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

§ 26-4-1. Short title

This chapter shall be known and may be cited as the "Georgia Pharmacy Practice Act."

§ 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.

§ 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.

§ 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.

§ 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.

(1.1) "Biological product" means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act, 42 U.S.C. Section 262.

(2) "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.

(3.1) "Cognizant member" means that member of the Georgia State Board of Pharmacy who is charged with conducting investigative interviews relating to investigations involving licensees, registrants, and permit holders.

(4) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug by a pharmacist or pharmacy licensed or registered by the board or by a practitioner in compliance with rules established by the board regarding pharmaceutical compounding:

(A) As the result of a practitioner's prescription drug order or initiative for a specific patient based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice;

(B) For use by a practitioner in the administration of a dangerous drug or controlled substance to a patient in his or her professional practice office or setting;

(C) For use within the hospital or health system in which the pharmacy is located or in which the practitioner or pharmacist practices or for use within clinics or other entities owned or operated by such hospital or health system; or

(D) 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 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.

(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, by a means 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. "Electronic data prescription drug order" also includes any digitalized prescription drug order transmitted to a pharmacy that is converted into a visual image of a prescription order during the transmission process, is received by the pharmacy through a facsimile, and includes the practitioner's electronic signature.

(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.

(15.1) "Executive director" means the executive director appointed by the Georgia State Board of Pharmacy pursuant to Code Section 26-4-20.

(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, assisted living community, personal care home, hospice, health clinic, or prison clinic.

(18.2) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in subsection (k)(4) of 42 U.S.C. Section 262 or has been deemed therapeutically equivalent by the federal Food and Drug Administration.

(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 Behavioral Health and Developmental Disabilities 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, optometrist, 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.

(37.1) "Remote automated medication system" means an automated mechanical system that is located in a skilled nursing facility or hospice licensed as such pursuant to Chapter 7 of Title 31 that does not have an on-site pharmacy and in which medication may be dispensed in a manner that may be specific to a patient.

(37.2) "Remote order entry" means the entry made by a pharmacist located within the State of Georgia from a remote location indicating that the pharmacist has reviewed the patient specific drug order for a hospital patient, has approved or disapproved the administration of the drug for such patient, and has entered the information in the hospital's patient record system.

(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:

(A) A prescription pad or paper that has been approved by the board for use and contains the following characteristics:

(i) One or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

(ii) One or more industry recognized features designed to prevent the erasure or modification of information written on the prescription form by the practitioner; and

(iii) One or more industry recognized features designed to prevent the use of counterfeit prescription forms; or

(B) A prescription pad or paper that is an approved prescription pad or paper of the Centers for Medicare and Medicaid Services on January 1, 2013.

(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.

(40.5) "USP-NF" means the United States Pharmacopeia and National Formulary.

(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.

§ 26-4-6. Provisions of chapter not applicable to facilities engaged solely in distribution of dialysate drugs or certain dialysis equipment under certain conditions

The provisions of this chapter shall not apply to a facility engaged solely in the distribution of dialysate drugs, or devices necessary to perform home kidney dialysis to patients with end stage renal disease, provided that the following criteria are met:

(1) The dialysate drugs, or devices are approved or cleared by the federal Food and Drug Administration as required by federal law;

(2) The dialysate drugs, or devices are lawfully held by a manufacturer or manufacturer's agent that is properly registered with the board as a manufacturer or wholesale distributor;

(3) The dialysate drugs, or devices are held and delivered in their original, sealed packaging from the manufacturing facility;

(4) The dialysate drugs, or devices are delivered only by the manufacturer or the manufacturer's agent and only upon receipt of a physician's order; and

(5) The manufacturer or manufacturer's agent delivers the dialysate drugs, or devices directly to:

(A) A patient with end stage renal disease or such patient's designee for the patient's self-administration of the dialysis therapy; or

(B) A health care provider or institution for administration or delivery of the dialysis therapy to a patient with end stage renal disease.

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; board to be autonomous division of Department of Community Health; compensation; venue for actions involving board members

(a) The Georgia State Board of Pharmacy existing immediately preceding July 1, 2013, 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.

(c) On and after July 1, 2013, the board shall not be under the jurisdiction of the Secretary of State but shall be a division of the Department of Community Health; provided, however, that except as otherwise specifically provided, the board shall be autonomous from the Board of Community Health and the commissioner of community health and shall exercise its quasi-judicial, rule-making, licensing, or policy-making functions independently of the department and without approval or control of the department and prepare its budget and submit its budgetary requests, if any, through the department. Such transfer shall in no way affect any existing obligations, liabilities, or rights of the board, as such existed on June 30, 2013. The board shall have with respect to all matters within the jurisdiction of the board as provided under this chapter the powers, duties, and functions of professional licensing boards as provided in Chapter 1 of Title 43.

(d) The board shall appoint and fix the compensation, which shall be approved by the Board of Community Health, of an executive director of such board who shall serve at the pleasure of the board.

(e) The venue of any action involving members of the board shall be the county in which is found the primary office of the board. The executive director of the board shall not be considered a member of the board in determining the venue of any such action, and no court shall have jurisdiction over any such action solely by virtue of the executive director residing or maintaining a residence within its jurisdiction.

§ 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, and the oath shall be filed with the office of the Governor, whereupon the office of the Governor shall issue to each appointee a certificate of appointment.

§ 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 and confirmed by the Senate 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 this 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.

§ 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 in the same manner as provided in Code Section 43-1-17.

§ 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 vice president shall serve as the cognizant member of 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 executive director at his or her office in the county of domicile of the board.

§ 26-4-25. Expense and mileage allowances; reimbursement of certain costs and fees

Each member of the board may receive the expense allowance as provided by subsection (b) of Code Section 45-7-21 and the same mileage allowance for the use of a personal car as that received by other state officials and employees or a travel allowance of actual transportation costs if traveling by public carrier within this state. Each board member shall also be reimbursed for any conference or meeting registration fee incurred in the performance of his or her duties as a board member. For each day's service outside of this state as a board member, such member shall receive actual expenses as an expense allowance as well as the mileage allowance for the use of a personal car equal to that received by other state officials and employees or a travel allowance of actual transportation costs if traveling by public carrier or by rental motor vehicle. Expense vouchers submitted by board members shall be subject to approval of the president and executive director. Out-of-state travel by board members shall be approved by the board president and the executive director.

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

(a) To transact its business, the board shall hold regular meetings at least once each month unless, in the discretion of the president, it is deemed unnecessary for a particular month. 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) Meetings and hearings of the board shall be held at the site of the office of the board or at such other site as may be specified by the president of the board.

(e) 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.

(f) Proceedings before the board wherein a licensee's or permit holder's right to practice pursuant to this chapter in this state is terminated, suspended, or limited or wherein a public reprimand is administered shall require prior notice to the licensee and an opportunity for hearing; and such proceedings shall be considered contested cases within the meaning of Chapter 13 of Title 50, the "Georgia Administrative Procedure Act." Neither refusal of a license or permit nor a private reprimand nor a letter of concern shall be considered a contested case within the meaning of Chapter 13 of Title 50; provided, however, that the applicant shall be allowed to appear before the board, if the applicant so requests, prior to the board making a final decision regarding the issuance of the license or permit. The power to subpoena as set forth in Chapter 13 of Title 50 shall include the power to subpoena any relevant book, writing, paper, or document. If any licensee or permit holder fails to appear at any hearing after reasonable notice, the board may proceed to hear the evidence against such licensee or permit holder and take action as if such licensee or permit holder had been present.

§ 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.

§ 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) (A) The regulation of other employees in the prescription or pharmacy department, including but not limited to the registration and regulation of pharmacy technicians. The board shall be required to establish the minimum qualifications for the registration of pharmacy technicians and shall be authorized to require the completion of a background check and criminal history record check for each person applying for registration as a pharmacy technician in this state. The certificate of registration, once issued, may be valid for no more than two years and shall be renewable biennially upon payment of a renewal fee and compliance with such other conditions as the board may establish by rule or regulation. The board shall be authorized to deny registration, to deny renewal, or to revoke or suspend the registration of a pharmacy technician for any of the grounds set forth in Code Section 26-4-60 or Code Section 43-1-19. However, said denial of a technician application, denial of the renewal of a certificate, or suspension or revocation of a technician registration shall not be considered a contested case under Chapter 13 of Title 50, the "Georgia Administrative Procedure Act," but said applicant or registrant shall be entitled to an appearance before the board. The board shall be required to establish and maintain a registry of pharmacy technicians in this state which contains the name and home address of each pharmacy technician and his or her employer and location of employment. The board shall establish a process by which the pharmacist in charge of each pharmacy shall provide updated information on the pharmacy technicians in the pharmacy. The board may establish and collect fees from pharmacy technicians, their employers, or both for the registration of pharmacy technicians and maintenance of the registry.

(B) (i) In enforcing this paragraph, the board may, upon reasonable grounds, require a registrant or applicant to submit to a mental or physical examination by licensed health care providers designated by the board. The results of such examination shall be admissible in any hearing before the board, notwithstanding any claim of privilege under a contrary rule of law or statute, including, but not limited to, Code Section 24-9-21. Every person who shall accept the privilege of practicing as a pharmacy technician in this state or who shall file an application for a certificate of registration to practice pharmacy in this state shall be deemed to have given his or her consent to submit to such mental or physical examination and to have waived all objections to the admissibility of the results in any hearing before the board, upon the grounds that the same constitutes a privileged communication. If a registrant or applicant fails to submit to such an examination when properly directed to do so by the board, unless such failure was due to circumstances beyond his or her control, the board may enter a final order upon proper notice, hearing, and proof of such refusal. Any registrant or applicant who is prohibited from practicing as a pharmacy technician under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate to the board that he or she can resume or begin practicing as a pharmacy technician with reasonable skill and safety to patients.

(ii) For the purposes of this paragraph, the board may, upon reasonable grounds, obtain any and all records relating to the mental or physical condition of a registrant or applicant, including psychiatric records; and such records shall be admissible in any hearing before the board, notwithstanding any claim of privilege under a contrary rule of law or statute, including, but not limited to, Code Section 24-9-21. Every person who shall accept the privilege of practicing as a pharmacy technician in this state or who shall file an application for a certificate of registration to practice as a pharmacy technician in this state shall be deemed to have given his or her consent to the board's obtaining any such records and to have waived all objections to the admissibility of such records in any hearing before the board, upon the grounds that the same constitutes a privileged communication.

(iii) If any registrant or applicant could, in the absence of this paragraph, invoke a privilege to prevent the disclosure of the results of the examination provided for in division (i) of this subparagraph or the records relating to the mental or physical condition of such registrant or applicant obtained pursuant to division (ii) of this subparagraph, all such information shall be received by the board in camera and shall not be disclosed to the public, nor shall any part of the record containing such information be used against any registrant or applicant in any other type of proceeding;

(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;

(12.1) (A) The licensure for the use of remote automated medication systems and the regulation and establishment of minimum standards for the use and operation of remote automated medication systems to ensure safe and efficient dispensing, including, but not limited to, appropriate security measures, requirements for skilled nursing facilities and hospices that utilize such systems, training requirements, accuracy and quality assurance measures, recordkeeping requirements, and such other appropriate requirements as determined by the board.

(B) The regulation and establishment of minimum standards for the use and operation of remote automated medication systems by the board as provided for in subparagraph (A) of this paragraph shall permit a pharmacy technician registered pursuant to this chapter to fill a remote automated medication system. If the remote automated medication system utilizes radio frequency identification or bar coding in the filling process, the pharmacy shall retain an electronic record of the filling activities of the pharmacy technician. If the remote automated medication system does not utilize radio frequency identification or bar coding in the filling process, a pharmacist shall supervise continuously the filling activities of the pharmacy technician through a two-way audiovisual system.

(C) The board may establish rules and regulations to implement the requirements of this paragraph;

(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 Department of Community Health, 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;

(20) The requiring of background checks, including, but not limited to, criminal history record checks, on any persons or firms applying for licensure or registration pursuant to this chapter;

(21) 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;

(22) To adopt a seal by which the board shall authenticate the acts of the board;

(23) To keep a docket of public proceedings, actions, and filings;

(24) To set its office hours;

(25) To require licensees and permit holders to report a change of business address or personal address within ten days of the change in either address;

(26) To adopt necessary rules concerning proceedings, hearings, review hearings, actions, filings, depositions, and motions related to uncontested cases;

(27) (A) To authorize the Georgia Drugs and Narcotics Agency to conduct inspections and initiate investigations on its behalf for the purpose of discovering violations of this chapter, Chapter 3 of this title, and Chapter 13 of Title 16.

(B) When conducting investigations and inspections on behalf of the board, the Georgia Drugs and Narcotics Agency shall have the same access to and may examine any relevant writing, document, or other material relating to any licensee, registrant, permittee, or applicant as the board. The executive director may issue subpoenas to compel access to any writing, document, or other material upon a determination that reasonable grounds exist for the belief that a violation of this chapter, Chapter 3 of this title, Chapter 13 of Title 16, or any other

law relating to the practice of pharmacy may have taken place. The results of all investigations and inspections initiated by the Georgia Drugs and Narcotics Agency which relate to an individual licensed or permitted by the board shall be reported by the Georgia Drugs and Narcotics Agency to the board, and the records of such investigations shall be kept for the board by the director of the Georgia Drugs and Narcotics Agency, and the board shall retain the right to have access to such records at any time. Notwithstanding the provisions of this subparagraph, Code Section 16-13-60 shall control the access to or release of information.

(C) Nothing in this chapter shall be construed to prohibit or limit the authority of the executive director or the director of the Georgia Drugs and Narcotics Agency to conduct inspections and initiate investigations on its own initiative for the purpose of discovering violations of this chapter, Chapter 3 of this title, and Chapter 13 of Title 16 and disclose such information to any law enforcement agency or prosecuting attorney. Notwithstanding the provisions of this subparagraph, Code Section 16-13-60 shall control the access to or release of information.

(D) The executive director or the director of the Georgia Drugs and Narcotics Agency may also disclose to any person or entity information concerning the existence of any investigation for unlicensed practice being conducted against any person who is neither licensed nor an applicant for licensure by the board;

(28) To administer oaths, subpoena witnesses and documentary evidence, including relevant medical records, and take testimony in all matters relating to its duties;

(29) To conduct hearings, reviews, and other proceedings according to Chapter 13 of Title 50;

(30) To have the cognizant member of the board conduct investigative interviews in conjunction with the Georgia Drugs and Narcotics Agency and thereafter to report his or her findings, with recommendations, to the board. In order to obtain a nonprejudicial decision, such report and recommendations shall not disclose the identity of the subject of the investigation. The cognizant member shall not vote on matters which he or she has presented to the board as the cognizant member;

(31) To issue cease and desist orders to stop the unlicensed practice of pharmacy or other professions licensed, certified, or permitted under this chapter and impose penalties for such violations;

(32) To refer cases for criminal prosecution or injunctive relief to appropriate prosecuting attorneys or other law enforcement authorities of this state, another state, or the United States;

(33) To release investigative or applicant files to another enforcement agency or lawful licensing authority in another state;

(34) To sue and be sued in a court of competent jurisdiction;

(35) To enter into contracts;

(36) To assess fines for violations of this chapter or board rules; and

(37) To set all reasonable fees by adoption of a schedule of fees approved by the board. The board shall set such fees sufficient to cover costs of operation.

(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 or another business or profession licensed by the board under this chapter 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 and his or her legal counsel 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.

§ 26-4-28.1. Power, duties, and authority of the executive director

(a) The executive director:

(1) Shall be a full-time employee of the board and shall serve as the chief executive officer and secretary of the board. Any person, in order to qualify for appointment as the executive director, shall be of good moral character and shall possess such qualifications as the board may require. The executive director shall have, with respect to the board, the same powers, duties, and functions granted to the division director with respect to professional licensing boards under Chapter 1 of Title 43 but shall not be subject to any approval or other powers exercised by the Secretary of State;

(2) With the approval of the board, may employ or contract with and fix the compensation of administrative assistants, secretaries, and any other such staff as deemed necessary to assist in the duties of the board. The director of the Georgia Drugs and Narcotics Agency shall serve as the assistant executive director, who shall act on behalf of the executive director in his or her absence. The executive director and other board staff shall be allowed reimbursement for travel and other expenses necessarily incurred in the performance of their duties in the same manner as other state officers and employees, and shall receive payment of the same in the manner provided for the board;

(3) Shall take an oath to discharge faithfully the duties of the office; and

(4) Shall be charged with the duties and powers as prescribed by the board.

(b) The executive director shall prepare and maintain a public roster containing the names and business addresses of all current licensees, registration holders, and permit holders for each of the various registrants regulated by the board. A copy of the roster shall be available to any person upon request at a fee prescribed by the board sufficient to cover the cost of printing and distribution. The following shall be treated as confidential, not subject to Article 4 of Chapter 18 of Title 50, relating to open records, and shall not be disclosed without the approval of the board:

(1) Applications and other personal information submitted by applicants, except to the applicant, the staff, and the board;

(2) Information, favorable or unfavorable, submitted by a reference source concerning an applicant, except to the staff and the board;

(3) Examination questions and other examination materials, except to the staff and the board; and

(4) The deliberations of the board with respect to an application, an examination, a complaint, an investigation, or a disciplinary proceeding, except as may be contained in official board minutes; provided, however, that such deliberations may be released to a law enforcement agency or prosecuting attorney of this state or to another state or federal enforcement agency or lawful licensing authority. Releasing the documents pursuant to this paragraph shall not subject any otherwise privileged documents to the provisions of Code Section 50-18-70.

§ 26-4-28.2. Notification to board of convictions

Any licensee, registration holder, or permit holder who is convicted under the laws of this state, the United States, or any other state, territory, or country of a felony shall be required to notify the board of the conviction within ten days of the conviction. The failure to notify the board of a conviction shall be considered grounds for revocation of his or her license, registration, permit, or other authorization to engage in the practice of pharmacy or another profession regulated under this chapter.

§ 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; investigations; 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 45-12-71; provided, however, that the agency shall be assigned for administrative purposes only, as defined in Code Section 50-4-3, to the Department of Community Health, except that such department shall prepare and submit the budget for the Georgia Drugs and Narcotics Agency. 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 Georgia Drugs and Narcotics 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 such office for any cause whatsoever, the board shall appoint a successor at a regular or called meeting. The director shall be a pharmacist registered in this state. The director shall serve as the assistant executive director for the board and act on behalf of the executive director during his or her absence. 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 Georgia Drugs and Narcotics 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 such 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.

(d) 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.

(e) The Georgia Drugs and Narcotics Agency may employ personnel who are not special agents to conduct and assist with inspections.

(f) 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 may 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.

(g) The Georgia Drugs and Narcotics Agency may contract with and submit invoices for payment of services rendered to other professional licensing boards for the purposes of conducting investigations on their behalf and under the authority of such other professional licensing boards. Such investigations and subsequent reports and summaries shall be subject to the same confidentiality restrictions and disclosure as required for investigations and reports for

the requesting professional licensing board. Any such payment of services received by the agency shall be deposited into the general fund of the state treasury.

(h) 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.

(i) The State Board of Pharmacy is authorized and directed to publish in print or electronically 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.

(j) 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.

§ 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.

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.

§ 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 an 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 so 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 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.

(3) Any person who takes the board approved examination and fails the examination may repeat the examination at regular intervals of administration; however, a person shall not take the examination more than three times without permission from the board. A person who has taken the board approved examination and failed the examination for the third time shall not practice as a pharmacy intern. A person who takes the board approved 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.

(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.

§ 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 examinations as determined by the board, one of which shall include an examination 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, 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 an 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.

§ 26-4-43. Temporary licenses

A temporary license may be issued by the executive 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.

§ 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 executive 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.

§ 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.

§ 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.

§ 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 executive 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.

§ 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 an 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.

§ 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.

§ 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.

§ 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 executive 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.

§ 26-4-50. Drug therapy modification certification

(a) No pharmacist shall be authorized to modify drug therapy pursuant to Code Section 43-34-24 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.

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) Engaging in any unprofessional, immoral, unethical, deceptive, or deleterious conduct or practice harmful to the public, which conduct or practice materially affects the fitness of the licensee or applicant to practice pharmacy or another business or profession licensed under this chapter, or of a nature likely to jeopardize the interest of the public, which conduct or practice need not have resulted in actual injury to any person or be directly related to the practice of pharmacy or another licensed business or profession but shows that the licensee or applicant has committed any act or omission which is indicative of bad moral character or untrustworthiness; unprofessional conduct shall also include any departure from, or the failure to conform to, the minimal reasonable standards of acceptable and prevailing practices of the business or profession licensed under this chapter;

(2) Incapacity that prevents a licensee from engaging in the practice of pharmacy or another business or profession licensed under this chapter with reasonable skill, competence, and safety to the public;

(3) Being:

(A) Convicted of a felony;

(B) Convicted of any crime involving moral turpitude in this state or any other state, territory, or country or in the courts of the United States; or

(C) Convicted or guilty of 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) Knowingly making misleading, deceptive, untrue, or fraudulent representations in the practice of a business or profession licensed under this chapter or on any document connected therewith; practicing fraud or deceit or intentionally making any false statement in obtaining a

license to practice the licensed business or profession; or making a false statement or deceptive registration with the board;

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

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

(ii) 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.

(B) In enforcing this paragraph, the board may, upon reasonable grounds, require a licensee or applicant to submit to a mental or physical examination by licensed health care providers designated by the board. The results of such examination shall be admissible in any hearing before the board, notwithstanding any claim of privilege under a contrary rule of law or statute, including, but not limited to, Code Section 24-5-501. Every person who accepts the privilege of practicing pharmacy in this state or who files an application for a license to practice pharmacy in this state shall be deemed to have given his or her consent to submit to such mental or physical examination and to have waived all objections to the admissibility of the results in any hearing before the board, upon the grounds that the same constitutes a privileged communication. If a licensee or applicant fails to submit to such an examination when properly directed to do so by the board, unless such failure was due to circumstances beyond his or her control, the board may enter a final order upon proper notice, hearing, and proof of such refusal. Any licensee or applicant who is prohibited from practicing pharmacy under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate to the board that he or she can resume or begin the practice of pharmacy with reasonable skill and safety to patients.

(C) For the purposes of this paragraph, the board may, upon reasonable grounds, obtain any and all records relating to the mental or physical condition of a licensee or applicant, including psychiatric records; and such records shall be admissible in any hearing before the board, notwithstanding any claim of privilege under a contrary rule of law or statute, including, but not limited to, Code Section 24-5-501. Every person who accepts the privilege of practicing pharmacy in this state or who files an application for a license to practice pharmacy in this state shall be deemed to have given his or her consent to the board's obtaining any such records and to have waived all objections to the admissibility of such records in any hearing before the board, upon the grounds that the same constitutes a privileged communication.

(D) If any licensee or applicant could, in the absence of this paragraph, invoke a privilege to prevent the disclosure of the results of the examination provided for in subparagraph (B) of this paragraph or the records relating to the mental or physical condition of such licensee or applicant obtained pursuant to subparagraph (C) of this paragraph, all such information shall be received by the board in camera and shall not be disclosed to the public, nor shall any part of the record containing such information be used against any licensee or applicant in any other type of proceeding;

(8) Being adjudged mentally incompetent by a court of competent jurisdiction within or outside this state; any such adjudication shall automatically suspend the license of any such person and shall prevent the reissuance or renewal of any license so suspended for as long as the adjudication of incompetence is in effect;

(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:

(A) A patient or directly to a patient's guardian or caregiver or a physician or physician acting as the patient's agent for whom the prescription drug was prescribed if:

(i) Such prescription drugs are prescribed for complex chronic, terminal, or rare conditions;

(ii) Such prescription drugs require special administration, comprehensive patient training, or the provision of supplies and medical devices or have unique patient compliance and safety monitoring requirements;

(iii) Due to the prescription drug's high monetary cost, short shelf life, special manufacturer specified packaging and shipping requirements or instructions which require temperature sensitive storage and handling, limited availability or distribution, or other factors, the drugs are not carried in the regular inventories of retail pharmacies such that the drugs could be immediately dispensed to multiple retail walk-in patients;

(iv) Such prescription drug has an annual retail value to the patient of more than $10,000.00;

(v) The patient receiving the prescription drug consents to the delivery of the prescription drug via expedited overnight common carrier and designates the specialty pharmacy to receive the prescription drug on his or her behalf;

(vi) The specialty pharmacy utilizes, 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

(vii) The specialty pharmacy establishes and notifies 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;

(B) An institution or to sell, distribute, or deliver prescription drugs, 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 or to a patient on behalf of a pharmacy. Any pharmacy using the mails or other common carriers to dispense prescriptions pursuant to this paragraph shall comply with the following conditions:

(i) 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;

(ii) 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;

(iii) 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

(iv) 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 subparagraph, 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; or

(C) A pharmacist or pharmacy to dispense a prescription and deliver it to another pharmacist or pharmacy to make available for a patient to receive the prescription and patient counseling according to Code Section 26-4-85. The State Board of Pharmacy shall adopt any rules and regulations necessary to implement this subparagraph;

(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, or 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, when such statute, law, rule, or regulation relates to or in part regulates the practice of pharmacy or another business or profession licensed under this chapter, when the licensee or applicant knows or should know that such action violates 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;

(14) Having his or her license to practice pharmacy or another business or profession licensed under this chapter 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 or renewal by any lawful licensing authority of this or any other state;

(15) Failure to demonstrate the qualifications or standards for a license contained in this Code section or under the laws, rules, or regulations under which licensure is sought or held; it shall be incumbent upon the applicant to demonstrate to the satisfaction of the board that he or she meets all the requirements for the issuance of a license, and if the board is not satisfied as to the applicant's qualifications, it may deny a license without a prior hearing; provided, however, that the applicant shall be allowed to appear before the board if he or she so desires; or

(16) Knowingly performing any act which in any way aids, assists, procures, advises, or encourages any unlicensed person or any licensee whose license has been suspended or revoked by the board to practice pharmacy or another business or profession licensed under this chapter or to practice outside the scope of any disciplinary limitation placed upon the licensee by the board.

(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 or a plea of guilty, nolo contendere, or no contest 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.

(l) (1) The executive director is vested with the power and authority to make or cause to be made through employees or agents of the board or the Georgia Drugs and Narcotics Agency such investigations as he or she or the board may deem necessary or proper for the enforcement of the provisions of this Code section and the laws relating to the practice of pharmacy and other businesses and professions licensed by the board. Any person properly conducting an investigation on behalf of the board shall have access to and may examine any writing, document, or other material relating to the fitness of any licensee or applicant. The executive director or his or her appointed representative may issue subpoenas to compel access to any writing, document, or other material upon a determination that reasonable grounds exist for the belief that a violation of this Code section or any other law relating to the practice of pharmacy or other business or profession subject to regulation or licensing by the board may have taken place. Notwithstanding the provisions of this paragraph, Code Section 16-13-60 shall control the access to or release of information.

(2) If a licensee is the subject of a board inquiry, all records relating to any person who receives services rendered by that licensee in his or her capacity as licensee shall be admissible at any hearing held to determine whether a violation of this chapter has taken place, regardless of any statutory privilege; provided, however, that any documentary evidence relating to a person who received those services shall be reviewed in camera and shall not be disclosed to the public.

(m) A person, firm, corporation, association, authority, or other entity shall be immune from civil and criminal liability for reporting or investigating the acts or omissions of a licensee or applicant which violate the provisions of subsection (a) of this Code section or any other

provision of law relating to a licensee's or applicant's fitness to practice a business or profession licensed under this chapter, or for initiating or conducting proceedings against such licensee or applicant, if such report is made or action is taken in good faith, without fraud or malice. Any person who testifies or who makes a recommendation to the board in the nature of peer review, in good faith, without fraud or malice, before the board in any proceeding involving the provisions of subsection (a) of this Code section or any other law relating to a licensee's or applicant's fitness to practice the business or profession licensed by the board shall be immune from civil and criminal liability for so testifying.

(n) Neither the issuance of a private reprimand nor the denial of a license by reciprocity nor the denial of a request for reinstatement of a revoked license nor the refusal to issue a previously denied license shall be considered to be a contested case within the meaning of Chapter 13 of Title 50, the "Georgia Administrative Procedure Act"; notice and hearing within the meaning of such chapter shall not be required, but the applicant or licensee shall be allowed to appear before the board if he or she so requests. The board may resolve a pending action by the issuance of a letter of concern. Such letter shall not be considered a disciplinary action or a contested case under Chapter 13 of Title 50 and shall not be disclosed to any person except the licensee or applicant.

(o) 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. A notice of hearing, initial or recommended decision, or final decision of the board in a disciplinary proceeding shall be served personally upon the licensee or applicant or served by certified mail or statutory overnight delivery, return receipt requested, to the last known address of record with the board. 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 diligent effort, be located, the executive director, or his or her designee, shall be deemed to be the agent for service for such licensee or applicant for purposes of this Code section, and service upon the executive director, or his or her designee, shall be deemed to be service upon the licensee or applicant.

(p) Board proceedings that result in the voluntary surrender of a license or the failure to renew a license by the end of an established penalty period shall have the same effect as a revocation of such license, subject to reinstatement in the discretion of the board. The board may restore and reissue a license to practice under this chapter and, as a condition thereof, may impose any disciplinary sanction provided by this Code section or the provisions of this chapter.

(q) This Code section shall apply equally to all licensees or applicants whether individuals, partners, or members of any other incorporated or unincorporated associations, corporations, limited liability companies, or other associations of any kind whatsoever.

§ 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.

§ 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.

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

§ 26-4-80. License required for practice of pharmacy; dispensing of prescription drugs; prescription drug orders; 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. A pharmacist shall have the same corresponding liability for prescriptions as an issuing practitioner as set forth in 21 C.F.R. Part 1304 as such regulation exists on January 1, 2013. Valid prescription drug orders shall include those issued by a physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state, or of any state or territory of the United States, to prescribe dangerous drugs or controlled substances or both.

(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 (l) 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 such 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 who 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) (A) The board shall promulgate rules and regulations 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.

(B) The rules established pursuant to subparagraph (A) of this paragraph shall specifically authorize hospital pharmacies to use remote order entry when:

(i) The licensed pharmacist is not physically present in the hospital, the hospital pharmacy is closed, and a licensed pharmacist will be physically present in the hospital pharmacy within 24 hours

(ii) At least one licensed pharmacist is physically present in the hospital pharmacy and at least one other licensed pharmacist is practicing pharmacy in the hospital but not physically present in the hospital pharmacy; or

(iii) At least one licensed pharmacist is physically present in a hospital within this state which remotely serves only on weekends not more than four other hospitals under the same ownership or management which have an average daily census of less than 12 acute patients.

(C) Before a hospital may engage in remote order entry as provided in this paragraph, the director of pharmacy of the hospital shall submit to the board written policies and procedures for the use of remote order entry. The required policies and procedures to be submitted to the board shall be in accordance with the American Society of Health-System Pharmacists and shall contain provisions addressing quality assurance and safety, mechanisms to clarify medication orders, processes for reporting medication errors, documentation and record keeping, secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to, access to hospital policies and procedures, confidentiality and security, and mechanisms for real-time communication with prescribers, nurses, and other caregivers responsible for the patient's health care.

(D) If the board concludes that the hospital's actual use of remote order entry does not comply with this paragraph or the rules adopted pursuant to this chapter, it may issue a cease and desist order after notice and hearing.

(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 24-12-1, 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) (1) 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 practitioner would indicate, unless extenuating circumstances are documented which would justify a shorter interval of time before the filling or refilling of the prescription.

(2) Notwithstanding paragraph (1) of this subsection, in order to prevent unintended interruptions in drug therapy for topical ophthalmic products:

(A) A pharmacist shall be authorized, without obtaining subsequent authorization from the practitioner or obtaining a new prescription from the practitioner, to permit refills at 70 percent of the predicted days of use; and

(B) At the patient's request, a practitioner shall be permitted to authorize refills earlier than 70 percent of the predicted days of use.

This paragraph shall apply to refills purchased through retail pharmacies and mail order sources.

(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 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. A pharmacist shall require a person picking up a Schedule II controlled substance prescription to present a government issued photo identification document or such other form of identification which documents legibly the full name of the person taking possession of the Schedule II controlled substance subject to the rules adopted by the board.

(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.

(p) Pharmacists dispensing prescriptions pursuant to a remote automated medication system in accordance with the rules and regulations adopted by the State Board of Pharmacy pursuant to paragraph (12.1) of subsection (a) of Code Section 26-4-28 shall be considered in compliance with this Code section.

§ 26-4-80.1. Use of security paper for hard copy prescription drug orders

(a) Effective October 1, 2011, every hard copy prescription drug order for any Schedule II controlled substance written in this state by a practitioner shall be written on security paper.

(b) A pharmacist shall not fill a hard copy prescription drug order for any Schedule II controlled substance from a practitioner unless it is written on security paper, except that a pharmacist may provide emergency supplies in accordance with the board and other insurance contract requirements.

(c) If a hard copy of an electronic data prescription drug order for any Schedule II controlled substance is given directly to the patient, the manually signed hard copy prescription drug order must be on security paper approved by the board that meets the requirements of subparagraph (A) of paragraph (38.5) of Code Section 26-4-5 or security paper that meets the requirements of subparagraph (B) of paragraph (38.5) of Code Section 26-4-5.

(d) Practitioners shall employ reasonable safeguards to assure against theft or unauthorized use of security paper and shall promptly report to appropriate authorities any theft or unauthorized use.

(e) The board shall create a seal of approval that confirms that security paper contains all three industry recognized characteristics required by paragraph (38.5) of Code Section 26-4-5. The seal shall be affixed to all security paper used in this state; provided, however, that security paper which meets the requirements of subparagraph (B) of paragraph (38.5) of Code Section 26-4-5 shall not be required to have such affixed seal.

(f) The board may adopt rules necessary for the administration of this Code section.

(g) The security paper requirements in this Code section shall not apply to:

(1) Prescriptions that are transmitted to the pharmacy by telephone, facsimile, or electronic means; or

(2) Prescriptions written for inpatients of a hospital, outpatients of a hospital, residents of a nursing home, inpatients or residents of a mental health facility, or individuals incarcerated in a local, state, or federal correctional facility when the health care practitioner authorized to write prescriptions writes the order into the patient's medical or clinical record, the order is given directly to the pharmacy, and the patient never has the opportunity to handle the written order.

§ 26-4-81. Substitution of generic drugs or interchangeable biological products for brand name drugs and prescribed biological products

(a) In accordance with this Code section, a pharmacist may substitute:

(1) 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; or

(2) A biological product with an interchangeable biological product.

(b) If a practitioner of the healing arts prescribes:

(1) 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; or

(2) A biological product by its nonproprietary name, the pharmacist shall dispense the lowest retail priced interchangeable biological product which is in stock.

(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:

(1) Drug product which is in stock and which is, in the pharmacist's reasonable professional opinion, both therapeutically equivalent and pharmaceutically equivalent; or

(2) Interchangeable biological product which is in stock.

(d) (1) 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 or interchangeable biological 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.

(2) If a pharmacist substitutes a generic drug product for a brand name prescribed drug product when dispensing a prescribed medication, the brand name and the generic name of the drug product, with an explanation of "generic for (insert name of brand name prescribed drug product)" or similar language to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the drug may not appear upon the prescription label; provided, however, that this paragraph shall not apply to medication dispensed for in-patient

hospital services or to medications in specialty packaging for dosing purposes as defined by the board.

(3) If a pharmacist substitutes an interchangeable biological product for a prescribed biological product when dispensing a prescribed medication, the name of the interchangeable biological product, with an explanation of "interchangeable biological product for (insert name of prescribed biological product)" or similar language to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the biological product may not appear upon the prescription label; provided, however, that this paragraph shall not apply to biological products dispensed for in-patient hospital services, to hospital administered biological products for outpatients, or to biological products in specialty packaging for dosing purposes as defined by the board. This paragraph shall apply to hospital retail pharmacies and to any biological products dispensed by a hospital for a patient's use or administration at home.

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

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

(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 or an interchangeable biological product in lieu of a prescribed biological product by including the words "brand necessary" in the body of the prescription. When a prescription is a hard copy prescription drug or biological product order, such indication of brand necessary must be in the practitioner's own handwriting and shall not be printed, applied by rubber stamp, or any such similar means. When the prescription is an electronic prescription drug or biological product order, the words "brand necessary" are not required to be in the practitioner's own handwriting and may be included on the prescription in any manner or by any method. When a practitioner has designated "brand necessary" on an electronic prescription drug or biological product order, a generic drug or interchangeable biological product shall not be substituted without the practitioner's express consent, which shall be documented by the pharmacist on the prescription and by the practitioner in the patient's medical record.

(h) Within 48 hours, excluding weekends and holidays, following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber by using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

(1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the prescribed product; or

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(i) The board shall maintain a link on its website to the current list of all biological products determined by the federal Food and Drug Administration to be interchangeable with a specific biological product.

(j) Code Section 26-4-118, "The Pharmacy Audit Bill of Rights," shall apply to biological products and interchangeable biological products dispensed pursuant to this Code section.

§ 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, including the establishment of a registry as required in paragraph (7) of subsection (a) of Code Section 26-4-28; 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.

§ 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.

§ 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.

§ 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 Public Health; provided, however, that pharmacists who provide drugs to patients in accordance with Code Section 43-34-23 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.

§ 26-4-86. Compounding and distribution of drug products

(a) The board shall establish rules and regulations governing the compounding and distribution of drug products by pharmacists, practitioners, and pharmacies licensed or registered by this state. Such rules and regulations shall include provisions ensuring compliance with USP-NF standards.

(b) All drug products compounded and labeled in accordance with board rules regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of Chapter 13 of Title 16 and Chapters 3 and 4 of this title.

(c) In regards to pharmacists compounding sterile drugs to be provided to practitioners to use in patient care or altering or repackaging such drugs for practitioners to use in patient care in the practitioner's office, such sterile compounding shall only be conducted as allowed by applicable federal law and board rule for pharmaceutical compounding using USP-NF standards for sterile compounding. Such sterile drugs may be compounded only in quantities determined by board rule following consultation with the Georgia Composite Medical Board. No Schedule II, III, IV, or V controlled substance, as defined in Article 2 of Chapter 13 of Title 16, shall be eligible for such designation. Nothing in this subsection shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners within or employed by an institution or affiliated entity; provided, however, that pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to other rules and regulations established by the board governing the compounding of medication.

(d) Practitioners who may lawfully compound drugs for administering or dispensing to their own

patients pursuant to Code Section 26-4-130 shall comply with all provisions of this Code section and board rules regarding pharmaceutical compounding.

§ 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.

§ 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) Except as otherwise required pursuant to Code Section 26-4-86, 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.

§ 26-4-89. Selling drugs in vending machines prohibited; remote automated medication system excluded

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

(b) A remote automated medication system shall not be considered a vending machine for purposes of this Code section.

§ 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.

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. The pharmacist in charge shall be responsible for notifying the board in accordance with its rules and regulations of updated information regarding the registration of pharmacy technicians.

(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.

§ 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.

§ 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.

§ 26-4-112. Occurrences requiring 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. If upon the board being notified of such change a replacement pharmacist in charge is not named in said notification, the license of that pharmacy shall stand suspended pending further findings by the board;

(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.

§ 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.

§ 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.

§ 26-4-114.1. Application to board for nonresident pharmacy permits; requirements

(a) Any person, pharmacy, or facility located outside this state may apply to the board for a nonresident pharmacy permit which shall entitle the holder thereof to ship, mail, or deliver dispensed drugs, including but not limited to dangerous drugs and controlled substances, into this state. The board shall establish an application and require such information as the board deems reasonably necessary to carry out a background investigation of applicants and to ensure that the purposes of this Code section are met. Such application shall include:

(1) Proof of a valid, unexpired license, permit, or registration to operate a pharmacy in compliance with the laws and rules of each state in which the applicant receives and dispenses prescription drug orders, including but not limited to orders for prescription drugs, dangerous drugs, and controlled substances;

(2) Addresses, names, and titles of all principal corporate officers and the pharmacist in charge of dispensing drugs to residents of this state; and

(3) A statement of whether the applicant is in compliance with all lawful directions and requests for information from the regulatory or licensing agencies of each state in which the applicant is licensed as well as all requests for information made by the board pursuant to this Code section.

(b) The board shall establish by rule an application fee and the biennial renewal fee for a permit under this Code section.

(c) The board may only deny an application for a nonresident pharmacy permit for failure to comply with rules of the board or any requirements of this Code section or for good cause related to substantial evidence of misfeasance or malfeasance by the applicant. Applicants granted a

permit under this Code section shall provide pharmacy care in a manner which does not endanger life and protects the health, safety, and welfare of the residents of this state. A pharmacy, facility, or entity licensed under Title 33 shall not be required to hold a nonresident pharmacy permit.

(d) After an effective date established by rule of the board for the enforcement of the nonresident pharmacy permits, it shall be unlawful for any person, pharmacy, or facility that is located outside this state and that does not possess a nonresident pharmacy permit to ship, mail, or deliver prescription drug orders or to advertise its services in this state, or for any person who is a resident of this state to advertise the services of such person, pharmacy, or facility with the knowledge that the advertisement will or is likely to induce residents of this state to use such person, pharmacy, or facility for pharmacy care. Nothing in this subsection shall be construed to limit or prohibit interstate commerce, including but not limited to the practice of pharmacy by mail.

(e) The board shall have the authority to promulgate rules and regulations governing the holder of a nonresident pharmacy permit under this Code section. Such rules and regulations shall minimally include the following requirements for nonresident pharmacy permit holders:

(1) A permit holder's pharmacist in charge of dispensing drugs to residents of this state shall be licensed in his or her state of location;

(2) A permit holder shall provide written notification to the board within ten days of any change of a permit holder's principal corporate officers or pharmacist in charge of dispensing drugs to residents of this state;

(3) A permit holder shall file a change of location application upon any change to the permit holder's state of registration in addition to proof of the license, permit, or registration from the permit holder's new state of registration and the United States Drug Enforcement Administration registration for such new location;

(4) A permit holder shall respond within ten calendar days to all communications from the board concerning emergency circumstances arising from errors in the dispensing of any drugs to residents of this state;

(5) A permit holder shall provide written notification to the board of each location at which the permit holder maintains its records for all prescription drug orders dispensed to patients in this state so that the records are readily retrievable from the business records of the permit holder; and

(6) A permit holder shall maintain a toll-free telephone number operational during the permit holder's regular hours of operation but not less than six days per week for a minimum of 60 hours per week that shall be used to provide and facilitate patient counseling. Such toll-free number shall be capable of receiving inbound calls from patients to the permit holder and shall be disclosed on the label affixed to each container of all dispensed and distributed drugs.

(f) The board may revoke, suspend, or refuse to renew a permit of a permit holder for failure to comply with rules of the board or with any requirement of this Code section or for conduct which causes serious bodily or psychological injury to a resident of this state, provided that the board has referred the matter involving the conduct to the regulatory or licensing agency in the state in which the permit holder is located and the regulatory or licensing agency fails to initiate an investigation into the matter within 180 days of such referral or fails, in the board's judgment,

to render sufficient resolution.

(g) (1) As a prerequisite to registering or renewing a registration with the board, a nonresident pharmacy conducting sterile or nonsterile compounding for practitioners to use in patient care in the practitioner's office shall submit a copy of the most recent and current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and nonsterile compounding. The inspection report required by this subsection shall not be required if the compounding within the facility is done pursuant to a prescription. Such inspection report shall be deemed current for the purpose of this subsection if the inspection was conducted:

(A) No more than six months prior to the date of submission of an application for registration with the board; or

(B) No more than two years prior to the date of submission of an application for renewal of a registration with the board.

(2) If the nonresident pharmacy conducting sterile or nonsterile compounding has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is located within the timeframes required in paragraph (1) of this subsection, the board may:

(A) Accept an inspection report or other documentation from another entity that is satisfactory to the board; or

(B) Make a request of the appropriate regulatory or licensing agency of the jurisdiction where the pharmacy is located to cause an inspection to be conducted by an agent duly authorized by the board.

A nonresident pharmacy shall be responsible for paying any inspection fee incurred pursuant to this paragraph.

§ 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 the 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 executive 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.

§ 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.

§ 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 pharmacies licensed in this state only in accordance with the provisions of this Code section.

(b) The medical director of an emergency service provider and an issuing pharmacy must have a signed contract or agreement designating such pharmacy as a provider of drugs and consultant services and a copy must be filed with the state board and the Department of Public Health prior to any drugs being issued.

(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 an 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 a 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.

§ 26-4-116.1. Licensed health practitioners authorized to prescribe auto-injectable epinephrine for schools; pharmacists authorized to fill prescriptions

(a) A physician licensed to practice medicine in this state, an advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-25, and a physician assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103 may prescribe auto-injectable epinephrine in the name of a public or private school for use in accordance with Code Section 20-2-776.2 and in accordance with protocol specified by such physician, advanced practice registered nurse, or physician assistant.

(b) A physician licensed to practice medicine in this state, an advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-25, and a physician assistant acting pursuant to the authority of subsection (e.l) of Code Section 43-34-103 may prescribe auto-injectable epinephrine in the name of an authorized entity in accordance with Code Section 31-1-14.

(c) A pharmacist may dispense auto-injectable epinephrine pursuant to a prescription issued in accordance with subsection (a) or (b) of this Code section.

§ 26-4-116.2. Authority of licensed health practitioners to prescribe opioid antagonists; immunity from liability

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

(1) "First responder" means any person or agency who provides on-site care until the arrival of a duly licensed ambulance service. This shall include, but not be limited to, persons who routinely respond to calls for assistance through an affiliation with law enforcement agencies, fire departments, and rescue agencies.

(2) "Harm reduction organization" means an organization which provides direct assistance and services, such as syringe exchanges, counseling, homeless services, advocacy, drug treatment, and screening, to individuals at risk of experiencing an opioid related overdose.

(3) "Opioid antagonist" means any drug that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors and that is approved by the federal Food and Drug Administration for the treatment of an opioid related overdose.

(4) "Opioid related overdose" means an acute condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, mania, or death, resulting from the consumption or use of an opioid or another substance with which an opioid was combined or that a layperson would reasonably believe to be resulting from the consumption or use of an opioid or another substance with which an opioid was combined for which medical assistance is required.

(5) "Pain management clinic" means a clinic licensed pursuant to Article 10 of Chapter 34 of Title 43.

(6) "Practitioner" means a physician licensed to practice medicine in this state.

(b) A practitioner acting in good faith and in compliance with the standard of care applicable to that practitioner may prescribe an opioid antagonist for use in accordance with a protocol

specified by such practitioner to a person at risk of experiencing an opioid related overdose or to a pain management clinic, first responder, harm reduction organization, family member, friend, or other person in a position to assist a person at risk of experiencing an opioid related overdose.

(c) A pharmacist acting in good faith and in compliance with the standard of care applicable to pharmacists may dispense opioid antagonists pursuant to a prescription issued in accordance with subsection (b) of this Code section.

(d) A person acting in good faith and with reasonable care to another person whom he or she believes to be experiencing an opioid related overdose may administer an opioid antagonist that was prescribed pursuant to subsection (b) of this Code section in accordance with the protocol specified by the practitioner.

(e) The following individuals are immune from any civil or criminal liability or professional licensing sanctions for the following actions authorized by this Code section:

(1) Any practitioner acting in good faith and in compliance with the standard of care applicable to that practitioner who prescribes an opioid antagonist pursuant to subsection (b) of this Code section;

(2) Any practitioner or pharmacist acting in good faith and in compliance with the standard of care applicable to that practitioner or pharmacist who dispenses an opioid antagonist pursuant to a prescription issued in accordance with subsection (b) of this Code section; and

(3) Any person acting in good faith, other than a practitioner, who administers an opioid antagonist pursuant to subsection (d) of this Code section.

§ 26-4-116.3. Licensed health practitioners authorized to prescribe levalbuterol sulfate or abuterol sulfate for schools; pharmacists authorized to fill prescriptions

(a) A physician licensed to practice medicine in this state, an advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-25, and a physician assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103 may prescribe levalbuterol sulfate or albuterol sulfate in the name of a public or private school for use in accordance with Code Section 20-2-776.3.

(b) A pharmacist may dispense levalbuterol sulfate or albuterol sulfate pursuant to a prescription issued in accordance with subsection (a) of this Code section.

§ 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.

§ 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, pharmacy benefits manager, any entity licensed by the Department of Insurance, the Department of Community Health under Article 7 of Chapter 4 of Title 49, any entity that represents such companies, groups, or department, or a private person bringing a claim pursuant to Article 7B of Chapter 4 of Title 49, 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 14 days prior to conducting the initial on-site audit for each audit cycle and include in such notice a comprehensive list of claims by prescription number to be audited, although the final two digits may be omitted;

(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, including but not limited to a typographical error, scrivener's error, or computer error, regarding a required document or record shall not in and of itself constitute fraud. No such claim shall be subject to criminal penalties without proof of intent to commit fraud. No recoupment of the cost of drugs or medicinal supplies properly dispensed shall be allowed if such error has occurred and been resolved in accordance with paragraph (4) of this subsection; provided, however, that recoupment shall be allowed to the extent that such error resulted in an overpayment, though recoupment shall be limited to the amount overpaid;

(4) A pharmacy shall be allowed at least 30 days following the conclusion of an on-site audit or receipt of the preliminary audit report in which to correct a clerical or record-keeping error or produce documentation to address any discrepancy found during an audit, including to secure and remit an appropriate copy of the record from a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication if the lack of such a record or an error in such a record is identified in the course of an on-site audit or noticed within the preliminary audit report;

(5) 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;

(6) 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;

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

(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, pharmacy benefits manager, any entity licensed by the Department of Insurance, the Department of Community Health under Article 7 of Chapter 4 of Title 49, 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) of this Code section, 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 internal appeals process under which a pharmacy shall have at least 30 days from the delivery of the preliminary audit report to 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 such 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 at its request or in an alternate format.

(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.

(g) The provisions of paragraph (3) of subsection (b) of this Code section shall not apply to the Department of Community Health conducting audits under Article 7 of Chapter 4 of Title 49.

(h) The entity conducting the audit may not pay the agent or employee who is conducting the audit based on a percentage of the amount recovered.

(i) The Commissioner of Insurance shall have enforcement authority over this Code section and shall have the authority granted pursuant to Chapter 64 of Title 33, relating to the regulation and licensure of pharmacy benefits managers.

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) Except as otherwise required pursuant to Code Section 26-4-86, 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 43-34-23 shall have the meaning provided for such term in Code Section 43-34-23. 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 43-34-23 to order, dispense, or administer drugs when such persons order, dispense, or administer those drugs in conformity with Code Section 43-34-23. When a person dispenses drugs pursuant to the authority delegated to that person under the provisions of Code Section 43-34-23, 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.

§ 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.

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."

§ 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.

§ 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.

§ 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."

§ 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.

§ 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.

§ 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.

§ 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.

§ 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.

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.

§ 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.

§ 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.

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

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

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."

§ 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.

§ 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 Community Health 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.

§ 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.

§ 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.

§ 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.

§ 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.

§ 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.

§ 26-4-178. Authorized to promulgate rules

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

§ 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.

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."

§ 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, assisted living community, 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.

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

(a) The Georgia State Board of Pharmacy, the Department of Public Health, 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 Public Health 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 Public Health, 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 Public Health 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.

§ 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.

§ 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.

§ 26-4-195. Construction of article

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

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 12. PRESCRIPTION MEDICATION INTEGRITY ACT

§ 26-4-200. (For effective date, see note.) Short title

This article shall be known and may be cited as the "Prescription Medication Integrity Act."

§ 26-4-201. (For effective date, see note.) Definitions

As used in this article, the term:

(1) "Authenticate" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.
(2) "Authorized distributor of record" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drugs.
(3) "Board" means the State Board of Pharmacy.

(4) "Broker" has the same meaning as a third-party logistics provider.
(5) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership or control.
(6) "Co-licensed pharmaceutical products" means pharmaceutical products:

(A) That have been approved by the federal Food and Drug Administration; and

(B) Concerning which two or more parties have the right to engage in a business activity or occupation concerning the pharmaceutical products.

(7) "Co-licensee" means a party to a co-licensed pharmaceutical product.
(8) "Distribute" means to deliver a drug or device other than by administering or dispensing.
(9) "Drop shipment arrangement" means the physical shipment of a prescription from a manufacturer, that manufacturer's co-licensee, that manufacturer's third-party logistics provider, or that manufacturer's authorized distributor of record directly to a chain pharmacy warehouse, pharmacy buying cooperative warehouse, pharmacy, or other persons authorized under law to dispense or administer prescription drugs but wherein the sale and title for the prescription drug passes between a wholesale drug distributor and the party that directly receives the prescription drug. In order to be considered part of the normal distribution channel and participate in a drop shipment as described in this paragraph, the wholesale drug distributor must be an authorized distributor of record.
(10) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.
(11) "Manufacturer" means a person licensed or approved by the federal Food and Drug Administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the regulations and interpreted guidances implementing the Prescription Drug Marketing Act.
(12) "Manufacturer's exclusive distributor" means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services for a manufacturer and takes title to that manufacturer's prescription drug. To be considered part of the normal distribution channel, a manufacturer's exclusive distribution must be an authorized distributor of record.
(13) "Normal distribution channel" means a chain of custody for a prescription drug, excluding all devices and veterinary prescription drugs, that goes directly or by drop shipment from a manufacturer of the prescription drug, or from that manufacturer to that manufacturer's co-licensed partner, or from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, to:

(A) Either a pharmacy or to other designated persons authorized by law to dispense or administer such drug;

(B) An authorized distributor or record, and then to either a pharmacy, or to other designated persons authorized by law to dispense or administer such drug;

(C) An authorized distributor of record to one other authorized distributor of record to an office based health care practitioner authorized by law to dispense or administer such drug to a patient;

(D) An authorized distributor of record to a pharmacy warehouse or other entity that redistributes by intracompany sale to a pharmacy or other designated persons authorized to dispense or administer the drug;

(E) A pharmacy warehouse or other entity that redistributes by intracompany sale to a pharmacy or other designated persons authorized to dispense or administer the drug; or

(F) Another entity as prescribed by the board's regulations.

(14) "Ongoing relationship" means an association that exists when a wholesale drug distributor, including any member of its affiliated group, as defined in Section 1504 of the Internal Revenue Code, of which the wholesale drug distributor is a member:

(A) Is listed on the manufacturer's list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis; or

(B) Has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship.

(15) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

(16) "Pharmacy buying cooperative warehouse" means a permanent physical location that acts as a central warehouse for drugs and from which sales of drugs are made to a group of pharmacies that are member owners of the buying cooperative operating the warehouse. Pharmacy buying cooperative warehouses must be licensed as wholesale distributors.

(17) "Prescription drug" means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal law (including federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(18) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug; provided, however, that this shall not apply to pharmacists in the dispensing of prescription drugs to the patient.

(19) "Repackager" means a person who repackages.

(20) "Third-party logistics provider" means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer but does not take title to a drug or have general responsibility to direct the sale or other disposition of the drug. To be considered part of the normal distribution channel, a third party logistics provider must be an authorized distributor of record.

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

(22) "Wholesale distribution" shall not include:

(A) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership or control of a corporate entity, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(B) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons including transfers of a prescription drug from retail pharmacy to retail pharmacy, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(C) The distribution of prescription drug samples by manufacturers' representatives;

(D) Prescription drug returns when conducted by a retail pharmacy or chain pharmacy warehouse, by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. Section 203.23, or by any designated persons authorized by law to dispense or administer the prescription drug except in cases where a pedigree is already required under the provisions of this article, in which case any return of that prescription drug to a wholesaler or manufacturer shall be subject to the provisions of Code Section 26-4-202;

(E) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(F) Retail pharmacies' delivery of prescription drugs to a patient or patient's agent pursuant to the lawful order of a licensed practitioner;

(G) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, and such common carrier does not store, warehouse, or take legal ownership of the prescription drug;

(H) The sale or transfer from a retail pharmacy, pharmacy buying cooperative warehouse, or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, originating wholesale distributor, or to a third party returns processor, to the extent permitted by federal rule, regulation, or law; or

(I) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

§ 26-4-202. (For effective date, see note.) Pedigrees for prescription drugs

(a) (1) Each person who is engaged in wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave or have ever left the normal distribution channel in accordance with rules and regulations adopted by the board.

(2) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this Code section only if the retail pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(3) The board shall conduct a study to be completed no later than July 1, 2009, which shall include consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. Based on the results of the study, the board shall establish a mandated implementation date for electronic pedigrees which shall be no sooner than December 31, 2011, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply; provided, however, that no provision of this article shall be effective until such time as the General Assembly appropriates reasonable funds for administration of this subsection. Effective at a date established by the board, pedigrees may be implemented through an approved and readily available system based on electronic track and trace pedigree technology. This electronic tracking system will be deemed to be readily available for use on a wide scale across the entire pharmaceutical supply chain which includes manufacturers,

wholesale distributors, and pharmacies. Consideration must be given to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product.

(b) Each person in possession of a pedigree for a prescription drug who is engaged in the wholesale distribution of a prescription drug, including repackagers but excluding the original manufacturer of the finished form of the prescription drug and any entity engaged in the activities listed in paragraph (9) of Code Section 26-4-201, and who attempts to further distribute that prescription drug shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(c) The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, to acquisition and sale by any wholesale distributor or repackager, and to final sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the pedigree shall include:

(1) The name, address, telephone number, and, if available, e-mail address of each owner of the prescription drug and each wholesale distributor of the prescription drug;

(2) The name and address of each location from which the prescription drug was shipped, if different from the owner's;

(3) Transaction dates;

(4) Certification that each recipient, excluding retail or hospital pharmacies, has authenticated the pedigree;

(5) The name of the prescription drug;

(6) Dosage form and strength of the prescription drug;

(7) Size of the container;

(8) Number of containers;

(9) Lot number of the prescription drug; and

(10) The name of the manufacturer of the finished dosage form.

(d) Each pedigree shall be:

(1) Maintained by the wholesale distributor at its licensed location, unless given written authorization from the board to do otherwise, for three years from the date of sale or transfer; and

(2) Available for inspection, copying, or use at the licensed location upon a verbal request by the board or its designee.

(e) The board shall adopt rules and regulations, including a standard form, relating to the requirements of this article no later than 90 days after the effective date of this article.

(f) Pharmacies licensed pursuant to this chapter shall not be required to possess or maintain any pedigree issued pursuant to this Code section.

§ 26-4-203. (For effective date, see note.) Violations; falsified prescription drugs

(a) If the board finds that there is a reasonable probability that:

(1) A wholesale distributor, other than a manufacturer, has:

(A) Violated a provision of this article; or

(B) Falsified a pedigree, provided a falsified pedigree, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;

(2) The prescription drug at issue in subparagraph (B) of paragraph (1) of this subsection could cause serious, adverse health consequences or death; and

(3) Other procedures would result in unreasonable delay,

the board shall issue an order requiring the appropriate person including the distributors or retailers of the prescription drug to immediately cease distribution of the prescription drug in or to this state.

(b) An order under subsection (a) of this Code section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten calendar days after the date of the issuance of the order, on the actions required by the order. If, after such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

§ 26-4-204. (For effective date, see note.) Prohibited acts

It shall be unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

(1) Selling, distributing, or transferring a prescription drug to a person that is not authorized to receive the prescription drug under the law of the jurisdiction in which the person receives the prescription drug;

(2) Failing to maintain or provide pedigrees as required by the board;

(3) Failing to obtain, transfer, or authenticate a pedigree as required by the board;

(4) Providing the board or any of its representatives or any federal official with false or fraudulent records, including, but not limited to falsified pedigrees, or making false or fraudulent statements regarding any matter within the provisions of this article;

(5) Obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug; and

(6) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the Food and Drug Administration, the manufacturing, repackaging, selling, transferring, delivering, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution.

§ 26-4-205. (For effective date, see note.) Penalty

(a) Notwithstanding Code Section 26-4-115, any person who engages without knowledge in the wholesale distribution of prescription drugs, including providing a falsified pedigree or other records, in violation of this article may be fined not more than $10,000.00.

(b) If a person engages in wholesale distribution of prescription drugs in violation of this article,

including providing a falsified pedigree or other records, and acts in a grossly negligent manner in violation of this article, the person may be punished by imprisonment for not more than 15 years, fined not more than $50,000.00, or both.

(c) Notwithstanding Code Section 26-4-115, any person who knowingly engages in wholesale distribution of prescription drugs in violation of this article, including providing a falsified pedigree or other records, shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than 25 years, by fine not to exceed $500,000.00, or both.

TITLE 26. FOOD, DRUGS, AND COSMETICS
CHAPTER 4. PHARMACISTS AND PHARMACIES
ARTICLE 13. SAFE MEDICATIONS PRACTICE ACT

§ 26-4-210. Short title

This article shall be known and may be cited as the "Safe Medications Practice Act."

§ 26-4-211. Legislative findings and intent

(a) The General Assembly finds and declares that:

(1) Medications are essential for the effective treatment and prevention of illness and disease, and medications, particularly dangerous drugs, are recognized to be complex chemical compounds which may cause untoward side effects, adverse reactions, and other undesirable and potentially harmful effects;

(2) Hospital pharmacists are highly trained in the therapeutic use of medications and have expertise in the safe, appropriate, and cost-effective use of medications; and

(3) Therefore, it is essential that physicians, pharmacists, and other clinical health care practitioners in an institutional setting collaborate to promote safe and effective medication therapy for the institution's patients.

(b) The intent of the General Assembly in enacting this legislation is to maximize patient safety, to ensure safe and desirable medication therapy outcomes, and to achieve desired therapeutic goals.

§ 26-4-212. Definitions

As used in this article, the term:

(1) "Collaborate" means to work jointly with others as approved by an order from a physician member of the institution's medical staff for care and treatment of the ordering physician's patients or pursuant to a protocol established in accordance with medical staff policy.
(2) "Hospital pharmacist" means a pharmacist that is employed by, or under contract with, an institution and practicing in an institutional setting.

(3) "Institution" means any licensed hospital, nursing home, assisted living community, personal care home, or hospice.

§ 26-4-213. Collaboration

Hospital pharmacists shall be authorized to collaborate with members of the medical staff in an institution on drug therapy management.

§ 26-4-214. Role of State Board of Pharmacy and Georgia Composite Medical Board in establishing rules and regulations

(a) The State Board of Pharmacy shall establish rules and regulations governing a hospital pharmacist acting pursuant to Code Section 26-4-213 in the provision of drug therapy management in institutions in consultation or collaboration with physicians. Such rules may include the utilization of a hospital pharmacist's skills regarding dangerous drugs to promote medication safety. Such rules shall include the ordering of clinical laboratory tests in the institutional setting and the interpretation of results related to medication use when approved by a physician member of the institution's medical staff for the care and treatment of the ordering physician's patients or pursuant to a protocol established in accordance with medical staff policy.

(b) The Georgia Composite Medical Board shall establish rules and regulations governing a physician acting pursuant to this article.