

Senate Bill 346

By: Senators Balfour of the 9th, Carter of the 1st and Henson of the 41st

AS PASSED SENATE

**A BILL TO BE ENTITLED
AN ACT**

1 To amend Code Section 26-4-60 of the Official Code of Georgia Annotated, relating to
2 grounds for suspension, revocation, or refusal to grant licenses by the State Board of
3 Pharmacy, so as to change certain provisions relating to selling, distributing, and delivering
4 prescription drugs by mail or other common carriers; to amend Code Sections 26-4-5 and 26-
5 4-80 of the Official Code of Georgia Annotated, relating to definitions and dispensing of
6 prescription drugs, respectively, so as to authorize the use of remote order entry for hospital
7 pharmacies; to provide for submission of policies; to provide for related matters; to repeal
8 conflicting laws; and for other purposes.

9 **BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:**

10 **SECTION 1.**

11 Code Section 26-4-60 of the Official Code of Georgia Annotated, relating to grounds for
12 suspension, revocation, or refusal to grant licenses by the State Board of Pharmacy, is
13 amended by revising paragraph (11) of subsection (a) as follows:

14 "(11) Regularly employing the mails or other common carriers to sell, distribute, and
15 deliver a drug which requires a prescription directly to a patient; provided, however, that
16 this provision shall not prohibit the use of the mails or other common carriers to sell,
17 distribute, and deliver a prescription drug directly to:

18 (A) A patient or directly to a patient's guardian or caregiver or a physician or physician
19 acting as the patient's agent for whom the prescription drug was prescribed if:

20 (i) Such prescription drugs are prescribed for complex chronic, terminal, or rare
21 conditions;

22 (ii) Such prescription drugs require special administration, comprehensive patient
23 training, or the provision of supplies and medical devices or have unique patient
24 compliance and safety monitoring requirements;

25 (iii) Due to the prescription drug's high monetary cost, short shelf life, special
26 manufacturer specified packaging and shipping requirements or instructions which

27 require temperature sensitive storage and handling, limited availability or distribution,
 28 or other factors, the drugs are not carried in the regular inventories of retail
 29 pharmacies such that the drugs could be immediately dispensed to multiple retail
 30 walk-in patients;

31 (iv) Such prescription drug has an annual retail value to the patient of more than
 32 \$10,000.00;

33 (v) The patient receiving the prescription drug consents to the delivery of the
 34 prescription drug via expedited overnight common carrier and designates the specialty
 35 pharmacy to receive the prescription drug on his or her behalf;

36 (vi) The specialty pharmacy utilizes, as appropriate and in accordance with standards
 37 of the manufacturer, United States Pharmacopeia, and Federal Drug Administration
 38 and other standards adopted by the State Board of Pharmacy, temperature tags, time
 39 temperature strips, insulated packaging, or a combination of these; and

40 (vii) The specialty pharmacy establishes and notifies the enrollee of its policies and
 41 procedures to address instances in which medications do not arrive in a timely manner
 42 or in which they have been compromised during shipment and to assure that the
 43 pharmacy replaces or makes provisions to replace such drugs; ~~or~~

44 (B) An institution or to sell, distribute, or deliver prescription ~~drug-refills~~ drugs, upon
 45 his or her request, to an enrollee in a health benefits plan of a group model health
 46 maintenance organization or its affiliates by a pharmacy which is operated by that same
 47 group model health maintenance organization and licensed under Code Section
 48 26-4-110 or to a patient on behalf of a pharmacy. Any pharmacy using the mails or
 49 other common carriers to dispense prescriptions pursuant to this paragraph shall comply
 50 with the following conditions:

51 (i) The pharmacy shall provide an electronic, telephonic, or written communications
 52 mechanism which reasonably determines whether the medications distributed by the
 53 mails or other common carriers have been received by the enrollee and through which
 54 a pharmacist employed by the group model health maintenance organization or a
 55 pharmacy intern under his or her direct supervision is enabled to offer counseling to
 56 the enrollee as authorized by and in accordance with his or her obligations under Code
 57 Section 26-4-85, unless the enrollee refuses such consultation or counseling pursuant
 58 to subsection (e) of such Code section. In addition, the enrollee shall receive
 59 information indicating what he or she should do if the integrity of the packaging or
 60 medication has been compromised during shipment;

61 (ii) In accordance with clinical and professional standards, the State Board of
 62 Pharmacy shall promulgate a list of medications which may not be delivered by the
 63 mails or other common carriers. However, until such list is promulgated, the group

64 model health maintenance organization shall not deliver by use of the mails or other
 65 common carriers Class II controlled substance medications, medications which
 66 require refrigeration, chemotherapy medications deemed by the federal
 67 Environmental Protection Agency as dangerous, medications in suppository form, and
 68 other medications which, in the professional opinion of the dispensing pharmacist,
 69 may be clinically compromised by distribution through the mail or other common
 70 carriers;

71 (iii) The pharmacy shall utilize, as appropriate and in accordance with standards of
 72 the manufacturer, United States Pharmacopeia, and Federal Drug Administration and
 73 other standards adopted by the State Board of Pharmacy, temperature tags, time
 74 temperature strips, insulated packaging, or a combination of these; and

75 (iv) The pharmacy shall establish and notify the enrollee of its policies and
 76 procedures to address instances in which medications do not arrive in a timely manner
 77 or in which they have been compromised during shipment and to assure that the
 78 pharmacy replaces or makes provisions to replace such drugs.

79 For purposes of subparagraph (B) of this paragraph, the term 'group model health
 80 maintenance organization' means a health maintenance organization that has an
 81 exclusive contract with a medical group practice to provide or arrange for the provision
 82 of substantially all physician services to enrollees in health benefits plans of the health
 83 maintenance organization; or

84 (C) A pharmacist or pharmacy to dispense a prescription and deliver it to another
 85 pharmacist or pharmacy to make available for a patient to receive the prescription and
 86 patient counseling according to Code Section 26-4-85. The State Board of Pharmacy
 87 shall adopt any rules and regulations necessary to implement this subparagraph."

88 **SECTION 1A.**

89 Code Section 26-4-5 of the Official Code of Georgia Annotated, relating to definitions
 90 relative to pharmacists and pharmacies, by adding a new paragraph to read as follows:

91 "(37.2) 'Remote order entry' means the entry made by a pharmacist located within the
 92 State of Georgia from a remote location indicating that the pharmacist has reviewed the
 93 patient specific drug order for a hospital patient, has approved or disapproved the
 94 administration of the drug for such patient, and has entered the information in the
 95 hospital's patient record system."

96 **SECTION 1B.**

97 Code Section 26-4-80 of the Official Code of Georgia Annotated, relating to dispensing of
 98 prescription drugs, is amended by revising paragraph (7) of subsection (c) as follows:

99 ~~“(7)(A) The board shall promulgate rules and regulations which may provide specific~~
100 ~~exceptions~~ under this Code section for institutional settings such as hospital
101 pharmacies, nursing home pharmacies, clinic pharmacies, or pharmacies owned or
102 operated directly by health maintenance organizations.

103 (B) The rules established pursuant to subparagraph (A) of this paragraph shall
104 specifically authorize hospital pharmacies to use remote order entry when:

105 (i) The licensed pharmacist is not physically present in the hospital, the hospital
106 pharmacy is closed, and a licensed pharmacist will be physically present in the
107 hospital pharmacy within 16 hours; or

108 (ii) When at least one licensed pharmacist is physically present in the hospital
109 pharmacy and at least one other licensed pharmacist is practicing pharmacy in the
110 hospital but not physically present in the hospital pharmacy.

111 (C) Before a hospital may engage in remote order entry as provided in this paragraph,
112 the director of pharmacy of the hospital shall submit to the board written policies and
113 procedures for the use of remote order entry. The required policies and procedures to
114 be submitted to the board shall be in accordance with the American Society of
115 Health-System Pharmacists and shall contain provisions addressing quality assurance
116 and safety, mechanisms to clarify medication orders, processes for reporting medication
117 errors, documentation and record keeping, secure electronic access to the hospital
118 pharmacy's patient information system and to other electronic systems that the on-site
119 pharmacist has access to, access to hospital policies and procedures, confidentiality and
120 security, and mechanisms for real-time communication with prescribers, nurses, and
121 other care givers responsible for the patient's health care.

122 (D) If the board concludes that the hospital's actual use of remote order entry does not
123 comply with this paragraph or the rules adopted pursuant to this chapter, it may issue
124 a cease and desist order after notice and hearing.”

125 **SECTION 2.**

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