

The Senate Health and Human Services Committee offered the following substitute to SB 85:

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 a specially prepared antigen which~~
 38 ~~upon administration to a person will result in immunity to hepatitis A; hepatitis A and B;~~

39 ~~hepatitis B; herpes zoster; influenza; meningococcal disease; measles, mumps, and~~
 40 ~~rubella; pneumococcal disease; tetanus and diphtheria; tetanus, diphtheria, and pertussis;~~

41 ~~or varicella. to the influenza virus; provided, however, that a live attenuated virus shall~~
 42 ~~not be administered pursuant to this Code section to any individual younger than 13 or~~

43 ~~older than 49 years of age; and provided, further, that a No live attenuated virus shall not~~
 44 ~~be administered pursuant to this Code section unless the patient or his or her parent, if a~~

45 ~~minor, has signed an informed consent that he or she does not have a contraindication to~~
 46 ~~this vaccine. The informed consent form shall list the contraindications to the vaccine.~~

47 ~~(5)(9) 'Vaccine order' 'Influenza vaccine order' means a prescription drug order,~~
 48 ~~contained in an influenza a vaccine protocol agreement, for influenza a vaccine issued by~~

49 ~~a physician for a group of patients who meet certain criteria and to be administered by a~~
 50 ~~pharmacist or a nurse. An influenza A vaccine order shall also mean a prescription drug~~

51 ~~order, contained in an influenza a vaccine protocol agreement, for epinephrine issued by~~
 52 ~~a physician for a group of patients who meet certain criteria and to be administered by a~~

53 ~~pharmacist or a nurse only upon the occurrence of an actual or perceived anaphylactic~~
 54 ~~adverse reaction to the administered influenza vaccine provided that the influenza vaccine~~

55 ~~protocol agreement sets forth the signs and symptoms that warrant the administration of~~
 56 ~~epinephrine.~~

57 ~~(6)(10) 'Vaccine protocol agreement' 'Influenza vaccine protocol agreement' means a~~
 58 ~~written document mutually agreed upon and signed by a physician and a pharmacist or~~

59 ~~by a physician and a nurse, by which document the physician prescribes influenza a~~
 60 ~~vaccine and epinephrine, if determined appropriate by the physician, by means of an~~

61 ~~influenza a vaccine order for administration by a pharmacist or a nurse.~~

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

64 ~~paragraph (5) of Code Section 43-26-32 who is regularly employed by a physician who~~
 65 ~~actively engaged in the private practice of medicine.~~

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

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

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

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

88 (c) A physician engaged in the active practice of medicine may prescribe influenza a
 89 vaccine for a group of patients via ~~an influenza a vaccine order contained in an influenza~~
 90 a vaccine protocol agreement to be administered by a nurse, provided the physician is
 91 registered with the vaccination registry established by the Department of Public Health
 92 pursuant to Code Section 31-12-3.1, commonly known as the Georgia Registry of
 93 Immunization Transactions and Services, the nurse is located within the county of the
 94 physician's place of registration with the vaccination registry or a county contiguous
 95 thereto, and the nurse holds current certification in Basic Cardiac Life Support. A
 96 physician who is a party to ~~an influenza a vaccine protocol agreement~~ may also prescribe
 97 epinephrine via ~~an influenza a vaccine order contained in an influenza a vaccine protocol~~
 98 agreement for administration by a nurse upon the occurrence of an actual or perceived
 99 anaphylactic adverse reaction to the administered ~~influenza vaccine~~ provided that the

100 influenza vaccine protocol agreement sets forth the signs and symptoms that warrant the
 101 administration of epinephrine.

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

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

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

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

113 (4) Require the pharmacist or nurse or his or her employer to retain documentation of
 114 each dose of influenza vaccine administered. Such documentation shall include, but not
 115 be limited to:

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

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

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

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

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

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

127 (5) If the vaccine recipient has notified the pharmacist or nurse that the vaccine recipient
 128 has a primary care provider, require the pharmacist or nurse to provide the vaccine
 129 recipient with a form that shall contain a checkbox, or another selection mechanism,
 130 which authorizes the pharmacist or nurse to notify the vaccine recipient's primary care
 131 provider of a vaccine administered by the pharmacist or nurse, or which prohibits the
 132 pharmacist or nurse from notifying the vaccine recipient's primary care provider of the
 133 vaccine administered by the pharmacist or nurse. If a vaccine recipient fails to select one
 134 of the two options, the pharmacist or nurse is not required to notify the vaccine recipient's
 135 primary care provider of the vaccine administered by the pharmacist or nurse;

- 136 ~~(5)~~(6) Require the pharmacist or nurse to enter the patient's ~~influenza~~ vaccine
 137 information in the Georgia Registry of Immunization Transactions and Services within
 138 the registry's designated time frame, or as designated by the Department of Community
 139 Health;
- 140 ~~(6)~~(7) Require, as a condition of administration of the ~~influenza~~ vaccine, the ~~influenza~~
 141 vaccine recipient to remain under the observation of the administering pharmacist or
 142 nurse for a period of not less than 15 minutes immediately subsequent to the
 143 administration of the ~~influenza~~ vaccine;
- 144 ~~(7)~~(8) Contain procedures to follow up on the occurrence of an adverse event or
 145 complication including, if prescribed via an ~~influenza~~ a vaccine order contained in an
 146 ~~influenza~~ a vaccine protocol agreement, the administration of epinephrine;
- 147 ~~(8)~~(9) Provide for prioritization of ~~influenza~~ vaccine recipients in the event the supply
 148 of ~~influenza~~ a vaccine is limited; and
- 149 ~~(9)~~(10) Be renewed and, if necessary, revised or updated biennially by the physician and
 150 the pharmacist or nurse. A ~~An~~ ~~influenza~~ vaccine protocol agreement that is not renewed
 151 biennially shall expire.
- 152 (e) A pharmacist who is a party to an ~~influenza~~ a vaccine protocol agreement pursuant to
 153 this Code section shall not delegate the administration of ~~influenza~~ a vaccine to any
 154 individual other than a pharmacy intern under the direct supervision of the pharmacist
 155 whether or not any such other individual is under the supervision, direct or otherwise, of
 156 the pharmacist.
- 157 (f) A nurse who is a party to an ~~influenza~~ a vaccine protocol agreement pursuant to this
 158 Code section shall not delegate the administration of ~~influenza~~ a vaccine to any individual,
 159 whether or not any such individual is under the supervision, direct or otherwise, of the
 160 nurse; provided, however, that notwithstanding the requirement of employment by a
 161 physician in paragraph ~~(7)~~ (4) of subsection (a) of this Code section, a registered
 162 professional nurse who is a party to an ~~influenza~~ a vaccine protocol agreement pursuant to
 163 this Code section may delegate the administration of ~~influenza~~ a vaccine to a licensed
 164 practical nurse under the direct on-site supervision of the registered professional nurse.
- 165 (g) Notwithstanding any law to the contrary, a nurse acting pursuant to an ~~influenza~~ a
 166 vaccine protocol agreement as provided in this Code section may possess and transport
 167 ~~influenza~~ such vaccine and epinephrine.
- 168 (h) A pharmacist or nurse administering ~~influenza~~ vaccines pursuant to an ~~influenza~~ a
 169 vaccine protocol agreement authorized by this Code section shall maintain policies and
 170 procedures for the handling and disposal of used or contaminated equipment and supplies.
- 171 (i) Nothing in this Code section shall be construed to authorize a physician to prescribe
 172 any other vaccines or other drugs pursuant to an ~~influenza~~ a vaccine protocol agreement

173 or ~~influenza~~ vaccine order contained in an ~~influenza~~ a vaccine protocol agreement other
 174 than ~~influenza~~ those vaccines and epinephrine specifically authorized in such vaccine
 175 protocol agreement or vaccine order.

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

184 (k) It shall be unlawful for a physician who is employed by a pharmacist or nurse to enter
 185 into an ~~influenza~~ a vaccine protocol agreement or otherwise delegate medical acts to such
 186 pharmacist or nurse. It shall be unlawful for a physician who is employed by a pharmacy
 187 to enter into an ~~influenza~~ a vaccine protocol agreement or otherwise delegate medical acts
 188 to a pharmacist or nurse who is also employed by such pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

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

220 (2) Any vaccines containing a live attenuated virus to a child under the age of 13.
 221 ~~and consent~~ Consent of the child's parent or legal guardian shall be a condition precedent
 222 to the administration of ~~an influenza~~ a vaccine to a child under the age of 18."

223 **SECTION 2.**

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