

The Senate Committee on Health and Human Services offers the following substitute to HB 504:

A BILL TO BE ENTITLED
AN ACT

1 To amend Code Section 31-12-3.2 of the Official Code of Georgia Annotated, relating to
2 meningococcal disease vaccinations and disclosures, so as to revise provisions regarding
3 vaccination against meningococcal disease of college students; to amend Article 2 of Chapter
4 34 of Title 43 of the Official Code of Georgia Annotated, relating to physicians, so as to
5 authorize the administration of vaccines by pharmacists or nurses pursuant to vaccine
6 protocol agreements with physicians; to provide for definitions; to provide requirements for
7 the content of vaccine protocol agreements; to provide that a party to a vaccine protocol
8 agreement shall not delegate his or her authority; to limit the number of vaccine protocol
9 agreements into which a physician may enter at any one time; to prohibit certain entities from
10 entering into vaccine protocol agreements; to provide for rules and regulations; to provide
11 for limited liability; to provide for applicability; to provide for statutory construction; to
12 provide for related matters; to repeal conflicting laws; and for other purposes.

13 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

14 Code Section 31-12-3.2 of the Official Code of Georgia Annotated, relating to
15 meningococcal disease vaccinations and disclosures, is amended by revising subsection (b)
16 as follows:
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18 "(b) In accordance with the recommendations of the Advisory Committee on Immunization
19 Practices of the Centers for Disease Control and Prevention, newly admitted students
20 Students who are 18 years of age or older residing in campus housing as defined by the
21 postsecondary educational institution or residing in sorority or fraternity houses shall be
22 required to sign a document provided by the postsecondary educational institution stating
23 that he or she has received a vaccination against meningococcal disease not more than five
24 years prior to such admittance or reviewed the information provided as required by
25 subsection (a) of this Code section. If a student is a minor, only a parent or guardian may
26 sign such document."

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SECTION 2.

Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to physicians, is amended by revising Code Section 43-34-26.1, relating to influenza vaccine protocol agreements, as follows:

"43-34-26.1.

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

(1) 'Administer' means the provision of a unit dose of ~~influenza~~ vaccine by a pharmacist or nurse pursuant to ~~an influenza a~~ vaccine order contained in ~~an influenza a~~ vaccine protocol agreement with a physician.

(2) 'Adverse event' means an event that is a negative consequence of the administration of ~~influenza~~ vaccine by a pharmacist or nurse that results in an unintended reaction, injury, or illness, which may or may not have been preventable.

(3) 'Board' means the Georgia Composite Medical Board.

(4) 'Nurse' means a registered professional nurse as defined in paragraph (9) of Code Section 43-26-3. The term shall also mean a licensed practical nurse as defined in paragraph (5) of Code Section 43-26-32 who is regularly employed by a physician engaged in the active practice of medicine.

(5) 'Pharmacist' means an individual licensed under Chapter 4 of Title 26 to engage in the practice of pharmacy in the State of Georgia.

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

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

~~(4)(8) 'Vaccine' 'Influenza vaccine' means an inactivated virus administered by injection or a live attenuated virus administered by nasal spray that is prepared for the applicable season and that is administered to produce or increase a specially prepared antigen which upon administration to a person will result in immunity to influenza, pneumococcal disease, shingles, or meningitis. to the influenza virus, provided, however, that a live attenuated virus shall not be administered pursuant to this Code section to any individual younger than 13 or older than 49 years of age; and provided, further, that a No live attenuated virus shall not be administered pursuant to this Code section unless the patient or his or her parent, if a minor, has signed an informed consent that he or she does not have a contraindication to this vaccine. The informed consent form shall list the contraindications to the vaccine.~~

~~(5)(9) 'Vaccine order' 'Influenza vaccine order' means a prescription drug order, contained in an influenza a vaccine protocol agreement, for influenza a vaccine issued by a physician for a group of patients who meet certain criteria and to be administered by a~~

64 pharmacist or a nurse. ~~An influenza~~ A vaccine order shall also mean a prescription drug
 65 order, contained in ~~an influenza~~ a vaccine protocol agreement, for epinephrine issued by
 66 a physician for a group of patients who meet certain criteria and to be administered by a
 67 pharmacist or a nurse only upon the occurrence of an actual or perceived anaphylactic
 68 adverse reaction to the administered ~~influenza~~ vaccine provided that the ~~influenza~~ vaccine
 69 protocol agreement sets forth the signs and symptoms that warrant the administration of
 70 epinephrine.

71 ~~(6)(10) 'Vaccine protocol agreement'~~ ~~'Influenza vaccine protocol agreement'~~ means a
 72 written document mutually agreed upon and signed by a physician and a pharmacist or
 73 by a physician and a nurse, by which document the physician prescribes ~~influenza~~ a
 74 vaccine and epinephrine, if determined appropriate by the physician, by means of ~~an~~
 75 ~~influenza~~ a vaccine order for administration by a pharmacist or a nurse.

76 ~~(7) 'Nurse' means a registered professional nurse as defined in paragraph (9) of Code~~
 77 ~~Section 43-26-3. The term shall also mean a licensed practical nurse as defined in~~
 78 ~~paragraph (5) of Code Section 43-26-32 who is regularly employed by a physician who~~
 79 ~~actively engaged in the private practice of medicine.~~

80 ~~(8) 'Pharmacist' means an individual licensed under Chapter 4 of Title 26 to engage in~~
 81 ~~the practice of pharmacy in the State of Georgia.~~

82 ~~(9) 'Pharmacy intern' means a pharmacy intern as defined in paragraph (19) of Code~~
 83 ~~Section 26-4-5.~~

84 ~~(10) 'Physician' means an individual licensed to practice medicine and surgery pursuant~~
 85 ~~to this article and whose principal place of practice is located in this state.~~

86 (b) A physician engaged in the active practice of medicine may prescribe ~~influenza~~ a
 87 vaccine for a group of patients via ~~an influenza~~ a vaccine order contained in ~~an influenza~~
 88 a vaccine protocol agreement to be administered by a pharmacist, provided the physician
 89 is registered with the vaccination registry established by the Department of Public Health
 90 pursuant to Code Section 31-12-3.1, commonly known as the Georgia Registry of
 91 Immunization Transactions and Services; ~~;~~ the pharmacist is located within the county of
 92 the physician's place of registration with the vaccination registry or a county contiguous
 93 thereto; ~~and;~~ the pharmacist holds current certification in Basic Cardiac Life Support and
 94 has completed a course of training accredited by the Accreditation Council for Pharmacy
 95 Education or similar health authority or professional body approved by the Georgia State
 96 Board of Pharmacy; ~~and the pharmacist completes a training program recognized by the~~
 97 Centers for Disease Control and Prevention in the basics of immunology which focuses on
 98 practice implementation and legal and regulatory issues, composed of: (1) at least 12 hours
 99 of self-study and an assessment exam; (2) at least eight hours of live seminar with a final
 100 exam; and (3) a hands-on assessment of intramuscular and subcutaneous injection

101 technique. A physician who is a party to an ~~influenza~~ a vaccine protocol agreement may
 102 also prescribe epinephrine via an ~~influenza~~ a vaccine order contained in an ~~influenza~~ a
 103 vaccine protocol agreement for administration by a pharmacist upon the occurrence of an
 104 actual or perceived anaphylactic adverse reaction to the administered ~~influenza~~ vaccine
 105 provided that the ~~influenza~~ vaccine protocol agreement sets forth the signs and symptoms
 106 that warrant the administration of epinephrine.

107 (c) A physician engaged in the active practice of medicine may prescribe ~~influenza~~ a
 108 vaccine for a group of patients via an ~~influenza~~ a vaccine order contained in an ~~influenza~~
 109 a vaccine protocol agreement to be administered by a nurse, provided the physician is
 110 registered with the vaccination registry established by the Department of Public Health
 111 pursuant to Code Section 31-12-3.1, commonly known as the Georgia Registry of
 112 Immunization Transactions and Services, the nurse is located within the county of the
 113 physician's place of registration with the vaccination registry or a county contiguous
 114 thereto, and the nurse holds current certification in Basic Cardiac Life Support. A
 115 physician who is a party to an ~~influenza~~ a vaccine protocol agreement may also prescribe
 116 epinephrine via an ~~influenza~~ a vaccine order contained in an ~~influenza~~ a vaccine protocol
 117 agreement for administration by a nurse upon the occurrence of an actual or perceived
 118 anaphylactic adverse reaction to the administered ~~influenza~~ vaccine provided that the
 119 ~~influenza~~ vaccine protocol agreement sets forth the signs and symptoms that warrant the
 120 administration of epinephrine.

121 (d) A ~~An~~ ~~influenza~~ vaccine protocol agreement between a physician and a pharmacist or
 122 a physician and a nurse pursuant to this Code section shall, without limitation:

123 (1) Contain the current names, addresses, telephone numbers, and professional license
 124 numbers of the physician and the pharmacist or nurse;

125 (2) Contain a provision for immediate consultation between the pharmacist or nurse and
 126 the physician. If the physician is not available, the physician for purposes of consultation
 127 may designate another physician who concurs with the terms of the ~~influenza~~ vaccine
 128 protocol agreement;

129 (3) Require the pharmacist or nurse to take a complete case history and determine
 130 whether the patient has had a physical examination within the past year and shall not
 131 administer a vaccine to a patient with any condition for which such vaccine is
 132 contraindicated;

133 ~~(3)~~(4) Require the pharmacist or nurse to provide the ~~influenza~~ vaccine recipient with the
 134 appropriate and current Vaccine Information Statement (~~VIS~~) as provided by the ~~federal~~
 135 Centers for Disease Control and Prevention;

136 (5) Require the pharmacist or nurse to provide written information to the vaccine
 137 recipient to be developed by the Department of Public Health on the importance of
 138 having and periodically seeing a primary care physician;

139 (6) Require the pharmacist or nurse to provide each new vaccine recipient with a
 140 personal immunization card on card stock paper containing the vaccine recipient's name,
 141 the pharmacist's or nurse's name and phone number, the name and dosage of the vaccine,
 142 the location of injection on the vaccine recipient, and the date of the administration of the
 143 vaccine in legible writing or printed type in a format made available by the Department
 144 of Public Health. The patient shall produce such card when he or she has subsequent
 145 vaccines and the pharmacist or nurse shall update such card, unless the patient does not
 146 have such card, in which case, a new card shall be provided. The written information
 147 required pursuant to paragraph (5) of this subsection may be included on the card
 148 provided pursuant to this paragraph;

149 ~~(4)~~(7) Require the pharmacist or nurse or his or her employer to retain documentation
 150 of each dose of influenza vaccine administered. Such documentation shall include, but
 151 not be limited to:

152 (A) The administering pharmacist's or nurse's name, address, telephone number, and
 153 professional license number;

154 (B) The name, dose, manufacturer, and lot number of the influenza vaccine;

155 (C) The vaccine 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 vaccine recipient acknowledges
 158 receipt of the ~~VIS~~ Vaccine Information Statement, and consents to the administration
 159 of the influenza vaccine, and authorizes the pharmacy or nurse to notify the vaccine
 160 recipient's primary care provider of the vaccine administered to the vaccine recipient;
 161 and

162 (F) Any adverse events or complications that occur;

163 (8) Require the pharmacist or nurse to make documented reasonable efforts to obtain the
 164 name of the vaccine recipient's primary care provider and to notify such primary care
 165 provider of the vaccine administered by the pharmacist or nurse within 72 hours of
 166 administration;

167 (9) Require the pharmacist or nurse to administer the vaccine to a patient in a private
 168 room, area with a privacy screen, or other interior area in which the patient's privacy can
 169 be maintained. In no event shall a pharmacist or nurse administer a vaccine to a patient
 170 in a manner that is designed so that the patient can be served while remaining in his or
 171 her personal vehicle. This paragraph shall not apply to mass immunizations in the event

172 of a public health emergency or for purposes of training in which vaccinations are
 173 administered to large groups of people at one or more locations in a short interval of time;
 174 ~~(5)~~(10) Require the pharmacist or nurse to enter the patient's influenza vaccine
 175 information in the Georgia Registry of Immunization Transactions and Services within
 176 the registry's designated time frame, or as designated by the Department of Public Health.
 177 The Georgia Drugs and Narcotics Agency shall have the authority to impose sanctions
 178 in accordance with subsection (r) of this Code section on any person subject to the
 179 requirements of this paragraph who does not submit the information required by this
 180 paragraph and to notify the delegating physician and the applicable licensing board for
 181 such person of violations of this paragraph;
 182 ~~(6)~~(11) Require, as a condition of administration of the influenza vaccine, the influenza
 183 vaccine recipient to remain under the observation of the administering pharmacist or
 184 nurse for a period of not less than 15 minutes immediately subsequent to the
 185 administration of the influenza vaccine;
 186 ~~(7)~~(12) Contain procedures to follow up on the occurrence of an adverse event or
 187 complication including, if prescribed via an influenza a vaccine order contained in an
 188 influenza a vaccine protocol agreement, the administration of epinephrine;
 189 ~~(8)~~(13) Provide for prioritization of influenza vaccine recipients in the event the supply
 190 of influenza a vaccine is limited; and
 191 (14) Require the pharmacist or nurse to maintain individual liability insurance coverage
 192 or be individually covered by his or her employer's liability insurance coverage in an
 193 amount not less than \$250,000.00 to cover claims arising from administration of vaccines
 194 by the pharmacist or nurse pursuant to a vaccine protocol agreement and to provide proof
 195 of such coverage to the physician for submission to the board with the vaccine protocol
 196 agreement. The pharmacist or nurse shall also retain a copy of the proof of insurance
 197 coverage, including the name of the insurer and policy number, onsite at his or her
 198 primary location for inspection by the Georgia Drugs and Narcotics Agency, upon
 199 request;
 200 (15) Require the pharmacist or nurse to post proof of the vaccine protocol agreement,
 201 including a list of the vaccines authorized by such protocol, in a conspicuous location
 202 within the pharmacy, local health department, or other setting in which the vaccine is
 203 being administered;
 204 (16) Require the pharmacist or nurse to submit a signed and notarized affidavit to the
 205 physician attesting to the following:
 206 (A) Compliance with paragraph (14) of this subsection regarding maintenance of
 207 liability insurance;

208 (B) Verification that the pharmacist or nurse holds current certification in Basic
 209 Cardiac Life Support as required by subsections (b) and (c) of this Code section and,
 210 for pharmacists, verification of completion of immunology training as required by
 211 subsection (b) of this Code section;

212 (C) The pharmacist or nurse has a copy of the vaccine protocol agreement and agrees
 213 to comply with its requirements; and

214 (D) Identification of the pharmacist's or nurse's location or locations in which he or she
 215 will be administering vaccinations pursuant to the vaccine protocol agreement.

216 The pharmacist or nurse shall keep a copy of the affidavit onsite at his or her primary
 217 location for inspection by the Georgia Drugs and Narcotics Agency, upon request. The
 218 Georgia Drugs and Narcotics Agency shall have the authority to impose sanctions in
 219 accordance with subsection (r) of this Code section on any person subject to the
 220 requirements of this paragraph who does not submit the information required by this
 221 paragraph and to notify the delegating physician and the applicable licensing board for
 222 such person of violations of this paragraph; and

223 ~~(9)~~(17) Be renewed and, if necessary, revised or updated biennially by the physician and
 224 the pharmacist or nurse. A ~~An~~ influenza vaccine protocol agreement that is not renewed
 225 biennially shall expire.

226 (e) A pharmacist who is a party to ~~an influenza~~ a vaccine protocol agreement pursuant to
 227 this Code section shall not delegate the administration of ~~influenza~~ a vaccine to any
 228 individual other than a pharmacy intern under the direct supervision of the pharmacist
 229 whether or not any such other individual is under the supervision, direct or otherwise, of
 230 the pharmacist.

231 (f) A nurse who is a party to ~~an influenza~~ a vaccine protocol agreement pursuant to this
 232 Code section shall not delegate the administration of ~~influenza~~ a vaccine to any individual,
 233 whether or not any such individual is under the supervision, direct or otherwise, of the
 234 nurse; provided, however, that notwithstanding the requirement of employment by a
 235 physician in paragraph ~~(7)~~(4) of subsection (a) of this Code section, a registered
 236 professional nurse who is a party to ~~an influenza~~ a vaccine protocol agreement pursuant to
 237 this Code section may delegate the administration of ~~influenza~~ a vaccine to a licensed
 238 practical nurse under the direct on-site supervision of the registered professional nurse.

239 (g) Notwithstanding any law to the contrary, a nurse acting pursuant to ~~an influenza~~ a
 240 vaccine protocol agreement as provided in this Code section may possess and transport
 241 ~~influenza~~ such vaccine and epinephrine.

242 (h) A pharmacist or nurse administering ~~influenza~~ vaccines pursuant to ~~an influenza~~ a
 243 vaccine protocol agreement authorized by this Code section shall maintain policies and
 244 procedures for the handling and disposal of used or contaminated equipment and supplies.

245 (i) Nothing in this Code section shall be construed to authorize a physician to prescribe
 246 any other vaccines or other drugs pursuant to ~~an influenza~~ a vaccine protocol agreement
 247 or ~~influenza~~ vaccine order contained in ~~an influenza~~ a vaccine protocol agreement other
 248 than ~~influenza~~ those vaccines and epinephrine specifically authorized in such vaccine
 249 protocol agreement or vaccine order.

250 (j) A delegating physician may not enter into ~~an influenza~~ a vaccine protocol agreement
 251 with more than ten pharmacists or nurses, or any combination thereof, at any one time;
 252 provided, however, and notwithstanding the geographic limitations provided in subsections
 253 (b) and (c) of this Code section, a delegating physician may enter into ~~an influenza~~ a
 254 vaccine protocol agreement with more than ten pharmacists or nurses, or any combination
 255 thereof, at any one time so long as the pharmacists or nurses are in the same public health
 256 district as established pursuant to Code Section 31-3-15 and are employees or agents of the
 257 same corporate entity.

258 (k) It shall be unlawful for a physician who is employed by a pharmacist or nurse to enter
 259 into ~~an influenza~~ a vaccine protocol agreement or otherwise delegate medical acts to such
 260 pharmacist or nurse. It shall be unlawful for a physician who is employed by a pharmacy
 261 to enter into ~~an influenza~~ a vaccine protocol agreement or otherwise delegate medical acts
 262 to a pharmacist or nurse who is also employed by such pharmacy.

263 (l) The board shall have the authority to promulgate rules and regulations governing a
 264 physician who is a party to ~~an influenza~~ a vaccine protocol agreement in order to carry out
 265 the intent and purposes of this Code section. Further, the board shall:

266 (1) Require that the ~~influenza~~ vaccine protocol agreement, along with the affidavit by the
 267 pharmacist or nurse submitted pursuant to paragraph (16) of subsection (d) of this Code
 268 section and the proof of insurance required pursuant to paragraph (14) of subsection (d)
 269 of this Code section, be filed by the physician with the board and be made available by
 270 the board for public inspection; and

271 (2) Promulgate by rule an approved standard protocol template that may be utilized as
 272 ~~an influenza~~ a vaccine protocol agreement and make such template available on the
 273 board's website.

274 (m) Nothing in this Code section shall be construed to require a physician to enter into ~~an~~
 275 ~~influenza~~ a vaccine protocol agreement. A public or private managed care system, health
 276 plan, hospital, insurance company, or similar entity shall not require a physician,
 277 pharmacist, or nurse to enter into ~~an influenza~~ a vaccine protocol agreement as a condition
 278 for participation in or reimbursement from such entity.

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

281 (1) Entering into ~~an influenza~~ a vaccine protocol agreement with a pharmacist or nurse;

282 (2) Issuing ~~an influenza a~~ vaccine order contained in ~~an influenza a~~ vaccine protocol
 283 agreement with a pharmacist or nurse; or

284 (3) The acts or omissions of a pharmacist or nurse pursuant to ~~an influenza a~~ vaccine
 285 protocol agreement including the administration of ~~influenza a~~ vaccine or epinephrine.

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

288 (o) This Code section shall not apply to any activities conducted within a hospital,
 289 physician's office, nursing home, or other health care facility designated by the department
 290 or conducted within any other facility or entity owned, operated, or leased by a hospital.

291 (p) This Code section shall not be interpreted as limiting the authority of any authorized
 292 person to dispense or administer ~~influenza vaccine~~ vaccines or other medications.

293 (q) No ~~influenza~~ vaccine protocol agreement entered into pursuant to this Code section
 294 shall permit a pharmacist or nurse to administer ~~an~~ any of the following:

295 (1) An influenza vaccine to any child under the age of 13 without an individual
 296 prescription from a physician;

297 (2) A pneumococcal disease vaccine to any child under the age of 18 without an
 298 individual prescription from a physician;

299 (3) Any vaccines containing a live attenuated virus to a child under the age of 13; or

300 (4) A meningitis vaccine to any child under the age of 18.

301 ~~and consent~~ Consent of the child's parent or legal guardian shall be a condition precedent
 302 to the administration of ~~an influenza a~~ vaccine to a child under the age of 18.

303 (r)(1) A pharmacist or nurse who knowingly does not comply with paragraph (14) of
 304 subsection (d) of this Code section may be assessed a fine of up to \$2,500.00 by the
 305 board.

306 (2) A pharmacist or nurse who knowingly administers a vaccine without a vaccine
 307 protocol agreement as required by this Code section may be assessed a fine of up to
 308 \$2,500.00 and may be prohibited from administering vaccines pursuant to this Code
 309 section for up to one year as determined by the board.

310 (3) A pharmacist or nurse who knowingly does not comply with paragraph (6) of
 311 subsection (d) of this Code section may be subject to the following sanctions by the
 312 board:

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

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

315 (C) Upon a third or subsequent violation, prohibited from administering vaccines
 316 pursuant to this Code section for up to one year.

317 (4) A pharmacist or nurse who knowingly does not comply with paragraph (15) of
318 subsection (d) of this Code section may be subject to the following sanctions by the
319 board:

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

321 (B) Upon a third or subsequent violation, prohibited from administering vaccines
322 pursuant to this Code section for up to six months.

323 (5) A pharmacist or nurse who knowingly does not comply with paragraph (10) or (16)
324 of subsection (d) of this Code section may be subject to the following sanctions by the
325 Georgia Drugs and Narcotics Agency:

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

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

328 (C) Upon a third or subsequent violation, prohibited from administering vaccines
329 pursuant to this Code section.

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

332 **SECTION 3.**

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