

The House Committee on Health and Human Services offers the following substitute to HB 926:

A BILL TO BE ENTITLED
AN ACT

1 To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
2 pharmacists and pharmacies, so as to provide for the licensure of third-party logistics
3 providers; to provide for definitions; to provide for temporary pharmacy licenses for service
4 members; to require that compounding of drug products for use in a practitioner's office can
5 only be conducted by outsourcing facilities to conform to federal law; to establish
6 requirements relating to drug supply chain security; to revise a provision relating to the return
7 of outdated drugs; to provide for related matters; to repeal conflicting laws; and for other
8 purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 style="text-align:center">**SECTION 1.**

11 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and
12 pharmacies, is amended in Code Section 26-4-5, relating to definitions, by adding new
13 paragraphs to read as follows:

14 "(1.05) 'Authorized' means, in the case of a wholesale distributor, having a valid license
15 pursuant to this chapter or 21 U.S.C. 360eee-1(a)(6) and complying with the licensure
16 reporting requirements under 21 U.S.C. 360eee-3(b)."

17 "(24.1) 'Outsourcing facility' means a facility that is engaged in the compounding of
18 drugs and is registered with the federal Food and Drug Administration as an outsourcing
19 facility pursuant to Section 503b of the federal act."

20 "(40.1) 'Third-party logistics provider' means an entity that provides or coordinates
21 warehousing, distribution, or other services on behalf of a manufacturer but does not take
22 title to a drug or have general responsibility to direct the sale or other disposition of the
23 drug."

24 **SECTION 2.**

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

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

33 **SECTION 3.**

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

36 "26-4-43.

37 (a) A temporary license may be issued by the executive director upon the approval of the
 38 president of the board if an applicant produces satisfactory evidence of fulfilling the
 39 requirements for licensure under this article, except the examination requirement, and
 40 evidence of an emergency situation justifying such temporary license. ~~At~~ Except as
 41 provided in subsection (b) of this Code section, temporary licenses shall expire at the end
 42 of the month ~~during which~~ following the ~~first third~~ board meeting ~~is conducted~~ following
 43 after the issuance of such license and may not be reissued or renewed.

44 (b) A temporary license may be issued to a service member, as defined in Code Section
 45 26-4-44.2, for a period of six months. The board shall promulgate rules and regulations to
 46 effectuate this subsection.

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

50 **SECTION 4.**

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

53 "26-4-86.

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

58 (b) All drug products compounded and labeled in accordance with board rules regarding
 59 pharmaceutical compounding and which have been compounded by an outsourcing facility
 60 in accordance with applicable current good manufacturing practices established by the
 61 federal Food and Drug Administration shall be deemed to meet the labeling requirements
 62 of Chapter 13 of Title 16 and Chapters 3 and 4 of this title.

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

78 (d) Practitioners who may lawfully compound drugs for administering or dispensing to
 79 their own patients pursuant to Code Section 26-4-130 shall comply with all provisions of
 80 this Code section and board rules regarding pharmaceutical compounding."

81 **SECTION 5.**

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

85 "(b) Except where otherwise permitted by law, it shall be unlawful for a manufacturer,
 86 wholesale distributor, ~~or a reverse drug distributor,~~ or third-party logistics provider to
 87 distribute or deliver drugs or devices to or receive drugs or devices from any person or firm
 88 in this state not licensed under this chapter. Any person who distributes or delivers drugs
 89 or devices to or receives drugs or devices from a person or firm not licensed under this
 90 chapter shall be subject to a fine to be imposed by the board for each offense in addition
 91 to such other disciplinary action the board may take under this chapter. Each such
 92 violation shall also constitute a misdemeanor."

SECTION 6.

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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,~~ or third-party logistics provider. 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 third-party logistics provider 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 third-party logistics provider 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~~

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

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

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

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

146 (c) The board shall be authorized to promulgate rules and regulations to facilitate
 147 compliance with this Code section. Such rules and regulations shall include a requirement
 148 that all wholesale drug distributors required to register pursuant to this Code section shall
 149 make adequate provision for the return of outdated drugs, both full and partial containers,
 150 for up to six months after the labeled expiration date for prompt full credit or replacement;
 151 provided, however, that such rules and regulations may also include a list of drugs
 152 exempted from the requirements of such provision that have been determined by the board
 153 as essential to health care treatment and having an expiration date of less than one year
 154 from the date such drug is manufactured.

155 (d) The provisions of subsection (b) of this Code section shall not apply to any wholesaler,
 156 manufacturer, distributor, ~~or supplier who,~~ or third-party logistics provider that only ships
 157 controlled substances directly to a licensed wholesaler within this state.

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

162 (f) Any practitioner who knowingly transfers any controlled substance or dangerous drug
 163 as such terms are defined in Chapter 13 of Title 16 by purchasing from or returning to a
 164 person, firm, or corporation which is not registered as required in subsection (a) of this
 165 Code section or as required in Chapter 13 of Title 16 shall be guilty of a felony and, upon

166 conviction thereof, shall be punished by imprisonment for not less than one year nor more
167 than three years or by a fine not to exceed \$10,000.00, or both."

168 **SECTION 7.**

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