Bill No. HB 389 (2020)

Amendment No. 1

COMMITTEE/SUBCOMMITTEE	ACTION
ADOPTED	(Y/N)
ADOPTED AS AMENDED	(Y/N)
ADOPTED W/O OBJECTION	(Y/N)
FAILED TO ADOPT	(Y/N)
WITHDRAWN	(Y/N)
OTHER	

1 Committee/Subcommittee hearing bill: Health & Human Services 2 Committee 3 Representative Sirois offered the following: 4 5 Amendment (with title amendment) 6 Remove everything after the enacting clause and insert: 7 Section 1. Subsection (2) of section 381.0031, Florida 8 Statutes, is amended to read: 9 381.0031 Epidemiological research; report of diseases of 10 public health significance to department.-11 (2) Any practitioner licensed in this state to practice 12 medicine, osteopathic medicine, chiropractic medicine, 13 naturopathy, or veterinary medicine; any licensed pharmacist authorized under a protocol with a supervising licensed 14 physician, under s. 465.1895, or a collaborative pharmacy 15 practice agreement, as defined in s. 465.1865, to perform or 16 632875 - h0389-strike.docx Published On: 2/25/2020 7:55:05 PM Page 1 of 17

Bill No. HB 389 (2020)

Amendment No. 1

17 order and evaluate laboratory and clinical tests; any hospital licensed under part I of chapter 395; or any laboratory 18 19 appropriately certified by the Centers for Medicare and Medicaid 20 Services under the federal Clinical Laboratory Improvement 21 Amendments and the federal rules adopted thereunder which 22 diagnoses or suspects the existence of a disease of public 23 health significance shall immediately report the fact to the 24 Department of Health.

25 Section 2. Subsection (13) of section 465.003, Florida 26 Statutes, is amended to read:

27

Statutes, is amended to read: 465.003 Definitions.—As used in this chapter, the term:

28 (13) "Practice of the profession of pharmacy" includes 29 compounding, dispensing, and consulting concerning contents, 30 therapeutic values, and uses of any medicinal drug; consulting 31 concerning therapeutic values and interactions of patent or 32 proprietary preparations, whether pursuant to prescriptions or 33 in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For 34 35 purposes of this subsection, "other pharmaceutical services" 36 means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and 37 includes review of the patient's drug therapy and communication 38 with the patient's prescribing health care provider as licensed 39 under chapter 458, chapter 459, chapter 461, or chapter 466, or 40 41 similar statutory provision in another jurisdiction, or such

632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 2 of 17

Bill No. HB 389 (2020)

Amendment No. 1

42 provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy; and 43 44 initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice 45 46 agreement. However, Nothing in this subsection may be 47 interpreted to permit an alteration of a prescriber's 48 directions, the diagnosis or treatment of any disease, the 49 initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by 50 51 law or specifically authorized by s. 465.1865 or s. 465.1895. 52 "Practice of the profession of pharmacy" also includes any other 53 act, service, operation, research, or transaction incidental to, 54 or forming a part of, any of the foregoing acts, requiring, 55 involving, or employing the science or art of any branch of the 56 pharmaceutical profession, study, or training, and shall 57 expressly permit a pharmacist to transmit information from 58 persons authorized to prescribe medicinal drugs to their 59 patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 60 465.189, the administration of long-acting medication pursuant 61 62 to s. 465.1893, the testing or screening for and treatment of 63 minor, nonchronic health conditions under s. 465.1895, and the preparation of prepackaged drug products in facilities holding 64 Class III institutional pharmacy permits. 65

632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 3 of 17

Bill No. HB 389 (2020)

Amendment No. 1

66	Section 3. Section 465.1865, Florida Statutes, is created
67	to read:
68	465.1865 Collaborative pharmacy practice for chronic
69	health conditions
70	(1) For purposes of this section, the term:
71	(a) "Collaborative pharmacy practice agreement" means a
72	written agreement between a pharmacist who meets the
73	qualifications of this section and a physician licensed under
74	chapter 458 or chapter 459 in which a collaborating physician
75	authorizes a pharmacist to provide specified patient care
76	services to the collaborating physician's patients.
77	(b) "Chronic health condition" means a condition that
78	typically lasts more than 1 year and requires ongoing medical
79	attention, limits activities of daily living, or both. Such
80	condition may include, but is not limited to:
81	1. Arthritis;
82	2. Asthma;
83	3. Congestive heart failure;
84	4. Chronic obstructive pulmonary diseases;
85	5. Diabetes;
86	6. Emphysema;
87	7. Human immunodeficiency virus or acquired
88	immunodeficiency syndrome;
89	8. Hypertension;
90	9. Obesity;
6	632875 - h0389-strike.docx
	Published On: 2/25/2020 7:55:05 PM

Page 4 of 17

Bill No. HB 389 (2020)

Amendment No. 1

10. Renal disease; or
11. Any other chronic condition or comorbidity identified
by the collaborating physician.
(2) To provide services under a collaborative pharmacy
practice agreement, a pharmacist must:
(a) Hold an active and unencumbered license to practice
pharmacy in this state.
(b) Have earned a degree of doctor of pharmacy or have
completed 5 years of experience as a licensed pharmacist.
(c) Complete an initial 20-hour course approved by the
board that includes, at a minimum, instruction on the following:
1. Performance of patient assessments.
2. Ordering, performing, and interpreting clinical and
laboratory tests related to collaborative pharmacy practice.
3. Evaluating and managing diseases and health conditions
in collaboration with other health care practitioners.
4. Any other area required by the board by rule.
(d) Maintain at least \$250,000 of professional liability
insurance coverage. However, a pharmacist who maintains
professional liability insurance coverage pursuant to s.
465.1895 satisfies this requirement.
(e) Submit a copy of the signed collaborative pharmacy
practice agreement and proof of satisfying the conditions of
this section to the board before commencing practice.
 632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 5 of 17

Bill No. HB 389 (2020)

Amendment No. 1

115	(f) Maintain records of all patients receiving services
116	under a collaborative pharmacy practice agreement for a period
117	of 5 years.
118	(3) The terms and conditions of the collaborative pharmacy
119	practice agreement must be appropriate to the pharmacist's
120	training and the services delegated to the pharmacist must be
121	within the collaborating physician's scope of practice.
122	(a) A collaborative pharmacy practice agreement must
123	include the following:
124	1. Name of the patient or patients for whom a pharmacist
125	may provide services.
126	2. Each chronic disease to be collaboratively managed.
127	3. Specific medicinal drug or drugs to be managed by the
128	pharmacist.
129	4. Circumstances under which the pharmacist may order or
130	perform and evaluate laboratory or clinical tests.
131	5. Conditions and events upon which the pharmacist must
132	notify the collaborating physician and the manner and timeframe
133	in which such notification must occur.
134	6. Beginning and ending dates for the collaborative
135	pharmacy practice agreement and termination procedures,
136	including procedures for patient notification and medical
137	records transfers.

632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 6 of 17

Bill No. HB 389 (2020)

Amendment No. 1

138	7. A statement that the collaborative pharmacy practice
139	agreement may be terminated, in writing, by either party at any
140	time.
141	(b) A collaborative pharmacy practice agreement must be
142	renewed at least every 2 years.
143	(c) The pharmacist, along with the collaborating
144	physician, must maintain on file the collaborative pharmacy
145	practice agreement at his or her practice location, and must
146	make such agreements available upon request or inspection.
147	(4) A pharmacist may not:
148	(a) Modify or discontinue medicinal drugs prescribed by a
149	health care practitioner with whom he or she does not have a
150	collaborative practice agreement.
151	(b) Enter into a collaborative pharmacy practice agreement
152	while acting as an employee without the written approval of the
153	owner of the pharmacy.
154	(5) A physician may not delegate the authority to initiate
155	or prescribe a controlled substance as defined in s. 893.03 or
156	21 U.S.C. s. 812 to a pharmacist.
157	(6) A pharmacist who practices under a collaborative
158	pharmacy practice agreement must complete an 8-hour continuing
159	education course approved by the board that addresses issues
160	related to collaborative pharmacy practice each biennial
161	licensure renewal in addition to the continuing education
162	requirements under s. 465.009. A pharmacist must submit
6	532875 - h0389-strike.docx
	Published On: 2/25/2020 7:55:05 PM

Page 7 of 17

Bill No. HB 389 (2020)

Amendment No. 1

163 confirmation of having completed such course when applying for 164 licensure renewal. A pharmacist who fails to comply with this 165 subsection shall be prohibited from practicing under a 166 collaborative pharmacy practice agreement as authorized in this 167 section. 168 (7) The board shall adopt rules pursuant to ss. 120.536(1) 169 and 120.54 to implement this section. Section 4. Subsections (2) through (8) of section 465.189, 170 Florida Statutes, are renumbered as sections (3) through (9), 171 respectively, subsection (1) and present subsection (6) are 172 173 amended, and a new subsection (2) is added to that section, to 174 read: 175 465.189 Administration of vaccines and epinephrine 176 autoinjection.-177 In accordance with guidelines of the Centers for (1)178 Disease Control and Prevention for each recommended immunization or vaccine, a pharmacist, or a registered intern under the 179 supervision of a pharmacist who is certified under subsection 180 (7) (6), may administer the following vaccines to an adult 181 182 within the framework of an established protocol under a 183 supervising physician licensed under chapter 458 or chapter 459: 184 Immunizations or vaccines listed in the Adult (a) 185 Immunization Schedule as of February 1, 2015, by the United States Centers for Disease Control and Prevention's Recommended 186 Prevention. The board may authorize, by rule, additional 187 632875 - h0389-strike.docx Published On: 2/25/2020 7:55:05 PM Page 8 of 17

Bill No. HB 389 (2020)

Amendment No. 1

188 immunizations or vaccines as they are added to the Adult 189 Immunization Schedule, the United States Centers for Disease 190 Control and Prevention's Health Information for International 191 Travel, or the United States Food and Drug Administration's 192 Vaccines Licensed for Use in the United States. 193 (b) Immunizations or vaccines recommended by the United 194 States Centers for Disease Control and Prevention for international travel as of July 1, 2015. The board may 195 authorize, by rule, additional immunizations or vaccines as they 196 197 are recommended by the United States Centers for Disease Control 198 and Prevention for international travel. 199 (b) (c) Immunizations or vaccines approved by the board in 200 response to a state of emergency declared by the Governor 201 pursuant to s. 252.36. 202 203 A registered intern who administers an immunization or vaccine 204 under this subsection must be supervised by a certified 205 pharmacist at a ratio of one pharmacist to one registered 206 intern. 207 (2) A pharmacist who is certified under subsection (7) may 208 administer influenza vaccines to individuals 7 years of age and 209 older within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459. 210 211 (7) (6) Any pharmacist or registered intern seeking to administer vaccines to adults under this section must be 212 632875 - h0389-strike.docx Published On: 2/25/2020 7:55:05 PM

Page 9 of 17

Bill No. HB 389 (2020)

Amendment No. 1

213 certified to administer such vaccines pursuant to a 214 certification program approved by the Board of Pharmacy in 215 consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a 216 217 minimum, require that the pharmacist attend at least 20 hours of 218 continuing education classes approved by the board and the registered intern complete at least 20 hours of coursework 219 220 approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of 221 such vaccines, including, but not limited to, potential allergic 222 223 reactions to such vaccines.

224 Section 5. Paragraph (a) of subsection (1) and paragraph 225 (a) of subsection (2) of section 465.1893, Florida Statutes, are 226 amended to read:

227 465.1893 Administration of antipsychotic medication by 228 injection.-

(1) (a) A pharmacist, at the direction of a physician
licensed under chapter 458 or chapter 459, may administer a
long-acting antipsychotic medication <u>and extended-release</u>
<u>medications, including controlled substances, to treat substance</u>
<u>abuse disorder or dependency that have been</u> approved by the
United States Food and Drug Administration by injection to a
patient if the pharmacist:

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

632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 10 of 17

Bill No. HB 389 (2020)

Amendment No. 1

238 2. Practices at a facility that accommodates privacy for 239 nondeltoid injections and conforms with state rules and 240 regulations regarding the appropriate and safe disposal of 241 medication and medical waste.

242

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

(2) (a) A pharmacist seeking to administer a long-acting antipsychotic medication as described in paragraph (1) (a) of this section by injection must complete an 8-hour continuing education course offered by:

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

253

2. A statewide association of pharmacists.

254 Section 6. Section 465.1895, Florida Statutes, is created 255 to read:

256 <u>465.1895</u> Testing or screening for and treatment of minor, 257 nonchronic health conditions.—

258 (1) The board, in consultation with the Board of Medicine
 259 and the Board of Osteopathic Medicine, shall adopt rules
 260 identifying the minor, nonchronic health conditions for which a
 261 pharmacist may test or screen for and treat. For purposes of
 262 this section a minor, nonchronic health condition is typically a

632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 11 of 17

Bill No. HB 389 (2020)

Amendment No. 1

263	short-term condition that is generally managed with minimal
264	treatment or self-care, including, but not limited to, the
265	following:
266	(a) Influenza.
267	(b) Streptococcus.
268	(c) Lice.
269	(d) Skin conditions, such as ringworm and athlete's foot.
270	(e) Minor, uncomplicated infections.
271	(2) A pharmacist who tests or screens for and treats
272	minor, nonchronic health conditions under this section must:
273	(a) Hold an active and unencumbered license to practice
274	pharmacy in this state.
275	(b) Complete an initial 20-hour education course approved
276	by the board. The course, at a minimum, must address patient
277	assessments; point-of-care testing procedures; safe and
278	effective treatment of minor, nonchronic health conditions; and
279	identification of contraindications.
280	(c) Maintain at least \$250,000 of liability coverage. A
281	pharmacist who maintains liability coverage pursuant to s.
282	465.1865 satisfies this requirement.
283	(d) Report a diagnosis or suspected existence of a disease
284	of public health significance to the department pursuant to s.
285	381.0031.
286	(e) Upon request of a patient, furnish patient records to
287	a health care practitioner designated by the patient.
I	632875 - h0389-strike.docx
	Published On: 2/25/2020 7:55:05 PM

Page 12 of 17

Bill No. HB 389 (2020)

Amendment No. 1

288	(f) Maintain records of all patients receiving services
289	under this section for a period of 5 years.
290	(3) The board shall adopt, by rule, a formulary of
291	medicinal drugs that a pharmacist may prescribe for the minor,
292	nonchronic health conditions approved under subsection (1). The
293	formulary must include medicinal drugs approved by the United
294	States Food and Drug Administration which are indicated for
295	treatment of the minor, nonchronic health condition, including
296	any over-the-counter medication. The formulary may not include
297	any controlled substance as defined in s. 893.03 or 21 U.S.C. s.
298	<u>812.</u>
299	(4) A pharmacist who tests or screens for and treats
300	minor, nonchronic health conditions under this section may use
301	any tests that may guide diagnosis or clinical decisionmaking
302	which the Centers for Medicare and Medicaid Services has
303	determined qualifies for a waiver under the federal Clinical
304	Laboratory Improvement Amendments of 1988, or the federal rules
305	adopted thereunder, or any established screening procedures that
306	can safely be performed by a pharmacist.
307	(5) A pharmacist who tests for and treats influenza or
308	streptococcus under this section may only provide such services
309	within the framework of an established written protocol with a
310	supervising physician licensed under chapter 458 or chapter 459,
311	and must submit the protocol to the board.

632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 13 of 17

Bill No. HB 389 (2020)

Amendment No. 1

312	(a) The protocol between a pharmacist and supervising
313	physician under this subsection must include particular terms
314	and conditions imposed by the supervising physician relating to
315	the testing for and treatment of influenza and streptococcus
316	under this section. The terms and conditions must be appropriate
317	to the pharmacist's training. At a minimum, the protocol shall
318	include:
319	1. Specific categories of patients who the pharmacist is
320	authorized to test for and treat influenza and streptococcus.
321	2. The supervising physician's instructions for the
322	treatment of influenza and streptococcus based on the patient's
323	age, symptoms, and test results, including negative results.
324	3. A process and schedule for the supervising physician to
325	review the pharmacist's actions under the protocol.
326	4. A process and schedule for the pharmacist to notify the
327	supervising physician of the patient's condition, tests
328	administered, test results, and course of treatment.
329	5. Other requirements as established by the board in rule.
330	(b) A pharmacist authorized to test for and treat
331	influenza and streptococcus under the protocol shall provide
332	evidence of current certification by the board to the
333	supervising physician. A supervising physician shall review the
334	pharmacist's actions in accordance with the protocol.

632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 14 of 17

Bill No. HB 389 (2020)

Amendment No. 1

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335	(6) A pharmacist providing services under this section may
336	not perform such services while acting as an employee without
337	the written approval of the owner of the pharmacy.
338	(7) A pharmacist providing services under this section
339	must complete a 3-hour continuing education course approved by
340	the board addressing issues related to minor, nonchronic health
341	conditions each biennial licensure renewal in addition to the
342	continuing education requirements under s. 465.009. Each
343	pharmacist must submit confirmation of having completed the
344	course when applying for licensure renewal. A pharmacist who
345	fails to comply with this subsection may not provide testing,
346	screening, or treatment services.
347	Section 7. This act shall take effect July 1, 2020.
348	
348 349	
	TITLE AMENDMENT
349	TITLE AMENDMENT Remove everything before the enacting clause and insert:
349 350	
349 350 351	Remove everything before the enacting clause and insert:
349 350 351 352	Remove everything before the enacting clause and insert: An act relating to the practice of pharmacy; amending s.
349 350 351 352 353	Remove everything before the enacting clause and insert: An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to
349 350 351 352 353 354	Remove everything before the enacting clause and insert: An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information relating to public health to the
 349 350 351 352 353 354 355 	Remove everything before the enacting clause and insert: An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information relating to public health to the Department of Health; amending s. 465.003, F.S.; revising the
 349 350 351 352 353 354 355 356 	Remove everything before the enacting clause and insert: An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information relating to public health to the Department of Health; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy";
349 350 351 352 353 354 355 356 357	Remove everything before the enacting clause and insert: An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information relating to public health to the Department of Health; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy"; creating s. 465.1865, F.S.; providing definitions; providing
349 350 351 352 353 354 355 356 357 358 359	Remove everything before the enacting clause and insert: An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information relating to public health to the Department of Health; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy"; creating s. 465.1865, F.S.; providing definitions; providing requirements for pharmacists to provide services under a
349 350 351 352 353 354 355 356 357 358 359	Remove everything before the enacting clause and insert: An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information relating to public health to the Department of Health; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy"; creating s. 465.1865, F.S.; providing definitions; providing requirements for pharmacists to provide services under a collaborative pharmacy practice agreement; requiring the terms

Page 15 of 17

Bill No. HB 389 (2020)

Amendment No. 1

360 and conditions of such agreement to be appropriate to the 361 training of the pharmacist and the scope of practice of the 362 physician; requiring notification to the board upon practicing 363 under a collaborative pharmacy practice agreement; requiring 364 pharmacists to submit a copy of the signed collaborative 365 practice agreement to the Board of Pharmacy; providing for the maintenance of patient records for a certain period of time; 366 367 providing for renewal of such agreement; requiring a pharmacist and the collaborating physician to maintain on file and make 368 available the collaborative pharmacy practice agreement; 369 370 prohibiting certain actions relating to the collaborative 371 pharmacy practice agreement; requiring specified continuing 372 education for a pharmacist who practices under a collaborative 373 pharmacy practice agreement; requiring the Board of Pharmacy to 374 adopt rules; amending s. 465.189, F.S.; revising the recommended 375 immunizations or vaccines a pharmacist, or a registered intern 376 under certain conditions, may administer; authorizing a certified pharmacist to administer the influenza vaccine to 377 378 specified individuals; amending s. 465.1893, F.S.; authorizing 379 pharmacists who meet certain requirements to administer certain 380 extended release medications; creating s. 465.1895, F.S.; 381 requiring the board to identify minor, nonchronic health conditions that a pharmacist may test or screen for and treat; 382 providing requirements for a pharmacist to test or screen for 383 and treat minor, nonchronic health conditions; requiring the 384 632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 16 of 17

Bill No. HB 389 (2020)

Amendment No. 1

board to develop a formulary of medicinal drugs that a pharmacist may prescribe; providing requirements for the written protocol between a pharmacist and a supervising physician; prohibiting a pharmacist from providing certain services under certain circumstances; requiring a pharmacist to complete a specified amount of continuing education; providing an effective date.

632875 - h0389-strike.docx

Published On: 2/25/2020 7:55:05 PM

Page 17 of 17