

1 A bill to be entitled
2 An act relating to the practice of pharmacy; amending
3 s. 381.0031, F.S.; requiring specified licensed
4 pharmacists to report certain information relating to
5 public health to the Department of Health; amending s.
6 465.003, F.S.; revising the definition of the term
7 "practice of the profession of pharmacy"; creating s.
8 465.1865, F.S.; providing definitions; providing
9 requirements for pharmacists to provide services under
10 a collaborative pharmacy practice agreement; requiring
11 the terms and conditions of such agreement to be
12 appropriate to the training of the pharmacist and the
13 scope of practice of the physician; requiring
14 notification to the board upon practicing under a
15 collaborative pharmacy practice agreement; requiring
16 pharmacists to submit a copy of the signed
17 collaborative pharmacy practice agreement to the Board
18 of Pharmacy; providing for the maintenance of patient
19 records for a certain period of time; providing for
20 renewal of such agreement; requiring a pharmacist and
21 the collaborating physician to maintain on file and
22 make available the collaborative pharmacy practice
23 agreement; prohibiting certain actions relating to
24 such agreement; requiring specified continuing
25 education for a pharmacist who practices under a

26 | collaborative pharmacy practice agreement; requiring
27 | the Board of Pharmacy to adopt rules; amending s.
28 | 465.189, F.S.; revising the recommended immunizations
29 | or vaccines a pharmacist or a certain registered
30 | intern may administer; authorizing a certified
31 | pharmacist to administer the influenza vaccine to
32 | specified persons; amending s. 465.1893, F.S.;
33 | authorizing pharmacists who meet certain requirements
34 | to administer certain extended release medications;
35 | creating s. 465.1895, F.S.; requiring the board to
36 | identify minor, nonchronic health conditions that a
37 | pharmacist may test or screen for and treat; providing
38 | requirements for a pharmacist to test or screen for
39 | and treat minor, nonchronic health conditions;
40 | requiring the board to develop a formulary of
41 | medicinal drugs that a pharmacist may prescribe;
42 | providing requirements for the written protocol
43 | between a pharmacist and a supervising physician;
44 | prohibiting a pharmacist from providing certain
45 | services under certain circumstances; requiring a
46 | pharmacist to complete a specified amount of
47 | continuing education; providing an effective date.

48 |
49 | Be It Enacted by the Legislature of the State of Florida:
50 |

51 Section 1. Subsection (2) of section 381.0031, Florida
 52 Statutes, is amended to read:

53 381.0031 Epidemiological research; report of diseases of
 54 public health significance to department.—

55 (2) Any practitioner licensed in this state to practice
 56 medicine, osteopathic medicine, chiropractic medicine,
 57 naturopathy, or veterinary medicine; any licensed pharmacist
 58 authorized under a protocol with a supervising physician under
 59 s. 465.1895, or a collaborative pharmacy practice agreement, as
 60 defined in s. 465.1865, to perform or order and evaluate
 61 laboratory and clinical tests; any hospital licensed under part
 62 I of chapter 395; or any laboratory appropriately certified by
 63 the Centers for Medicare and Medicaid Services under the federal
 64 Clinical Laboratory Improvement Amendments and the federal rules
 65 adopted thereunder which diagnoses or suspects the existence of
 66 a disease of public health significance shall immediately report
 67 the fact to the Department of Health.

68 Section 2. Subsection (13) of section 465.003, Florida
 69 Statutes, is amended to read:

70 465.003 Definitions.—As used in this chapter, the term:

71 (13) "Practice of the profession of pharmacy" includes
 72 compounding, dispensing, and consulting concerning contents,
 73 therapeutic values, and uses of any medicinal drug; consulting
 74 concerning therapeutic values and interactions of patent or
 75 proprietary preparations, whether pursuant to prescriptions or

76 | in the absence and entirely independent of such prescriptions or
77 | orders; and conducting other pharmaceutical services. For
78 | purposes of this subsection, "other pharmaceutical services"
79 | means the monitoring of the patient's drug therapy and assisting
80 | the patient in the management of his or her drug therapy, and
81 | includes review of the patient's drug therapy and communication
82 | with the patient's prescribing health care provider as licensed
83 | under chapter 458, chapter 459, chapter 461, or chapter 466, or
84 | similar statutory provision in another jurisdiction, or such
85 | provider's agent or such other persons as specifically
86 | authorized by the patient, regarding the drug therapy; and
87 | initiating, modifying, or discontinuing drug therapy for a
88 | chronic health condition under a collaborative pharmacy practice
89 | agreement. ~~However,~~ Nothing in this subsection may be
90 | interpreted to permit an alteration of a prescriber's
91 | directions, the diagnosis or treatment of any disease, the
92 | initiation of any drug therapy, the practice of medicine, or the
93 | practice of osteopathic medicine, unless otherwise permitted by
94 | law or specifically authorized by s. 465.1865 or s. 465.1895.
95 | "Practice of the profession of pharmacy" also includes any other
96 | act, service, operation, research, or transaction incidental to,
97 | or forming a part of, any of the foregoing acts, requiring,
98 | involving, or employing the science or art of any branch of the
99 | pharmaceutical profession, study, or training, and shall
100 | expressly permit a pharmacist to transmit information from

101 persons authorized to prescribe medicinal drugs to their
102 patients. The practice of the profession of pharmacy also
103 includes the administration of vaccines to adults pursuant to s.
104 465.189; the administration of long-acting medication pursuant
105 to s. 465.1893; the testing or screening for and treatment of
106 minor, nonchronic health conditions pursuant to s. 465.1895; and
107 the preparation of prepackaged drug products in facilities
108 holding Class III institutional pharmacy permits.

109 Section 3. Section 465.1865, Florida Statutes, is created
110 to read:

111 465.1865 Collaborative pharmacy practice for chronic
112 health conditions.—

113 (1) For purposes of this section, the term:

114 (a) "Collaborative pharmacy practice agreement" means a
115 written agreement between a pharmacist who meets the
116 qualifications of this section and a physician licensed under
117 chapter 458 or chapter 459 in which a collaborating physician
118 authorizes a pharmacist to provide specified patient care
119 services to the collaborating physician's patients.

120 (b) "Chronic health condition" means a condition that
121 typically lasts more than 1 year and requires ongoing medical
122 attention, limits activities of daily living, or both. Such
123 condition may include, but is not limited to:

124 1. Arthritis;

125 2. Asthma;

- 126 3. Congestive heart failure;
 127 4. Chronic obstructive pulmonary diseases;
 128 5. Diabetes;
 129 6. Emphysema;
 130 7. Human immunodeficiency virus or acquired
 131 immunodeficiency syndrome;
 132 8. Hypertension;
 133 9. Obesity;
 134 10. Renal disease; or
 135 11. Any other chronic condition or comorbidity identified
 136 by the collaborating physician.
 137 (2) To provide services under a collaborative pharmacy
 138 practice agreement, a pharmacist must:
 139 (a) Hold an active and unencumbered license to practice
 140 pharmacy in the state.
 141 (b) Have earned a degree of doctor of pharmacy or have
 142 completed 5 years of experience as a licensed pharmacist.
 143 (c) Complete an initial 20-hour course approved by the
 144 board that includes, at a minimum, instruction on the following:
 145 1. Performance of patient assessments.
 146 2. Ordering, performing, and interpreting clinical and
 147 laboratory tests related to collaborative pharmacy practice.
 148 3. Evaluating and managing diseases and health conditions
 149 in collaboration with other health care practitioners.
 150 4. Any other area required by board rule.

151 (d) Maintain at least \$250,000 of professional liability
152 insurance coverage. However, a pharmacist who maintains
153 professional liability insurance coverage pursuant to s.
154 465.1895 satisfies this requirement.

155 (e) Submit a copy of the signed collaborative pharmacy
156 practice agreement and proof of satisfying the conditions of
157 this section to the board before commencing practice.

158 (f) Maintain records of all patients receiving services
159 under a collaborative pharmacy practice agreement for a period
160 of 5 years.

161 (3) The terms and conditions of the collaborative pharmacy
162 practice agreement must be appropriate to the pharmacist's
163 training and the services delegated to the pharmacist must be
164 within the collaborating physician's scope of practice.

165 (a) A collaborative pharmacy practice agreement must
166 include the following:

167 1. Name of the patient or patients for whom a pharmacist
168 may provide services.

169 2. Each chronic health condition to be collaboratively
170 managed.

171 3. Specific medicinal drug or drugs to be managed by the
172 pharmacist.

173 4. Circumstances under which the pharmacist may order or
174 perform and evaluate laboratory or clinical tests.

175 5. Conditions and events upon which the pharmacist must

176 notify the collaborating physician and the manner and timeframe
177 in which such notification must occur.

178 6. Beginning and ending dates for the collaborative
179 pharmacy practice agreement and termination procedures,
180 including procedures for patient notification and medical
181 records transfers.

182 7. A statement that the collaborative pharmacy practice
183 agreement may be terminated, in writing, by either party at any
184 time.

185 (b) A collaborative pharmacy practice agreement must be
186 renewed at least every 2 years.

187 (c) The pharmacist, along with the collaborating
188 physician, must maintain on file the collaborative pharmacy
189 practice agreement at his or her practice location, and must
190 make such agreements available upon request or inspection.

191 (4) A pharmacist may not:

192 (a) Modify or discontinue medicinal drugs prescribed by a
193 health care practitioner with whom he or she does not have a
194 collaborative pharmacy practice agreement.

195 (b) Enter into a collaborative pharmacy practice agreement
196 while acting as an employee without the written approval of the
197 owner of the pharmacy.

198 (5) A physician may not delegate the authority to initiate
199 or prescribe a controlled substance as described in s. 893.03 or
200 21 U.S.C. s. 812 to a pharmacist.

201 (6) A pharmacist who practices under a collaborative
202 pharmacy practice agreement must complete an 8-hour continuing
203 education course approved by the board that addresses issues
204 related to collaborative pharmacy practice each biennial
205 licensure renewal in addition to the continuing education
206 requirements under s. 465.009. A pharmacist must submit
207 confirmation of having completed such course when applying for
208 licensure renewal. A pharmacist who fails to comply with this
209 subsection shall be prohibited from practicing under a
210 collaborative pharmacy practice agreement under this section.

211 (7) The board shall adopt rules pursuant to ss. 120.536(1)
212 and 120.54 to implement this section.

213 Section 4. Subsections (2) through (8) of section 465.189,
214 Florida Statutes, are renumbered as sections (3) through (9),
215 respectively, subsection (1) and present subsection (6) are
216 amended, and a new subsection (2) is added to that section, to
217 read:

218 465.189 Administration of vaccines and epinephrine
219 autoinjection.—

220 (1) In accordance with guidelines of the Centers for
221 Disease Control and Prevention for each recommended immunization
222 or vaccine, a pharmacist, or a registered intern under the
223 supervision of a pharmacist who is certified under subsection
224 (7) ~~(6)~~, may administer the following vaccines to an adult
225 within the framework of an established protocol under a

226 supervising physician licensed under chapter 458 or chapter 459:

227 (a) Immunizations or vaccines listed in the ~~Adult~~
 228 ~~Immunization Schedule as of February 1, 2015, by the United~~
 229 ~~States Centers for Disease Control and~~ Prevention's Recommended
 230 ~~Prevention. The board may authorize, by rule, additional~~
 231 ~~immunizations or vaccines as they are added to the Adult~~
 232 ~~Immunization Schedule,~~ the Centers for Disease Control and
 233 Prevention's Health Information for International Travel, or the
 234 United States Food and Drug Administration's Vaccines Licensed
 235 for Use in the United States.

236 ~~(b) Immunizations or vaccines recommended by the United~~
 237 ~~States Centers for Disease Control and Prevention for~~
 238 ~~international travel as of July 1, 2015. The board may~~
 239 ~~authorize, by rule, additional immunizations or vaccines as they~~
 240 ~~are recommended by the United States Centers for Disease Control~~
 241 ~~and Prevention for international travel.~~

242 (b)-(c) Immunizations or vaccines approved by the board in
 243 response to a state of emergency declared by the Governor
 244 pursuant to s. 252.36.

245
 246 A registered intern who administers an immunization or vaccine
 247 under this subsection must be supervised by a certified
 248 pharmacist at a ratio of one pharmacist to one registered
 249 intern.

250 (2) A pharmacist who is certified under subsection (7) may

251 administer influenza vaccines to persons 7 years of age and
252 older within the framework of an established protocol under a
253 supervising physician licensed under chapter 458 or chapter 459.

254 ~~(7)(6)~~ Any pharmacist or registered intern seeking to
255 administer vaccines ~~to adults~~ under this section must be
256 certified to administer such vaccines pursuant to a
257 certification program approved by the Board of Pharmacy in
258 consultation with the Board of Medicine and the Board of
259 Osteopathic Medicine. The certification program shall, at a
260 minimum, require that the pharmacist attend at least 20 hours of
261 continuing education classes approved by the board and the
262 registered intern complete at least 20 hours of coursework
263 approved by the board. The program shall have a curriculum of
264 instruction concerning the safe and effective administration of
265 such vaccines, including, but not limited to, potential allergic
266 reactions to such vaccines.

267 Section 5. Section 465.1893, Florida Statutes, is amended
268 to read:

269 465.1893 Administration of long-acting antipsychotic
270 medication by injection.—

271 (1) (a) A pharmacist, at the direction of a physician
272 licensed under chapter 458 or chapter 459, may administer a
273 long-acting antipsychotic medication and extended-release
274 medications, including controlled substances, to treat substance
275 abuse disorder or dependency which have been approved by the

276 United States Food and Drug Administration by injection to a
 277 patient if the pharmacist:

278 1. Is authorized by and acting within the framework of an
 279 established protocol with the prescribing physician.

280 2. Practices at a facility that accommodates privacy for
 281 nondeltoid injections and conforms with state rules and
 282 regulations regarding the appropriate and safe disposal of
 283 medication and medical waste.

284 3. Has completed the course required under subsection (2).

285 (b) A separate prescription from a physician is required
 286 for each injection administered by a pharmacist under this
 287 subsection.

288 (2) (a) A pharmacist seeking to administer ~~a long-acting~~
 289 antipsychotic medication as described in paragraph (1) (a) by
 290 injection must complete an 8-hour continuing education course
 291 offered by:

292 1. A statewide professional association of physicians in
 293 this state accredited to provide educational activities
 294 designated for the American Medical Association Physician's
 295 Recognition Award (AMA PRA) Category 1 Credit or the American
 296 Osteopathic Association (AOA) Category 1-A continuing medical
 297 education (CME) credit; and

298 2. A statewide association of pharmacists.

299 (b) The course may be offered in a distance learning
 300 format and must be included in the 30 hours of continuing

301 professional pharmaceutical education required under s.
 302 465.009(1). The course shall have a curriculum of instruction
 303 that concerns the safe and effective administration of
 304 behavioral health and antipsychotic medications by injection,
 305 including, but not limited to, potential allergic reactions to
 306 such medications.

307 Section 6. Section 465.1895, Florida Statutes, is created
 308 to read:

309 465.1895 Testing or screening for and treatment of minor,
 310 nonchronic health conditions.-

311 (1) The board, in consultation with the Board of Medicine
 312 and the Board of Osteopathic Medicine, shall adopt rules
 313 identifying the minor, nonchronic health conditions for which a
 314 pharmacist may test or screen for and treat. For purposes of
 315 this section a minor, nonchronic health condition is typically a
 316 short-term condition that is generally managed with minimal
 317 treatment or self-care, including, but not limited to, the
 318 following:

- 319 (a) Influenza.
- 320 (b) Streptococcus.
- 321 (c) Lice.
- 322 (d) Skin conditions, such as ringworm and athlete's foot.
- 323 (e) Minor, uncomplicated infections.

324 (2) A pharmacist who tests or screens for and treats
 325 minor, nonchronic health conditions under this section must:

326 (a) Hold an active and unencumbered license to practice
327 pharmacy in the state.

328 (b) Complete an initial 20-hour education course approved
329 by the board. The course, at a minimum, must address patient
330 assessments; point-of-care testing procedures; safe and
331 effective treatment of minor, nonchronic health conditions; and
332 identification of contraindications.

333 (c) Maintain at least \$250,000 of liability coverage. A
334 pharmacist who maintains liability coverage pursuant to s.
335 465.1865 satisfies this requirement.

336 (d) Report a diagnosis or suspected existence of a disease
337 of public health significance to the department pursuant to s.
338 381.0031.

339 (e) Upon request of a patient, furnish patient records to
340 a health care practitioner designated by the patient.

341 (f) Maintain records of all patients receiving services
342 under this section for a period of 5 years.

343 (3) The board shall adopt, by rule, a formulary of
344 medicinal drugs that a pharmacist may prescribe for the minor,
345 nonchronic health conditions approved under subsection (1). The
346 formulary must include medicinal drugs approved by the United
347 States Food and Drug Administration which are indicated for
348 treatment of the minor, nonchronic health condition, including
349 any over-the-counter medication. The formulary may not include
350 any controlled substance as described in s. 893.03 or 21 U.S.C.

351 s. 812.

352 (4) A pharmacist who tests or screens for and treats
353 minor, nonchronic health conditions under this section may use
354 any tests that may guide diagnosis or clinical decisionmaking
355 which the Centers for Medicare and Medicaid Services has
356 determined qualifies for a waiver under the federal Clinical
357 Laboratory Improvement Amendments of 1988, or the federal rules
358 adopted thereunder, or any established screening procedures that
359 can safely be performed by a pharmacist.

360 (5) A pharmacist who tests for and treats influenza or
361 streptococcus under this section may only provide such services
362 within the framework of an established written protocol with a
363 supervising physician licensed under chapter 458 or chapter 459,
364 and must submit the protocol to the board.

365 (a) The protocol between a pharmacist and supervising
366 physician under this subsection must include particular terms
367 and conditions imposed by the supervising physician relating to
368 the testing for and treatment of influenza and streptococcus
369 under this section. The terms and conditions must be appropriate
370 to the pharmacist's training. At a minimum, the protocol shall
371 include:

372 1. Specific categories of patients who the pharmacist is
373 authorized to test for and treat influenza and streptococcus.

374 2. The supervising physician's instructions for the
375 treatment of influenza and streptococcus based on the patient's

376 age, symptoms, and test results, including negative results.

377 3. A process and schedule for the supervising physician to
378 review the pharmacist's actions under the protocol.

379 4. A process and schedule for the pharmacist to notify the
380 supervising physician of the patient's condition, tests
381 administered, test results, and course of treatment.

382 5. Any other requirements as established by board rule.

383 (b) A pharmacist authorized to test for and treat
384 influenza and streptococcus under the protocol shall provide
385 evidence of current certification by the board to the
386 supervising physician. A supervising physician shall review the
387 pharmacist's actions in accordance with the protocol.

388 (6) A pharmacist providing services under this section may
389 not perform such services while acting as an employee without
390 the written approval of the owner of the pharmacy.

391 (7) A pharmacist providing services under this section
392 must complete a 3-hour continuing education course approved by
393 the board addressing issues related to minor, nonchronic health
394 conditions each biennial licensure renewal in addition to the
395 continuing education requirements under s. 465.009. Each
396 pharmacist must submit confirmation of having completed the
397 course when applying for licensure renewal. A pharmacist who
398 fails to comply with this subsection may not provide testing,
399 screening, or treatment services.

400 Section 7. This act shall take effect July 1, 2020.