

By Senator Rodriguez

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1 A bill to be entitled
2 An act relating to administration of vaccines;
3 amending s. 465.189, F.S.; authorizing certified
4 pharmacists to order, as well as administer, specified
5 vaccines; authorizing registered pharmacy technicians
6 to administer specified vaccines under certain
7 circumstances; deleting the requirement that certified
8 pharmacists administer vaccines or epinephrine using
9 an autoinjector only pursuant to a written protocol
10 with a supervising physician; revising the specified
11 immunizations or vaccines that certified pharmacists,
12 registered interns, and registered pharmacy
13 technicians may order or administer, as applicable;
14 deleting a certain staffing ratio requirement for
15 supervising pharmacists; making conforming changes;
16 requiring certified pharmacists, registered interns,
17 and registered pharmacy technicians to obtain a
18 certain medical consent form before administering an
19 immunization or a vaccine to a child younger than 18
20 years of age; specifying requirements for the consent
21 form; requiring the parent or guardian of such child
22 to provide an opt-out form to the pharmacist,
23 registered intern, or registered pharmacy technician
24 to exclude the minor from the department's
25 immunization registry; requiring pharmacists to submit
26 the opt-out form to the department; requiring
27 pharmacists to submit vaccination data to the
28 department if an opt-out form is not provided;
29 prohibiting public and private third-party payors from

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30 providing disparate coverage or reimbursement for
31 immunizations or vaccines ordered or administered by
32 certified pharmacists, registered interns, or
33 registered pharmacy technicians; amending ss. 381.003
34 and 465.003, F.S.; conforming provisions to changes
35 made by the act; providing an effective date.
36

37 Be It Enacted by the Legislature of the State of Florida:
38

39 Section 1. Section 465.189, Florida Statutes, is amended to
40 read:

41 465.189 Administration of vaccines and epinephrine
42 autoinjection.—

43 (1) In accordance with guidelines of the United States
44 Centers for Disease Control and Prevention for each recommended
45 immunization or vaccine, a pharmacist who is certified under
46 subsection (6) may order or administer, and ~~or~~ a registered
47 intern or registered pharmacy technician under the supervision
48 of a pharmacist who is certified under subsection (6), may
49 administer, any of the following immunizations or vaccines to an
50 adult within the framework of an established protocol under a
51 supervising physician licensed under chapter 458 or chapter 459:

52 (a) Immunizations or vaccines listed in the Adult
53 Immunization Schedule ~~as of February 1, 2015,~~ by the United
54 States Centers for Disease Control and Prevention. ~~The board may~~
55 ~~authorize, by rule, additional immunizations or vaccines as they~~
56 ~~are added to the Adult Immunization Schedule.~~

57 (b) Immunizations or vaccines recommended by the United
58 States Centers for Disease Control and Prevention Advisory

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59 Committee on Immunization Practices.

60 (c) Immunizations or vaccines listed in the Child and
61 Adolescent Immunization Schedule by the United States Centers
62 for Disease Control and Prevention.

63 (d) Immunizations or vaccines recommended by the United
64 States Centers for Disease Control and Prevention for
65 international travel as of July 1, 2015. The board may
66 authorize, by rule, additional immunizations or vaccines as they
67 are recommended by the United States Centers for Disease Control
68 and Prevention for international travel.

69 (e) ~~(e)~~ Immunizations or vaccines approved by the board in
70 response to a state of emergency declared by the Governor
71 pursuant to s. 252.36.

72
73 ~~A registered intern who administers an immunization or vaccine~~
74 ~~under this subsection must be supervised by a certified~~
75 ~~pharmacist at a ratio of one pharmacist to one registered~~
76 ~~intern.~~

77 (2) In order to address any unforeseen allergic reaction, a
78 pharmacist may administer epinephrine using an autoinjector
79 delivery system ~~within the framework of an established protocol~~
80 ~~under a supervising physician licensed under chapter 458 or~~
81 ~~chapter 459.~~

82 (3) A pharmacist may not order or administer an
83 immunization or a vaccine under this section ~~enter into a~~
84 ~~protocol~~ unless he or she maintains at least \$200,000 of
85 professional liability insurance and has completed training in
86 administering vaccines authorized under this section.

87 (4) A pharmacist ordering or administering immunizations or

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88 vaccines under this section shall maintain and make available
89 patient records using the same standards for confidentiality and
90 maintenance of such records as those that are imposed on health
91 care practitioners under s. 456.057. These records shall be
92 maintained for a minimum of 5 years.

93 ~~(5) The decision by a supervising physician licensed under~~
94 ~~chapter 458 or chapter 459 to enter into a protocol under this~~
95 ~~section is a professional decision on the part of the~~
96 ~~practitioner, and a person may not interfere with a physician's~~
97 ~~decision as to entering into such a protocol. A pharmacist may~~
98 ~~not enter into a protocol that is to be performed while acting~~
99 ~~as an employee without the written approval of the owner of the~~
100 ~~pharmacy.~~ Pharmacists shall forward vaccination records to the
101 department for inclusion in the state registry of immunization
102 information.

103 (6) Any pharmacist seeking to order or administer, or any
104 registered intern or registered pharmacy technician seeking to
105 administer, vaccines ~~to adults~~ under this section must be
106 certified to administer such vaccines pursuant to a
107 certification program approved by the Board of Pharmacy in
108 consultation with the Board of Medicine and the Board of
109 Osteopathic Medicine. The certification program shall, at a
110 minimum, require that the pharmacist attend at least 20 hours of
111 continuing education classes approved by the board and the
112 registered intern or registered pharmacy technician complete at
113 least 20 hours of coursework approved by the board. The program
114 shall have a curriculum of instruction concerning the safe and
115 effective administration of such vaccines, including, but not
116 limited to, potential allergic reactions to such vaccines.

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117 (7) To administer an immunization or a vaccine to a child
118 younger than 18 years of age, a pharmacist, registered intern,
119 or registered pharmacy technician certified under subsection (6)
120 must first obtain a medical consent form signed by a person who
121 has the power to consent to medical care or treatment on behalf
122 of the child in accordance with s. 743.0645. The medical consent
123 form must contain a notice stating that the parent or guardian
124 of such child may refuse to have the child included in the
125 immunization registry under s. 381.003. If a parent or guardian
126 does not want the child included in the immunization registry,
127 he or she must provide to the pharmacist, registered intern, or
128 registered pharmacy intern a completed opt-out form approved by
129 the department upon administration of the vaccine. The
130 pharmacist administering the vaccine or supervising the
131 registered intern or registered pharmacy technician who
132 administered the vaccine shall submit the opt-out form to the
133 department. If a parent or guardian of a child younger than 18
134 years of age does not provide an opt-out form, the pharmacist
135 must report the vaccination data for such child to the
136 department in accordance with s. 381.003 ~~The written protocol~~
137 ~~between the pharmacist and supervising physician under this~~
138 ~~section must include particular terms and conditions imposed by~~
139 ~~the supervising physician upon the pharmacist relating to the~~
140 ~~administration of vaccines by the pharmacist pursuant to this~~
141 ~~section. The written protocol shall include, at a minimum,~~
142 ~~specific categories and conditions among patients for whom the~~
143 ~~supervising physician authorizes the pharmacist to administer~~
144 ~~such vaccines. The terms, scope, and conditions set forth in the~~
145 ~~written protocol between the pharmacist and the supervising~~

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146 ~~physician must be appropriate to the pharmacist's training and~~
147 ~~certification for administering such vaccines. Pharmacists who~~
148 ~~have been delegated the authority to administer vaccines under~~
149 ~~this section by the supervising physician under the protocol~~
150 ~~shall provide evidence of current certification by the Board of~~
151 ~~Pharmacy to the supervising physician. A supervising physician~~
152 ~~shall review the administration of such vaccines by the~~
153 ~~pharmacist pursuant to the written protocol between them, and~~
154 ~~this review shall take place as outlined in the written~~
155 ~~protocol. The process and schedule for the review shall be~~
156 ~~outlined in the written protocol between the pharmacist and the~~
157 ~~supervising physician.~~

158 (8) A public or private third-party payor may not provide
159 coverage or reimbursement for immunizations or vaccines ordered
160 or administered under this section at a rate lower than that
161 provided for immunizations or vaccines ordered or administered
162 by other health care practitioners ~~The pharmacist shall submit~~
163 ~~to the Board of Pharmacy a copy of his or her protocol or~~
164 ~~written agreement to administer vaccines under this section.~~

165 Section 2. Paragraph (e) of subsection (1) of section
166 381.003, Florida Statutes, is amended to read:

167 381.003 Communicable disease and AIDS prevention and
168 control.—

169 (1) The department shall conduct a communicable disease
170 prevention and control program as part of fulfilling its public
171 health mission. A communicable disease is any disease caused by
172 transmission of a specific infectious agent, or its toxic
173 products, from an infected person, an infected animal, or the
174 environment to a susceptible host, either directly or

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175 indirectly. The communicable disease program must include, but
176 need not be limited to:

177 (e) Programs for the prevention and control of vaccine-
178 preventable diseases, including programs to immunize school
179 children as required by s. 1003.22(3)-(11) and the development
180 of an automated, electronic, and centralized database and
181 registry of immunizations. The department shall ensure that all
182 children in this state are immunized against vaccine-preventable
183 diseases. The immunization registry must allow the department to
184 enhance current immunization activities for the purpose of
185 improving the immunization of all children in this state.

186 1. Except as provided in subparagraph 2., the department
187 shall include all children born in this state in the
188 immunization registry by using the birth records from the Office
189 of Vital Statistics. The department shall add other children to
190 the registry as immunization services are provided.

191 2. The parent or guardian of a child may refuse to have the
192 child included in the immunization registry by signing a form
193 obtained from the department, or from the health care
194 practitioner or entity that provides the immunization, which
195 indicates that the parent or guardian does not wish to have the
196 child included in the immunization registry. Each consent to
197 treatment form provided by a health care practitioner or by an
198 entity that administers vaccinations or causes vaccinations to
199 be administered to children from birth through 17 years of age
200 must contain a notice stating that the parent or guardian of a
201 child may refuse to have his or her child included in the
202 immunization registry. The parent or guardian must provide such
203 opt-out form to the health care practitioner or entity upon

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204 administration of the vaccination. Such health care practitioner
205 or entity shall submit the form to the department. A parent or
206 guardian may submit the opt-out form directly to the department.
207 Any records or identifying information pertaining to the child
208 shall be removed from the registry, if the parent or guardian
209 has refused to have his or her child included in the
210 immunization registry.

211 3. A college or university student, from 18 years of age to
212 23 years of age, who obtains a vaccination from a college or
213 university student health center or clinic in the state may
214 refuse to be included in the immunization registry by signing a
215 form obtained from the department, health center, or clinic
216 which indicates that the student does not wish to be included in
217 the immunization registry. The student must provide such opt-out
218 form to the health center or clinic upon administration of the
219 vaccination. Such health center or clinic shall submit the form
220 to the department. A student may submit the opt-out form
221 directly to the department. Any records or identifying
222 information pertaining to the student shall be removed from the
223 registry if the student has refused to be included in the
224 immunization registry.

225 4. The immunization registry shall allow for immunization
226 records to be electronically available to entities that are
227 required by law to have such records, including, but not limited
228 to, schools and licensed child care facilities.

229 5. A health care practitioner licensed under chapter 458,
230 chapter 459, ~~or~~ chapter 464, or chapter 465 in this state who
231 administers vaccinations or causes vaccinations to be
232 administered to children from birth through 17 years of age is

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233 required to report vaccination data to the immunization
234 registry, unless a parent or guardian of a child has refused to
235 have the child included in the immunization registry by meeting
236 the requirements of subparagraph 2. A health care practitioner
237 licensed under chapter 458, chapter 459, ~~or~~ chapter 464, or
238 chapter 465 in this state who administers vaccinations or causes
239 vaccinations to be administered to college or university
240 students from 18 years of age to 23 years of age at a college or
241 university student health center or clinic is required to report
242 vaccination data to the immunization registry, unless the
243 student has refused to be included in the immunization registry
244 by meeting the requirements of subparagraph 3. Vaccination data
245 for students in other age ranges may be submitted to the
246 immunization registry only if the student consents to inclusion
247 in the immunization registry. The upload of data from existing
248 automated systems is an acceptable method for updating
249 immunization information in the immunization registry. The
250 information in the immunization registry must include the
251 child's name, date of birth, address, and any other unique
252 identifier necessary to correctly identify the child; the
253 immunization record, including the date, type of administered
254 vaccine, and vaccine lot number; and the presence or absence of
255 any adverse reaction or contraindication related to the
256 immunization. Information received by the department for the
257 immunization registry retains its status as confidential medical
258 information and the department must maintain the confidentiality
259 of that information as otherwise required by law. A health care
260 practitioner or other agency that obtains information from the
261 immunization registry must maintain the confidentiality of any

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262 medical records in accordance with s. 456.057 or as otherwise
263 required by law.

264 Section 3. Subsection (13) of section 465.003, Florida
265 Statutes, is amended to read:

266 465.003 Definitions.—As used in this chapter, the term:

267 (13) "Practice of the profession of pharmacy" includes
268 compounding, dispensing, and consulting concerning contents,
269 therapeutic values, and uses of any medicinal drug; consulting
270 concerning therapeutic values and interactions of patent or
271 proprietary preparations, whether pursuant to prescriptions or
272 in the absence and entirely independent of such prescriptions or
273 orders; and conducting other pharmaceutical services. For
274 purposes of this subsection, the term "other pharmaceutical
275 services" means monitoring the patient's drug therapy and
276 assisting the patient in the management of his or her drug
277 therapy, and includes reviewing, and making recommendations
278 regarding, the patient's drug therapy and health care status in
279 communication with the patient's prescribing health care
280 provider as licensed under chapter 458, chapter 459, chapter
281 461, or chapter 466, or a similar statutory provision in another
282 jurisdiction, or such provider's agent or such other persons as
283 specifically authorized by the patient; and initiating,
284 modifying, or discontinuing drug therapy for a chronic health
285 condition under a collaborative pharmacy practice agreement.
286 This subsection may not be interpreted to permit an alteration
287 of a prescriber's directions, the diagnosis or treatment of any
288 disease, the initiation of any drug therapy, the practice of
289 medicine, or the practice of osteopathic medicine, unless
290 otherwise permitted by law or specifically authorized by s.

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291 465.1865 or s. 465.1895. The term "practice of the profession of
292 pharmacy" also includes any other act, service, operation,
293 research, or transaction incidental to, or forming a part of,
294 any of the foregoing acts, requiring, involving, or employing
295 the science or art of any branch of the pharmaceutical
296 profession, study, or training, and shall expressly permit a
297 pharmacist to transmit information from persons authorized to
298 prescribe medicinal drugs to their patients. The practice of the
299 profession of pharmacy also includes the administration of
300 vaccines ~~to adults~~ pursuant to s. 465.189, the testing or
301 screening for and treatment of minor, nonchronic health
302 conditions pursuant to s. 465.1895, and the preparation of
303 prepackaged drug products in facilities holding Class III
304 institutional pharmacy permits. The term also includes the
305 ordering and evaluating of any laboratory or clinical testing;
306 conducting patient assessments; and modifying, discontinuing, or
307 administering medicinal drugs pursuant to s. 465.0125 by a
308 consultant pharmacist.

309 Section 4. This act shall take effect July 1, 2021.