

1 A bill to be entitled
2 An act relating to the administration of vaccines;
3 amending s. 465.189, F.S.; authorizing certified
4 pharmacists to order, as well as administer, specified
5 vaccines under certain circumstances; authorizing
6 registered pharmacy technicians to administer
7 specified vaccines to individuals 3 years of age and
8 older under certain circumstances; deleting the
9 requirement that certified pharmacists administer
10 vaccines or epinephrine using an autoinjector only
11 pursuant to a written protocol with a supervising
12 physician; revising the specified immunizations or
13 vaccines that certified pharmacists, registered
14 interns, and registered pharmacy technicians may order
15 or administer, as applicable; deleting a certain
16 staffing ratio requirement for supervising
17 pharmacists; making conforming changes; revising the
18 required number of continuing education hours for
19 certification; requiring certified pharmacists,
20 registered interns, and registered pharmacy
21 technicians to obtain a certain medical consent form
22 before administering an immunization or a vaccine to a
23 child younger than 18 years of age; specifying
24 requirements for the consent form; requiring the
25 parent or guardian of such child to provide an opt-out

26 form to the pharmacist, registered intern, or
27 registered pharmacy technician to exclude the minor
28 from the department's immunization registry; requiring
29 pharmacists to submit the opt-out form to the
30 department; requiring pharmacists to submit
31 vaccination data to the department if an opt-out form
32 is not provided; prohibiting public and private third-
33 party payors from providing disparate coverage or
34 reimbursement for immunizations or vaccines ordered or
35 administered by certified pharmacists, registered
36 interns, or registered pharmacy technicians; amending
37 ss. 381.003 and 465.003, F.S.; conforming provisions
38 to changes made by the act; providing an effective
39 date.

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41 Be It Enacted by the Legislature of the State of Florida:

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43 Section 1. Section 465.189, Florida Statutes, is amended
44 to read:

45 465.189 Administration of vaccines and epinephrine
46 autoinjection.—

47 (1) In accordance with guidelines of the United States
48 Centers for Disease Control and Prevention for each recommended
49 immunization or vaccine, a pharmacist who is certified under
50 subsection (6) may order or administer the following vaccines or

51 may order or administer the following vaccines within the
52 framework of an established protocol under a supervising
53 physician licensed under chapter 458 or chapter 459. ~~or A~~
54 registered intern or a registered technician under the
55 supervision of a pharmacist who is certified under subsection
56 (6) ~~may administer~~ any of the following immunizations or
57 vaccines to individuals 3 years of age and older ~~to an adult~~
58 ~~within the framework of an established protocol under a~~
59 ~~supervising physician licensed under chapter 458 or chapter 459:~~

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

65 (b) Immunizations or vaccines recommended by the United
66 States Centers for Disease Control and Prevention Advisory
67 Committee on Immunization Practices.

68 (c) Immunizations or vaccines listed in the Child and
69 Adolescent Immunization Schedule by the United States Centers
70 for Disease Control and Prevention.

71 (d) Immunizations or vaccines recommended by the United
72 States Centers for Disease Control and Prevention for
73 international travel as of July 1, 2015. The board may
74 authorize, by rule, additional immunizations or vaccines as they
75 are recommended by the United States Centers for Disease Control

76 and Prevention for international travel.

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

80
81 ~~A registered intern who administers an immunization or vaccine~~
82 ~~under this subsection must be supervised by a certified~~
83 ~~pharmacist at a ratio of one pharmacist to one registered~~
84 ~~intern.~~

85 (2) In order to address any unforeseen allergic reaction,
86 a pharmacist may administer epinephrine using an autoinjector
87 delivery system ~~within the framework of an established protocol~~
88 ~~under a supervising physician licensed under chapter 458 or~~
89 ~~chapter 459.~~

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

95 (4) A pharmacist ordering or administering immunizations
96 or vaccines under this section shall maintain and make available
97 patient records using the same standards for confidentiality and
98 maintenance of such records as those that are imposed on health
99 care practitioners under s. 456.057. These records shall be
100 maintained for a minimum of 5 years.

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

111 (6) Any pharmacist seeking to order or administer, or any
112 registered intern or registered pharmacy technician seeking to
113 administer, vaccines ~~to adults~~ under this section must be
114 certified to administer such vaccines pursuant to a
115 certification program approved by the Board of Pharmacy in
116 consultation with the Board of Medicine and the Board of
117 Osteopathic Medicine. The certification program shall, at a
118 minimum, require that the pharmacist or registered pharmacy
119 intern attend at least 20 hours of continuing education classes
120 approved by the board and a registered pharmacy technician ~~the~~
121 ~~registered intern~~ complete at least 2 ~~20~~ hours of coursework
122 approved by the board. The program shall have a curriculum of
123 instruction concerning the safe and effective administration of
124 such vaccines, including, but not limited to, potential allergic
125 reactions to such vaccines.

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

151 ~~specific categories and conditions among patients for whom the~~
152 ~~supervising physician authorizes the pharmacist to administer~~
153 ~~such vaccines. The terms, scope, and conditions set forth in the~~
154 ~~written protocol between the pharmacist and the supervising~~
155 ~~physician must be appropriate to the pharmacist's training and~~
156 ~~certification for administering such vaccines. Pharmacists who~~
157 ~~have been delegated the authority to administer vaccines under~~
158 ~~this section by the supervising physician under the protocol~~
159 ~~shall provide evidence of current certification by the Board of~~
160 ~~Pharmacy to the supervising physician. A supervising physician~~
161 ~~shall review the administration of such vaccines by the~~
162 ~~pharmacist pursuant to the written protocol between them, and~~
163 ~~this review shall take place as outlined in the written~~
164 ~~protocol. The process and schedule for the review shall be~~
165 ~~outlined in the written protocol between the pharmacist and the~~
166 ~~supervising physician.~~

167 (8) A public or private third-party payor may not provide
168 coverage or reimbursement for immunizations or vaccines ordered
169 or administered under this section at a rate lower than that
170 provided for immunizations or vaccines ordered or administered
171 by other health care practitioners ~~The pharmacist shall submit~~
172 ~~to the Board of Pharmacy a copy of his or her protocol or~~
173 ~~written agreement to administer vaccines under this section.~~

174 Section 2. Paragraph (e) of subsection (1) of section
175 381.003, Florida Statutes, is amended to read:

176 381.003 Communicable disease and AIDS prevention and
177 control.—

178 (1) The department shall conduct a communicable disease
179 prevention and control program as part of fulfilling its public
180 health mission. A communicable disease is any disease caused by
181 transmission of a specific infectious agent, or its toxic
182 products, from an infected person, an infected animal, or the
183 environment to a susceptible host, either directly or
184 indirectly. The communicable disease program must include, but
185 need not be limited to:

186 (e) Programs for the prevention and control of vaccine-
187 preventable diseases, including programs to immunize school
188 children as required by s. 1003.22(3)-(11) and the development
189 of an automated, electronic, and centralized database and
190 registry of immunizations. The department shall ensure that all
191 children in this state are immunized against vaccine-preventable
192 diseases. The immunization registry must allow the department to
193 enhance current immunization activities for the purpose of
194 improving the immunization of all children in this state.

195 1. Except as provided in subparagraph 2., the department
196 shall include all children born in this state in the
197 immunization registry by using the birth records from the Office
198 of Vital Statistics. The department shall add other children to
199 the registry as immunization services are provided.

200 2. The parent or guardian of a child may refuse to have

201 the child included in the immunization registry by signing a
202 form obtained from the department, or from the health care
203 practitioner or entity that provides the immunization, which
204 indicates that the parent or guardian does not wish to have the
205 child included in the immunization registry. Each consent to
206 treatment form provided by a health care practitioner or by an
207 entity that administers vaccinations or causes vaccinations to
208 be administered to children from birth through 17 years of age
209 must contain a notice stating that the parent or guardian of a
210 child may refuse to have his or her child included in the
211 immunization registry. The parent or guardian must provide such
212 opt-out form to the health care practitioner or entity upon
213 administration of the vaccination. Such health care practitioner
214 or entity shall submit the form to the department. A parent or
215 guardian may submit the opt-out form directly to the department.
216 Any records or identifying information pertaining to the child
217 shall be removed from the registry, if the parent or guardian
218 has refused to have his or her child included in the
219 immunization registry.

220 3. A college or university student, from 18 years of age
221 to 23 years of age, who obtains a vaccination from a college or
222 university student health center or clinic in the state may
223 refuse to be included in the immunization registry by signing a
224 form obtained from the department, health center, or clinic
225 which indicates that the student does not wish to be included in

226 the immunization registry. The student must provide such opt-out
227 form to the health center or clinic upon administration of the
228 vaccination. Such health center or clinic shall submit the form
229 to the department. A student may submit the opt-out form
230 directly to the department. Any records or identifying
231 information pertaining to the student shall be removed from the
232 registry if the student has refused to be included in the
233 immunization registry.

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

238 5. A health care practitioner licensed under chapter 458,
239 chapter 459, ~~or~~ chapter 464, or chapter 465 in this state who
240 administers vaccinations or causes vaccinations to be
241 administered to children from birth through 17 years of age is
242 required to report vaccination data to the immunization
243 registry, unless a parent or guardian of a child has refused to
244 have the child included in the immunization registry by meeting
245 the requirements of subparagraph 2. A health care practitioner
246 licensed under chapter 458, chapter 459, ~~or~~ chapter 464, or
247 chapter 465 in this state who administers vaccinations or causes
248 vaccinations to be administered to college or university
249 students from 18 years of age to 23 years of age at a college or
250 university student health center or clinic is required to report

251 vaccination data to the immunization registry, unless the
252 student has refused to be included in the immunization registry
253 by meeting the requirements of subparagraph 3. Vaccination data
254 for students in other age ranges may be submitted to the
255 immunization registry only if the student consents to inclusion
256 in the immunization registry. The upload of data from existing
257 automated systems is an acceptable method for updating
258 immunization information in the immunization registry. The
259 information in the immunization registry must include the
260 child's name, date of birth, address, and any other unique
261 identifier necessary to correctly identify the child; the
262 immunization record, including the date, type of administered
263 vaccine, and vaccine lot number; and the presence or absence of
264 any adverse reaction or contraindication related to the
265 immunization. Information received by the department for the
266 immunization registry retains its status as confidential medical
267 information and the department must maintain the confidentiality
268 of that information as otherwise required by law. A health care
269 practitioner or other agency that obtains information from the
270 immunization registry must maintain the confidentiality of any
271 medical records in accordance with s. 456.057 or as otherwise
272 required by law.

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

275 465.003 Definitions.—As used in this chapter, the term:

276 (13) "Practice of the profession of pharmacy" includes
277 compounding, dispensing, and consulting concerning contents,
278 therapeutic values, and uses of any medicinal drug; consulting
279 concerning therapeutic values and interactions of patent or
280 proprietary preparations, whether pursuant to prescriptions or
281 in the absence and entirely independent of such prescriptions or
282 orders; and conducting other pharmaceutical services. For
283 purposes of this subsection, the term "other pharmaceutical
284 services" means monitoring the patient's drug therapy and
285 assisting the patient in the management of his or her drug
286 therapy, and includes reviewing, and making recommendations
287 regarding, the patient's drug therapy and health care status in
288 communication with the patient's prescribing health care
289 provider as licensed under chapter 458, chapter 459, chapter
290 461, or chapter 466, or a similar statutory provision in another
291 jurisdiction, or such provider's agent or such other persons as
292 specifically authorized by the patient; and initiating,
293 modifying, or discontinuing drug therapy for a chronic health
294 condition under a collaborative pharmacy practice agreement.
295 This subsection may not be interpreted to permit an alteration
296 of a prescriber's directions, the diagnosis or treatment of any
297 disease, the initiation of any drug therapy, the practice of
298 medicine, or the practice of osteopathic medicine, unless
299 otherwise permitted by law or specifically authorized by s.
300 465.1865 or s. 465.1895. The term "practice of the profession of

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

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