

The Senate Health and Human Services Committee offered the following substitute to SB 288:

A BILL TO BE ENTITLED
AN ACT

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

11 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

12 Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to
13 physicians, is amended by revising Code Section 43-34-26.1, relating to influenza vaccine
14 protocol agreements, as follows:
15

16 "43-34-26.1.

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

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

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

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

25 (4) 'Nurse' means a registered professional nurse as defined in paragraph (9) of Code
26 Section 43-26-3. The term shall also mean a licensed practical nurse as defined in

27 paragraph (5) of Code Section 43-26-32 who is regularly employed by a physician
 28 engaged in the active practice of medicine.

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

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

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

35 ~~(4)~~(8) 'Vaccine' 'Influenza vaccine' means an inactivated virus administered by injection
 36 or a live attenuated virus administered by nasal spray that is ~~prepared for the applicable~~
 37 ~~season and that is~~ administered to produce or increase immunity ~~to the influenza virus;~~
 38 provided, however, that a live attenuated virus shall not be administered pursuant to this
 39 Code section to any individual younger than 13 or older than 49 years of age; and
 40 provided, further, that a live attenuated virus shall not be administered pursuant to this
 41 Code section unless the patient or his or her parent, if a minor, has signed an informed
 42 consent that he or she does not have a contraindication to this vaccine. The informed
 43 consent form shall list the contraindications to the vaccine. The term 'vaccine' shall not
 44 include the vaccine for human papillomavirus.

45 ~~(5)~~(9) 'Vaccine order' 'Influenza vaccine order' means a prescription drug order,
 46 contained in ~~an influenza~~ a vaccine protocol agreement, for ~~influenza~~ a vaccine issued by
 47 a physician for a group of patients who meet certain criteria and to be administered by a
 48 pharmacist or a nurse. ~~An influenza~~ A vaccine order shall also mean a prescription drug
 49 order, contained in ~~an influenza~~ a vaccine protocol agreement, for epinephrine issued by
 50 a physician for a group of patients who meet certain criteria and to be administered by a
 51 pharmacist or a nurse only upon the occurrence of an actual or perceived anaphylactic
 52 adverse reaction to the administered ~~influenza~~ vaccine provided that the ~~influenza~~ vaccine
 53 protocol agreement sets forth the signs and symptoms that warrant the administration of
 54 epinephrine.

55 ~~(6)~~(10) 'Vaccine protocol agreement' 'Influenza vaccine protocol agreement' means a
 56 written document mutually agreed upon and signed by a physician and a pharmacist or
 57 by a physician and a nurse, by which document the physician prescribes ~~influenza~~ a
 58 vaccine and epinephrine, if determined appropriate by the physician, by means of an
 59 ~~influenza~~ a vaccine order for administration by a pharmacist or a nurse.

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

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

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

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

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

86 (c) 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 nurse, provided the physician is~~
 89 ~~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 nurse is located within the county of the~~
 92 ~~physician's place of registration with the vaccination registry or a county contiguous~~
 93 ~~thereto, and the nurse holds current certification in Basic Cardiac Life Support. A~~
 94 ~~physician who is a party to an influenza a vaccine protocol agreement may also prescribe~~
 95 ~~epinephrine via an influenza a vaccine order contained in an influenza a vaccine protocol~~
 96 ~~agreement for administration by a nurse upon the occurrence of an actual or perceived~~
 97 ~~anaphylactic adverse reaction to the administered influenza vaccine provided that the~~
 98 ~~influenza vaccine protocol agreement sets forth the signs and symptoms that warrant the~~
 99 ~~administration of epinephrine.~~

- 100 (d) ~~A An~~ influenza vaccine protocol agreement between a physician and a pharmacist or
 101 a physician and a nurse pursuant to this Code section shall, without limitation:
- 102 (1) Contain the current names, addresses, telephone numbers, and professional license
 103 numbers of the physician and the pharmacist or nurse;
- 104 (2) Contain a provision for immediate consultation between the pharmacist or nurse and
 105 the physician. If the physician is not available, the physician for purposes of consultation
 106 may designate another physician who concurs with the terms of the ~~influenza~~ vaccine
 107 protocol agreement;
- 108 (3) Require the pharmacist or nurse to provide the ~~influenza~~ vaccine recipient with the
 109 appropriate and current Vaccine Information Statement (VIS) as provided by the federal
 110 Centers for Disease Control and Prevention;
- 111 (4) Require the pharmacist or nurse or his or her employer to retain documentation of
 112 each dose of ~~influenza~~ vaccine administered. Such documentation shall include, but not
 113 be limited to:
- 114 (A) The administering pharmacist's or nurse's name, address, telephone number, and
 115 professional license number;
- 116 (B) The name, dose, manufacturer, and lot number of the ~~influenza~~ vaccine;
- 117 (C) The vaccine recipient's name, address, date of birth, and telephone number;
- 118 (D) The date of administration and injection site;
- 119 (E) A signed and dated consent form by which the vaccine recipient acknowledges
 120 receipt of the VIS and consents to the administration of the ~~influenza~~ vaccine; and
- 121 (F) Any adverse events or complications that occur;
- 122 (5) Require the pharmacist or nurse to enter the patient's ~~influenza~~ vaccine information
 123 in the Georgia Registry of Immunization Transactions and Services within the registry's
 124 designated time frame, or as designated by the Department of Community Health;
- 125 (6) Require, as a condition of administration of the ~~influenza~~ vaccine, the ~~influenza~~
 126 vaccine recipient to remain under the observation of the administering pharmacist or
 127 nurse for a period of not less than 15 minutes immediately subsequent to the
 128 administration of the ~~influenza~~ vaccine;
- 129 (7) Contain procedures to follow up on the occurrence of an adverse event or
 130 complication including, if prescribed via ~~an influenza a~~ vaccine order contained in ~~an~~
 131 ~~influenza a~~ vaccine protocol agreement, the administration of epinephrine;
- 132 (8) Provide for prioritization of ~~influenza~~ vaccine recipients in the event the supply of
 133 ~~influenza a~~ vaccine is limited; and
- 134 (9) Be renewed and, if necessary, revised or updated biennially by the physician and the
 135 pharmacist or nurse. ~~A An~~ influenza vaccine protocol agreement that is not renewed
 136 biennially shall expire.

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

142 (f) A nurse who is a party to ~~an influenza~~ a vaccine protocol agreement pursuant to this
143 Code section shall not delegate the administration of ~~influenza~~ a vaccine to any individual,
144 whether or not any such individual is under the supervision, direct or otherwise, of the
145 nurse; provided, however, that notwithstanding the requirement of employment by a
146 physician in paragraph ~~(7)~~ (4) of subsection (a) of this Code section, a registered
147 professional nurse who is a party to ~~an influenza~~ a vaccine protocol agreement pursuant to
148 this Code section may delegate the administration of ~~influenza~~ a vaccine to a licensed
149 practical nurse under the direct on-site supervision of the registered professional nurse.

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

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

156 (i) Nothing in this Code section shall be construed to authorize a physician to prescribe
157 any other vaccines or other drugs pursuant to ~~an influenza~~ a vaccine protocol agreement
158 or ~~influenza~~ vaccine order contained in ~~an influenza~~ a vaccine protocol agreement other
159 than ~~influenza~~ those vaccines and epinephrine specifically authorized in such vaccine
160 protocol agreement or vaccine order.

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

169 (k) It shall be unlawful for a physician who is employed by a pharmacist or nurse to enter
170 into ~~an influenza~~ a vaccine protocol agreement or otherwise delegate medical acts to such
171 pharmacist or nurse. It shall be unlawful for a physician who is employed by a pharmacy
172 to enter into ~~an influenza~~ a vaccine protocol agreement or otherwise delegate medical acts
173 to a pharmacist or nurse who is also employed by such pharmacy.

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

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

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

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

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

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

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

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

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

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

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

200 (q) No ~~influenza~~ vaccine protocol agreement entered into pursuant to this Code section
 201 shall permit a pharmacist or nurse to administer ~~an influenza~~ a vaccine to any child person
 202 under the age of ~~13~~ 19 without an individual prescription from a physician, and consent of
 203 the child's parent or legal guardian shall be a condition precedent to the administration of
 204 ~~an influenza~~ a vaccine to a child under the age of 18."

205 **SECTION 2.**

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