

Senate Bill 195

By: Senators Hufstetler of the 52nd, Kirkpatrick of the 32nd, Watson of the 1st, Parent of the 44th and Orrock of the 36th

AS PASSED

A BILL TO BE ENTITLED

AN ACT

1 To amend Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated,
2 relating to pharmacies, so as to provide that pharmacists are authorized to dispense
3 preexposure prophylaxis and postexposure prophylaxis under certain conditions; to amend
4 Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to
5 medical practice, so as to provide for the approval or development of a training program for
6 pharmacists by the State Board of Pharmacy; to require pharmacists to complete such
7 training program before dispensing preexposure prophylaxis or postexposure prophylaxis;
8 to provide for patient requirements; to provide for limitations and conditions; to provide for
9 sanctions; to provide for definitions; to provide for related matters; to repeal conflicting laws;
10 and for other purposes.

11 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

12 **SECTION 1.**

13 Article 6 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
14 pharmacies, is amended by adding a new Code section to read as follows:

15 "26-4-120.

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

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17 (1) 'CLIA-waived' means a test system which is listed on the federal Food and Drug
18 Administration's Clinical Laboratory Improvement Assessment program data base with
19 a complexity rating of 'waived.'

20 (2) 'Dispense' shall have the same meaning as set forth in paragraph (10) of Code Section
21 26-4-5.

22 (3) 'HIV' shall have the same meaning as set forth in paragraph (10) of Code Section
23 31-22-9.1.

24 (4) 'HIV test' shall have the same meaning as set forth in paragraph (12) of Code Section
25 31-22-9.1.

26 (5) 'Licensed practitioner' means a physician licensed to practice medicine in this state
27 or an advanced practice registered nurse or physician assistant acting pursuant to
28 delegated authority by a physician in accordance with Code Section 43-34-23 or 43-34-25
29 or subsection (e.1) of Code Section 43-34-103.

30 (6) 'Pharmacist' means an individual licensed under Chapter 4 of Title 26 to engage in
31 the practice of pharmacy in the State of Georgia, who is located and practicing in the
32 State of Georgia.

33 (7) 'Postexposure prophylaxis' means any HIV prevention drug or drug combination
34 determined by the State Board of Pharmacy to meet the same clinical eligibility
35 recommendations provided in the federal Centers for Disease Control and Prevention
36 guidelines for postexposure prophylaxis for the prevention of HIV infection and other
37 infections.

38 (8) 'Preexposure prophylaxis' means any HIV prevention drug or drug combination
39 determined by the State Board of Pharmacy to meet the same clinical eligibility
40 recommendations provided in the federal Centers for Disease Control and Prevention
41 guidelines for preexposure prophylaxis for the prevention of HIV infection and other
42 infections.

43 (b) Notwithstanding any other law to the contrary, a pharmacist, pursuant to a PEP or PrEP
44 protocol agreement, is authorized to issue a PEP or PrEP order and to dispense and
45 administer preexposure prophylaxis and postexposure prophylaxis pursuant to such PEP
46 or PrEP order in accordance with this Code section and Code Section 43-34-26.2.

47 (c) Before dispensing or administering preexposure prophylaxis or postexposure
48 prophylaxis to a patient, a pharmacist shall complete a training program, accredited by the
49 Accreditation Council for Pharmacy Education or a similar health authority or professional
50 body and approved by the State Board of Pharmacy, on the use of preexposure prophylaxis
51 and postexposure prophylaxis. Such training program shall be approved no later than
52 January 1, 2027. The training program shall include, but is not limited to:

53 (1) Pharmacology education of preexposure prophylaxis and postexposure prophylaxis;

54 (2) Preexposure prophylaxis and postexposure prophylaxis and contraindicated
55 medications;

56 (3) Financial assistance programs for preexposure prophylaxis and postexposure
57 prophylaxis; and

58 (4) Relevant federal guidelines, including those issued by the federal Centers for Disease
59 Control and Prevention, regarding preexposure prophylaxis and postexposure
60 prophylaxis.

61 (d) A pharmacist shall be authorized to dispense at least a 30 day supply and up to a 90
62 day supply or administer a long-acting injectable of preexposure prophylaxis if:

63 (1) The patient is HIV negative, as documented by a test result obtained by the patient
64 within the previous seven days from an HIV antigen/antibody test or antibody-only test
65 or from a rapid point-of-care fingerstick blood test approved by the federal Food and
66 Drug Administration; provided, however, that, if the patient does not provide such a test
67 result, the pharmacist may order and administer a CLIA-waived HIV test. The results of
68 any such test shall either be sent directly to the pharmacist or verified by the pharmacist
69 prior to prescribing, dispensing, or administering the drugs;

- 70 (2) The patient does not report taking any contraindicated medications;
71 (3) The pharmacist documents, to the extent possible, the services provided by the
72 pharmacist in the patient's record in the pharmacy's record system;
73 (4) The pharmacist dispenses or administers preexposure prophylaxis to a single patient
74 pursuant to the Centers for Disease Control and Prevention clinical practice guidelines
75 for preexposure prophylaxis for the prevention of HIV infection or as directed otherwise
76 by a licensed practitioner;
77 (5) The pharmacist notifies the patient's primary care provider of any actions taken or
78 tests conducted under this subsection, or, if the patient does not have a primary care
79 provider or refuses to consent to the notification of such provider, the pharmacist shall
80 provide the patient with a list of physicians, clinics, or other healthcare service providers
81 to contact regarding ongoing care for preexposure prophylaxis; and
82 (6) The pharmacist is otherwise in compliance with the requirements of Code Section
83 43-34-26.2.
84 (e) A pharmacist shall be authorized to dispense or administer a 30 day supply of
85 postexposure prophylaxis if:
86 (1) The pharmacist, upon screening the patient, determines the patient meets the clinical
87 criteria set forth in the Centers for Disease Control and Prevention guidelines for
88 postexposure prophylaxis; and
89 (2) The pharmacist notifies the patient's primary care provider of the postexposure
90 prophylaxis treatment, or, if the patient does not have a primary care provider or refuses
91 to consent to the notification of such provider, the pharmacist shall provide the patient
92 with a list of physicians, clinics, or other healthcare service providers to contact regarding
93 follow-up care for postexposure prophylaxis."

94 **SECTION 2.**

95 Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to
96 medical practice, is amended by adding a new Code section to read as follows:

97 "43-34-26.2.

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

99 (1) 'Administer' means the provision of a unit dose of a long-acting injectable for PEP
100 or PrEP by a pharmacist or nurse pursuant to a PEP or PrEP order contained in a PEP or
101 PrEP protocol agreement with a physician.

102 (2) 'Adverse event' means an event that is a negative consequence of the administration
103 of a long-acting injectable for PEP or PrEP that results in an unintended reaction, injury,
104 or illness, which may or may not have been preventable.

105 (3) 'PEP' means any HIV prevention drug or drug combination determined by the State
106 Board of Pharmacy to meet the same clinical eligibility recommendations provided in the
107 federal Centers for Disease Control and Prevention guidelines for postexposure
108 prophylaxis for the prevention of HIV infection and other infections.

109 (4) 'PrEP' means any HIV prevention drug or drug combination determined by the State
110 Board of Pharmacy to meet the same clinical eligibility recommendations provided in the
111 federal Centers for Disease Control and Prevention guidelines for preexposure
112 prophylaxis for the prevention of HIV infection and other infections.

113 (5) 'PEP or PrEP order' means a prescription drug order, issued by a pharmacist pursuant
114 to authority delegated by a physician pursuant to a PEP or PrEP protocol agreement, for
115 a long-acting injectable for PEP or PrEP to patients who meet certain criteria.

116 (6) 'PEP or PrEP protocol agreement' means a written document mutually agreed upon
117 and signed by a physician and a pharmacist, by which document the physician delegates
118 prescriptive authority to the pharmacist to prescribe a long-acting injectable for PEP or
119 PrEP to patients who meet certain criteria determined by the physician.

120 (7) 'Pharmacist' means an individual licensed under Chapter 4 of Title 26 to engage in
121 the practice of pharmacy in the State of Georgia, who is located and practicing in the state
122 of Georgia.

123 (8) 'Pharmacy intern' means a pharmacy intern as defined in paragraph (19) of Code
124 Section 26-4-5.

125 (9) 'Physician' means an individual licensed to practice medicine and surgery pursuant
126 to this article and whose principal place of practice is located in this state.

127 (b) A physician engaged in the active practice of medicine may prescribe a long-acting
128 injectable for PEP or PrEP for a group of patients via a PEP or PrEP order contained in a
129 PEP or PrEP protocol agreement to be administered by a pharmacist, provided that the
130 physician resides in Georgia and the pharmacist holds current certification in Basic Cardiac
131 Life Support.

132 (c) A PEP or PrEP protocol agreement between a physician and a pharmacist pursuant to
133 this Code section shall, without limitation:

134 (1) Contain the current names, addresses, telephone numbers, and professional license
135 numbers of the physician and the pharmacist;

136 (2) Contain a provision for immediate consultation between the pharmacist and the
137 physician. If the physician is not available, the physician for purposes of consultation
138 may designate another physician who concurs with the terms of the PEP or PrEP protocol
139 agreement;

140 (3) Require the pharmacist to take an appropriate case history and determine whether the
141 patient has had a physical examination within the past year and shall not administer a
142 long-acting injectable for PEP or PrEP to a patient with any condition for which such
143 long-acting injectable for PEP or PrEP is contraindicated;

144 (4) Require the pharmacist to provide the recipient with the appropriate and current PEP
145 or PrEP information;

- 146 (5) Require the pharmacist to provide written information to the recipient to be
147 developed by the Department of Public Health on the importance of having and
148 periodically seeing a primary care physician;
- 149 (6) Require the pharmacist or his or her employer to retain documentation of each dose
150 of PEP or PrEP administered. Such documentation shall include, but not be limited to:
- 151 (A) The administering pharmacist's name, address, telephone number, and professional
152 license number;
- 153 (B) The name, dose, manufacturer, and lot number of the long-acting injectable for
154 PEP or PrEP;
- 155 (C) The recipient's name, address, date of birth, and telephone number;
- 156 (D) The date of administration and injection site;
- 157 (E) A signed and dated consent form by which the recipient consents to the
158 administration of the long-acting injectable for PEP or PrEP and authorizes the
159 pharmacy or nurse to notify the recipient's primary care provider of the long-acting
160 injectable for PEP or PrEP administered to the recipient; and
- 161 (F) Any adverse events or complications that occur;
- 162 (7) Require the pharmacist to make documented reasonable efforts to obtain the name
163 of the recipient's primary care provider and to notify such primary care provider of the
164 long-acting injectable for PEP or PrEP administered by the pharmacist within 72 hours
165 of administration;
- 166 (8) Require the pharmacist to administer the long-acting injectable for PEP or PrEP to
167 a patient in a private room, area with a privacy screen, or other interior area in which the
168 patient's privacy can be maintained. In no event shall a pharmacist administer a
169 long-acting injectable for PEP or PrEP to a patient in a manner that is designed so that
170 the patient can be served while remaining in his or her personal vehicle;
- 171 (9) Require, as a condition of administration of the long-acting injectable for PEP or
172 PrEP, the recipient to remain under the observation of a pharmacist for a period of not

173 less than 15 minutes immediately subsequent to the administration of the long-acting
174 injectable for PEP or PrEP;
175 (10) Contain procedures to follow up on the occurrence of an adverse event or
176 complication;
177 (11) Require the pharmacist to maintain individual liability insurance coverage or be
178 individually covered by his or her employer's liability insurance coverage in an amount
179 not less than \$250,000.00 to cover claims arising from administration of long-acting
180 injectables for PEP or PrEP by the pharmacist pursuant to a PEP or PrEP protocol
181 agreement and to provide proof of such coverage to the physician for submission to the
182 board with the PEP or PrEP protocol agreement. The pharmacist shall also retain a copy
183 of the proof of insurance coverage, including the name of the insurer and policy number,
184 on site at his or her primary location in such form as it may be readily accessible for
185 inspection by the Georgia Drugs and Narcotics Agency, upon request;
186 (12) Require the pharmacist to post proof of the PEP or PrEP protocol agreement in a
187 conspicuous location within the pharmacy or other setting in which the long-acting
188 injectables for PEP or PrEP are being administered;
189 (13) Require the pharmacist to submit a signed and notarized affidavit to the physician
190 for submission to the board with the PEP or PrEP protocol agreement attesting to the
191 following:
192 (A) Compliance with paragraph (11) of this subsection regarding maintenance of
193 liability insurance;
194 (B) Verification that the pharmacist holds current certification in Basic Cardiac Life
195 Support as required by subsection (b) of this Code section;
196 (C) The pharmacist has a copy of the PEP or PrEP protocol agreement and agrees to
197 comply with its requirements; and

198 (D) Identification of the pharmacist's location or locations in which he or she will be
199 administering long-acting injectables for PEP or PrEP pursuant to the PEP or PrEP
200 protocol agreement.

201 The pharmacist shall keep a copy of the affidavit on site at his or her primary location for
202 inspection by the State Board of Pharmacy or agents of the Georgia Drugs and Narcotics
203 Agency, upon request. The State Board of Pharmacy shall have the authority to impose
204 sanctions in accordance with subsection (n) of this Code section on any pharmacist
205 subject to the requirements of this paragraph who does not submit the information
206 required by this paragraph and to notify the delegating physician and the applicable
207 licensing board for such person of violations of this paragraph; and

208 (14) Be renewed and, if necessary, revised or updated biennially by the physician and
209 the pharmacist. A PEP or PrEP protocol agreement that is not renewed biennially shall
210 expire.

211 (d)(1) A pharmacist who is a party to a PEP or PrEP protocol agreement pursuant to this
212 Code section shall not delegate the administration of a long-acting injectable for PEP or
213 PrEP to any individual other than:

214 (A) A pharmacy intern; or

215 (B) A qualified pharmacy technician in accordance with paragraph (2) of this
216 subsection.

217 under the direct supervision of the pharmacist whether or not any such other individual
218 is under the supervision, direct or otherwise, of the pharmacist.

219 (2) A pharmacist who is a party to a PEP or PrEP protocol agreement pursuant to this
220 Code section may authorize one or more qualified pharmacy technicians to administer
221 long-acting injectables for PEP or PrEP pursuant to Code Section 26-4-52 so long as:

222 (A) The physician with whom the PEP or PrEP protocol agreement is entered into has
223 approved such authorization; and

224 (B) Such authorization is included in the PEP or PrEP protocol agreement between the
225 physician and pharmacist.

226 (e) A pharmacist administering long-acting injectables for PEP or PrEP pursuant to a PEP
227 or PrEP protocol agreement authorized by this Code section shall maintain policies and
228 procedures for the handling and disposal of used or contaminated equipment and supplies.

229 (f) Nothing in this Code section shall be construed to authorize a physician to prescribe
230 any other drugs pursuant to a PEP or PrEP protocol agreement or a PEP or PrEP order
231 other than those long-acting injectables for PEP or PrEP specifically authorized in such
232 PEP or PrEP protocol agreement or PEP or PrEP order.

233 (g) A delegating physician may not enter into a PEP or PrEP protocol agreement with
234 more than ten pharmacists at any one time.

235 (h) It shall be unlawful for a physician who is employed by a pharmacist to enter into a
236 PEP or PrEP protocol agreement or otherwise delegate medical acts to such pharmacist.
237 It shall be unlawful for a physician who is employed by a pharmacy to enter into a PEP or
238 PrEP protocol agreement or otherwise delegate medical acts to a pharmacist who is also
239 employed by such pharmacy.

240 (i) The board shall have the authority to promulgate rules and regulations governing a
241 physician who is a party to a PEP or PrEP protocol agreement in order to carry out the
242 intent and purposes of this Code section. Further, the board shall:

243 (1) Require that the PEP or PrEP protocol agreement, along with the affidavit by the
244 pharmacist submitted pursuant to paragraph (13) of subsection (c) of this Code section
245 and the proof of insurance required pursuant to paragraph (11) of subsection (c) of this
246 Code section, be filed by the physician with the board and be made available by the board
247 for public inspection; and

248 (2) Promulgate by rule an approved standard protocol template that may be utilized as
249 a PEP or PrEP protocol agreement and make such template available on the board's
250 website.

251 (j) Nothing in this Code section shall be construed to require a physician to enter into a
252 PEP or PrEP protocol agreement. A public or private managed care system, health plan,
253 hospital, insurance company, or similar entity shall not require a physician, pharmacist, or
254 nurse to enter into a PEP or PrEP protocol agreement as a condition for participation in or
255 reimbursement from such entity.

256 (k) No physician who complies with the provisions of this Code section shall be subject
257 to criminal or civil liability or discipline for unprofessional conduct for:

258 (1) Entering into a PEP or PrEP protocol agreement with a pharmacist;

259 (2) The acts or omissions of a pharmacist to whom prescriptive authority has been
260 delegated in the issuance of a PEP or PrEP order contained in a PEP or PrEP protocol
261 agreement with a pharmacist; or

262 (3) The acts or omissions of a pharmacist pursuant to a PEP or PrEP protocol agreement
263 including the administration of a long-acting injectable for PEP or PrEP.

264 Nothing in this subsection shall be interpreted as altering liability of an employer for acts
265 of his or her employees.

266 (l) This Code section shall not apply to any activities conducted by a hospital, physician's
267 office, nursing home, or other healthcare facility designated by the Department of Public
268 Health or conducted within any other facility or entity owned, operated, or leased by a
269 hospital.

270 (m) This Code section shall not be interpreted as limiting the authority of any authorized
271 person to dispense or administer long-acting injectables for PEP or PrEP.

272 (n)(1) A pharmacist who fails to comply with paragraph (11) of subsection (c) of this
273 Code section may be assessed a fine of up to \$2,500.00 by the State Board of Pharmacy.

274 (2) A pharmacist who administers a long-acting injectable for PEP or PrEP without a
275 PEP or PrEP protocol agreement as required by this Code section may be assessed a fine
276 of up to \$2,500.00 and may be prohibited from administering long-acting injectables for

277 PEP or PrEP pursuant to this Code section for up to one year as determined by the State
278 Board of Pharmacy.

279 (3) A pharmacist who fails to comply with paragraph (5) of subsection (c) of this Code
280 section may be subject to any or all of the following sanctions by the State Board of
281 Pharmacy:

282 (A) The issuance of a written warning;

283 (B) A fine of up to \$500.00; and

284 (C) Prohibition from administering long-acting injectables for PEP or PrEP pursuant
285 to this Code section for up to one year.

286 (4) A pharmacist who fails to comply with paragraph (12) of subsection (c) of this Code
287 section may be subject to any or all of the following sanctions by the State Board of
288 Pharmacy:

289 (A) The issuance of a written warning; and

290 (B) Prohibition from administering long-acting injectables for PEP or PrEP pursuant
291 to this Code section for up to six months.

292 (5) A pharmacist who fails to comply with paragraph (13) of subsection (c) of this Code
293 section may be subject to any or all of the following sanctions by the State Board of
294 Pharmacy:

295 (A) The issuance of a written warning;

296 (B) A fine of up to \$5,000.00; and

297 (C) Prohibition from administering long-acting injectables for PEP or PrEP pursuant
298 to this Code section.

299 (6) The sanctions contained in this subsection shall be supplemental to any other
300 sanctions or penalties to which a pharmacist may otherwise be subject."

301 **SECTION 3.**

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