Georgia Drugs and Narcotics Agency shall assist the State Board of Pharmacy during each annual legislative session by compiling and submitting a list of substances to add to or reschedule substances enumerated in the schedules in Code Sections 16-13-25 through 16-13-29 by using the guidelines set forth in Code Section 16-13-22.

(1) The State Board of Pharmacy is authorized and directed to publish and distribute the "Dangerous Drug List" as prepared by the Georgia Drugs and Narcotics Agency and the "Georgia Controlled Substances Act" as enacted by law.

(2) The Georgia State Board of Pharmacy shall provide for a fee as deemed reasonable or at no cost, such number of copies of the "Dangerous Drug List" and "Georgia Controlled Substances Act" to law enforcement officials, school officials, parents, and other interested citizens as are required.

HISTORY: Code 1981, § 26-4-29, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26

§ 26-4-30. Construction of chapter

This chapter shall not be construed to prohibit the sale by general merchants or other nonpharmacy retailers of nonprescription drugs when sold only in their original and unbroken packages.

HISTORY: Code 1981, § 26-4-30, enacted by Ga. L. 1998, p. 686, § 1.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 3. PRACTICE OF PHARMACY

§ 26-4-40. Unlawful to practice pharmacy without license; exception; fine

(a) Except as otherwise provided in this chapter, it shall be unlawful for any individual to engage in the practice of pharmacy unless currently licensed to practice under the provisions of this chapter.

(b) Practitioners authorized under the laws of this state to compound drugs and to dispense drugs to their patients in the practice of their respective professions shall not be required to be licensed under the provisions of this chapter; however, practitioners shall meet the same standards, record-keeping requirements, and all other requirements for the dispensing of drugs applicable to pharmacists.

(c) Any individual who, after hearing, shall be found by the board to have unlawfully engaged in the practice of pharmacy shall be subject to a fine to be imposed by the board for each offense. Each violation of this chapter pertaining to unlawfully engaging in the practice of pharmacy shall also constitute a felony punishable upon conviction thereof by a fine of not less than \$500.00 nor more than \$1,000.00 or by imprisonment for not less than two nor more than five years, or both.

HISTORY: Code 1981, § 26-4-40, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-41. Qualifications for license; examination; internship and other training programs

(a) *Qualifications.* To obtain a license to engage in the practice of pharmacy, an applicant for licensure by examination shall:

- (1) Have submitted a written application in the form prescribed by the board;
- (2) Have attained the age of majority;
- (3) Be of good moral character;

(4) Have graduated and received a professional undergraduate degree from a college or school of pharmacy as the same may be approved by the board; provided, however, that, since it would be impractical for the board to evaluate a school or college of pharmacy located in another country, the board may accept a graduate from such a school or college as long as the graduate has completed all requirements of the Foreign Pharmacy Equivalency Certification Program administered by the National Association of Boards of Pharmacy. This shall include successful completion of all required examinations and

the issuance of the equivalency certificate and be based upon an individual evaluation by the board of the applicant's educational experience, professional background, and proficiency in the English language;

(5) Have completed an internship or other program that has been approved by the board or demonstrated to the board's satisfaction that experience in the practice of pharmacy which meets or exceeds the minimum internship requirements of the board;

(6) Have successfully passed an examination or examinations approved by the board; and

(7) Have paid the fees specified by the board for the examination and any related materials and have paid for the issuance of the license.

(b) *Examinations.*

(1) The examination for licensure required under paragraph (6) of subsection (a) of this Code section shall be made available by the board at least two times during each year. The board shall determine the content and subject matter of each examination, and the place, time, and date of administration of the examination;

(2) The examination shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ, cooperate, and contract with any organization or consultant in the preparation and grading of an examination, but shall retain the sole discretion and responsibility for determining which applicants have successfully passed such an examination; and

(3) Any person who takes the board examination and fails the examination may repeat the examination at regular intervals of administration; however, a person may not take the examination more than three times without permission from the board. A person who has taken the board examination and failed the examination for the third time may not practice as a pharmacy intern. A person who takes the board examination and successfully completes the examination must become licensed within two years of the examination date or the results of the examination shall become invalid.

(c) *Internship and other training programs.*

(1) All applicants for licensure by examination shall obtain practical experience in the practice of pharmacy concurrent with or after college attendance or both under such terms and conditions as the board shall determine; and

(2) The board shall establish such licensure requirements for interns and standards for internship or any other experiential program necessary to qualify an applicant for the licensure examination and shall also determine the qualifications of preceptors used in practical experience programs.

HISTORY: Code 1981, § 26-4-41, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 277, § 4; Ga. L. 2000, p. 136, § 26.

§ 26-4-42. License transfers for pharmacists licensed in another jurisdiction

(a) In order for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist by license transfer in this state, an applicant shall:

(1) Complete and file a form applying for licensure with the board, which form shall include the applicant's name, address, and other such information as prescribed by the board, and, after an investigation by agents acting on behalf of the board, if so requested by the board, produce evidence satisfactory to the board which shows the applicant has the age, moral character, background, education, and experience demanded of applicants for registration by examination under this chapter and by the rules and regulations promulgated under 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 has not been 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 an examination by the board on Georgia pharmacy law and board regulations; and

(8) Have paid the fees specified by the board.

(b) No applicant shall be eligible for license transfer unless the state in which the applicant was licensed as a pharmacist also grants licensure transfer to pharmacists duly licensed by examination in this state under like circumstances and conditions.

(c) To obtain a license to engage in the practice of pharmacy in this state, a pharmacist who is a graduate of a pharmacy school or college located in another country must complete all requirements of the Foreign Pharmacy Equivalency Certification Program administered by the National Association of Boards of Pharmacy. This shall include without being limited to successful completion of all required examinations and the issuance of the equivalency certificate, and an individual evaluation by the board of the

applicant's proficiency in the English language. Additionally, a foreign pharmacy graduate applicant shall:

- (1) Have submitted a written application in the form prescribed by the board;
- (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 graduated and been granted a pharmacy degree from a college or school of pharmacy recognized by the National Association of Boards of Pharmacy Foreign Pharmacy Graduate Examination Committee;
- (6) Have successfully passed an examination approved by the board; and
- (7) Have paid the fees specified by the board.

HISTORY: Code 1981, § 26-4-42, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 277, § 5.

§ 26-4-43. Temporary licenses

A temporary license may be issued by the division director upon the approval of the president of the board if an applicant produces satisfactory evidence of fulfilling the requirements for licensure under this article, except the examination requirement, and evidence of an emergency situation justifying such temporary license. All temporary licenses shall expire at the end of the month during which the first board meeting is conducted following the issuance of such license and may not be reissued or renewed.

HISTORY: Code 1981, § 26-4-43, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2000, p. 1706, § 19.

§ 26-4-44. Renewal of licenses

(a) Each pharmacist shall apply for renewal of his or her license biennially pursuant to the rules and regulations promulgated by the board. A pharmacist who desires to continue in the practice of pharmacy in this state shall file with the board an application in such form and containing such data as the board may require for renewal of the license. Notice of any change of employment or change of business address shall be filed with the division director within ten days after such change. If the board finds that the applicant has been licensed and that such license has not been revoked or placed under suspension and that the applicant has paid the renewal fee, has continued his or her pharmacy education in accordance with Code Section 26-4-45 and the rules and regulations of the board, and is entitled to continue in the practice of pharmacy, then the board shall issue a license to the applicant.

(b) If a pharmacist fails to make application to the board for renewal of his or her license as set forth in and in accordance with the provisions of this chapter, the pharmacist must apply for reinstatement pursuant to the rules of the board.

HISTORY: Code 1981, § 26-4-44, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2000, p. 1706, § 19.

§ 26-4-44.1. Inactive license status

(a) The board shall provide by rule for an inactive pharmacist license status for those individuals who elect to apply for such status. Persons who are granted inactive status shall be exempt from the requirements of continuing pharmaceuticals education.

(b) The board shall provide by rule for reactivation of a pharmacist license for those persons who wish to have an active license. Such individuals must first file a reactivation application with the board and comply with the requirements for reactivation as set forth by board rule.

HISTORY: Code 1981, § 26-4-44.1, enacted by Ga. L. 1999, p. 277, § 6.

§ 26-4-44.2. Exceptions for active duty service members

(a) As used in this Code section, the term "service member" means an active duty member of the regular or reserve component of the United States Armed forces, the United States Coast Guard, the Georgia National Guard, or the Georgia Air National Guard who was on ordered federal duty for a period of 90 days or longer.

(b) Any service member whose license issued pursuant to this article expired while such service member was serving on active duty outside the state shall be permitted to practice pharmacy in accordance with such expired license and shall not be charged with a violation of this chapter related to practicing pharmacy with an expired license for a period of six months from the date of his or her discharge from active duty or reassignment to a location within the state. Any such service member shall be entitled to renew such expired license without penalty within six months after the date of his or her discharge from active duty or reassignment to a location within the state. The service member must present to the board either a copy of the official military orders or a written verification signed by the service member's commanding officer to waive any charges.

HISTORY: Code 1981, § 26-4-44.2, enacted by Ga. L. 2005, p. 213, § 2/SB 258.

§ 26-4-45. Continuing professional pharmaceutical education requirements

The board shall establish a program of continuing professional pharmaceutical education for the renewal of pharmacist licenses. Notwithstanding any other provision of this chapter, no pharmacist license shall be renewed by the board or the division director until the pharmacist submits to the board satisfactory proof of his or her participation, during the biennium preceding his or her application for renewal, in a minimum of 30 hours of approved programs of continuing professional pharmacy education as defined in

this Code section. Continuing professional pharmacy education shall consist of educational programs providing training pertinent to the practice of pharmacy and approved by the board under this Code section. The board shall approve educational programs for persons practicing pharmacy in this state on a reasonable nondiscriminatory fee basis and may contract with institutions of higher learning, professional organizations, or qualified individuals for the providing of approved programs. In addition to such programs, the board shall allow the continuing professional pharmacy education requirement to be fulfilled by the completion of approved correspondence courses which provide the required hours of approved programs of continuing professional pharmaceutical education or to be fulfilled by a combination of approved correspondence courses and other approved educational programs. The board may, consistent with the requirements of this Code section, promulgate rules and regulations to implement and administer this Code section, including the establishment of a committee to prescribe standards, approve and contract for educational programs, and set the required minimum number of hours per year.

HISTORY: Code 1981, § 26-4-45, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2000, p. 1706, § 19.

§ 26-4-46. Pharmacy interns -- Eligibility and requirements for licenses

(a) To obtain a license as a pharmacy intern, an applicant shall:

(1) Have submitted a written application in the form prescribed by the board of pharmacy;

(2) Have attained the age of majority;

(3) Be of good moral character; and

(4) Have paid the fees specified by the board for the issuance of the license.

(b) The following individuals shall be eligible to be licensed as a pharmacy intern:

(1) A student who is currently enrolled in an approved school or college of pharmacy;

(2) An individual who is 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

(3) An individual who does not meet the requirements of paragraphs (1) and (2) of this subsection and is a graduate of a pharmacy school or college located in another country but who has completed all requirements of the Foreign Pharmacy Equivalency Certification Program administered by the National Association of Boards of Pharmacy. This shall include without being limited to successful completion of all required examinations, the issuance of the equivalency certificate, and an individual evaluation by the board of the applicant's proficiency in the English language.

(c) The board shall approve all internship programs for the purpose of providing the practical experience necessary for licensure as a pharmacist. A pharmacy intern is authorized to engage in the practice of pharmacy under the supervision of a pharmacist. The board shall adopt rules regarding the licensure of interns and the standards for internship programs.

HISTORY: Code 1981, § 26-4-46, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 277, § 7.

§ 26-4-47. Pharmacy interns -- Validity of licenses

(a) Licenses issued under Code Section 26-4-46 shall bear the date of issuance and shall be valid for up to five years. Unless said license is renewed by the board, the license shall expire.

(b) Any license issued pursuant to Code Section 26-4-46 shall expire at the time a pharmacy intern is expelled, suspended, dismissed, or withdraws from an approved school or college of pharmacy or is otherwise licensed as a pharmacist pursuant to this title.

(c) Any license issued pursuant to Code Section 26-4-46 shall expire upon notification that a person has taken and failed the board examination for the third time.

HISTORY: Code 1981, § 26-4-47, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-48. Pharmacy interns -- Renewal of licenses; exceptions

Licenses issued pursuant to Code Section 26-4-46 which shall expire by lapse of time may be renewed upon application, unless, at the time of expiration, there shall be pending action before the board to suspend or revoke such license.

HISTORY: Code 1981, § 26-4-48, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-49. Drug researcher permits; application for registration; fees; suspension or revocation; penalty for violations

(a) Every person, firm, corporation, agency, department, or other entity located within this state which handles, possesses, or utilizes controlled substances or dangerous drugs, as defined in Chapter 13 of Title 16, for the purposes of conducting research, analysis, animal training, or drug education, as such purposes may be further defined by the board, and is not otherwise registered as a pharmacist, pharmacy, drug wholesaler, distributor, supplier, or practitioner shall biennially register with the State Board of Pharmacy for a drug researcher permit which shall entitle the holder thereof to purchase, receive, possess, or dispose of such controlled substances and dangerous drugs for such purposes. In applying for the permit:

(1) The application for registration shall be made on a form to be prescribed and furnished by said board and shall show at a minimum the name of the person responsible

for filing the application, the name of the applying firm, corporation, agency, department, or other entity, if applicable, the address where the controlled substances or dangerous drugs will be kept secured and can be inspected by the board, together with such other information as may be required by the board;

(2) The person filing the application for the permit shall be the responsible person for the safe and proper storage and accountability, as defined under Chapter 13 of Title 16, for any and all controlled substances and dangerous drugs. Such person shall be responsible for maintaining exact and accurate records regarding the purchase, receipt, utilization, and disposal of all controlled substances and dangerous drugs utilized for purposes granted by this permit. All records must be maintained for a minimum of two years and be readily available for inspection by agents of the board; and

(3) Before approval by the board for any permit issued under this Code section, the application for registration must successfully undergo a thorough investigation by agents of the board to ensure the applicant complies with all applicable laws, rules, and regulations pursuant to handling controlled substances and dangerous drugs as defined under Chapter 13 of Title 16.

(b) The board may require that the application for registration as a drug researcher be accompanied by a fee in an amount established under rules promulgated by the board, and the board may establish conditions for exemptions from such fees. Such registration shall not be transferable and shall expire on the expiration date established by the division director and may be renewed pursuant to rules and regulations promulgated by the board. If not renewed, the registration shall lapse and become null and void.

(c) The board shall have the authority to promulgate rules and regulations governing the holder of a drug researcher permit as defined under this Code section.

(d) A drug researcher permit may be suspended or revoked or the registrant may be reprimanded, fined, or placed on probation by the board if the registrant fails to comply with all applicable local, state, or federal laws, rules, and regulations.

(e) A holder of a drug researcher permit who is not also licensed as a pharmacist practicing in a duly licensed pharmacy shall not engage in the sale, distribution, or dispensing of controlled substances or dangerous drugs.

(f) Any person, firm, or corporation which violates any provision of this Code section shall be guilty of a felony and, upon conviction thereof, be punished by imprisonment for not less than one year nor more than five years or by a fine not to exceed \$10,000.00 or both.

HISTORY: Code 1981, § 26-4-49, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2000, p. 1706, § 19; Ga. L. 2003, p. 140, § 26.

§ 26-4-50. Drug therapy modification certification

(a) No pharmacist shall be authorized to modify drug therapy pursuant to Code Section 43-34-26.2 unless that pharmacist:

(1) Is licensed to practice as a pharmacist in this state;

(2) Has successfully completed a course of study regarding modification of drug therapy and approved by the board;

(3) Annually successfully completes a continuing education program regarding modification of drug therapy and approved by the board; and

(4) Is certified by the board as meeting the requirements of paragraphs (1) through (3) of this subsection.

(b) Nothing in this Code section shall be construed to expand or change any existing authority for a pharmacist to substitute drugs.

HISTORY: Code 1981, § 26-4-50, enacted by Ga. L. 2000, p. 558, § 1.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 4. DISCIPLINE

§ 26-4-60. Grounds for suspension, revocation, or refusal to grant licenses

(a) The board of pharmacy may refuse to issue or renew, or may suspend, revoke, or restrict the licenses of, or fine any person pursuant to the procedures set forth in this Code section, upon one or more of the following grounds:

(1) Unprofessional conduct as that term is defined by the rules of the board;

(2) Incapacity that prevents a licensee from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public;

(3) Being guilty of one or more of the following:

(A) A felony;

(B) Any act involving moral turpitude; or

(C) Violations of the pharmacy or drug laws of this state, or rules and regulations pertaining thereto, or of laws, rules, and regulations of any other state, or of the federal government;

(4) Misrepresentation of a material fact by a licensee in securing the issuance or renewal of a license;

(5) Engaging or aiding and abetting an individual to engage in the practice of pharmacy without a license falsely using the title of "pharmacist" or "pharmacy intern," or falsely using the term "pharmacy" in any manner;

(6) Failing to pay the costs assessed in a disciplinary hearing pursuant to subsection (c) of Code Section 26-4-28;

(7) Becoming unfit or incompetent to practice pharmacy by reason of:

(A) Intemperance in the use of alcoholic beverages, narcotics, or habit-forming drugs or stimulants; or

(B) Any abnormal physical or mental condition which threatens the safety of persons to whom such person may compound or dispense prescriptions, drugs, or devices or for whom he or she might manufacture, prepare, or package or supervise the manufacturing, preparation, or packaging of prescriptions, drugs, or devices;

(8) Being adjudicated to be mentally ill or insane;

(9) Violating any rules and regulations promulgated by the board;

(10) Promoting to the public in any manner a drug which may be dispensed only pursuant to prescription;

(11) Regularly employing the mails or other common carriers to sell, distribute, and deliver a drug which requires a prescription directly to a patient; provided, however, that this provision shall not prohibit the use of the mails or other common carriers to sell, distribute, and deliver a prescription drug directly to an institution or to sell, distribute, or deliver prescription drug refills, upon his or her request, to an enrollee in a health benefits plan of a group model health maintenance organization or its affiliates by a pharmacy which is operated by that same group model health maintenance organization and licensed under Code Section 26-4-110. Any pharmacy using the mails or other common carriers to dispense prescriptions pursuant to this paragraph shall comply with the following conditions:

(A) The pharmacy shall provide an electronic, telephonic, or written communications mechanism which reasonably determines whether the medications distributed by the mails or other common carriers have been received by the enrollee and through which a pharmacist employed by the group model health maintenance organization or a pharmacy intern under his or her direct supervision is enabled to offer counseling to the enrollee as authorized by and in accordance with his or her obligations under Code Section 26-4-85, unless the enrollee refuses such consultation or counseling pursuant to subsection (e) of such Code section. In addition, the enrollee shall receive information indicating what he or she should do if the integrity of the packaging or medication has been compromised during shipment;

(B) In accordance with clinical and professional standards, the State Board of Pharmacy shall promulgate a list of medications which may not be delivered by the mails or other common carriers. However, until such list is promulgated, the group model health maintenance organization shall not deliver by use of the mails or other common carriers Class II controlled substance medications, medications which require refrigeration, chemotherapy medications deemed by the federal Environmental Protection Agency as dangerous, medications in suppository form, and other medications which, in the professional opinion of the dispensing pharmacist, may be clinically compromised by distribution through the mail or other common carriers;

(C) The pharmacy shall utilize, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other standards adopted by the State Board of Pharmacy, temperature tags, time temperature strips, insulated packaging, or a combination of these; and

(D) The pharmacy shall establish and notify the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner or

in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs.

For purposes of this paragraph, the term "group model health maintenance organization" means a health maintenance organization that has an exclusive contract with a medical group practice to provide or arrange for the provision of substantially all physician services to enrollees in health benefits plans of the health maintenance organization;

(12) Unless otherwise authorized by law, dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the prior authorization of the practitioner ordering or prescribing the same;

(13) Violating or attempting to violate a statute, law, any lawfully promulgated rule or regulation of this state, any other state, the board, the United States, or any other lawful authority without regard to whether the violation is criminally punishable, which statute, law, rule, or regulation relates to or in part regulates the practice of pharmacy, when the licensee or applicant knows or should know that such action is violative of such statute, law, or rule; or violating either a public or confidential lawful order of the board previously entered by the board in a disciplinary hearing, consent decree, or license reinstatement; or

(14) Having his or her license to practice pharmacy revoked, suspended, or annulled by any lawful licensing authority of this or any other state, having disciplinary action taken against him or her by any lawful licensing authority of this or any other state, or being denied a license by any lawful licensing authority of this or any other state.

(b) The board shall have the power to suspend or revoke the license of the pharmacist in charge when a complete and accurate record of all controlled substances on hand, received, manufactured, sold, dispensed, or otherwise disposed of has not been kept by the pharmacy in conformance with the record-keeping and inventory requirements of federal law and the rules of the board.

(c) Any person whose license to practice pharmacy in this state has been suspended, revoked, or restricted pursuant to this chapter, whether voluntarily or by action of the board, shall have the right, at reasonable intervals, to petition the board for reinstatement of such license pursuant to rules and regulations promulgated by the board. Such petition shall be made in writing and in the form prescribed by the board. The board may, in its discretion, grant or deny such petition, or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant such modifications.

(d) Nothing in this Code section shall be construed as barring criminal prosecutions for violations of this chapter.

(e) All final decisions by the board shall be subject to judicial review pursuant to Chapter 13 of Title 50, the "Georgia Administrative Procedure Act."

(f) Any individual or entity whose license to practice pharmacy is revoked, suspended, or not renewed shall return his or her license to the offices of the board within ten days after receipt of notice of such action.

(g) For purposes of this Code section, a conviction shall include a finding or verdict of guilty, a plea of guilty, or a plea of nolo contendere in a criminal proceeding, regardless of whether the adjudication of guilt or sentence is withheld or not entered thereon.

(h) Nothing in this Code section shall be construed as barring or prohibiting pharmacists from providing or distributing health or drug product information or materials to patients which are intended to improve the health care of patients.

(i) The board shall have the power to suspend any license issued under Article 3 of this chapter when such holder is not in compliance with a court order for child support as provided in Code Section 19-6-28.1 or 19-11-9.3. The board shall also have the power to deny the application for issuance or renewal of a license under Article 3 of this chapter when such applicant is not in compliance with a court order for child support as provided in either of such Code sections. The hearings and appeals procedures provided for in such Code sections shall be the only such procedures required to suspend or deny any license issued under Article 3 of this chapter.

(j) Nothing in this chapter shall prohibit any person from assisting any duly licensed pharmacist or practitioner in the measuring of quantities of medication and the typing of labels therefor, but excluding the dispensing, compounding, or mixing of drugs, provided that such duly licensed pharmacist or practitioner shall be physically present in the dispensing area and actually observing 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 pharmacist or practitioner.

(k) The board shall have the power to suspend any license issued under Article 3 of this chapter when such holder is a borrower in default who is not in satisfactory repayment status as provided in Code Section 20-3-295. The board shall also have the power to deny the application for issuance or renewal of a license under Article 3 of this chapter when such applicant is a borrower in default who is not in satisfactory repayment status as provided in Code Section 20-3-295. The hearings and appeals procedures provided for in Code Section 20-3-295 shall be the only such procedures required to suspend or deny any license issued under Article 3 of this chapter.

HISTORY: Code 1981, § 26-4-60, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26; Ga. L. 1999, p. 277, § 8; Ga. L. 2006, p. 444, § 1/ HB 246.

§ 26-4-61. Temporary suspension of license; notice; disciplinary hearings

(a) The provisions of subsection (c) of Code Section 50-13-18 with respect to emergency action by a professional licensing board and summary suspension of a license are adopted and incorporated by reference into this Code section.

(b) Whenever a notice of summary suspension, notice of hearing, initial or recommended decision, or final decision of the board in a disciplinary proceeding is docketed, it shall be personally served 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. If such material is served by certified mail or statutory overnight delivery and is returned marked "unclaimed" or "refused" or is otherwise undeliverable and if the licensee or applicant cannot, after reasonable effort, be located, the director for the board shall be deemed to be the agent for service for such licensee or applicant for purposes of this Code section and service upon the director shall be deemed to be service upon the licensee or applicant.

(c) If any licensee or applicant after reasonable notice fails to appear at any hearing of the board for that licensee or applicant, the board may proceed to hear the evidence against such licensee or applicant and take action as if such licensee or applicant had been present.

HISTORY: Code 1981, § 26-4-61, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26; Ga. L. 1999, p. 277, § 9; Ga. L. 2000, p. 1589, § 3; Ga. L. 2000, p. 1706, § 19.

§ 26-4-62. Penalty for violation of chapter

Except as otherwise provided in this chapter or in Chapter 13 of Title 16, any violation of this chapter shall constitute a misdemeanor.

HISTORY: Code 1981, § 26-4-62, enacted by Ga. L. 1998, p. 686, § 1.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 5. PRESCRIPTION DRUGS

§ 26-4-80. Dispensing; electronically transmitted drug orders; refills; Schedule II controlled substance prescriptions

(a) All persons engaging in the practice of pharmacy in this state must be licensed by the board.

(b) 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.

(c) A prescription drug order may be accepted by a pharmacist or pharmacy intern or extern in written form, orally, via an electronic visual image prescription drug order, or via an electronic data prescription drug order as set forth in this chapter or as set forth in regulations promulgated by the board. Provisions for accepting a prescription drug order for a Schedule II controlled substance are set forth in subsection (1) of this Code section, the board's regulations, or the regulations of the United States Drug Enforcement Administration in 21 C.F.R. 1306. Electronic prescription drug orders shall either be an electronic visual image of a prescription drug order or an electronic data prescription drug order and shall meet the requirements set forth in regulations promulgated by the board. A hard copy prescription prepared by a practitioner or a practitioner's agent, which bears an electronic visual image of the practitioner's signature and is not sent by facsimile, must be printed on security paper. Prescriptions transmitted either electronically or via facsimile shall meet the following requirements:

(1) Electronically transmitted prescription drug orders shall be transmitted by the practitioner or, in the case of a prescription drug order to be transmitted via facsimile, by the practitioner or the practitioner's agent under supervision of the practitioner, to the pharmacy of the patient's choice with no intervening person or intermediary having access to the prescription drug order. For purposes of this paragraph, "intervening person or intermediary" shall not include a person who electronically formats or reconfigures data or information for purposes of integrating into and between computer or facsimile systems of practitioners and pharmacists;

(2) Prescription drug orders transmitted by facsimile or computer shall include:

(A) In the case of a prescription drug order for a dangerous drug, the complete name and address of the practitioner;

(B) In the case of a prescription drug order for a controlled substance, the complete name, address, and DEA registration number of the practitioner;

(C) The telephone number of the practitioner for verbal confirmation;

(D) The name and address of the patient;

(E) The time and date of the transmission;

(F) The full name of the person transmitting the order; and

(G) The signature of the practitioner in a manner as defined in regulations promulgated by the board or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22;

(3) An electronically transmitted, issued, or produced prescription drug order which meets the requirements of this Code section shall be deemed the original order;

(4) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of any electronically transmitted, issued, or produced prescription drug order consistent with federal and state laws and rules and regulations adopted pursuant to the same;

(5) An electronically encrypted, issued, or produced prescription drug order transmitted from a practitioner to a pharmacist shall be considered a highly confidential transaction and the said transmission, issuance, or production shall not be compromised by unauthorized interventions, control, change, altering, manipulation, or accessing patient record information by any other person or party in any manner whatsoever between the time after the practitioner has electronically transmitted, issued, or produced a prescription drug order and such order has been received by the pharmacy of the patient's choice. For purposes of this paragraph, "unauthorized interventions, control, change, altering, manipulation, or accessing patient record information" shall not include electronic formatting or reconfiguring of data or information for purposes of integrating into and between computer or facsimile systems of practitioners and pharmacists;

(6) Any 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 and any information contained therein; and

(7) The board shall promulgate rules and regulations which may provide specific exceptions under this Code section for institutional settings such as hospital pharmacies, nursing home pharmacies, clinic pharmacies, or pharmacies owned or operated directly by health maintenance organizations.

(d) Information contained in the patient medication record or profile shall be considered confidential information as defined in this title. Confidential information may be released to the patient or the patient's authorized representative, the prescriber or other licensed

health care practitioners then caring for the patient, another licensed pharmacist, the board or its representative, or any other person duly authorized to receive such information. In accordance with Code Section 24-9-40, confidential information may be released to others only on the written release of the patient, court order, or subpoena.

(e) Except as authorized under subsection (j) of this Code section, a prescription may not be refilled without authorization. When refills are dispensed pursuant to authorization contained on the original prescription or when no refills are authorized on the original prescription but refills are subsequently authorized by the practitioner, the refill authorization shall be recorded on the original prescription document and the record of any refill made shall be maintained on the back of the original prescription document or on some other uniformly maintained record and the dispensing pharmacist shall record the date of the refill, the quantity of the drug dispensed, and the dispensing pharmacist's initials; provided, however, that an original prescription for a Schedule III, IV, or V controlled substance which contains no refill information may not be authorized to be refilled more than five times or after six months from the date of issuance, whichever occurs first. Authorization for any additional refill of a Schedule III, IV, or V controlled substance prescription in excess of five refills or after six months from the date of issuance of the prescription shall be treated as a new prescription.

(f) When filling a prescription or refilling a prescription which may be refilled, the pharmacist shall exercise professional judgment in the matter. No prescription shall be filled or refilled with greater frequency than the approximate interval of time that the dosage regimen ordered by the prescriber would indicate, unless extenuating circumstances are documented which would justify a shorter interval of time before the filling or refilling of the prescription.

(g) The pharmacist who fills or refills a prescription shall record the date of dispensing and indicate the identity of the dispensing pharmacist on the prescription document or some other appropriate and uniformly maintained record. If this record is maintained on the original prescription document, the original dispensing and any refills must be recorded on the back of the prescription.

(h) When the patient no longer seeks personal consultation or treatment from the practitioner, the practitioner and patient relationship is terminated. A prescription becomes invalid after the practitioner and patient relationship is terminated which is defined as a reasonable period of time not to exceed six months in which the patient could have established a new practitioner and patient relationship as established by the board through the promulgation of rules and regulations.

(i) All prescription drug orders must bear the signature of the prescribing practitioner as defined in Code Section 16-13-21. Physician's assistants must comply with all applicable laws regarding signatures. Further, the nature of such signature must meet the requirements set forth in regulations promulgated by the board. A physically applied signature stamp is not acceptable in lieu of an original signature. Except as otherwise provided for in this subsection, when an oral prescription drug order or the oral

authorization for the refilling of a prescription drug order is received which has been transmitted by someone other than the practitioner, the name of the individual making the transmission and the date, time, and location of the origin of the transmission must be recorded on the original prescription drug order or other record by the pharmacist receiving the transmission. No one other than the practitioner or an agent authorized by the practitioner shall transmit such prescriptions in any manner. In institutional settings such as hospital pharmacies, nursing home pharmacies, clinic pharmacies, or pharmacies owned or operated directly by health maintenance organizations, the name of the individual making the transmission is not required to be placed on the order.

(j) A pharmacist licensed by the board may dispense up to a 72 hour supply of a prescribed medication in the event the pharmacist is unable to contact the practitioner to obtain refill authorization, provided that:

(1) The prescription is not for a controlled substance;

(2) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort;

(3) The dispensing pharmacist notifies the practitioner or his or her agent of the dispensing within seven working days after the prescription is refilled pursuant to this subsection;

(4) The pharmacist properly records the dispensing as a separate nonrefillable prescription. Said document shall be filed as is required of all other prescription records. This document shall be serially numbered and contain all information required of other prescriptions. In addition it shall contain the number of the prescription from which it was refilled;

(5) The pharmacist shall record on the patient's record and on the new document the circumstances which warrant such dispensing; and

(6) The pharmacist does not employ this provision regularly for the same patient on the same medication.

(k) All out-patient prescription drug orders which are dispensed shall be appropriately labeled in accordance with the rules and regulations promulgated by the board as follows:

(1) Before an out-patient prescription drug is released from the dispensing area, the prescription drug shall bear a label containing the name and address of the pharmacy, a prescription number, the name of the prescriber, the name of the patient, directions for taking the medication, the date of the filling or refilling of the prescription, the initials or identifying code of the dispensing pharmacist, and any other information which is necessary, required, or, in the pharmacist's professional judgment, appropriate; and

(2) The pharmacist who fills an out-patient prescription drug order shall indicate the identity of the dispensing pharmacist on the label of the prescription drug. Identification may be made by placing initials on the label of the dispensed drug. The label shall be affixed to the outside of the container of the dispensed drug by means of adhesive or tape or any other means which will assure that the label remains attached to the container.

(l) A Schedule II controlled substance prescription drug order in written form signed in indelible ink by the practitioner may be accepted by a pharmacist and the Schedule II controlled substance may be dispensed by such pharmacist. Other forms of Schedule II controlled substance prescription drug orders may be accepted by a pharmacist and the Schedule II controlled substance may be dispensed by such pharmacist in accordance with regulations promulgated by the board and in accordance with DEA regulations found in 21 C.F.R. 1306.

(m) No licensee nor any other entity shall be permitted to provide facsimile machines or equipment, computer software, technology, hardware, or supplies related to the electronic transmission of prescription drug orders 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 may be transmitted.

(n) Institutions including, but not limited to, hospitals, long-term care facilities, and inpatient hospice facilities which utilize electronic medical record systems that meet the information requirements for prescription drug orders for patients pursuant to this Code section shall be considered to be in compliance with this Code section.

(o) Nothing in this Code section shall be construed to prohibit any insurance company, hospital or medical service plan, health care provider network, health maintenance organization, health care plan, employer, or other similar entity providing health insurance from offering incentives to pharmacies, pharmacists, and practitioners that accept or utilize electronic data prescription drug orders.

HISTORY: Code 1981, § 26-4-80, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26; Ga. L. 2004, p. 738, §§ 4, 5; Ga. L. 2006, p. 444, § 2/HB 246.

§ 26-4-81. Substitution of generic drugs for name brand drugs

(a) In accordance with this Code section, a pharmacist may substitute a drug with the same generic name in the same strength, quantity, dose, and dosage form as the prescribed brand name drug product which is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent.

(b) If a practitioner of the healing arts prescribes a drug by its generic name, the pharmacist shall dispense the lowest retail priced drug product which is in stock and which is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent.

(c) Substitutions as provided for in subsections (a) and (b) of this Code section are authorized for the express purpose of making available to the consumer the lowest retail priced drug product which is in stock and which is, in the pharmacist's reasonable professional opinion, both therapeutically equivalent and pharmaceutically equivalent.

(d) Whenever a substitution is made, the pharmacist shall record on the original prescription the fact that there has been a substitution and the identity of the dispensed drug product and its manufacturer. Such prescription shall be made available for inspection by the board or its representative in accordance with the rules of the board.

(e) The substitution of any drug by a registered pharmacist pursuant to this Code section does not constitute the practice of medicine.

(f) A patient for whom a prescription drug order is intended may instruct a pharmacist not to substitute a generic name drug in lieu of a brand name drug.

(g) A practitioner of the healing arts may instruct the pharmacist not to substitute a generic name drug in lieu of a brand name drug by including the words "brand necessary" in the body of the prescription. When a prescription is a hard copy prescription drug 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.

(h) The substitution of any drug by a registered pharmacist pursuant to this Code section does not constitute the practice of medicine.

HISTORY: Code 1981, § 26-4-81, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2004, p. 738, § 6.

§ 26-4-82. Duties requiring professional judgment; responsibilities of licensed pharmacist

(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 that no other employee of the pharmacy, including pharmacy technicians, performs or conducts those duties or functions which require professional judgment.

(b) For all prescriptions, it shall be the responsibility of the pharmacist on duty at a facility to ensure that only a pharmacist or a pharmacy intern under the direct supervision of a pharmacist provides professional consultation and counseling with patients or other licensed health care professionals, and that only a pharmacist or a pharmacy intern under the direct supervision of a pharmacist accepts initial telephoned prescription orders or provides information in any manner relative to prescriptions or prescription drugs.

(c) In the dispensing of all prescription drug orders:

(1) The pharmacist shall be responsible for all activities of the 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 the pharmacy technician at all times;

(3) When electronic systems are employed within the pharmacy, 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 of the information entered and the label produced in conjunction with the prescription drug order;

(4) When a prescription drug order is presented for refilling, it shall be the responsibility of the pharmacist to review all appropriate information and make the determination as to whether to refill the prescription drug order; and

(5) Pharmacy technicians in the dispensing area shall be easily identifiable.

(d) The board of pharmacy shall promulgate rules and regulations regarding the activities and utilization of pharmacy technicians in pharmacies; provided, however, that the pharmacist to pharmacy technician ratio shall not exceed one pharmacist providing direct supervision of three pharmacy technicians. 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 must be submitted to the board by the pharmacist in charge of a specific hospital pharmacy in this state. 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 either the Pharmacy Technician Certification Board or any other nationally recognized certifying body approved by the board of pharmacy.

(e) In addition to the utilization of pharmacy technicians, a pharmacist may be assisted by and directly supervise one pharmacy intern and one pharmacy extern.

HISTORY: Code 1981, § 26-4-82, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2002, p. 1492, § 1.

§ 26-4-83. Patient record systems

(a) The board of pharmacy may refuse to renew or may suspend, revoke, or restrict the licenses of or fine any person or pharmacy pursuant to the procedures set forth in this Code section and rules and regulations established by the board upon the failure to maintain an appropriate patient record system.

(b) 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 by the pharmacist to identify previously

dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist or the pharmacist's designee shall make a reasonable effort to obtain, record, and maintain the following information:

- (1) The full name of the patient for whom the drug is intended;
- (2) The address and telephone number of the patient;
- (3) The date of birth of the patient; and
- (4) The gender of the patient.

(c) 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 identify any other drugs, including over-the-counter drugs or devices, currently being used by the patient which may relate to prospective drug use review unless the patient or the patient's agent refuses to provide such information. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

(1) A list of all prescription drug orders obtained by the patient at the pharmacy where the prescription drug order is being filled for at least the preceding two years, showing the prescription number, the name and strength of the drug, the quantity and date dispensed, and the name of the prescribing practitioner; and

(2) Comments from the pharmacist relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(d) 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 of a computerized form.

HISTORY: Code 1981, § 26-4-83, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-84. Restriction of license for failure to review patient records and prescription drug orders

(a) The board of pharmacy may refuse to renew or may suspend, revoke, or restrict the licenses of or fine any person or pharmacy pursuant to the procedures set forth in this Code section upon the failure to review patient records and prescription drug orders.

(b) A pharmacist shall review the patient record and each prescription drug order presented for dispensing for the purposes of promoting therapeutic appropriateness by identifying:

- (1) Overutilization or underutilization;

- (2) Therapeutic duplications;
- (3) Drug-disease contraindications;
- (4) Drug-drug interactions;
- (5) Incorrect drug dosage, dosage form, or duration of drug therapy;
- (6) Drug-allergy interactions; and
- (7) Clinical abuse or misuse.

(c) Upon recognizing any of the above situations, the pharmacist shall take appropriate steps to avoid or resolve the situation or problem which shall, if necessary, include consultation with the prescribing practitioner.

HISTORY: Code 1981, § 26-4-84, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-85. Patient counseling; optimizing drug therapy

(a) The board of pharmacy may refuse to renew or may suspend, revoke, or restrict the licenses of or fine any person or pharmacy pursuant to the procedures set forth in this Code section upon the failure to offer to counsel patients.

(b) Upon receipt of a prescription drug order and following a review of the patient's record, the pharmacist or the pharmacy intern operating under the direct supervision of the pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such a 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:

- (1) The name and description of the drug;
- (2) The dosage form, dose, route of administration and duration of therapy;
- (3) The intended use of the drug and expected action or result;
- (4) Any special directions or precautions for preparation, administration, or use by the patient;
- (5) Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if such side effect, adverse effect, interaction, or therapeutic contraindication occurs;
- (6) Techniques for self-monitoring of drug therapy;

- (7) The proper storage of the drug;
- (8) Prescription refill information;
- (9) The action to be taken in the event of a missed dose; and
- (10) The comments of the pharmacist relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Additional forms of patient information may be used to supplement verbal patient counseling when appropriate or available.

(d) Patient counseling, as described in this Code section, shall not be required for:

(1) In-patients of a hospital or institution where other health care professionals are authorized to administer the drug or drugs;

(2) Inmates of corrections institutions where pharmacy services are provided by the Department of Corrections or by a county or municipal political subdivision either directly or by a subcontractor of the above; or

(3) Patients receiving drugs from the Department of Human Resources Division of Public Health; provided, however, that pharmacists who provide drugs to patients in accordance with Code Section 43-34-26.1 shall include in all dispensing procedures a written process whereby the patient or the caregiver of the patient is provided with the information required under this Code section.

(e) A pharmacist shall not be required to counsel a patient or the caregiver of the patient when the patient or the caregiver of the patient refuses such consultation or counseling.

HISTORY: Code 1981, § 26-4-85, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-86. Compounding of medications

The board may establish regulations governing the compounding of medication by pharmacists and pharmacies licensed in this state.

HISTORY: Code 1981, § 26-4-86, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-87. Storage and handling of controlled substances and dangerous drugs

The board shall promulgate rules and regulations governing the appropriate and proper storage and handling of controlled substances and dangerous drugs as defined in Chapter 13 of Title 16 which are consistent with those standards established by the United States Pharmacopeial Convention.

HISTORY: Code 1981, § 26-4-87, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-88. Restrictions on dispensing of medicines, drugs, or poisons; functions which require the professional judgment of a pharmacist

(a) No person shall engage in the dispensing of any medicines, drugs, or poisons unless said person is a pharmacist licensed in accordance with this chapter or a pharmacy intern dispensing such items in accordance with this chapter.

(b) This chapter shall not apply to practitioners of the healing arts prescribing, compounding their own prescriptions, or dispensing drugs or medicines except as provided in Code Section 26-4-130.

(c) Nothing in this Code section shall prohibit any person from assisting any duly licensed pharmacist or practitioner, provided that such duly licensed pharmacist or practitioner shall be physically present in the prescription area and actually observing the actions of such person performing such tasks; 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 pharmacist or practitioner.

(d) With respect to pharmacy technicians, the following functions require the professional judgment of a pharmacist, or pharmacy intern under the supervision of a pharmacist, and may not be performed by a pharmacy technician:

(1) Acceptance of initial oral prescriptions;

(2) Certification of a filled or finished prescription or prescription drug order;

(3) Weighing or measuring active ingredients without a mechanism of verification;

(4) Reconstitution of prefabricated medication without a mechanism of verification;

(5) Verification of the constituents of final IV admixtures for accuracy, efficacy, and patient utilization;

(6) Entry of orders on patient medication profiles without verification by a pharmacist; and

(7) Provision of drug information that has not been prepared or approved by the pharmacist.

HISTORY: Code 1981, § 26-4-88, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-89. Selling drugs in vending machines prohibited

Any person who shall sell or dispense drugs by the use of vending machines shall be guilty of a misdemeanor.

HISTORY: Code 1981, § 26-4-89, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26.

§ 26-4-90. Remuneration for professional pharmacy care services

Nothing in this chapter shall be interpreted to prohibit a pharmacist or pharmacy from being remunerated for professional pharmacy care services.

HISTORY: Code 1981, § 26-4-90, enacted by Ga. L. 1998, p. 686, § 1.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 6. PHARMACIES

§ 26-4-110. Pharmacy licenses -- Classifications; applications; fees; investigations; prescription department requirements

(a) All facilities engaged in the manufacture, production, sale, or distribution of drugs or devices utilized in the practice of pharmacy or pharmacies where drugs or devices are dispensed or pharmacy care is provided shall be licensed by the board and shall biennially renew their license with the board. Where operations are conducted at more than one location, each such location shall be licensed by the board.

(b) The board may by rule determine the licensure classifications of all persons and facilities licensed as a pharmacy under this article and establish minimum standards for such persons and facilities.

(c)(1) The board shall establish by rule, under the powers granted to it under Article 2 of this chapter and as may be required from time to time under federal law the criteria which each person must meet to qualify for licensure as a pharmacy in each classification. The board may issue licenses with varying restrictions to such persons where the board deems it necessary.

(2) All applications for a new license shall be accompanied by a fee. Upon the filing of an application for a license, the board may cause a thorough investigation of the applicant to be made, and, if satisfied that the applicant possesses the necessary qualifications and that the pharmacy will be conducted in accordance with law, shall issue a license.

(d) Each pharmacy shall have a pharmacist in charge. Whenever an applicable rule requires or prohibits action by a pharmacy, responsibility shall be that of the owner and the pharmacist in charge of the pharmacy, whether the owner is a sole proprietor, partnership, association, corporation, or otherwise.

(e) The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning licensure of any pharmacy.

(f) The board may deny or refuse to renew a pharmacy license if it determines that the granting or renewing of such license would not be in the public interest.

(g) It shall be unlawful for any person in connection with any place of business or in any manner to take, use, or exhibit the title "drug store," "pharmacy," "apothecary," or any combination of such titles or any title or designation of like import or other term to take the place of such title, unless such place of business is licensed as a pharmacy under the provisions of this chapter, has submitted a written request to the board and received a waiver from this subsection, or meets the provisions of any rule or regulation regarding

use of such titles and promulgated by the board.

(h) Every pharmacy licensed under this chapter shall have a prescription department which shall be kept clean and free of all materials not currently in use in the practice of compounding or preparing a medication for dispensing. The space behind the prescription counter shall be kept free of obstruction at all times.

(i) During hours of operation, every pharmacy licensed pursuant to this chapter shall have a prescription department under the personal supervision of a duly licensed pharmacist who shall have personal supervision of not more than one pharmacy at the same time, provided that nothing in this chapter shall be construed to prohibit any pharmacist from having personal supervision of a pharmacy located in a hospital, nursing home, college of pharmacy, or a pharmacy owned and operated directly by a health maintenance organization. Every pharmacy licensed under this chapter, except those located within and owned and operated by a duly licensed and accredited hospital, nursing home, or college of pharmacy or a pharmacy complying with subsection (j) of this Code section, shall have a prescription department open for business at all times that the business establishment is open to the public, except that during temporary absences of any licensed pharmacist not to exceed three hours daily or more than one and one-half hours at any one time the prescription department shall be closed and no prescription shall be filled or dispensed.

(j) If a pharmacy is located in a general merchandising establishment, or if the owner of the pharmacy so chooses, a portion of the space of the business establishment may be set aside and permanently enclosed or otherwise secured. Only that permanently enclosed or otherwise secured area shall be subject to the provisions of this chapter and shall be registered as a pharmacy. In such case, the area to be registered as a pharmacy shall be permanently enclosed with a partition built from the floor to the ceiling or otherwise secured in a manner as provided by the board through rules and regulations.

HISTORY: Code 1981, § 26-4-110, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26; Ga. L. 1999, p. 757, § 1.

§ 26-4-110.1. Definitions; license required; condition for licensing

(a) As used in this Code section, the term:

(1) "Enrollee" means a person eligible to receive health care benefits under a health benefit plan.

(2) "Health benefit plan" means any hospital or medical insurance policy or certificate, health care plan contract or certificate, qualified higher deductible health plan, health maintenance organization subscriber contract, or any managed care plan.

(3) "Insurer" means a corporation or other entity which is licensed or otherwise authorized to offer a health benefit plan in this state.

(4) "Pharmacy benefits manager" means any person, corporation, or other entity that administers the prescription drug, prescription device, or both prescription drug and device portion of a health benefit plan on behalf of an insurer but shall not include any pharmacy benefits manager offered pursuant to Chapter 18 of Title 45 or offered on behalf of recipients of medical assistance under Titles XIX and XXI of the federal Social Security Act.

(b) 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 to practice as a pharmacy in this state and shall comply with those provisions of Code Section 26-4-110, except subsections (h), (i), and (j) thereof. As a condition for licensing, every pharmacy benefit manager shall permit the board or agents or employees thereof to inspect the premises of such pharmacy benefit manager whether those premises are located within or outside this state.

HISTORY: Code 1981, § 26-4-110.1, enacted by Ga. L. 2002, p. 1492, § 2.

§ 26-4-111. Pharmacy licenses -- Minimum standards; transferability

(a) The board shall specify by rule the pharmacy licensure procedures to be followed, including but not limited to specification of forms for use in applying for such licensure and times, places, and applicable fees.

(b) Applicants for licensure to distribute, manufacture, sell, purchase, or produce drugs or devices within this state shall file with the board a verified application containing such information as the board requires of the applicant relative to the qualifications for a license.

(c) Pharmacy licenses issued by the board pursuant to this chapter shall not be transferable or assignable.

(d) The board shall specify by rule minimum standards for responsibility of any person or pharmacy that has employees or personnel engaged in the practice of pharmacy, manufacture, distribution, production, sale, or use of drugs or devices in the conduct of their business. If the licensed person is a pharmacy located in this state, that portion of the facility to which such license applies shall be operated only under the direct supervision of a pharmacist licensed to practice in this state.

HISTORY: Code 1981, § 26-4-111, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-112. Occurrences which require immediate notification to board

The board shall be notified immediately upon the occurrence of any of the following:

- (1) Permanent closing of a licensed pharmacy;
- (2) Change of ownership, management, or location of a licensed pharmacy;

- (3) Change of the pharmacist in charge of a licensed pharmacy;
- (4) Any theft or loss of drugs or devices of a licensed pharmacy;
- (5) Any known conviction of any employee of a licensed pharmacy of any state or federal drug laws;
- (6) Disasters, accidents, theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law;
- (7) Occurrence at a licensed pharmacy of a significant adverse drug reaction as defined by rules of the board; or
- (8) Any and all other matters and occurrences at a licensed pharmacy as the board may require by rule.

HISTORY: Code 1981, § 26-4-112, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-113. Wholesale distributors; licensing requirements; suspension or revocation of license; reinstatement

- (a) No person shall operate as a pharmacy until a pharmacy license has been issued to such person by the board.
- (b) Except where otherwise permitted by law, it shall be unlawful for a manufacturer, wholesale distributor, or a reverse drug distributor to distribute or deliver drugs or devices to or receive drugs or devices from any person or firm in this state not licensed under this chapter. Any person who distributes or delivers drugs or devices to or receives drugs or devices from a person or firm not licensed under this chapter shall be subject to a fine to be imposed by the board for each offense in addition to such other disciplinary action the board may take under this chapter. Each such violation shall also constitute a misdemeanor.
- (c) The board may suspend, revoke, deny, or refuse to renew the pharmacy license of, reprimand, issue a letter of concern to, or fine any person licensed under this article on any of the following grounds:
 - (1) The finding by the board of violations of any federal or state laws relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;
 - (2) Any felony convictions under federal or state laws;
 - (3) The furnishing of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;

(4) Suspension or revocation by the federal or state government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs or devices including controlled substances;

(5) Obtaining any remuneration by fraud, misrepresentation, or deception;

(6) Dealing with drugs or devices that are known or should have been known to be stolen drugs or devices;

(7) Purchasing or receiving of a drug or device from a source other than a person or pharmacy licensed under the laws of the state except where otherwise provided;

(8) Wholesale drug distributors, other than pharmacies, dispensing or distributing drugs or devices directly to patients; or

(9) Violations of any of the provisions of this chapter or of any of the rules adopted by the board under this chapter.

(d) Reinstatement of a pharmacy license that has been suspended, revoked, or restricted by the board may be granted in accordance with the rules of the board.

HISTORY: Code 1981, § 26-4-113, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-114. Special pharmacy permits

(a) A pharmacy located within and owned and operated by a school or college of pharmacy in this state may apply to the board for a special pharmacy permit which shall entitle the holder thereof to purchase, receive, possess, or dispose of drugs for educational or research purposes. The application shall include the name of a registered pharmacist who shall be responsible for maintaining accurate records regarding the purchase, receipt, possession, and disposal of drugs utilized for educational or research purposes. If the board certifies that the application complies with applicable laws and rules and regulations, the board shall issue the permit.

(b) A holder of a special pharmacy permit under subsection (a) of this Code section shall not engage in the sale or dispensing of drugs.

(c) The board shall have the authority to promulgate rules and regulations governing the holder of a special pharmacy permit under this Code section and may exempt the holder thereof from requirements otherwise applicable to other pharmacies.

HISTORY: Code 1981, § 26-4-114, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-115. Wholesale drug distributors; registration; fees; reports of excessive purchases; penalty for violations

(a) All persons, firms, or corporations, whether located in this state or in any other state, engaged in the business of selling or distributing drugs at wholesale in this state, in the business of supplying drugs to manufacturers, compounders, and processors in this state, or in the business of a reverse drug distributor shall biennially register with the board as a drug wholesaler, distributor, reverse drug distributor, or supplier. The application for registration shall be made on a form to be prescribed and furnished by said board and shall show each place of business of the applicant for registration, together with such other information as may be required by the board. The application shall be accompanied by a fee in an amount established by the board for each place of business registered by the applicant. Such registration shall not be transferable and shall expire on the expiration date established by the division director. Registration shall be renewed pursuant to the rules and regulations of the board and a renewal fee prescribed by the board shall be required. If not renewed, the registration shall lapse and become null and void. Registrants shall be subject to such rules and regulations with respect to sanitation or equipment as the board may, from time to time, adopt for the protection of the public health and safety. Such registration may be suspended or revoked or the registrant may be reprimanded, fined, or placed on probation by the board if the registrant fails to comply with any law of this state, the United States, or any other state having to do with the control of pharmacists, pharmacies, wholesale distribution, or reverse drug distribution of controlled substances or dangerous drugs as defined in Chapter 13 of Title 16; if the registrant fails to comply with any rule or regulation promulgated by the board; or if any registration or license issued to the registrant under the federal act is suspended or revoked.

(b) Every drug wholesaler, distributor, or supplier registered as provided in Chapter 13 of Title 16 or in subsection (a) of this Code section, except reverse drug distributors, shall:

(1) Submit reports, upon request from the Georgia Drugs and Narcotics Agency, to account for all transactions with licensed persons or firms located within this state; such reportable transactions shall include all dangerous drugs and controlled substances as defined in Chapter 13 of Title 16. Such reports shall be submitted to the Georgia Drugs and Narcotics Agency; and

(2) Automatically submit reports of any excessive purchases of controlled substances by licensed persons or firms located within this state using the federal Drug Enforcement Administration guidelines to define "excessive purchases" as set forth under the provisions of 21 C.F.R. Sec. 1301. Such reports shall be submitted to the Georgia Drugs and Narcotics Agency.

(c) The board shall be authorized to promulgate rules and regulations to facilitate compliance with this Code section. Such rules and regulations shall include a requirement that all wholesale drug distributors required to register pursuant to this Code section shall make adequate provision for the return of outdated drugs, both full and partial containers,

for up to six months after the labeled expiration date for prompt full credit or replacement.

(d) The provisions of subsection (b) of this Code section shall not apply to any wholesaler, manufacturer, distributor, or supplier who only ships controlled substances directly to a licensed wholesaler within this state.

(e) Any person, firm, or corporation which violates any provision of this Code section shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not less than one year nor more than five years or by a fine not to exceed \$25,000.00, or both.

(f) Any practitioner who knowingly transfers any controlled substance or dangerous drug as such terms are defined in Chapter 13 of Title 16 by purchasing from or returning to a person, firm, or corporation which is not registered as required in subsection (a) of this Code section or as required in Chapter 13 of Title 16 shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not less than one year nor more than three years or by a fine not to exceed \$10,000.00, or both.

HISTORY: Code 1981, § 26-4-115, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2000, p. 1706, § 19; Ga. L. 2002, p. 1492, § 3.

§ 26-4-115.1. Requirement that certain wholesale distributors of controlled substances and dangerous drugs provide price and quantity information

Every wholesale distributor registered as provided in Chapter 13 of Title 16 or subsection (a) of Code Section 26-4-115, except those which are exclusively reverse drug distributors, shall provide to the Department of Community Health such information, with regard to the controlled substances and dangerous drugs which are distributed by that wholesale distributor, as is determined by that department to be necessary or useful in the department's efficient administration of the state plan for medical assistance, as defined in Code Section 49-4-141, and in the department's determination of possible violations of Chapter 13 of Title 16, which information shall include but not be limited to price and quantity information.

HISTORY: Code 1981, § 26-4-115.1, enacted by Ga. L. 2001, p. 816, § 6.1.

§ 26-4-116. Emergency service providers; contracts with issuing pharmacy; record keeping; inspections

(a) Dangerous drugs and controlled substances as defined under Chapter 13 of Title 16 shall only be issued to the medical director of an emergency service provider from a pharmacy licensed in this state only in accordance with the provisions of this Code section.

(b) The medical director of an emergency service provider and the issuing pharmacy must have a signed contract or agreement designating the issuing pharmacy as the

provider of drugs and consultant services and a copy must be filed with the state board and the Department of Human Resources prior to any drugs being issued. The medical director of an emergency service provider may only have one contractual relationship with one pharmacy per county serviced by such emergency service provider.

(c) A manual of policies and procedures for the handling, storage, labeling, and record keeping of all drugs must be written, approved, and signed by the medical director of an emergency service provider and the pharmacist in charge of the issuing pharmacy. The manual shall contain procedures for the safe and effective use of drugs from acquisition to final disposition.

(d) A written record of all drugs issued to the medical director of an emergency service provider must be maintained by the issuing pharmacy and emergency service provider. Agents of the Georgia Drugs and Narcotics Agency may review all records to determine the accuracy and proper accountability for the use of all drugs.

(e) To provide for the proper control and accountability of drugs, a written record of all drugs used by such emergency service provider shall be provided to the issuing pharmacy within 72 hours of use.

(f) A pharmacist from the contracting issuing pharmacy shall physically inspect the drugs of such emergency service provider to determine compliance with appropriate policies and procedures for the handling, storage, labeling, and record keeping of all drugs not less than annually and maintain records of such inspection for a period of not less than two years. Such an inspection shall, at a minimum, verify that:

- (1) Drugs are properly stored, especially those requiring special storage conditions;
- (2) Drugs are properly accounted for by personnel of such emergency service provider;
- (3) Proper security measures to prohibit unauthorized access to the drugs are implemented; and
- (4) All policies and procedures are followed and enforced.

(g) All outdated, expired, unused, or unusable drugs shall be returned to the issuing pharmacy for proper disposition in a manner acceptable to the board.

HISTORY: Code 1981, § 26-4-116, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26.

§ 26-4-117. Duty to prosecute violations

(a) It shall be the duty of the prosecuting attorney of the court of competent jurisdiction to whom the board or some other person shall report a violation of this chapter to cause appropriate proceedings to be commenced and prosecuted for the enforcement of the penalties as in such case may be provided.

(b) The board, or any person, corporation, or association, in addition to the remedies set forth in this chapter, may bring an action in a court having competent jurisdiction over the parties and subject matter to enjoin violations of this chapter. Such injunction may issue notwithstanding the existence of an adequate remedy at law.

HISTORY: Code 1981, § 26-4-117, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-118. Pharmacy Audit Bill of Rights; recoupment of disputed funds; appeals process for unfavorable reports; final audit report; investigative audits based on criminal offenses

(a) This Code section shall be known and may be cited as "The Pharmacy Audit Bill of Rights."

(b) Notwithstanding any other law, when an audit of the records of a pharmacy is conducted by a managed care company, insurance company, third-party payor, the Department of Community Health under Article 7 of Chapter 4 of Title 49, or any entity that represents such companies, groups, or department, it shall be conducted in accordance with the following bill of rights:

(1) The entity conducting the initial on-site audit must give the pharmacy notice at least one week prior to conducting the initial on-site audit for each audit cycle;

(2) Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;

(3) Any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record may not in and of itself constitute fraud; however, such claims may be subject to recoupment. No such claim shall be subject to criminal penalties without proof of intent to commit fraud;

(4) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

(5) A finding of an overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs; however, recoupment of claims must be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacy;

(6) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

(7) A pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during

an audit;

(8) The period covered by an audit may not exceed two years from the date the claim was submitted to or adjudicated by a managed care company, insurance company, third-party payor, the Department of Community Health under Article 7 of Chapter 4 of Title 49, or any entity that represents such companies, groups, or department;

(9) An audit may not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled during that time unless otherwise consented to by the pharmacy;

(10) The preliminary audit report must be delivered to the pharmacy within 120 days after conclusion of the audit. A final audit report shall be delivered to the pharmacy within six months after receipt of the preliminary audit report or final appeal, as provided for in subsection (c), whichever is later; and

(11) The audit criteria set forth in this subsection shall apply only to audits of claims submitted for payment after July 1, 2006. Notwithstanding any other provision in this subsection, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

(c) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth in subsection (d) of this Code section.

(d) Each entity conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity. If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or said portion without the necessity of any further proceedings.

(e) Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor.

(f) This Code section shall not apply to any investigative audit which involves fraud, willful misrepresentation, or abuse including without limitation investigative audits under Article 7 of Chapter 4 of Title 49, Code Section 33-1-16, or any other statutory provision which authorizes investigations relating to insurance fraud.

HISTORY: Code 1981, § 26-4-118, enacted by Ga. L. 2006, p. 198, § 1/ HB 1371.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 7. PRACTITIONERS OF THE HEALING ARTS

§ 26-4-130. Dispensing drugs; compliance with labeling and packaging requirements; records available for inspection by board; renewal of licenses

(a) For purposes of this Code section, the term:

(1) "Drugs" means drugs as defined in this chapter and controlled substances as defined in Article 2 of Chapter 13 of Title 16.

(2) "Practitioner" or "practitioner of the healing arts" means, notwithstanding Code Section 26-4-5, a person licensed as a dentist, physician, podiatrist, or veterinarian under Chapter 11, 34, 35, or 50, respectively, of Title 43.

(b) The other provisions of this chapter and Article 3 of Chapter 13 of Title 16 shall not apply to practitioners of the healing arts prescribing or compounding their own prescriptions and dispensing drugs except as provided in this Code section. Nor shall such provisions prohibit the administration of drugs by a practitioner of the healing arts or any person under the supervision of such practitioner or by the direction of such practitioner except as provided in this Code section. Any term used in this subsection and defined in Code Section 43-34-26.1 shall have the meaning provided for such term in Code Section 43-34-26.1. The other provisions of this chapter and Articles 2 and 3 of Chapter 13 of Title 16 shall not apply to persons authorized by Code Section 43-34-26.1 to order, dispense, or administer drugs when such persons order, dispense, or administer those drugs in conformity with Code Section 43-34-26.1. When a person dispenses drugs pursuant to the authority delegated to that person under the provisions of Code Section 43-34-26.1, with regard to the drugs so dispensed, that person shall comply with the requirements placed upon practitioners by subsections (c) and (d) of this Code section.

(c) 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 pursuant to this chapter and Chapter 13 of Title 16.

(d) All practitioners who dispense drugs shall make all records required to be kept under subsection (c) of this Code section available for inspection by the board.

(e) Any practitioner who desires to dispense drugs shall notify, at the time of the renewal of that practitioner's license to practice, that practitioner's respective licensing board of that practitioner's intention to dispense drugs. That licensing board shall notify the board regarding each practitioner concerning whom that board has received a notification of intention to dispense drugs. The licensing board's notification shall include the following information:

(1) The name and address of the practitioner;

- (2) The state professional license number of the practitioner;
- (3) The practitioner's Drug Enforcement Administration license number; and
- (4) The name and address of the office or facility from which such drugs shall be dispensed and the address where all records pertaining to such drugs shall be maintained.
- (f) The board shall have the authority to promulgate rules and regulations governing the dispensing of drugs pursuant to this Code section.
- (g) This Code section shall not apply to practitioners who provide to their patients at no cost manufacturer's samples of drugs.

HISTORY: Code 1981, § 26-4-130, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 2000, p. 1706, § 24.

§ 26-4-131. Examination of food, drug, and cosmetic specimens; violations of federal law

The examination of specimens of foods, drugs, and cosmetics shall be made by the state chemist or under direction of that chemist and supervision for the purpose of determining from such examination whether such articles are adulterated or misbranded within the meaning of this title; and, in the case of drugs and cosmetics, if it shall appear from any such examination that any such specimens are adulterated or misbranded within the meaning of this title, a copy of the results of the analysis of the examination of such article, duly authenticated by the analyst or officer making such examination under the oath of such analyst or officer, shall be forwarded to the board without delay. If it shall appear to the satisfaction of the board and the Attorney General, in the case of adulterated or misbranded drugs, that the article involved was shipped in interstate commerce or the act complained of comes under the supervision and jurisdiction of the United States, the board shall certify the case to the United States district attorney in whose district the violation may have been committed.

HISTORY: Code 1981, § 26-4-131, enacted by Ga. L. 1998, p. 686, § 1.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 8. THIRD-PARTY PRESCRIPTION PROGRAMS

§ 26-4-140. Short title

This article shall be known and may be cited as the "Third-party Prescription Program Law of 1983."

HISTORY: Code 1981, § 26-4-140, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-141. Legislative findings

The General Assembly finds that certain practices are unfair to providers of pharmaceuticals, are burdensome and costly to those providers, result in unfair increased costs to certain consumers, and threaten the availability of pharmaceuticals to the public. The General Assembly further finds that there is a need for regulation of certain practices engaged in by some third-party prescription program administrators.

HISTORY: Code 1981, § 26-4-141, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-142. Definitions

As used in this article, the term:

(1) "Administrator" means that person, corporation, or business entity which administers a program, is legally liable for any payments to a participating pharmacy under a program, or both.

(2) "Commissioner" means the Commissioner of Insurance.

(3) "Contract" means a program contract.

(4) "Enrollee" means a consumer who receives pharmaceuticals under a program.

(5) "Participating pharmacy" means a pharmacy having a contract to provide pharmaceuticals to enrollees under a program.

(6) "Pharmaceuticals" means drugs, devices, or services available from a pharmacy.

(7) "Prevailing rate" means the average wholesale price of the pharmaceutical during the applicable period, plus the usual, customary, and reasonable dispensing fee added thereto, provided that in no event shall the amount submitted for reimbursement by a pharmacy under this article exceed the eighty-fifth percentile of the retail prices charged by all pharmacies in Georgia for the same or similar pharmaceuticals during such period of time or the actual price charged by the submitting pharmacy to consumers, other than enrollees, for the same or similar pharmaceuticals during such period of time, whichever

is less.

(8) "Program" means a third-party prescription program.

(9) "Program contract" means that contract creating rights and obligations between a participating pharmacy and a program or administrator.

(10) "Program identification card" means a document which identifies enrollees as participants in a program.

(11) "Third-party prescription program" means any system of providing payments or reimbursement of payments made for pharmaceuticals pursuant to a contract between a pharmacy and another party, including insurance companies and administrators of programs, who are not consumers of the pharmaceuticals under that contract and shall include, without being limited to, insurance plans whereby an enrollee receives pharmaceuticals which are paid for by insurance companies or administrators, or by an agent of his employer, or by others.

HISTORY: Code 1981, § 26-4-142, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-143. Approval of program by Commissioner; exemptions

(a) Unless the program is exempt under subsection (b) of this Code section, no administrator, person, corporation, or business entity shall offer, operate, or administer a program in this state unless that program has been submitted to the Commissioner, in a manner provided by the Commissioner, and is approved by the Commissioner as complying with the requirements of this article.

(b)(1) A program contract existing immediately prior to January 1, 1984, shall be exempt from the requirements of this article but shall not be renewed or otherwise extended beyond its renewal or expiration date, respectively, as specified immediately prior to January 1, 1984, unless the program under the renewed or extended contract is approved by the Commissioner under subsection (a) of this Code section, except that if no such expiration or renewal date is provided in that program contract, the program contract shall be submitted not later than March 1, 1984, to the Commissioner for approval.

(2) A program providing pharmaceuticals pursuant to Article 7 of Chapter 4 of Title 49, the "Georgia Medical Assistance Act of 1977," shall be exempt from the requirements of this article.

(3) A policy or plan regulated under Title 33, relating to insurance, which does not include or utilize a third-party prescription program or contract shall be exempt from the requirements of this article.

(c) A program approved by the Commissioner may have that approval revoked or suspended if it fails to meet any requirements therefor specified in this article or if it fails to be administered in conformity with those requirements.

(d) Disapproval or revocation or suspension of approval of a program by the Commissioner shall constitute a contested case for purposes of Chapter 13 of Title 50, the "Georgia Administrative Procedure Act."

HISTORY: Code 1981, § 26-4-143, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-144. Participating pharmacies; claim reimbursements; cancellation of contracts

(a) A program offered in this state and not exempt under subsection (b) of Code Section 26-4-143 shall provide all of the following:

(1) A statement of the method, frequency, and amount of claim reimbursement to participating pharmacies;

(2) That any valid claim for pharmaceuticals under this program will be paid to a participating pharmacy within 30 days after the claim is received by the administrator if that claim is complete, accurate, and legible, as determined by the administrator;

(3) That any valid claim not paid as required in paragraph (2) of this Code section shall be subject to interest at the rate specified in paragraph (1) of subsection (b) of Code Section 33-25-10, relating to payment of interest on life insurance proceeds;

(4) That reimbursement rates for pharmaceuticals shall not be less than the prevailing rates therefor paid by consumers who are not enrollees;

(5) That each participating pharmacy and enrollee will be notified in writing by the administrator of the cancellation of any program at least 30 days prior to the effective date of cancellation, except that where the administrator is not notified of such cancellation at least 30 days prior to the effective date of cancellation, the written notice shall be provided within 30 days after the administrator received his or her notification;

(6) That program identification cards issued to an enrollee show an expiration date;

(7) That the administrator shall make reasonable efforts to gain possession of all program identification cards upon cancellation of a program for which the cards were issued;

(8) That a valid claim by a participating pharmacy will not be denied upon the basis of the fraudulent use of a program identification card;

(9) That at least 30 days prior to the date a program becomes effective, the program contract therefor shall be offered to all pharmacies located within those counties wherein reside enrollees in that program, which pharmacies shall have at least 30 days from the time they receive the offer to accept that offer and become participating pharmacies;

(10) That any audit by a program to verify claims by a participating pharmacy shall

comply with generally accepted accounting principles and procedures but shall not extrapolate randomly sampled data as a basis for reimbursement from the pharmacy which is audited or from one participating pharmacy to be the corresponding data for another participating pharmacy. In the event a claim against a participating pharmacy for reimbursement is based upon a program audit, the administrator of the program shall submit details of the audit to that participating pharmacy, and any dispute relating thereto shall be resolved under the dispute resolution procedures required under paragraph (11) of this subsection, with the Commissioner to render a final binding decision in the dispute if either party is dissatisfied with the outcome under the dispute resolution procedure; and

(11) A dispute resolution procedure for disputes between the program or administrator and participating pharmacies and between the program or administrator and enrollees.

(b) A program which meets the requirements of subsection (a) of this Code section shall not be administered except in conformity with those requirements, and the administration of that program except in conformity with those requirements shall constitute a violation of this Code section by the administrator of that program.

HISTORY: Code 1981, § 26-4-142, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-145. Excessive charges to enrollees prohibited

A participating pharmacy shall not submit claims for payment for pharmaceuticals under a program for charges in excess of those charged by that pharmacy to consumers, other than enrollees, for the same or similar pharmaceuticals.

HISTORY: Code 1981, § 26-4-145, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-146. Administrator; registration; bond

(a) On and after January 1, 1984, no person, corporation, or business entity shall serve as administrator of a program which has no administrator registered under this Code section unless that person, corporation, or business entity is registered as administrator of that program with the Commissioner.

(b) No administrator may be registered unless the administrator gives bond to the Commissioner conditioned to pay all losses, damages, and expenses incurred as a result of any violation of this article by the administrator or the program being administered thereby. The bond shall be with a surety approved by the Commissioner in the amount of \$200,000.00 or the total annual payments made in the immediately preceding year by all programs administered by that administrator, whichever is greater; provided, however, if the administrator is an insurance company licensed to transact insurance in this state or if the administrator is a self-insurer and is approved by the Commissioner, then such administrator shall not be required to give bond to the Commissioner.

(c) No program shall be required to have more than one administrator registered and bonded under this Code section.

(d) An administrator may have his or her registration suspended or revoked by the Commissioner upon any violation of this article by the administrator or when any program administered by the administrator fails to conform to the requirements of this article. The refusal by the Commissioner to register an administrator and the suspension or revocation of an administrator's registration shall constitute a contested case for purposes of Chapter 13 of Title 50, the "Georgia Administrative Procedure Act."

(e) Records, information, and other identifying matter obtained through the submission of a claim for reimbursement by a participating pharmacy shall be used exclusively and solely for the purposes of verification and payment to the participating pharmacy and policyholder and for no other purposes.

HISTORY: Code 1981, § 26-4-146, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26.

§ 26-4-147. Liability of enrollees

No enrollee may utilize a program identification card to obtain pharmaceuticals after the program has been canceled and after the enrollee has received notification of the cancellation, and if such card is so utilized, that enrollee shall be liable to the administrator of that program for the cost of those pharmaceuticals.

HISTORY: Code 1981, § 26-4-147, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-148. Violations of article; penalties

(a) Any person, corporation, or business entity which violates subsection (a) of Code Section 26-4-146 shall be guilty of a misdemeanor.

(b) Any person, corporation, or business entity which violates any provision of this article shall be subject to a civil penalty in the amount of \$1,000.00 for each act in violation of this article or, if the violation was knowing and willful, a civil penalty of \$5,000.00 for each act in violation of this article.

(c) Any person injured as a result of a violation of this article may bring an action against that person, corporation, or business entity violating this article for the recovery of all actual damages occurring as a result thereof, plus attorneys' fees.

(d) An action may be brought against any person, corporation, or business entity subject to civil penalties or an action for damages under this Code section in the county in this state in which the person resides or corporation or business entity maintains an office or, if neither residing nor maintaining an office in this state, in the Superior Court of Fulton County.

(e) All penalties and remedies provided in this Code section are cumulative of each other and of any other penalties and remedies otherwise provided by law.

HISTORY: Code 1981, § 26-4-148, enacted by Ga. L. 1998, p. 686, § 1.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 9. POISONS

§ 26-4-160. Sales and labeling

No person shall furnish by retail sale any poison enumerated in this Code section without distinctly labeling the bottle, box, vessel, or paper in which the poison is contained, and also the outside wrapper or cover thereof, with the name of the article, the word "Poison," and the name and place of business of the person who furnishes the same; and no poison shall be furnished unless upon due inquiry it shall be found that the person to whom it is delivered is aware of its poisonous character and shall represent that it is to be used for a legitimate purpose:

(1) Schedule "A." Arsenic and its preparations, corrosive sublimate, white precipitate, red precipitate, biniodide of mercury, cyanide of potassium, hydrocyanic acid, strychnia, and all other poisonous vegetable alkaloids and their salts; essential oil of bitter almonds, opium and its preparations, except paregoric and other preparations of opium containing less than two grains to the ounce; and

(2) Schedule "B." Aconite, belladonna, colchicum, conium, nux vomica, henbane, creosote, digitalis, and their pharmaceutical preparations; croton oil, chloroform, chloral hydrate, sulfate of zinc, mineral acids, carbolic acid, and oxalic acid.

HISTORY: Code 1981, § 26-4-160, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-161. Procedure on sale or delivery of listed poisons.

No licensed pharmacist shall sell or deliver any of the poisons included in paragraph (1) of Code Section 26-4-160 without first making an entry in a book for that purpose, stating the date of the delivery, the name and address of the person receiving the poison, the name and quantity of the poison, the purpose for which it is represented by such person to be required, and the name of the dispenser. Such book shall always be open for inspection by the proper authorities and shall be preserved for reference for at least five years.

HISTORY: Code 1981, § 26-4-161, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-162. Prescriptions by practitioners of the healing arts

This article shall not apply to the dispensing of poisons in not unusual quantities or doses, upon the prescriptions of practitioners of the healing arts.

HISTORY: Code 1981, § 26-4-162, enacted by Ga. L. 1998, p. 686, § 1.

§ 26-4-163. Penalty for violation of article

Any person violating this article shall be guilty of a misdemeanor.

HISTORY: Code 1981, § 26-4-163, enacted by Ga. L. 1998, p. 686, § 1.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 10. NUCLEAR PHARMACY LAW

§ 26-4-170. Short title

This article shall be known and may be cited as the "Nuclear Pharmacy Law."

HISTORY: Code 1981, § 26-4-170, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-171. Definitions

As used in this article, the term:

(1) "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.

(2) "Board" means the State Board of Pharmacy.

(3) "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 reagent kits to prepare radiopharmaceuticals; preparing reagent kits; aliquoting 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.

(4) "Department" means the Department of Natural Resources.

(5) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(6) "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.

(7) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical service.

(8) "Radiopharmaceutical" means radioactive drugs and chemical products used for diagnostic and therapeutic purposes and includes the terms radioactive pharmaceuticals, radioisotopes, and radioactive tracers.

(9) "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.

(10) "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.

HISTORY: Code 1981, § 26-4-171, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-172. License requirements generally

(a) All persons, firms, pharmacies, or corporations which receive, possess, transfer, or manufacture for sale or resale radiopharmaceuticals shall be licensed in accordance with the provisions of this article. No person may receive, acquire, possess, compound, or dispense any radiopharmaceutical except in accordance with the provisions of this article and the conditions of rules and regulations promulgated by the Board of Natural Resources for radioactive materials and administered by the department. The requirements of this article are in addition to, and not in substitution of, other applicable statutes and regulations administered by the State Board of Pharmacy or the department.

(b) Nothing in this article shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when his or her use of radiopharmaceuticals is limited to the diagnosis and treatment of his or her own patients.

(c) Nothing in this article shall be construed so as to require a licensed clinical laboratory, which is licensed by the Department of Human Resources 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.

(d) Nothing in this article 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.

HISTORY: Code 1981, § 26-4-172, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-173. Applicant requirements

(a) An applicant for a license as a nuclear pharmacist shall:

- (1) Be a currently licensed pharmacist in the State of Georgia;
- (2) Meet the minimum requirements and be licensed to possess and use radioactive materials for medical use, as authorized by the department; and
- (3) Have met all requirements for training and experience established by the board in rules and regulations promulgated pursuant to this authority; provided, however, rules and regulations prescribing training and experience requirements for nuclear pharmacists shall have first been approved by the department.

(b) A license as a nuclear pharmacist shall be issued to any pharmacist who makes application to the board, together with a required fee, and meets the requirements of subsection (a) of this Code section.

HISTORY: Code 1981, § 26-4-173, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-174. Nuclear pharmacy operators permit; separate entity; quality; maintain records; compliance of laws; authorized dispensing; transfer; labeling; redistribution

(a) A permit to operate a nuclear pharmacy shall only be issued in accordance with Article 6 of this chapter with the added designation that the pharmacist in charge be a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a licensed nuclear pharmacist. All acts of compounding and dispensing 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.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services provided and, as required by rules and regulations promulgated by the board pursuant to implementation of this article, shall meet minimal space requirements established for all pharmacies in the state. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from unauthorized personnel.

(c) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(d) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with requirements of the board and the department.

(e) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs and pharmaceuticals.

(f) Radiopharmaceuticals are to be dispensed only upon prescription order by a physician who is authorized by the department to possess, use, and administer radioactive materials.

(g) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with department regulations for radioactive materials. A nuclear pharmacy may also furnish radioactive materials for use to physicians, for individual patient use in accordance with subsection (f) of this Code section.

(h) In addition to any labeling requirements required by rules and regulations of the board for nonradiopharmaceuticals, the immediate outer container of a radiopharmaceutical to be dispensed shall also be labeled as required in rules and regulations of the board and of the department.

(i) The amount of radioactivity dispensed in each individual preparation shall be determined by the nuclear pharmacist through radiometric methods immediately prior to dispensing.

(j) Nuclear pharmacies may redistribute federal Food and Drug Administration approved radiopharmaceuticals if the pharmacy does not process 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.

HISTORY: Code 1981, § 26-4-174, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-175. Meeting requirements of the board

Nuclear pharmacies shall meet all requirements for items and articles of equipment as required through rules and regulations of the board. Nuclear pharmacies shall also have equipment required for the safe handling and storage of radioactive materials, as established by rules of the department.

HISTORY: Code 1981, § 26-4-175, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-176. Limiting, suspending, or revoking license

The board may limit, suspend, or revoke licenses issued under the provisions of this article, or impose any other reasonable sanctions upon holders of such licenses upon proof of any of the violations specified in Code Sections 26-4-60 and 26-4-113.

HISTORY: Code 1981, § 26-4-176, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-177. Board refusing to grant license

The board may refuse to grant a license to any person, firm, or corporation for any of the grounds set forth in Code Sections 26-4-60 and 26-4-113. In addition, the board may refuse to grant a license if any applicant shall make any false statement in the application or cheats in any manner upon any examination administered pursuant to this article.

HISTORY: Code 1981, § 26-4-177, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-178. Authorized to promulgate rules

The board is authorized to promulgate rules and regulations to implement the provisions of this article.

HISTORY: Code 1981, § 26-4-178, enacted by Ga. L. 1999, p. 277, § 10.

§ 26-4-179. Authority of department

Nothing in this article shall be construed to repeal the authority of the Department of Natural Resources to regulate the use of radioactive materials.

HISTORY: Code 1981, § 26-4-179, enacted by Ga. L. 1999, p. 277, § 10.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 11. UTILIZATION OF UNUSED PRESCRIPTION DRUGS

§ 26-4-190. Short title

This article shall be known and may be cited as the "Utilization of Unused Prescription Drugs Act."

HISTORY: Code 1981, § 26-4-190, enacted by Ga. L. 2006, p. 152, § 1/HB 1178.

§ 26-4-191. Definitions

As used in this article, the term:

(1) "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 21 C.F.R. Part 1308.

(2) "Health care facility" means an institution which is licensed as a nursing home, intermediate care home, personal care home, home health agency, or hospice pursuant to Chapter 7 of Title 31.

(3) "Medically indigent person" means:

(A) A person who is Medicaid eligible under the laws of this state; or

(B) A person:

(i) Who is without health insurance; or

(ii) Who has health insurance that does not cover the injury, illness, or condition for which treatment is sought; and

whose family income does not exceed 200 percent of the federal poverty level as defined annually by the federal Office of Management and Budget.

HISTORY: Code 1981, § 26-4-191, enacted by Ga. L. 2006, p. 152, § 1/HB 1178.

§ 26-4-192. State-wide program for distribution of unused prescription drugs for benefit of medically indigent persons; pilot program; rules and regulations; time for implementation

(a) The Georgia State Board of Pharmacy, the Department of Human Resources, and the Department of Community Health shall jointly develop and implement a state-wide

program consistent with public health and safety standards through which unused prescription drugs, other than prescription drugs defined as controlled substances, may be transferred from health care facilities to pharmacies designated or approved by the Department of Human Resources for the purpose of distributing such drugs to residents of this state who are medically indigent persons.

(b) The Georgia State Board of Pharmacy, the Department of Human Resources, and the Department of Community Health shall be authorized to develop and implement a pilot program to determine the safest and most beneficial manner of implementing the program prior to the state-wide implementation of the program required in subsection (a) of this Code section.

(c) The Georgia State Board of Pharmacy, in consultation with the Department of Human Resources and the Department of Community Health, shall develop and promulgate rules and regulations to establish procedures necessary to implement the program and pilot program, if applicable, provided for in this Code section. The rules and regulations shall provide, at a minimum:

(1) For an inclusionary formulary for the prescription drugs to be distributed pursuant to the program;

(2) For the protection of the privacy of the individual for whom a prescription drug was originally prescribed;

(3) For the integrity and safe storage and safe transfer of the prescription drugs, which may include, but shall not be limited to, limiting the drugs made available through the program to those that were originally dispensed by unit dose or an individually sealed dose and that remain in intact packaging; provided, however, that the rules and regulations shall authorize the use of any remaining prescription drugs;

(4) For the tracking of and accountability for the prescription drugs; and

(5) For other matters necessary for the implementation of the program.

(d) The state-wide program required by this Code section shall be implemented no later than January 1, 2007, unless a pilot program is implemented pursuant to subsection (b) of this Code section, in which case state-wide implementation shall occur no later than July 1, 2008.

HISTORY: Code 1981, § 26-4-192, enacted by Ga. L. 2006, p. 152, § 1/ HB 1178.

§ 26-4-193. Donated drugs for dispensation

In accordance with the rules and regulations promulgated pursuant to Code Section 26-4-192, the resident of a health care facility, or the representative or guardian of a resident, may donate unused prescription drugs, other than prescription drugs defined as controlled substances, for dispensation to medically indigent persons.

HISTORY: Code 1981, § 26-4-193, enacted by Ga. L. 2006, p. 152, § 1/HB 1178.

§ 26-4-194. Immunity from liability for those dispensing donated drugs

(a) Physicians, pharmacists, other health care professionals when acting within the scope of practice of their respective licenses, and health care facilities shall not be subject to liability for transferring or receiving unused prescription drugs pursuant to this article and in good faith compliance with the rules and regulations promulgated pursuant to Code Section 26-4-192.

(b) Pharmacists and pharmacies shall not be subject to liability for dispensing unused prescription drugs pursuant to this article when such services are provided without reimbursement and when performed within the scope of their practice and in good faith compliance with the rules and regulations promulgated pursuant to Code Section 26-4-192. For purposes of this subsection, a restocking fee paid to a pharmacy pursuant to Code Section 49-4-152.5 shall not be considered reimbursement.

(c) Nothing in this Code section shall be construed as affecting, modifying, or eliminating the liability of a manufacturer of prescription drugs or its employees or agents under any legal claim, including but not limited to product liability claims. Drug manufacturers shall not be subject to liability for any acts or omissions of any physician, pharmacist, other health care professional, health care facility, or pharmacy providing services pursuant to this article.

(d) Drug manufacturers shall not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for the donation, acceptance, or dispensing of a drug under the program or for the failure to transfer or communicate product or consumer information or the expiration date of a drug donated under the program.

HISTORY: Code 1981, § 26-4-194, enacted by Ga. L. 2006, p. 152, § 1/HB 1178.

§ 26-4-195. Construction of article

This article shall be construed in concert with Code Section 49-4-152.3.

HISTORY: Code 1981, § 26-4-195, enacted by Ga. L. 2006, p. 152, § 1/HB 1178.

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