O.C.G.A. § 26-4-80.1

GEORGIA CODE

*** Current Through the 2011 Regular Session ***
*** Annotations Current Through April 22, 2011 ***

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

O.C.G.A. § 26-4-80.1 (2011)

§ 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 must 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 approved security paper that meets the requirements 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) All vendors shall have their security paper approved by the board prior to marketing or sale in this state.

(f) 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.

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

(h) 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.

HISTORY: Code 1981, § 26-4-80.1, enacted by Ga. L. 2011, p. 659, § 5/SB 36.

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

O.C.G.A. § 26-4-5 (2011)

§ 26-4-5. Definitions

As used in this chapter, the term:

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

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

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

(4) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription drug order or initiative based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine and regularly observed prescribing patterns.

(5) "Confidential information" means information maintained by the pharmacist in the patient's records or which is communicated to the patient as part of patient counseling which is privileged and may be released only to the patient or, as the patient directs, to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being; and to such other persons or governmental agencies authorized by law to receive such confidential information.

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

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

(8) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(9) "Device" means an instrument, apparatus, contrivance, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician."

(10) "Dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient, patient's caregiver, or patient's agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

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

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

(12) "Drug" means:

(A) Articles recognized as drugs in any official compendium, or supplement thereto, designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(B) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(C) Articles, other than food, intended to affect the structure or any function of the body of humans or animals; and

(D) Articles intended for use as a component of any articles specified in subparagraph (A), (B), or (C) of this paragraph but does not include devices.

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

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

(i) Known allergies;

(ii) Rational therapy-contraindications;

(iii) Reasonable dose and route of administration; and

(iv) Reasonable directions for use;

(B) Evaluation of any prescription drug order and patient record for duplication of therapy;

(C) Evaluation of any prescription drug order and patient record for the following interactions:

(i) Drug-drug;

(ii) Drug-food;

(iii) Drug-disease; and

(iv) Adverse drug reactions; and

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

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

(14.1) "Electronic data prescription drug order" means any digitalized prescription drug order transmitted to a pharmacy, 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.

(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.

(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, 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.

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

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

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

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

Where security paper is in the form of a prescription pad, each pad shall bear an identifying lot number, and each piece of paper in the pad shall be numbered sequentially beginning with the number one.

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

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

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

HISTORY: Code 1981, § 26-4-5, enacted by Ga. L. 1998, p. 686, § 1; Ga. L. 1999, p. 81, § 26; Ga. L. 1999, p. 277, § 1.1; Ga. L. 2000, p. 1706, § 22; Ga. L. 2004, p. 738, §§ 2, 3; Ga. L. 2007, p. 47, § 26/SB 103; Ga. L. 2009, p. 453, § 3-2/HB 228; Ga. L. 2010, p. 266, § 1/SB 195; Ga. L. 2011, p. 227, § 7/SB 178; Ga. L. 2011, p. 308, § 5/HB 457; Ga. L. 2011, p. 659, § 3/SB 36.
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