

House Bill 926

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

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 regulation of certain facilities and
3 entities involved in the wholesale, manufacture, and distribution of drugs; to provide
4 definitions; to provide for licensure and registration; to provide for temporary pharmacy
5 licenses for service members; to revise provisions relating to the compounding of drug
6 products to conform with federal law; to establish requirements relating to drug supply chain
7 security; to revise a provision relating to the return of outdated drugs; to provide for related
8 matters; to repeal conflicting laws; and for other purposes.

9 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

10 **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 distributor of record' means a wholesale distributor with whom a
15 manufacturer has established an ongoing relationship to distribute the manufacturer's
16 prescription drugs."

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. To be considered part of the normal distribution channel, a third-party logistics
24 provider must be an authorized distributor of record."

25 "(40.8) 'Virtual drug manufacturer' includes, but is not limited to, a person, firm, or
26 corporation solely composed of managers and consultants who coordinate and monitor

27 contracts with outside providers that perform all operational research and manufacturing
 28 activities in order to develop, market, or distribute one or more drug products."

29 **SECTION 2.**

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

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

38 **SECTION 3.**

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

41 "26-4-43.

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

49 (b) A temporary license may be issued to a service member, as defined in Code Section
 50 26-4-44.2, for a period of six months. The board shall promulgate rules and regulations to
 51 effectuate this subsection.

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

55 **SECTION 4.**

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

58 "26-4-86.

59 (a) The board shall establish rules and regulations governing the compounding and
 60 distribution of drug products by pharmacists, practitioners, and pharmacies licensed or

61 registered by this state. Such rules and regulations shall include provisions ensuring
62 compliance with USP-NF standards.

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

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

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

86

SECTION 5.

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

90 "(b) Except where otherwise permitted by law, it shall be unlawful for a manufacturer,
91 wholesale distributor, ~~or a reverse drug distributor,~~ pharmacy, third-party logistics
92 provider, outsourcing facility, or virtual drug manufacturer to distribute or deliver drugs
93 or devices to or receive drugs or devices from any person or firm in this state not licensed
94 under this chapter. Any person who distributes or delivers drugs or devices to or receives
95 drugs or devices from a person or firm not licensed under this chapter shall be subject to
96 a fine to be imposed by the board for each offense in addition to such other disciplinary

97 action the board may take under this chapter. Each such violation shall also constitute a
98 misdemeanor."

99 **SECTION 6.**

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

103 "26-4-115.

104 (a) All persons, firms, or corporations, whether located in this state or in any other state,
105 engaged in the business of selling or distributing drugs at wholesale in this state, in the
106 business of supplying drugs to manufacturers, compounders, and processors in this state,
107 or in the business of a reverse drug distributor shall biennially register with the board as a
108 drug wholesaler, distributor, reverse drug distributor, ~~or supplier, pharmacy, third-party~~
109 logistics provider, outsourcing facility, or virtual drug manufacturer. The application for
110 registration shall be made on a form to be prescribed and furnished by the board and shall
111 show each place of business of the applicant for registration, together with such other
112 information as may be required by the board. The application shall be accompanied by a
113 fee in an amount established by the board for each place of business registered by the
114 applicant. Such registration shall not be transferable and shall expire on the expiration date
115 established by the executive director. Registration shall be renewed pursuant to the rules
116 and regulations of the board, and a renewal fee prescribed by the board shall be required.
117 If not renewed, the registration shall lapse and become null and void. Registrants shall be
118 subject to such rules and regulations with respect to sanitation or equipment as the board
119 may, from time to time, adopt for the protection of the public health and safety. Such
120 registration may be suspended or revoked or the registrant may be reprimanded, fined, or
121 placed on probation by the board if the registrant fails to comply with any law of this state,
122 the United States, or any other state having to do with the control of pharmacists,
123 pharmacies, wholesale distribution, ~~or reverse drug distribution, third-party logistics~~
124 provider distribution, outsourcing facility distribution, or virtual drug manufacturer
125 distribution of controlled substances or dangerous drugs as defined in Chapter 13 of Title
126 16; if the registrant fails to comply with any rule or regulation promulgated by the board;
127 or if any registration or license issued to the registrant under the federal act is suspended
128 or revoked.

129 (b) Every drug wholesaler, distributor, ~~or supplier, pharmacy, third-party logistics~~
130 provider, outsourcing facility, or virtual drug manufacturer registered as provided in
131 Chapter 13 of Title 16 or in subsection (a) of this Code section, except reverse drug
132 distributors, shall:

133 (1) Submit reports, upon request from the Georgia Drugs and Narcotics Agency, to
 134 account for all transactions with licensed persons or firms located within this state; such
 135 reportable transactions shall include all dangerous drugs and controlled substances as
 136 defined in Chapter 13 of Title 16. Such reports shall be submitted to the Georgia Drugs
 137 and Narcotics Agency; ~~and~~

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

143 (3)(A) Except for a manufacturer or authorized distributor of record, comply with the
 144 requirements of 21 U.S.C. 360eee, et seq., relating to drug supply chain security, before
 145 each wholesale distribution of a drug, including each distribution to an authorized
 146 distributor of record or to a retail pharmacy, and provide to the person that receives the
 147 drug a statement in such form and containing such information as the federal Food and
 148 Drug Administration may require, identifying each prior sale, purchase, or trade of such
 149 drug, including the date of the transaction and the names and addresses of all parties to
 150 the transaction.

151 (B) Each manufacturer of a drug subject to 21 U.S.C. 360eee, et seq., shall maintain
 152 at its corporate offices a current list of the authorized distributors of record of such
 153 drug.

154 (C) The board shall be authorized to establish rules and regulations, including the
 155 requirements of 21 U.S.C. 360eee, et seq., relating to drug supply chain security.

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

165 (d) The provisions of subsection (b) of this Code section shall not apply to any wholesaler,
 166 manufacturer, distributor, ~~or supplier who,~~ pharmacy, third-party logistics provider,
 167 outsourcing facility, or virtual drug manufacturer that only ships controlled substances
 168 directly to a licensed wholesaler within this state.

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

173 (f) Any practitioner who knowingly transfers any controlled substance or dangerous drug
174 as such terms are defined in Chapter 13 of Title 16 by purchasing from or returning to a
175 person, firm, or corporation which is not registered as required in subsection (a) of this
176 Code section or as required in Chapter 13 of Title 16 shall be guilty of a felony and, upon
177 conviction thereof, shall be punished by imprisonment for not less than one year nor more
178 than three years or by a fine not to exceed \$10,000.00, or both."

179 **SECTION 7.**

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