House Bill 926 (AS PASSED HOUSE AND SENATE)

By: Representatives Broadrick of the 4th, Stephens of the 164th, Harden of the 148th, and Parrish of the 158th

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 provide for the licensure of outsourcing facilities and third-party logistics providers; to provide for definitions; to provide for temporary pharmacy licenses for service members; to require that compounding of drug products for use in a practitioner's office can only be conducted by outsourcing facilities to conform to federal law; to establish requirements relating to drug supply chain security; to revise a provision relating to the return of outdated drugs; to provide for related matters; to repeal conflicting laws; and for other purposes.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 in Code Section 26-4-5, relating to definitions, by adding new paragraphs to read as follows:

"(1.05) 'Authorized' means, in the case of a wholesale distributor, having a valid license pursuant to this chapter or 21 U.S.C. 360eee-1(a)(6) and complying with the licensure reporting requirements under 21 U.S.C. 360eee-3(b)."

"(24.1) 'Outsourcing facility' means a facility that is engaged in the compounding of drugs and is registered with the federal Food and Drug Administration as an outsourcing facility pursuant to Section 503b of the federal act."

"(40.1) 'Third-party logistics provider' means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, wholesale distributor, or chain pharmacy but does not take title to a drug or have general responsibility to direct the sale or other disposition of the drug."

SECTION 2.

Said chapter is further amended in Code Section 26-4-28, relating to the powers, duties, and authority of the Georgia State Board of Pharmacy, by revising paragraph (13) of subsection (a) as follows:

"(13) The issuance and renewal of licenses or permits of all persons engaged in the manufacture and distribution of drugs, including but not limited to all types of drug manufacturers, wholesale distributors, reverse drug distributors, outsourcing facilities, and third-party logistics providers. The board shall be authorized to establish all licensing and permit requirements of such entities by rule and regulation;"

SECTION 3.

Said chapter is further amended by revising Code Section 26-4-43, relating to temporary pharmacy licenses, as follows:

"26-4-43.

(a) 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~~ Except as provided in subsection (b) of this Code section, temporary licenses shall expire at the end of the month ~~during which~~ following the ~~first~~ third board meeting ~~is~~ conducted ~~following~~ after the issuance of such license and may not be reissued or renewed.

(b) A temporary license may be issued to a service member, as defined in Code Section 26-4-44.2, for a period of six months. The board shall promulgate rules and regulations to effectuate this subsection.

(c) Notwithstanding subsection (a) of this Code section, applicants who have been accepted for a pharmacy resident position in this state may be issued a temporary license if they meet the examination requirement for licensure as specified by the board."

SECTION 4.

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

"26-4-86.

(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)(1) 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.

(2) All drug products compounded by a licensed outsourcing facility shall also be compounded in accordance with applicable current good manufacturing practices established by the federal Food and Drug Administration.

(c) In regards to pharmacists compounding nonpatient specific 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 nonpatient specific sterile compounding shall only be conducted by an outsourcing facility and 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 requirements, rules, and regulations established by the board and the federal Food and Drug Administration governing the compounding of medication.

(d)(1) 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.

(2) Nothing in this Code section shall be construed to prohibit or interfere with the ability of a practitioner to compound drugs for administering or dispensing to their own patients pursuant to Code Section 26-4-130."

SECTION 5.

Said chapter is further amended in Code Section 26-4-113, relating to wholesale distributors, licensing requirements, suspension or revocation of license, and reinstatement, by revising subsection (b) as follows:

"(b) Except where otherwise permitted by law, it shall be unlawful for ~~a~~ any type of manufacturer, wholesale distributor, ~~or a~~ reverse drug distributor, outsourcing facility, or third-party logistics provider 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; provided, however, that out-of-state firms that conduct intracompany transfers of drugs or devices

to and have the same ownership as a licensed firm in this state shall not be required to be licensed in this state pursuant to this chapter; and provided, further, that out-of-state third-party logistics providers that are licensed by their resident state or by the federal Food and Drug Administration shall not be required to obtain a license pursuant to 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."

SECTION 6.

Said chapter is further amended by revising Code Section 26-4-115, relating to wholesale drug distributors, registration, fees, reports of excessive purchases, and penalty for violations, as follows:

"26-4-115.

(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, outsourcing facility, or third-party logistics provider; provided, however, that out-of-state firms that conduct intracompany transfers of drugs to and have the same ownership as a licensed firm in this state shall not be required to register pursuant to this subsection; and provided, further, that out-of-state third-party logistics providers that are licensed by their resident state or by the federal Food and Drug Administration shall not be required to register pursuant to this subsection. 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, or outsourcing facility 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, or outsourcing facility 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'~~ excessive purchases as set forth under the provisions of 21 C.F.R. ~~Sec.~~ Section 1301. Such reports shall be submitted to the Georgia Drugs and Narcotics Agency~~.~~; and

(3)(A) Comply with the requirements of Section 360eee, et seq., of the federal act, relating to drug supply chain security.

(B) Each manufacturer of a drug subject to Section 360eee, et seq., of the federal act shall maintain at its corporate offices a current list of the authorized wholesale distributors of such drug.

(C) The board shall establish rules and regulations relating to drug supply chain security based on the requirements of Section 360eee, et seq., of the federal act which are not inconsistent with, more stringent than, or in addition to any requirements applicable under Section 353(e) or Section 360eee of the federal act or any regulations issued thereunder and which are not inconsistent with any waiver, exception, or exemption pursuant to Section 360eee, et seq., of the federal act or any restrictions specified in Section 360eee-1 of the federal act.

(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; provided, however, that such rules and regulations may also include a list of drugs

exempted from the requirements of such provision that have been determined by the board as essential to health care treatment and having an expiration date of less than one year from the date such drug is manufactured.

(d) The provisions of subsection (b) of this Code section shall not apply to any wholesaler, manufacturer, distributor, or supplier ~~who~~ that 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."

SECTION 7.

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