

The House 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:

14 style="text-align:center">**SECTION 1.**

15 Code Section 31-12-3.2 of the Official Code of Georgia Annotated, relating to  
16 meningococcal disease vaccinations and disclosures, is amended by revising subsection (b)  
17 as follows:

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."

27 **SECTION 2.**

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

31 "43-34-26.1.

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

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

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

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

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

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

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

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

50 ~~(4)(8) 'Vaccine' 'Influenza vaccine' means an inactivated virus administered by injection~~  
 51 ~~or a live attenuated virus administered by nasal spray that is prepared for the applicable~~  
 52 ~~season and that is administered to produce or increase~~ a specially prepared antigen which  
 53 upon administration to a person will result in immunity to influenza, pneumococcal  
 54 disease, shingles, or meningitis. ~~to the influenza virus; provided, however, that a live~~  
 55 ~~attenuated virus shall not be administered pursuant to this Code section to any individual~~  
 56 ~~younger than 13 or older than 49 years of age; and provided, further, that a No live~~  
 57 ~~attenuated virus shall not be administered pursuant to this Code section unless the patient~~  
 58 ~~or his or her parent, if a minor, has signed an informed consent that he or she does not~~  
 59 ~~have a contraindication to this vaccine. The informed consent form shall list the~~  
 60 ~~contraindications to the vaccine.~~

61 ~~(5)(9) 'Vaccine order' 'Influenza vaccine order' means a prescription drug order,~~  
 62 ~~contained in an influenza a vaccine protocol agreement, for influenza a vaccine issued by~~  
 63 ~~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 approved 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 at least 12 hours of  
 99 self-study and an assessment exam, at least eight hours of live seminar with a final exam,  
 100 and a hands-on assessment of intramuscular and subcutaneous injection technique. A

101 physician who is a party to ~~an influenza~~ a vaccine protocol agreement may also prescribe  
 102 epinephrine via ~~an influenza~~ a vaccine order contained in ~~an influenza~~ a vaccine protocol  
 103 agreement for administration by a pharmacist upon the occurrence of an actual or perceived  
 104 anaphylactic adverse reaction to the administered ~~influenza~~ vaccine provided that the  
 105 ~~influenza~~ vaccine protocol agreement sets forth the signs and symptoms that warrant the  
 106 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 be developed by  
 137 the Department of Public Health to the vaccine recipient on the importance of having and  
 138 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 their  
 171 personal vehicle;

172 ~~(5)~~(10) Require the pharmacist or nurse to enter the patient's influenza vaccine  
 173 information in the Georgia Registry of Immunization Transactions and Services within  
 174 the registry's designated time frame, or as designated by the Department of Public Health.  
 175 The Georgia Drugs and Narcotics Agency shall have the authority to impose sanctions  
 176 in accordance with subsection (r) of this Code section on any person subject to the  
 177 requirements of this paragraph who does not submit the information required by this  
 178 paragraph and to notify the delegating physician and the applicable licensing board for  
 179 such person of violations of this paragraph;

180 ~~(6)~~(11) Require, as a condition of administration of the influenza vaccine, the influenza  
 181 vaccine recipient to remain under the observation of the administering pharmacist or  
 182 nurse for a period of not less than 15 minutes immediately subsequent to the  
 183 administration of the influenza vaccine;

184 ~~(7)~~(12) Contain procedures to follow up on the occurrence of an adverse event or  
 185 complication including, if prescribed via an influenza a vaccine order contained in an  
 186 influenza a vaccine protocol agreement, the administration of epinephrine;

187 ~~(8)~~(13) Provide for prioritization of influenza vaccine recipients in the event the supply  
 188 of influenza a vaccine is limited; and

189 (14) Require the pharmacist or nurse to maintain individual liability insurance coverage  
 190 or be individually covered by his or her employer's liability insurance coverage in an  
 191 amount not less than \$250,000.00 to cover claims arising from administration of vaccines  
 192 by the pharmacist or nurse pursuant to a vaccine protocol agreement and to provide proof  
 193 of such coverage to the physician for submission to the board with the vaccine protocol  
 194 agreement;

195 (15) Require the pharmacist or nurse to post proof of the vaccine protocol agreement,  
 196 including a list of the vaccines authorized by such protocol, in a conspicuous location  
 197 within the pharmacy, local health department, or other setting in which the vaccine is  
 198 being administered; and

199 ~~(9)~~(16) Be renewed and, if necessary, revised or updated biennially by the physician and  
 200 the pharmacist or nurse. ~~A~~ An influenza vaccine protocol agreement that is not renewed  
 201 biennially shall expire.

202 (e) A pharmacist who is a party to an influenza a vaccine protocol agreement pursuant to  
 203 this Code section shall not delegate the administration of influenza a vaccine to any  
 204 individual other than a pharmacy intern under the direct supervision of the pharmacist  
 205 whether or not any such other individual is under the supervision, direct or otherwise, of  
 206 the pharmacist.

207 (f) A nurse who is a party to an influenza a vaccine protocol agreement pursuant to this  
 208 Code section shall not delegate the administration of influenza a vaccine to any individual,

209 whether or not any such individual is under the supervision, direct or otherwise, of the  
 210 nurse; provided, however, that notwithstanding the requirement of employment by a  
 211 physician in paragraph ~~(7)~~(4) of subsection (a) of this Code section, a registered  
 212 professional nurse who is a party to ~~an influenza~~ a vaccine protocol agreement pursuant to  
 213 this Code section may delegate the administration of ~~influenza~~ a vaccine to a licensed  
 214 practical nurse under the direct on-site supervision of the registered professional nurse.

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

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

221 (i) Nothing in this Code section shall be construed to authorize a physician to prescribe  
 222 any other vaccines or other drugs pursuant to ~~an influenza~~ a vaccine protocol agreement  
 223 or ~~influenza~~ vaccine order contained in ~~an influenza~~ a vaccine protocol agreement other  
 224 than ~~influenza~~ those vaccines and epinephrine specifically authorized in such vaccine  
 225 protocol agreement or vaccine order.

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

234 (k) It shall be unlawful for a physician who is employed by a pharmacist or nurse to enter  
 235 into ~~an influenza~~ a vaccine protocol agreement or otherwise delegate medical acts to such  
 236 pharmacist or nurse. It shall be unlawful for a physician who is employed by a pharmacy  
 237 to enter into ~~an influenza~~ a vaccine protocol agreement or otherwise delegate medical acts  
 238 to a pharmacist or nurse who is also employed by such pharmacy.

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

242 (1) Require that the ~~influenza~~ vaccine protocol agreement be filed by the physician with  
 243 the board and be made available by the board for public inspection. The physician shall  
 244 submit proof of the liability insurance coverage required pursuant to paragraph (14) of  
 245 subsection (d) of this Code section, verification that the pharmacist or nurse holds current

246 certification in Basic Cardiac Life Support as required by subsections (b) and (c) of this  
 247 Code section with the vaccine protocol agreement, and for pharmacists, verification of  
 248 completion of immunology training as required by subsection (b) of this Code section;  
 249 and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

285 (2) A pharmacist or nurse who knowingly administers a vaccine without a vaccine  
 286 protocol agreement as required by this Code section may be assessed a fine of up to  
 287 \$2,500.00 and may be prohibited from administering vaccines pursuant to this Code  
 288 section for up to one year as determined by the board.

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

292 (A) Upon the first violation, the issuance of a warning:

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

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

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

299 (A) Upon the first or second violation, the issuance of a warning:

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

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

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

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

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

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

311 **SECTION 3.**

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