

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

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 Georgia State Board of Pharmacy; to require pharmacists to complete
7 such training program before dispensing preexposure prophylaxis or postexposure
8 prophylaxis; to provide for patient requirements; to provide for limitations and conditions;
9 to provide for sanctions; to provide for definitions; to provide for related matters; to repeal
10 conflicting laws; 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:

- 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' means to issue one or more doses of a drug in a suitable container with
21 appropriate labeling for subsequent administration to, or use by, a patient.
- 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) 'Postexposure prophylaxis' means any HIV prevention drug or drug combination
31 determined by the Georgia State Board of Pharmacy to meet the clinical eligibility
32 recommendations provided in the federal Centers for Disease Control and Prevention
33 guidelines for postexposure prophylaxis for the prevention of HIV infection and other
34 infections.
- 35 (7) 'Preexposure prophylaxis' means any HIV prevention drug or drug combination
36 determined by the Georgia State Board of Pharmacy to meet the same clinical eligibility
37 recommendations provided in the federal Centers for Disease Control and Prevention
38 guidelines for preexposure prophylaxis for the prevention of HIV infection and other
39 infections.
- 40 (b) Notwithstanding any other law to the contrary, a pharmacist is authorized to dispense
41 and administer preexposure prophylaxis and postexposure prophylaxis without a
42 prescription from a licensed practitioner in accordance with this Code section.

43 (c) Before dispensing or administering preexposure prophylaxis or postexposure
44 prophylaxis to a patient, a pharmacist shall complete a training program, accredited by the
45 Accreditation Council for Pharmacy Education or a similar health authority or professional
46 body and approved by the Georgia State Board of Pharmacy, on the use of preexposure
47 prophylaxis and postexposure prophylaxis. Such training program shall be approved no
48 later than January 1, 2026. The training program shall include, but is not limited to:

- 49 (1) Pharmacology education of preexposure prophylaxis and postexposure prophylaxis;
50 (2) Preexposure prophylaxis and postexposure prophylaxis and contraindicated
51 medications;
52 (3) Financial assistance programs for preexposure prophylaxis and postexposure
53 prophylaxis; and
54 (4) Relevant federal guidelines, including those issued by the federal Centers for Disease
55 Control and Prevention, regarding preexposure prophylaxis and postexposure
56 prophylaxis.

57 (d) A pharmacist shall be authorized to dispense at least a 30 day supply and up to a 60
58 day supply or administer a long-acting injectable of preexposure prophylaxis if:

- 59 (1) The patient is HIV negative, as documented by a test result obtained by the patient
60 within the previous seven days from an HIV antigen/antibody test or antibody-only test
61 or from a rapid point-of-care fingerstick blood test approved by the federal Food and
62 Drug Administration; provided, however, that, if the patient does not provide such a test
63 result, the pharmacist may order and administer a CLIA-waived HIV test. The results of
64 any such test shall either be sent directly to the pharmacist or verified by the pharmacist
65 prior to prescribing, dispensing, or administering the drugs;
66 (2) The patient does not report taking any contraindicated medications;
67 (3) The pharmacist documents, to the extent possible, the services provided by the
68 pharmacist in the patient's record in the pharmacy's record system;

69 (4) The pharmacist dispenses or administers preexposure prophylaxis to a single patient
70 pursuant to Centers for Disease Control and Prevention clinical practice guidelines for
71 preexposure prophylaxis for the prevention of HIV infection or as directed otherwise by
72 a licensed practitioner;

73 (5) The pharmacist notifies the patient's primary care provider of any actions taken or
74 tests conducted under this subsection, or, if the patient does not have a primary care
75 provider or refuses to consent to the notification of such provider, the pharmacist shall
76 provide the patient with a list of physicians, clinics, or other healthcare service providers
77 to contact regarding ongoing care for preexposure prophylaxis; and

78 (6) The pharmacist is otherwise in compliance with the requirements of Code Section
79 43-34-26.2.

80 (e) A pharmacist shall be authorized to dispense or administer a 28 day supply of
81 postexposure prophylaxis if:

82 (1) The pharmacist, upon screening the patient, determines the patient meets the clinical
83 criteria set forth in the Centers for Disease Control and Prevention guidelines for
84 postexposure prophylaxis; and

85 (2) The pharmacist notifies the patient's primary care provider of the postexposure
86 prophylaxis treatment, or, if the patient does not have a primary care provider or refuses
87 to consent to the notification of such provider, the pharmacist shall provide the patient
88 with a list of physicians, clinics, or other healthcare service providers to contact regarding
89 follow-up care for postexposure prophylaxis."

90 **SECTION 2.**

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

93 "43-34-26.2.

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

- 95 (1) 'Administer' means the provision of a unit dose of a long-acting injectable for PEP
96 or PrEP by a pharmacist or nurse pursuant to a PEP or PrEP order contained in a PEP or
97 PrEP protocol agreement with a physician.
- 98 (2) 'Adverse event' means an event that is a negative consequence of the administration
99 of a long-acting injectable for PEP or PrEP by a pharmacist that results in an unintended
100 reaction, injury, or illness, which may or may not have been preventable.
- 101 (3) 'PEP' means any HIV prevention drug or drug combination determined by the
102 Georgia State Board of Pharmacy to meet the clinical eligibility recommendations
103 provided in the federal Centers for Disease Control and Prevention guidelines for
104 postexposure prophylaxis for the prevention of HIV infection and other infections.
- 105 (4) 'PrEP' means any HIV prevention drug or drug combination determined by the
106 Georgia State Board of Pharmacy to meet the same clinical eligibility recommendations
107 provided in the federal Centers for Disease Control and Prevention guidelines for
108 preexposure prophylaxis for the prevention of HIV infection and other infections.
- 109 (5) 'PEP or PrEP order' means a prescription drug order, contained in a PEP or PrEP
110 protocol agreement, for a long-acting injectable for PEP or PrEP issued by a physician
111 for a group of patients who meet certain criteria and to be administered by a pharmacist.
- 112 (6) 'PEP or PrEP protocol agreement' means a written document mutually agreed upon
113 and signed by a physician and a pharmacist, by which document the physician prescribes
114 a long-acting injectable for PEP or PrEP, if determined appropriate by the physician, by
115 means of a PEP or PrEP order for administration by a pharmacist.
- 116 (7) 'Pharmacist' means an individual licensed under Chapter 4 of Title 26 to engage in
117 the practice of pharmacy in the State of Georgia.
- 118 (8) 'Pharmacy intern' means a pharmacy intern as defined in paragraph (19) of Code
119 Section 26-4-5.
- 120 (9) 'Physician' means an individual licensed to practice medicine and surgery pursuant
121 to this article and whose principal place of practice is located in this state.

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

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

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

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

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

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

141 (5) Require the pharmacist to provide written information to the recipient to be
142 developed by the Department of Public Health on the importance of having and
143 periodically seeing a primary care physician;

144 (6) Require the pharmacist or his or her employer to retain documentation of each dose
145 of PEP or PrEP administered. Such documentation shall include, but not be limited to:

146 (A) The administering pharmacist's name, address, telephone number, and professional
147 license number;

- 148 (B) The name, dose, manufacturer, and lot number of the long-acting injectable for
149 PEP or PrEP;
- 150 (C) The recipient's name, address, date of birth, and telephone number;
- 151 (D) The date of administration and injection site;
- 152 (E) A signed and dated consent form by which the recipient consents to the
153 administration of the long-acting injectable for PEP or PrEP and authorizes the
154 pharmacy or nurse to notify the recipient's primary care provider of the long-acting
155 injectable for PEP or PrEP administered to the recipient; and
- 156 (F) Any adverse events or complications that occur;
- 157 (7) Require the pharmacist to make documented reasonable efforts to obtain the name
158 of the recipient's primary care provider and to notify such primary care provider of the
159 long-acting injectable for PEP or PrEP administered by the pharmacist within 72 hours
160 of administration;
- 161 (8) Require the pharmacist to administer the long-acting injectable for PEP or PrEP to
162 a patient in a private room, area with a privacy screen, or other interior area in which the
163 patient's privacy can be maintained. In no event shall a pharmacist administer a
164 long-acting injectable for PEP or PrEP to a patient in a manner that is designed so that
165 the patient can be served while remaining in his or her personal vehicle;
- 166 (9) Require, as a condition of administration of the long-acting injectable for PEP or
167 PrEP, the recipient to remain under the observation of a pharmacist for a period of not
168 less than 15 minutes immediately subsequent to the administration of the long-acting
169 injectable for PEP or PrEP;
- 170 (10) Contain procedures to follow up on the occurrence of an adverse event or
171 complication;
- 172 (11) Require the pharmacist to maintain individual liability insurance coverage or be
173 individually covered by his or her employer's liability insurance coverage in an amount
174 not less than \$250,000.00 to cover claims arising from administration of long-acting

175 injectables for PEP or PrEP by the pharmacist pursuant to a PEP or PrEP protocol
176 agreement and to provide proof of such coverage to the physician for submission to the
177 board with the PEP or PrEP protocol agreement. The pharmacist shall also retain a copy
178 of the proof of insurance coverage, including the name of the insurer and policy number,
179 on site at his or her primary location for inspection by the Georgia Drugs and Narcotics
180 Agency, upon request;

181 (12) Require the pharmacist to post proof of the PEP or PrEP protocol agreement in a
182 conspicuous location within the pharmacy or other setting in which the long-acting
183 injectables for PEP or PrEP is being administered;

184 (13) Require the pharmacist to submit a signed and notarized affidavit to the physician
185 attesting to the following:

186 (A) Compliance with paragraph (11) of this subsection regarding maintenance of
187 liability insurance;

188 (B) Verification that the pharmacist holds current certification in Basic Cardiac Life
189 Support as required by subsection (b) of this Code section;

190 (C) The pharmacist has a copy of the PEP or PrEP protocol agreement and agrees to
191 comply with its requirements; and

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

195 The pharmacist shall keep a copy of the affidavit on site at his or her primary location for
196 inspection by the Georgia Drugs and Narcotics Agency upon request. The Georgia Drugs
197 and Narcotics Agency shall have the authority to impose sanctions in accordance with
198 subsection (n) of this Code section on any pharmacist subject to the requirements of this
199 paragraph who does not submit the information required by this paragraph and to notify
200 the delegating physician and the applicable licensing board for such person of violations
201 of this paragraph; and

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

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

208 (A) A pharmacy intern; or

209 (B) A qualified pharmacy technician in accordance with paragraph (2) of this
210 subsection,

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

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

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

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

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

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

227 (g) A delegating physician may not enter into a PEP or PrEP protocol agreement with
228 more than ten pharmacists at any one time; provided, however, a delegating physician may

229 enter into a PEP or PrEP protocol agreement with more than ten pharmacists at any one
230 time so long as the pharmacists are employees or agents of the same corporate entity.

231 (h) It shall be unlawful for a physician who is employed by a pharmacist to enter into a
232 PEP or PrEP protocol agreement or otherwise delegate medical acts to such pharmacist.

233 It shall be unlawful for a physician who is employed by a pharmacy to enter into a PEP or
234 PrEP protocol agreement or otherwise delegate medical acts to a pharmacist who is also
235 employed by such pharmacy.

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

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

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

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

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

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

255 (2) Issuing a PEP or PrEP order contained in a PEP or PrEP protocol agreement with a
256 pharmacist; or

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

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

261 (l) This Code section shall not apply to any activities conducted by a hospital, physician's
262 office, nursing home, or other health care facility designated by the Department of Public
263 Health or conducted within any other facility or entity owned, operated, or leased by a
264 hospital.

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

267 (n)(1) A pharmacist who knowingly does not comply with paragraph (11) of
268 subsection (c) of this Code section may be assessed a fine of up to \$2,500.00 by the
269 board.

270 (2) A pharmacist who knowingly administers a long-acting injectable for PEP or PrEP
271 without a PEP or PrEP protocol agreement as required by this Code section may be
272 assessed a fine of up to \$2,500.00 and may be prohibited from administering long-acting
273 injectables for PEP or PrEP pursuant to this Code section for up to one year as
274 determined by the board.

275 (3) A pharmacist who knowingly does not comply with paragraph (5) of subsection (c)
276 of this Code section may be subject to the following sanctions by the board:

277 (A) Upon the first violation, the issuance of a warning;

278 (B) Upon the second violation, a fine of up to \$500.00; and

279 (C) Upon a third or subsequent violation, prohibition from administering long-acting
280 injectables for PEP or PrEP pursuant to this Code section for up to one year.

281 (4) A pharmacist who knowingly does not comply with paragraph (12) of subsection (c)
282 of this Code section may be subject to the following sanctions by the board:

283 (A) Upon the first or second violation, the issuance of a warning; and

284 (B) Upon a third or subsequent violation, prohibition from administering long-acting
285 injectables for PEP or PrEP pursuant to this Code section for up to six months.

286 (5) A pharmacist who knowingly does not comply with paragraph (13) of subsection (c)
287 of this Code section may be subject to the following sanctions by the Georgia Drugs and
288 Narcotics Agency:

289 (A) Upon the first violation, the issuance of a warning;

290 (B) Upon the second violation, a fine of up to \$5,000.00; and

291 (C) Upon a third or subsequent violation, prohibition from administering long-acting
292 injectables for PEP or PrEP pursuant to this Code section.

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

295 **SECTION 3.**

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