

The House Committee on Health and Human Services offers the following substitute to SB 380:

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 pharmacist and pharmacies, so as to provide for a change to the definition of security paper;
3 to provide for certain revisions to the powers, duties, and authority of the state board of
4 pharmacy; to authorize the Georgia Drugs and Narcotics Agency to accept certain funds; to
5 provide for a definition of valid prescription orders; to remove certain requirements for
6 vendors and seals of approval; to amend Code Section 16-13-59, relating to information to
7 include for each Schedule II, III, IV, or V controlled substance prescription and compliance,
8 so as to provide a definition relating to dispensers located outside this state that deliver
9 dangerous drugs into this state; to provide for related matters; to provide for an effective
10 date; to repeal conflicting laws; and for other purposes.

11 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

12 SECTION 1.

13 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and
14 pharmacies, is amended by revising paragraph (38.5) of Code Section 26-4-5, relating to the
15 definition of security paper, as follows:

16 "(38.5) 'Security paper' means:

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

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

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

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

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

28 (B) A prescription pad or paper that has been approved by the Centers for Medicare
 29 and Medicaid Services."

30 **SECTION 2.**

31 Said chapter is further amended by adding a new paragraph to subsection (a) of Code
 32 Section 26-4-28, relating to the power, duty, and authority of the Georgia State Board of
 33 Pharmacy over the licensure and regulation of pharmacies and pharmacy interns, to read as
 34 follows:

35 "(6.1)(A) The registration of any pharmacy or facility, other than one owned by or
 36 operated by an entity licensed or registered under Title 33, which is located outside this
 37 state which ships, mails, or delivers, in any manner, a dispensed dangerous drug or
 38 controlled substance, or medical device medicinal into this state by issuing a
 39 nonresident pharmacy or a nonresident device distributor permit. The board may only
 40 deny a registration for good cause related to substantial evidence of misfeasance or
 41 malfeasance by an applicant. A firms registered with the board and which has been
 42 issued a nonresident pharmacy or nonresident device distributor permit shall provide
 43 pharmacy and medical device services to the residents of this state in a manner which
 44 does not endanger life and protects the health, safety, and welfare of these residents and
 45 shall disclose to the board the following specific information:

46 (i) That it maintains at all times and provides proof of a valid unexpired license,
 47 permit, or registration to operate a pharmacy and a device distributor in compliance
 48 with the laws and rules of the state in which the facility is located where it receives
 49 prescription drug orders or medical device orders and from which it dispenses
 50 dangerous drugs and controlled substances or medical devices;

51 (ii) The location, names, and titles of all principal corporate officers and the
 52 pharmacist who serves as the pharmacist in charge for dispensing all drugs or the
 53 person responsible for dispensing medical devices to residents of this state. This
 54 disclosure shall be made within ten days after any change of such corporate officer
 55 or pharmacist serving as the pharmacist in charge for dispensing all drugs or the
 56 person responsible for dispensing medical devices to residents of this state;

57 (iii) When it changes the location of its registered location, it must file a change of
 58 location application with the board and submit a copy of its new state and United
 59 States Drug Enforcement Administration registration for the new location;

60 (iv) That it complies with all lawful directions and requests for information from the
61 regulatory or licensing agency of all states in which it is licensed as well as with all
62 requests for information made by the board pursuant to this Code section. It shall
63 respond directly within ten days to all communications from the board concerning
64 emergency circumstances arising from errors in the dispensing of all drugs or medical
65 devices to the residents of this state;

66 (v) That each pharmacy or medical device distributor location notifies the board in
67 writing of the location at which it maintains its records for all prescription drug or
68 medical device orders dispensed to patients in this state so that the records are readily
69 retrievable from the other business records of the pharmacy; and

70 (vi) That during its regular hours of operation but not less than six days per week, for
71 a minimum of 60 hours per week, a toll-free telephone service shall be provided to
72 facilitate communication between patients in this state and a pharmacist at the
73 pharmacy or person at the medical device distributor who has access to the patient's
74 records. This toll-free number must be disclosed on the label affixed to each
75 container of all dispensed drugs.

76 (B) Applications for a nonresident pharmacy or medical device distributor permit
77 under this Code section shall be made on a written or electronic form made available
78 by the board. The board may require such information as the board deems reasonably
79 necessary to carry out a background investigation to ensure the purposes of this Code
80 section will be met by the applicant.

81 (C) The registration fee and the biennial renewal fee for a permit shall be set by board
82 rule.

83 (D) The board may deny, revoke, or suspend registration of, or fine or reprimand, a
84 nonresident pharmacy or medical device distributor for failure to comply with rules of
85 the board or with any requirement of this Code section in accordance with the
86 provisions of this chapter.

87 (E) In addition to the prohibitions of subparagraph (D) of this Code section, the board
88 may deny, revoke, sanction, or suspend the registration of, or fine or reprimand, a
89 nonresident pharmacy or medical device distributor in accordance with the provisions
90 of this chapter for conduct which causes serious bodily injury or serious psychological
91 injury to a resident of this state if the board has referred the matter to the regulatory or
92 licensing agency in the state in which the pharmacy medical device distributor is
93 located and the regulatory or licensing agency fails to investigate the matter within 180
94 days of the referral.

95 (F) After the effective date set by the board for all nonresident pharmacies and medical
96 device distributors to hold a registration in this state, it shall be unlawful for any

97 nonresident pharmacy or medical device distributor which is not registered pursuant to
 98 this Code section to advertise its services in this state, or for any person who is a
 99 resident of this state to advertise the services of a nonresident pharmacy or medical
 100 device distributor which has not registered with the board, with the knowledge that the
 101 advertisement will or is likely to induce members of the public in this state to use the
 102 pharmacy or medical device distributor to fill prescriptions.

103 (G) Notwithstanding the rules of the board, for purposes of this Code section, the
 104 nonresident pharmacy and the pharmacist designated as the pharmacist in charge of the
 105 nonresident pharmacy or the equivalent must be licensed in his or her state of location
 106 in order for a nonresident pharmacy to dispense into this state.

107 (H) Such registration shall only be enabled when legislation amends Code
 108 Section 26-4-60 enabling a person or pharmacy regulated by the board to regularly
 109 employ the mails or other common carriers to sell, distribute, or deliver a drug which
 110 requires a prescription drug order directly to a patient.

111 (I) Nothing in this paragraph shall be construed to limit or prohibit interstate
 112 commerce, including but not limited to the practice of pharmacy by mail."

113 **SECTION 3.**

114 Said chapter is further amended by adding a new subsection to Code Section 26-4-29,
 115 relating to the Georgia Drugs and Narcotics Agency continuance, appointment, requirements,
 116 duties of director, power to make arrests, report of violations of drug laws, and dangerous
 117 drug list, to read as follows:

118 "(f) The Georgia Drugs and Narcotics Agency is authorized to accept donations,
 119 contributions, grants, or bequests of funds or property, including funds or property from
 120 the disposition of forfeited property for purposes of operating the prescription drug
 121 monitoring program established pursuant to Part 2 of Article 2 of Chapter 13 of Title 16,
 122 and the agency shall submit an annual report to the appropriate chairperson of the
 123 Appropriations Committees of the House of Representatives and Senate regarding the use
 124 of funds and property received pursuant to this subsection."

125 **SECTION 4.**

126 Said chapter is further amended by revising subsection (b) of Code Section 26-4-80,
 127 dispensing of valid prescription drug orders, as follows:

128 "(b) Prescription drugs shall be dispensed only pursuant to a valid prescription drug order.
 129 A pharmacist shall not dispense a prescription which the pharmacist knows or should know
 130 is not a valid prescription. As used in this subsection, the term 'valid prescription drug
 131 order' means a prescription drug order issued by a physician, dentist, podiatrist,

132 veterinarian, or other person licensed, registered, or otherwise authorized under the laws
 133 of this state, or any other state or territory of the United States, to prescribe dangerous
 134 drugs and controlled substances."

135 **SECTION 5.**

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

138 "26-4-80.1.

139 (a) Effective October 1, 2011, every hard copy prescription drug order for any Schedule
 140 II controlled substance written in this state by a practitioner must be written on security
 141 paper.

142 (b) A pharmacist shall not fill a hard copy prescription drug order for any Schedule II
 143 controlled substance from a practitioner unless it is written on security paper, except that
 144 a pharmacist may provide emergency supplies in accordance with the board and other
 145 insurance contract requirements.

146 (c) If a hard copy of an electronic data prescription drug order for any Schedule II
 147 controlled substance is given directly to the patient, the manually signed hard copy
 148 prescription drug order must be on approved security paper approved by the board that
 149 meets the requirements of subparagraph (A) of paragraph (38.5) of Code Section 26-4-5
 150 or security paper that meets the requirements of subparagraph (B) of paragraph (38.5) of
 151 Code Section 26-4-5.

152 (d) Practitioners shall employ reasonable safeguards to assure against theft or unauthorized
 153 use of security paper and shall promptly report to appropriate authorities any theft or
 154 unauthorized use.

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

157 ~~(f)~~(e) The board shall create a seal of approval that confirms that security paper contains
 158 all three industry recognized characteristics required by subparagraph (A) of paragraph
 159 (38.5) of Code Section 26-4-5. The seal shall be affixed to all security paper used in this
 160 state; provided, however, that security paper which meets the requirements of subparagraph
 161 (B) of paragraph (38.5) of Code Section 26-4-5 shall not be required to have such affixed
 162 seal.

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

164 ~~(h)~~(g) The security paper requirements in this Code section shall not apply to:

165 (1) Prescriptions that are transmitted to the pharmacy by telephone, facsimile, or
 166 electronic means; or

167 (2) Prescriptions written for inpatients of a hospital, outpatients of a hospital, residents
168 of a nursing home, inpatients or residents of a mental health facility, or individuals
169 incarcerated in a local, state, or federal correctional facility when the health care
170 practitioner authorized to write prescriptions writes the order into the patient's medical
171 or clinical record, the order is given directly to the pharmacy, and the patient never has
172 the opportunity to handle the written order."

173 **SECTION 6.**

174 Code Section 16-13-59 of the Official Code of Georgia Annotated, relating to information
175 to include for each Schedule II, III, IV, or V controlled substance prescription and
176 compliance, is amended by adding a new subsection to read as follows:

177 "(g) For purposes of this Code section, the term 'dispenser' shall also include any pharmacy
178 or facility which is located outside this state and which ships, mails, or delivers, in any
179 manner, a dispensed dangerous drug or controlled substance into this state."

180 **SECTION 7.**

181 This Act shall become effective on July 1, 2012.

182 **SECTION 8.**

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