

The Senate Health and Human Services Committee offered the following substitute to HB 209:

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 add and revise definitions; to revise requirements for  
3 license transfers for pharmacists licensed in another jurisdiction; to revise provisions relating  
4 to dispensing prescription drugs; to revise requirements for the use of security paper for hard  
5 copy prescription drug orders; to revise provisions relating to compounding drug products;  
6 to enable nonresident pharmacy permits; to amend Part 2 of Article 2 of Chapter 13 of Title  
7 16 of the Official Code of Georgia Annotated, relating to electronic data base of prescription  
8 information, so as to revise the definition of "dispenser" relative to information to include  
9 for each Schedule II, III, IV, or V controlled substance prescription; to provide for related  
10 matters; to repeal conflicting laws; and for other purposes.

11 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

**SECTION 1.**

12 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and  
13 pharmacies, is amended by revising paragraphs (4) and (38.5) and adding a new paragraph  
14 to Code Section 26-4-5, relating to definitions, as follows:  
15

16 "(4) 'Compounding' means the preparation, mixing, assembling, packaging, or labeling  
17 of a drug or device by a pharmacist or pharmacy licensed or registered by the board or  
18 by a practitioner in compliance with rules established by the board regarding  
19 pharmaceutical compounding:

20 (A) As as the result of a practitioner's prescription drug order or initiative for a specific  
21 patient based on the relationship between the practitioner, patient, and pharmacist in the  
22 course of professional practice;

23 (B) For use by a practitioner in the administration of a dangerous drug or controlled  
24 substance to a patient in his or her professional practice office or setting;

25 (C) For use within the hospital or health system in which the pharmacy is located or  
 26 in which the practitioner or pharmacist practices or for use within clinics or other  
 27 entities owned or operated by such hospital or health system; or

28 (D) For for the purpose of, or as an incident to, research, teaching, or chemical analysis  
 29 and not for sale or dispensing.

30 Compounding also includes the preparation of drugs ~~or devices~~ in anticipation of  
 31 prescription drug orders based on routine and regularly observed prescribing patterns."

32 "(38.5) 'Security paper' means:

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

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

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

39 (C)(iii) One or more industry recognized features designed to prevent the use of  
 40 counterfeit prescription forms; or

41 ~~Where security paper is in the form of a prescription pad, each pad shall bear an~~  
 42 ~~identifying lot number, and each piece of paper in the pad shall be numbered~~  
 43 ~~sequentially beginning with the number one.~~

44 (B) A prescription pad or paper that is an approved prescription pad or paper of the  
 45 Centers for Medicare and Medicaid Services on January 1, 2013."

46 "(40.5) 'USP-NF' means the United States Pharmacopeia and National Formulary."

## 47 **SECTION 2.**

48 Said chapter is further amended by revising paragraph (7) of subsection (a) of Code Section  
 49 26-4-42, relating to license transfers for pharmacists licensed in another jurisdiction, as  
 50 follows:

51 "(7) Have successfully passed an examination examinations as determined by the board,  
 52 one of which shall include an examination on Georgia pharmacy law and board  
 53 regulations; and"

## 54 **SECTION 3.**

55 Said chapter is further amended by revising subsection (b) and subparagraph (c)(7)(B) of  
 56 Code Section 26-4-80, relating to dispensing prescription drugs, as follows:

57 "(b) Prescription drugs shall be dispensed only pursuant to a valid prescription drug  
 58 order. A pharmacist shall not dispense a prescription which the pharmacist knows or  
 59 should know is not a valid prescription. A pharmacist shall have the same corresponding

60 liability for prescriptions as an issuing practitioner as set forth in 21 C.F.R. Part 1304 as  
 61 such regulation exists on January 1, 2013. Valid prescription drug orders shall include  
 62 those issued by a physician, dentist, podiatrist, veterinarian, or other person licensed,  
 63 registered, or otherwise authorized under the laws of this state, or of any state or territory  
 64 of the United States, to prescribe dangerous drugs or controlled substances or both."

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

67 (i) The licensed pharmacist is not physically present in the hospital, the hospital  
 68 pharmacy is closed, and a licensed pharmacist will be physically present in the  
 69 hospital pharmacy within ~~16~~ 24 hours; ~~or~~

70 (ii) ~~When at~~ At least one licensed pharmacist is physically present in the hospital  
 71 pharmacy and at least one other licensed pharmacist is practicing pharmacy in the  
 72 hospital but not physically present in the hospital pharmacy; or

73 (iii) At least one licensed pharmacist is physically present in a hospital within this  
 74 state which remotely serves only on weekends another hospital or hospitals under the  
 75 same ownership or management which have an average daily census of less than ten  
 76 acute patients."

#### 77 SECTION 4.

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

80 "26-4-80.1.

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

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

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

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

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

99 ~~(f)~~(e) The board shall create a seal of approval that confirms that security paper contains  
 100 all three industry recognized characteristics required by paragraph (38.5) of Code Section  
 101 26-4-5. The seal shall be affixed to all security paper used in this state; provided, however,  
 102 that security paper which meets the requirements of subparagraph (B) of paragraph (38.5)  
 103 of Code Section 26-4-5 shall not be required to have such affixed seal.

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

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

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

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

#### 114 SECTION 5.

115 Said chapter is further amended by revising Code Section 26-4-86, relating to compounding  
 116 of medications, as follows:

117 "26-4-86.

118 (a) The board ~~may~~ shall establish rules and regulations governing the compounding and  
 119 distribution of drug products of medication by pharmacists, practitioners, and pharmacies  
 120 licensed or registered by in this state. Such rules and regulations shall include provisions  
 121 ensuring compliance with USP-NF standards.

122 (b) All drug products compounded and labeled in accordance with board rules regarding  
 123 pharmaceutical compounding shall be deemed to meet the labeling requirements of Chapter  
 124 13 of Title 16 and Chapters 3 and 4 of this title.

125 (c) In regards to pharmacists compounding sterile drugs to be provided to practitioners to  
 126 use in patient care or altering or repackaging such drugs for practitioners to use in patient  
 127 care in the practitioner's office, such sterile compounding shall only be conducted as  
 128 allowed by applicable federal law and board rule for pharmaceutical compounding using  
 129 USP-NF standards for sterile compounding. Such sterile drugs may be compounded only

130 in quantities determined by board rule following consultation with the Georgia Composite  
 131 Medical Board. No Schedule II, III, IV, or V controlled substance, as defined in Article  
 132 2 of Chapter 13 of Title 16, shall be eligible for such designation. Nothing in this  
 133 subsection shall be construed to apply to pharmacies owned or operated by institutions or  
 134 to pharmacists or practitioners within or employed by an institution or affiliated entity;  
 135 provided, however, that pharmacies owned or operated by institutions and pharmacists and  
 136 practitioners within or employed by institutions or affiliated entities shall remain subject  
 137 to other rules and regulations established by the board governing the compounding of  
 138 medication.

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

142 **SECTION 6.**

143 Said chapter is further amended by revising subsection (b) of Code Section 26-4-88, relating  
 144 to restrictions on dispensing of medicines, drugs, or poisons, as follows:

145 "(b) Except as otherwise required pursuant to Code Section 26-4-86, this This chapter shall  
 146 not apply to practitioners of the healing arts prescribing, compounding their own  
 147 prescriptions, or dispensing drugs or medicines except as provided in Code Section  
 148 26-4-130."

149 **SECTION 7.**

150 Said chapter is further amended by revising paragraph (3) of Code Section 26-4-112, relating  
 151 to occurrences which require immediate notification to board, as follows:

152 "(3) Change of the pharmacist in charge of a licensed pharmacy. If upon the board being  
 153 notified of such change a replacement pharmacist in charge is not named in said  
 154 notification, the license of that pharmacy shall stand suspended pending further findings  
 155 by the board;"

156 **SECTION 8.**

157 Said chapter is further amended by adding a new Code section to read as follows:

158 "26-4-114.1.

159 (a) Any person, pharmacy, or facility located outside this state may apply to the board for  
 160 a nonresident pharmacy permit which shall entitle the holder thereof to ship, mail, or  
 161 deliver dispensed drugs, including but not limited to dangerous drugs and controlled  
 162 substances, into this state. The board shall establish an application and require such  
 163 information as the board deems reasonably necessary to carry out a background

164 investigation of applicants and to ensure that the purposes of this Code section are met.  
165 Such application shall include:

166 (1) Proof of a valid, unexpired license, permit, or registration to operate a pharmacy in  
167 compliance with the laws and rules of each state in which the applicant receives and  
168 dispenses prescription drug orders, including but not limited to orders for prescription  
169 drugs, dangerous drugs, and controlled substances;

170 (2) Addresses, names, and titles of all principal corporate officers and the pharmacist in  
171 charge of dispensing drugs to residents of this state; and

172 (3) A statement of whether the applicant is in compliance with all lawful directions and  
173 requests for information from the regulatory or licensing agencies of each state in which  
174 the applicant is licensed as well as all requests for information made by the board  
175 pursuant to this Code section.

176 (b) The board shall establish by rule an application fee and the biennial renewal fee for a  
177 permit under this Code section.

178 (c) The board may only deny an application for a nonresident pharmacy permit for failure  
179 to comply with rules of the board or any requirements of this Code section or for good  
180 cause related to substantial evidence of misfeasance or malfeasance by the applicant.  
181 Applicants granted a permit under this Code section shall provide pharmacy care in a  
182 manner which does not endanger life and protects the health, safety, and welfare of the  
183 residents of this state. A pharmacy, facility, or entity licensed under Title 33 shall not be  
184 required to hold a nonresident pharmacy permit.

185 (d) After an effective date established by rule of the board for the enforcement of the  
186 nonresident pharmacy permits, it shall be unlawful for any person, pharmacy, or facility  
187 that is located outside this state and that does not possess a nonresident pharmacy permit  
188 to ship, mail, or deliver prescription drug orders or to advertise its services in this state, or  
189 for any person who is a resident of this state to advertise the services of such person,  
190 pharmacy, or facility with the knowledge that the advertisement will or is likely to induce  
191 residents of this state to use such person, pharmacy, or facility for pharmacy care. Nothing  
192 in this subsection shall be construed to limit or prohibit interstate commerce, including but  
193 not limited to the practice of pharmacy by mail.

194 (e) The board shall have the authority to promulgate rules and regulations governing the  
195 holder of a nonresident pharmacy permit under this Code section. Such rules and  
196 regulations shall minimally include the following requirements for nonresident pharmacy  
197 permit holders:

198 (1) A permit holder's pharmacist in charge of dispensing drugs to residents of this state  
199 shall be licensed in his or her state of location;

- 200 (2) A permit holder shall provide written notification to the board within ten days of any  
201 change of a permit holder's principal corporate officers or pharmacist in charge of  
202 dispensing drugs to residents of this state;
- 203 (3) A permit holder shall file a change of location application upon any change to the  
204 permit holder's state of registration in addition to proof of the license, permit, or  
205 registration from the permit holder's new state of registration and the United States Drug  
206 Enforcement Administration registration for such new location;
- 207 (4) A permit holder shall respond within ten calendar days to all communications from  
208 the board concerning emergency circumstances arising from errors in the dispensing of  
209 any drugs to residents of this state;
- 210 (5) A permit holder shall provide written notification to the board of each location at  
211 which the permit holder maintains its records for all prescription drug orders dispensed  
212 to patients in this state so that the records are readily retrievable from the business records  
213 of the permit holder; and
- 214 (6) A permit holder shall maintain a toll-free telephone number operational during the  
215 permit holder's regular hours of operation but not less than six days per week for a  
216 minimum of 60 hours per week that shall be used to provide and facilitate patient  
217 counseling. Such toll-free number shall be capable of receiving inbound calls from  
218 patients to the permit holder and shall be disclosed on the label affixed to each container  
219 of all dispensed and distributed drugs.
- 220 (f) The board may revoke, suspend, or refuse to renew a permit of a permit holder for  
221 failure to comply with rules of the board or with any requirement of this Code section or  
222 for conduct which causes serious bodily or psychological injury to a resident of this state,  
223 provided that the board has referred the matter involving the conduct to the regulatory or  
224 licensing agency in the state in which the permit holder is located and the regulatory or  
225 licensing agency fails to initiate an investigation into the matter within 180 days of such  
226 referral or fails, in the board's judgment, to render sufficient resolution.
- 227 (g)(1) As a prerequisite to registering or renewing a registration with the board, a  
228 nonresident pharmacy conducting sterile or nonsterile compounding for practitioners to  
229 use in patient care in the practitioner's office shall submit a copy of the most recent and  
230 current inspection report resulting from an inspection conducted by the regulatory or  
231 licensing agency of the jurisdiction in which it is located that indicates compliance with  
232 the requirements of this chapter, including compliance USP-NF standards for pharmacies  
233 performing sterile and nonsterile compounding. The inspection report required by this  
234 subsection shall not be required if the compounding within the facility is done pursuant  
235 to a prescription. Such inspection report shall be deemed current for the purpose of this  
236 subsection if the inspection was conducted;

- 237 (A) No more than six months prior to the date of submission of an application for  
 238 registration with the board; or
- 239 (B) No more than two years prior to the date of submission of an application for  
 240 renewal of a registration with the board.
- 241 (2) If the nonresident pharmacy conducting sterile or nonsterile compounding has not  
 242 been inspected by the regulatory or licensing agency of the jurisdiction in which it is  
 243 located within the timeframes required in paragraph (1) of this subsection, the board may:
- 244 (A) Accept an inspection report or other documentation from another entity that is  
 245 satisfactory to the board; or
- 246 (B) Make a request of the appropriate regulatory or licensing agency of the jurisdiction  
 247 where the pharmacy is located to cause an inspection to be conducted by an agent duly  
 248 authorized by the board.
- 249 A nonresident pharmacy shall be responsible for paying any inspection fee incurred  
 250 pursuant to this paragraph."

251 **SECTION 9.**

252 Said chapter is further amended by revising subsection (b) of Code Section 26-4-130, relating  
 253 to dispensing drugs, compliance with labeling and packaging requirements, records available  
 254 for inspection by board, and renewal of licenses, as follows:

255 "(b) Except as otherwise required pursuant to Code Section 26-4-86, the ~~The~~ other  
 256 provisions of this chapter and Article 3 of Chapter 13 of Title 16 shall not apply to  
 257 practitioners of the healing arts prescribing or compounding their own prescriptions and  
 258 dispensing drugs except as provided in this Code section. Nor shall such provisions  
 259 prohibit the administration of drugs by a practitioner of the healing arts or any person under  
 260 the supervision of such practitioner or by the direction of such practitioner except as  
 261 provided in this Code section. Any term used in this subsection and defined in Code  
 262 Section 43-34-23 shall have the meaning provided for such term in Code Section 43-34-23.  
 263 The other provisions of this chapter and Articles 2 and 3 of Chapter 13 of Title 16 shall not  
 264 apply to persons authorized by Code Section 43-34-23 to order, dispense, or administer  
 265 drugs when such persons order, dispense, or administer those drugs in conformity with  
 266 Code Section 43-34-23. When a person dispenses drugs pursuant to the authority delegated  
 267 to that person under the provisions of Code Section 43-34-23, with regard to the drugs so  
 268 dispensed, that person shall comply with the requirements placed upon practitioners by  
 269 subsections (c) and (d) of this Code section."



270

**SECTION 10.**

271

Part 2 of Article 2 of Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to electronic data base of prescription information, is amended by revising Code Section 16-13-59, relating to information to include for each Schedule II, III, IV, or V controlled substance prescription, by adding a new subsection to read as follows:

272

273

274

275

"(g) For purposes of this Code section, the term 'dispenser' shall include any pharmacy or facility physically located in another state or foreign country that in any manner ships, mails, or delivers a dispensed controlled substance into this state."

276

277

278

**SECTION 11.**

279

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