

The Senate Committee on Health and Human Services offers the following substitute to HB 511:

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 minimum standards for pharmacy
3 technicians to fill remote automated medication systems under certain circumstances; to
4 amend Article 6 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating
5 to respiratory care, so as to provide for the licensure of durable medical equipment suppliers;
6 to amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
7 pharmacists and pharmacies, so as to provide for expansion of certain medical professionals
8 to prescribe auto-injectable epinephrine to an authorized entity and for other emergency
9 purposes; to amend Chapter 2A of Title 31 of the Official Code of Georgia Annotated,
10 relating to the Department of Public Health, so as to provide for expansion of treatment for
11 allergy reactions; to authorize certain health care practitioners to prescribe auto-injectable
12 epinephrine; to authorize certain individuals to administer auto-injectable epinephrine under
13 certain circumstances; to provide immunity from liability; to amend Chapter 34 of Title 43
14 of the Official Code of Georgia Annotated, relating to physicians, physician assistants, and
15 others, so as to provide for emergency public access stations to allow a lay rescuer to consult
16 with a medical professional to administer or make available auto-injectable epinephrine
17 under certain circumstances; to provide for immunity; to provide for related matters; to
18 repeal conflicting laws; and for other purposes.

19 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

PART I
SECTION 1-1.

22 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and
23 pharmacies, is amended in Code Section 26-4-28, relating to the powers, duties, and
24 authority of the Georgia State Board of Pharmacy, by revising paragraph (12.1) of subsection
25 (a) as follows:

59 "(6.1) Issue, suspend, deny, and renew licenses for suppliers of durable medical
 60 equipment pursuant to Code Section 43-34-151.1:"

61 **SECTION 2-3.**

62 Said article is further amended by adding a new Code section to read as follows:

63 "43-34-151.1.

64 (a) Any person who delivers disposable medical supplies or durable medical equipment
 65 for which a prescription is required and any person who accepts a physician order to
 66 provide disposable medical supplies or durable medical equipment shall possess a durable
 67 medical equipment supplier license issued by the board.

68 (b) The board shall issue a license to an applicant for licensure as a durable medical
 69 equipment supplier if the applicant:

70 (1) Completes the license application required by the board;

71 (2) Maintains a physical location in the State of Georgia, which location is accredited by
 72 an accrediting organization recognized by the federal Centers for Medicare and Medicaid
 73 Services; and

74 (3) Pays the license fee required by the board, which in no event shall exceed the license
 75 fee for a respiratory technician.

76 (c) Licenses issued pursuant to this Code section shall be effective for 24 months from the
 77 date of issuance and shall not be transferable or assignable.

78 (d) The board may deny, revoke, or suspend a license issued pursuant to this Code section
 79 upon a finding that the applicant or licensee:

80 (1) Made a material misrepresentation to the board; or

81 (2) Has violated any state or federal law or regulation that is related to the provision of
 82 health care services, including disposable medical supplies and durable medical
 83 equipment.

84 If a license is denied, revoked, or suspended pursuant to this subsection, the applicant or
 85 licensee may appeal the board's decision in the same manner as provided in Code Section
 86 43-34-152.

87 (e) This Code section shall not apply to the sale of disposable medical supplies or durable
 88 medical equipment for which a prescription is required by:

89 (1) Licensed pharmacists or pharmacies;

90 (2) Physicians who do not sell, lease, or rent home medical equipment;

91 (3) Licensed dialysis providers, include those offering in-center dialysis, home dialysis
 92 services, or both;

93 (4) Suppliers of insulin infusion pumps and related supplies or services; or

- 94 (5) Persons who do not sell, lease, or rent home medical equipment and have an existing
 95 state license or permit to operate:
 96 (A) A skilled nursing facility;
 97 (B) A hospital;
 98 (C) An ambulatory surgical center;
 99 (D) A health care facility owned or operated by the state or federal government;
 100 (E) An assisted living facility that provides disposable medical supplies or durable
 101 medical equipment only to its residents; or
 102 (F) As a manufacturer or wholesale distributor that provides disposable medical
 103 supplies or durable medical equipment directly to consumers."

104 **PART III**
 105 **SECTION 3-1.**

106 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and
 107 pharmacies, is amended by revising Code Section 26-4-116.1, relating to licensed health
 108 practitioners authorized to prescribe auto-injectable epinephrine for schools and pharmacists
 109 authorized to fill prescriptions, as follows:

110 "26-4-116.1.

111 (a) A physician licensed to practice medicine in this state, an advanced practice registered
 112 nurse acting pursuant to the authority of Code Section 43-34-25, and a physician assistant
 113 acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103 may
 114 prescribe auto-injectable epinephrine in the name of a public or private school for use in
 115 accordance with Code Section 20-2-776.2 and in accordance with protocol specified by
 116 such physician, advanced practice registered nurse, or physician assistant.

117 ~~(b) A pharmacist may dispense auto-injectable epinephrine pursuant to a prescription~~
 118 ~~issued in accordance with subsection (a) of this Code section~~ A physician licensed to
 119 practice medicine in this state, an advanced practice registered nurse acting pursuant to the
 120 authority of Code Section 43-34-25, and a physician assistant acting pursuant to the
 121 authority of subsection (e.1) of Code Section 43-34-103 may prescribe auto-injectable
 122 epinephrine in the name of an authorized entity in accordance with Code Section 31-2A-18.

123 (c) A medical professional, as defined in Code Section 43-34-26.2, may prescribe
 124 auto-injectable epinephrine to an entity described in Code Section 31-2A-18. A pharmacist
 125 may dispense auto-injectable epinephrine pursuant to a prescription issued in accordance
 126 with subsection (a), (b), or (c) of this Code section."

SECTION 3-2.

Chapter 2A of Title 31 of the Official Code of Georgia Annotated, relating to the Department of Public Health, is amended by adding a new Code section to read as follows:

"31-2A-18.

(a) As used in this Code section, the term:

(1) 'Administer' means the direct application of auto-injectable epinephrine to the body of an individual.

(2) 'Authorized entity' means any entity or organization, other than a school described in Code Section 20-2-776.2, in connection with or at which allergens capable of causing anaphylaxis may be present, as identified by the State Board of Pharmacy. The State Board of Pharmacy shall, through rule or other guidance, identify the types of entities and organizations that are considered authorized entities no later than January 1, 2016, and shall review and update such rule or guidance at least annually thereafter.

(3) 'Auto-injectable epinephrine' means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

(4) 'Health care practitioner' means a physician licensed to practice medicine in this state, an advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-25, and a physician assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103.

(5) 'Provide' means the supply of one or more auto-injectable epinephrine to an individual.

(b) A health care practitioner may prescribe auto-injectable epinephrine in the name of an authorized entity for use in accordance with this Code section, and pharmacists and health care practitioners may dispense auto-injectable epinephrine pursuant to a prescription issued in the name of an authorized entity. A prescription issued pursuant to this Code section shall be valid for two years.

(c) An authorized entity may acquire and stock a supply of auto-injectable epinephrine pursuant to a prescription issued in accordance with this Code section. Such auto-injectable epinephrine shall be stored in a location readily accessible in an emergency and in accordance with the auto-injectable epinephrine's instructions for use and any additional requirements that may be established by the State Board of Pharmacy. An authorized entity shall designate employees or agents who have completed the training required by subsection (e) of this Code section to be responsible for the storage, maintenance, control, and general oversight of auto-injectable epinephrine acquired by the authorized entity.

162 (d) An employee or agent of an authorized entity, or any other individual, who has
163 completed the training required by subsection (e) of this Code section may use
164 auto-injectable epinephrine prescribed pursuant to subsection (b) of this Code section to:

165 (1) Provide auto-injectable epinephrine to any individual who the employee, agent, or
166 other individual believes in good faith is experiencing anaphylaxis, or to the parent,
167 guardian, or caregiver of such individual, for immediate administration, regardless of
168 whether the individual has a prescription for auto-injectable epinephrine or has previously
169 been diagnosed with an allergy; and

170 (2) Administer auto-injectable epinephrine to any individual who the employee, agent,
171 or other individual believes in good faith is experiencing anaphylaxis, regardless of
172 whether the individual has a prescription for auto-injectable epinephrine or has previously
173 been diagnosed with an allergy.

174 (e) An employee, agent, or other individual described in subsection (c) or (d) of this Code
175 section must complete an anaphylaxis training program and repeat such training at least
176 every two years following completion of the initial anaphylaxis training program. Such
177 training shall be conducted by a nationally recognized organization experienced in training
178 laypersons in emergency health treatment or an entity or individual approved by the State
179 Board of Pharmacy. The State Board of Pharmacy may approve specific entities or
180 individuals or may approve classes of entities or individuals to conduct training. Training
181 may be conducted online or in person and, at a minimum, shall cover:

182 (1) How to recognize signs and symptoms of severe allergic reactions, including
183 anaphylaxis;

184 (2) Standards and procedures for the storage and administration of auto-injectable
185 epinephrine; and

186 (3) Emergency follow-up procedures.

187 The entity that conducts the training shall issue a certificate, on a form developed or
188 approved by the State Board of Pharmacy, to each individual who successfully completes
189 the anaphylaxis training program.

190 (f) An authorized entity that possesses and makes available auto-injectable epinephrine
191 and its employees, agents, and other individuals; a health care practitioner that prescribes
192 or dispenses auto-injectable epinephrine to an authorized entity; a pharmacist or health care
193 practitioner that dispenses auto-injectable epinephrine to an authorized entity; and an
194 individual or entity that conducts the training described in subsection (d) of this Code
195 section shall not be liable for any injuries or related damages that result from any act or
196 omission taken pursuant to this Code section; provided, however, that this immunity does
197 not apply to acts or omissions constituting willful or wanton misconduct. The
198 administration of auto-injectable epinephrine in accordance with this Code section is not

199 the practice of medicine or any other profession that otherwise requires licensure. This
 200 Code section does not eliminate, limit, or reduce any other immunity or defense that may
 201 be available under state law, including that provided under Code Section 51-1-29. An
 202 entity located in this state shall not be liable for any injuries or related damages that result
 203 from the provision or administration of auto-injectable epinephrine outside of this state if
 204 the entity:

205 (1) Would not have been liable for such injuries or related damages had the provision or
 206 administration occurred within this state; or

207 (2) Is not liable for such injuries or related damages under the law of the state in which
 208 such provision or administration occurred.

209 (g) An authorized entity that possesses and makes available auto-injectable epinephrine
 210 shall submit to the State Board of Pharmacy, on a form developed by the State Board of
 211 Pharmacy, a report of each incident on the authorized entity's premises that involves the
 212 administration of auto-injectable epinephrine pursuant to subsection (d) of this Code
 213 section. The State Board of Pharmacy shall annually publish a report that summarizes and
 214 analyzes all reports submitted to it under this subsection."

215 **SECTION 3-3.**

216 Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to physicians,
 217 physician assistants, and others, is amended by adding a new Code section to read as follows:

218 "43-34-26.2.

219 (a) As used in this Code section, the term:

220 (1) 'Auto-injectable epinephrine' means a single-use device used for the automatic
 221 injection of a premeasured dose of epinephrine into the human body.

222 (2) 'Emergency Public Access Station' or 'EPAS' means a locked, secure container for
 223 the storage of auto-injectable epinephrine which:

224 (A) Allows a lay rescuer to consult with a medical professional in real time by audio,
 225 video, or other similar means of electronic communication;

226 (B) Upon authorization of the consulting medical professional, may be unlocked to
 227 make available the auto-injectable epinephrine;

228 (C) Has received any approval required under Title 21 of the United States Code from
 229 the United States Food and Drug Administration; and

230 (D) Is maintained under the general oversight of a medical professional.

231 (3) 'Medical professional' means any physician or other person authorized under this title
 232 to treat, use, or prescribe medicine and drugs in this state or the state in which such
 233 physician or other person is located.

234 (b) A medical professional may prescribe a stock supply of auto-injectable epinephrine to
235 any entity or organization for storage in an Emergency Public Access Station or may place
236 a stock supply of auto-injectable epinephrine at any entity or organization in an EPAS in
237 accordance with protocols established by the medical professional and approved by the
238 State Board of Pharmacy.

239 (c) A medical professional may provide consultation to the user of an EPAS and may
240 make the auto-injectable epinephrine stored in the EPAS available to the user in accordance
241 with protocols established by the medical professional and approved by the State Board of
242 Pharmacy.

243 (d) Any person may use an EPAS and may administer or provide auto-injectable
244 epinephrine made available through the EPAS to a specific individual believed in good
245 faith to be experiencing anaphylaxis or to the parent, guardian, or caregiver of such
246 individual.

247 (e) Any person, including any entity or organization at which an EPAS is located, a
248 medical professional, and any user of an EPAS who undertakes in good faith any act or
249 omission pursuant to this Code section shall not be liable for any injuries or related
250 damages that result from any such act or omission; provided, however, that this immunity
251 does not apply to acts or omissions constituting willful or wanton misconduct. This Code
252 section does not eliminate, limit, or reduce any other immunity or defense that may be
253 available under state law, including that provided under Code Section 51-1-29. Use of an
254 EPAS in accordance with this Code section is not the practice of medicine or any other
255 profession that otherwise requires licensure."

256

PART IV

257

SECTION 4-1.

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