

Senators Bethel of the 54th and Carter of the 1st offered the following amendment:

1 *Amend SB 134 by inserting after the semicolon on line 2 the following:*

2 to amend Code Section 31-12-3.1 of the Official Code of Georgia Annotated, relating to a
3 vaccination registry, so as to authorize the Department of Public Health to enforce the
4 requirements of the registry; to amend Article 2 of Chapter 34 of Title 43 of the Official
5 Code of Georgia Annotated, relating to physicians, so as to authorize the administration of
6 vaccines by pharmacists or nurses pursuant to vaccine protocol agreements with physicians;
7 to provide for definitions; to provide requirements for the content of vaccine protocol
8 agreements; to provide that a party to a vaccine protocol agreement shall not delegate his or
9 her authority; to limit the number of vaccine protocol agreements into which a physician may
10 enter at any one time; to prohibit certain entities from entering into vaccine protocol
11 agreements; to provide for rules and regulations; to provide for limited liability; to provide
12 for applicability; to provide for statutory construction; to provide for related matters;

13 *By inserting after line 11 the following:*

14 **SECTION 1A.**

15 Code Section 31-12-3.1 of the Official Code of Georgia Annotated, relating to a vaccination
16 registry, is amended by adding a new subsection to read as follows:

17 "(j) The department shall have the authority to impose sanctions, including fines or
18 prohibitions from making entries into the registry, on any person subject to the
19 requirements of subsection (b) of this Code section who does not submit the required
20 information to the department and to notify the applicable licensing board for such person
21 of violations of this Code section."

22 **SECTION 1B.**

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

26 "43-34-26.1.

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

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

- 31 (2) 'Adverse event' means an event that is a negative consequence of the administration
 32 of ~~influenza~~ vaccine by a pharmacist or nurse that results in an unintended reaction,
 33 injury, or illness, which may or may not have been preventable.
- 34 (3) 'Board' means the Georgia Composite Medical Board.
- 35 (4) 'Nurse' means a registered professional nurse as defined in paragraph (9) of Code
 36 Section 43-26-3. The term shall also mean a licensed practical nurse as defined in
 37 paragraph (5) of Code Section 43-26-32 who is regularly employed by a physician
 38 engaged in the active practice of medicine.
- 39 (5) 'Pharmacist' means an individual licensed under Chapter 4 of Title 26 to engage in
 40 the practice of pharmacy in the State of Georgia.
- 41 (6) 'Pharmacy intern' means a pharmacy intern as defined in paragraph (19) of Code
 42 Section 26-4-5.
- 43 (7) 'Physician' means an individual licensed to practice medicine and surgery pursuant
 44 to this article and whose principal place of practice is located in this state.
- 45 (4)(8) ~~'Vaccine' 'Influenza vaccine'~~ means an inactivated virus administered by injection
 46 or a live attenuated virus administered by nasal spray that is prepared for the applicable
 47 season and that is administered to produce or increase a specially prepared antigen which
 48 upon administration to a person will result in immunity to hepatitis A; hepatitis B; herpes
 49 zoster; influenza; meningococcal disease; measles, mumps, and rubella; pneumococcal
 50 disease; or tetanus, diphtheria, and pertussis. ~~to the influenza virus; provided, however,~~
 51 ~~that a live attenuated virus shall not be administered pursuant to this Code section to any~~
 52 ~~individual younger than 13 or older than 49 years of age; and provided, further, that a No~~
 53 live attenuated virus shall ~~not~~ be administered pursuant to this Code section unless the
 54 patient or his or her parent, if a minor, has signed an informed consent that he or she does
 55 not have a contraindication to this vaccine. The informed consent form shall list the
 56 contraindications to the vaccine.
- 57 (5)(9) ~~'Vaccine order' 'Influenza vaccine order'~~ means a prescription drug order,
 58 contained in ~~an influenza~~ a vaccine protocol agreement, for influenza a vaccine issued by
 59 a physician for a group of patients who meet certain criteria and to be administered by a
 60 pharmacist or a nurse. An influenza A vaccine order shall also mean a prescription drug
 61 order, contained in an influenza a vaccine protocol agreement, for epinephrine issued by
 62 a physician for a group of patients who meet certain criteria and to be administered by a
 63 pharmacist or a nurse only upon the occurrence of an actual or perceived anaphylactic
 64 adverse reaction to the administered influenza vaccine provided that the influenza vaccine
 65 protocol agreement sets forth the signs and symptoms that warrant the administration of
 66 epinephrine.

67 ~~(6)(10) 'Vaccine protocol agreement'~~ ~~'Influenza vaccine protocol agreement'~~ means a
 68 written document mutually agreed upon and signed by a physician and a pharmacist or
 69 by a physician and a nurse, by which document the physician prescribes influenza a
 70 vaccine and epinephrine, if determined appropriate by the physician, by means of ~~an~~
 71 influenza a vaccine order for administration by a pharmacist or a nurse.

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

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

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

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

82 (b) A physician engaged in the active practice of medicine may prescribe influenza a
 83 vaccine for a group of patients via ~~an influenza a~~ vaccine order contained in ~~an influenza~~
 84 a vaccine protocol agreement to be administered by a pharmacist, provided the physician
 85 is registered with the vaccination registry established by the Department of Public Health
 86 pursuant to Code Section 31-12-3.1, commonly known as the Georgia Registry of
 87 Immunization Transactions and Services, the pharmacist is located within the county of the
 88 physician's place of registration with the vaccination registry or a county contiguous
 89 thereto, and the pharmacist holds current certification in Basic Cardiac Life Support and
 90 has completed a course of training accredited by the Accreditation Council for Pharmacy
 91 Education or similar health authority or professional body approved by the Georgia State
 92 Board of Pharmacy. A physician who is a party to ~~an influenza a~~ vaccine protocol
 93 agreement may also prescribe epinephrine via ~~an influenza a~~ vaccine order contained in ~~an~~
 94 influenza a vaccine protocol agreement for administration by a pharmacist upon the
 95 occurrence of an actual or perceived anaphylactic adverse reaction to the administered
 96 ~~influenza~~ vaccine provided that the ~~influenza~~ vaccine protocol agreement sets forth the
 97 signs and symptoms that warrant the administration of epinephrine.

98 (c) A physician engaged in the active practice of medicine may prescribe influenza a
 99 vaccine for a group of patients via ~~an influenza a~~ vaccine order contained in ~~an influenza~~
 100 a vaccine protocol agreement to be administered by a nurse, provided the physician is
 101 registered with the vaccination registry established by the Department of Public Health
 102 pursuant to Code Section 31-12-3.1, commonly known as the Georgia Registry of
 103 Immunization Transactions and Services, the nurse is located within the county of the

104 physician's place of registration with the vaccination registry or a county contiguous
 105 thereto, and the nurse holds current certification in Basic Cardiac Life Support. A
 106 physician who is a party to an influenza a vaccine protocol agreement may also prescribe
 107 epinephrine via an influenza a vaccine order contained in an influenza a vaccine protocol
 108 agreement for administration by a nurse upon the occurrence of an actual or perceived
 109 anaphylactic adverse reaction to the administered influenza vaccine provided that the
 110 influenza vaccine protocol agreement sets forth the signs and symptoms that warrant the
 111 administration of epinephrine.

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

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

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

120 (3) Require the pharmacist or nurse to provide the influenza vaccine recipient with the
 121 appropriate and current Vaccine Information Statement (VIS) as provided by the federal
 122 Centers for Disease Control and Prevention;

123 (4) Require the pharmacist or nurse to provide written information to be developed by
 124 the board to the vaccine recipient on the importance of having and periodically seeing a
 125 primary care physician;

126 ~~(4)~~(5) Require the pharmacist or nurse or his or her employer to retain documentation
 127 of each dose of influenza vaccine administered. Such documentation shall include, but
 128 not be limited to:

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

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

132 (C) The vaccine recipient's name, address, date of birth, and telephone number;

133 (D) The date of administration and injection site;

134 (E) A signed and dated consent form by which the vaccine recipient acknowledges
 135 receipt of the ~~VIS~~ Vaccine Information Statement, and consents to the administration
 136 of the influenza vaccine, and directs the pharmacy or nurse to notify or not to notify the
 137 vaccine recipient's primary care provider of the vaccine administered to the vaccine
 138 recipient, where applicable; and

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

140 (6) If the vaccine recipient has notified the pharmacist or nurse that the vaccine recipient
 141 has a primary care provider, require the pharmacist or nurse to provide the vaccine
 142 recipient with a form that shall contain a checkbox, or another selection mechanism,
 143 which authorizes the pharmacist or nurse to notify the vaccine recipient's primary care
 144 provider of a vaccine administered by the pharmacist or nurse, or which prohibits the
 145 pharmacist or nurse from notifying the vaccine recipient's primary care provider of the
 146 vaccine administered by the pharmacist or nurse. If a vaccine recipient fails to select one
 147 of the two options, the pharmacist or nurse is not required to notify the vaccine recipient's
 148 primary care provider of the vaccine administered by the pharmacist or nurse;

149 ~~(5)~~(7) Require the pharmacist or nurse to enter the patient's influenza vaccine
 150 information in the Georgia Registry of Immunization Transactions and Services within
 151 the registry's designated time frame, or as designated by the Department of Public Health.
 152 The Department of Public Health shall be authorized to enforce this paragraph pursuant
 153 to Code Section 31-12-3.1 and to notify the applicable licensing board of violations of
 154 this paragraph;

155 ~~(6)~~(8) Require, as a condition of administration of the influenza vaccine, the influenza
 156 vaccine recipient to remain under the observation of the administering pharmacist or
 157 nurse for a period of not less than 15 minutes immediately subsequent to the
 158 administration of the influenza vaccine;

159 ~~(7)~~(9) Contain procedures to follow up on the occurrence of an adverse event or
 160 complication including, if prescribed via ~~an influenza a~~ vaccine order contained in an
 161 ~~influenza a~~ vaccine protocol agreement, the administration of epinephrine;

162 ~~(8)~~(10) Provide for prioritization of influenza vaccine recipients in the event the supply
 163 of ~~influenza a~~ vaccine is limited; and

164 ~~(9)~~(11) Be renewed and, if necessary, revised or updated biennially by the physician and
 165 the pharmacist or nurse. A ~~An~~ influenza vaccine protocol agreement that is not renewed
 166 biennially shall expire.

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

172 (f) A nurse who is a party to ~~an influenza a~~ vaccine protocol agreement pursuant to this
 173 Code section shall not delegate the administration of ~~influenza a~~ vaccine to any individual,
 174 whether or not any such individual is under the supervision, direct or otherwise, of the
 175 nurse; provided, however, that notwithstanding the requirement of employment by a
 176 physician in paragraph ~~(7)~~(4) of subsection (a) of this Code section, a registered

177 professional nurse who is a party to ~~an influenza a~~ influenza a vaccine protocol agreement pursuant to
 178 this Code section may delegate the administration of ~~influenza a~~ influenza a vaccine to a licensed
 179 practical nurse under the direct on-site supervision of the registered professional nurse.

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

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

186 (i) Nothing in this Code section shall be construed to authorize a physician to prescribe
 187 any other vaccines or other drugs pursuant to ~~an influenza a~~ influenza a vaccine protocol agreement
 188 or ~~influenza~~ influenza vaccine order contained in ~~an influenza a~~ influenza a vaccine protocol agreement other
 189 than ~~influenza~~ those vaccines and epinephrine specifically authorized in such vaccine
 190 protocol agreement or vaccine order.

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

199 (k) It shall be unlawful for a physician who is employed by a pharmacist or nurse to enter
 200 into ~~an influenza a~~ influenza a vaccine protocol agreement or otherwise delegate medical acts to such
 201 pharmacist or nurse. It shall be unlawful for a physician who is employed by a pharmacy
 202 to enter into ~~an influenza a~~ influenza a vaccine protocol agreement or otherwise delegate medical acts
 203 to a pharmacist or nurse who is also employed by such pharmacy.

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

207 (1) Require that the ~~influenza~~ influenza vaccine protocol agreement be filed by the physician with
 208 the board and be made available by the board for public inspection; and

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

212 (m) Nothing in this Code section shall be construed to require a physician to enter into ~~an~~ an
 213 ~~influenza a~~ influenza a vaccine protocol agreement. A public or private managed care system, health

214 plan, hospital, insurance company, or similar entity shall not require a physician,
 215 pharmacist, or nurse to enter into ~~an influenza a~~ vaccine protocol agreement as a condition
 216 for participation in or reimbursement from such entity.

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

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

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

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

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

226 (o) This Code section shall not apply to any activities conducted within a hospital or
 227 within any other facility or entity owned, operated, or leased by a hospital.

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

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

232 (1) An influenza vaccine to any child under the age of 13 without an individual
 233 prescription from a physician, or any other types of vaccines to any child under the age
 234 of 18 without an individual prescription from a physician; or

235 (2) Any vaccines containing a live attenuated virus to a child under the age of 13.

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