House Bill 209 (AS PASSED HOUSE AND SENATE)

By: Representatives Watson of the 166th, Stephens of the 164th, Parrish of the 158th, Cooper of the 43rd, Broadrick of the 4th, and others

A BILL TO BE ENTITLED

AN ACT

To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, so as to add and revise definitions; to revise requirements for license transfers for pharmacists licensed in another jurisdiction; to revise provisions relating to dispensing prescription drugs; to revise requirements for the use of security paper for hard copy prescription drug orders; to revise provisions relating to compounding drug products; to enable nonresident pharmacy permits; to amend Part 2 of Article 2 of Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to electronic data base of prescription information, so as to revise the definition of "dispenser" relative to information to include for each Schedule II, III, IV, or V controlled substance prescription; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, is amended by revising paragraphs (4) and (38.5) and adding a new paragraph to Code Section 26-4-5, relating to definitions, as follows:

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

″(38.5) 'Security paper' means:

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

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

~~(B)~~(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

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

~~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.~~

(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.″

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

SECTION 2.

Said chapter is further amended by revising paragraph (7) of subsection (a) of Code Section 26-4-42, relating to license transfers for pharmacists licensed in another jurisdiction, as follows:

″(7) Have successfully passed ~~an examination~~ examinations as determined by the board, one of which shall include an examination on Georgia pharmacy law and board regulations; and″

SECTION 3.

Said chapter is further amended by revising subsection (b) and subparagraph (c)(7)(B) of Code Section 26-4-80, relating to dispensing prescription drugs, as follows:

″(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."

"(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 ~~16~~ 24 hours; ~~or~~

(ii) ~~When at~~ 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 another hospital or hospitals under the same ownership or management which have an average daily census of less than ten acute patients."

SECTION 4.

Said chapter is further amended by revising Code Section 26-4-80.1, relating to use of security paper for hard copy prescription drug orders, as follows:

"26-4-80.1.

(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~~ 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 ~~approved~~ 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) All vendors shall have their security paper approved by the board prior to marketing or sale in this state.~~

~~(f)~~(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.

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

~~(h)~~(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.″

SECTION 5.

Said chapter is further amended by revising Code Section 26-4-86, relating to compounding of medications, as follows:

″26-4-86.

(a) The board ~~may~~ shall establish rules and regulations governing the compounding and distribution of drug products ~~of medication~~ by pharmacists, practitioners, and pharmacies licensed or registered by ~~in~~ 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.″

SECTION 6.

Said chapter is further amended by revising subsection (b) of Code Section 26-4-88, relating to restrictions on dispensing of medicines, drugs, or poisons, as follows:

″(b) Except as otherwise required pursuant to Code Section 26-4-86, this ~~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.″

SECTION 7.

Said chapter is further amended by revising paragraph (3) of Code Section 26-4-112, relating to occurrences which require immediate notification to board, as follows:

″(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;″

SECTION 8.

Said chapter is further amended by adding a new Code section to read as follows:

″26-4-114.1.

(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 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."

SECTION 9.

Said chapter is further amended by revising subsection (b) of Code Section 26-4-130, relating to dispensing drugs, compliance with labeling and packaging requirements, records available for inspection by board, and renewal of licenses, as follows:

"(b) Except as otherwise required pursuant to Code Section 26-4-86, the ~~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."

SECTION 10.

Part 2 of Article 2 of Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to electronic data base of prescription information, is amended by revising Code Section 16-13-59, relating to information to include for each Schedule II, III, IV, or V controlled substance prescription, by adding a new subsection to read as follows:

"(g) For purposes of this Code section, the term 'dispenser' shall include any pharmacy or facility physically located in another state or foreign country that in any manner ships, mails, or delivers a dispensed controlled substance into this state."

SECTION 11.

All laws and parts of laws in conflict with this Act are repealed.