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LEGISLATIVE ACTION

Senate

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House

The Committee on Innovation, Industry, and Technology (Hutson) recommended the following:

Senate Amendment (with title amendment)

Between lines 87 and 88

insert:

Section 2. Section 465.003, Florida Statutes, is reordered and amended to read:

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

(1) "Administration" means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.



11 ~~(3)-(2)~~ "Board" means the Board of Pharmacy.
12 ~~(9)-(3)~~ "Consultant pharmacist" means a pharmacist licensed
13 by the department and certified as a consultant pharmacist
14 pursuant to s. 465.0125.
15 ~~(10)-(4)~~ "Data communication device" means an electronic
16 device that receives electronic information from one source and
17 transmits or routes it to another, including, but not limited
18 to, any such bridge, router, switch, or gateway.
19 ~~(11)-(5)~~ "Department" means the Department of Health.
20 ~~(12)-(6)~~ "Dispense" means the transfer of possession of one
21 or more doses of a medicinal drug by a pharmacist to the
22 ultimate consumer or her or his agent. As an element of
23 dispensing, the pharmacist shall, prior to the actual physical
24 transfer, interpret and assess the prescription order for
25 potential adverse reactions, interactions, and dosage regimen
26 she or he deems appropriate in the exercise of her or his
27 professional judgment, and the pharmacist shall certify that the
28 medicinal drug called for by the prescription is ready for
29 transfer. The pharmacist shall also provide counseling on proper
30 drug usage, either orally or in writing, if in the exercise of
31 her or his professional judgment counseling is necessary. The
32 actual sales transaction and delivery of such drug shall not be
33 considered dispensing. The administration shall not be
34 considered dispensing.
35 (13) "Establishment" means a place of business that is
36 located at one general physical location and that may extend to
37 one or more contiguous suites, units, floors, or buildings
38 operated and controlled exclusively by entities under common
39 operation and control. The term includes multiple buildings with



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40 an intervening thoroughfare if the buildings are under common
41 exclusive ownership, operation, and control. For purposes of
42 permitting, each suite, unit, floor, or building must be
43 identified in the most recent permit application.

44 (14)-(7) "Institutional formulary system" means a method
45 whereby the medical staff evaluates, appraises, and selects
46 those medicinal drugs or proprietary preparations that, which in
47 the medical staff's clinical judgment, are most useful in
48 patient care, and that which are available for dispensing by a
49 practicing pharmacist in a Class II or Class III institutional
50 pharmacy.

51 (15)-(8) "Medicinal drugs" or "drugs" means those substances
52 or preparations commonly known as "prescription" or "legend"
53 drugs which are required by federal or state law to be dispensed
54 only on a prescription, but does shall not include patents or
55 proprietary preparations as hereafter defined in subsection
56 (18).

57 (18)-(9) "Patent or proprietary preparation" means a
58 medicine in its unbroken, original package which is sold to the
59 public by, or under the authority of, the manufacturer or
60 primary distributor thereof and which is not misbranded under
61 the provisions of the Florida Drug and Cosmetic Act.

62 (19)-(10) "Pharmacist" means any person licensed pursuant to
63 this chapter to practice the profession of pharmacy.

64 (20)-(11) (a) "Pharmacy" includes a community pharmacy, an
65 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
66 and an Internet pharmacy.

67 1. The term "community pharmacy" includes every location
68 where medicinal drugs are compounded, dispensed, stored, or sold



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69 or where prescriptions are filled or dispensed on an outpatient
70 basis.

71 2. The term "institutional pharmacy" includes every
72 location in a hospital, clinic, nursing home, dispensary,
73 sanitarium, extended care facility, or other facility,
74 ~~hereinafter~~ referred to as "health care institutions," where
75 medicinal drugs are compounded, dispensed, stored, or sold.

76 3. The term "nuclear pharmacy" includes every location
77 where radioactive drugs and chemicals within the classification
78 of medicinal drugs are compounded, dispensed, stored, or sold.
79 The term "nuclear pharmacy" does not include hospitals licensed
80 under chapter 395 or the nuclear medicine facilities of such
81 hospitals.

82 4. The term "special pharmacy" includes every location
83 where medicinal drugs are compounded, dispensed, stored, or sold
84 if such locations are not otherwise defined in this subsection.

85 5. The term "Internet pharmacy" includes locations not
86 otherwise licensed or issued a permit under this chapter, within
87 or outside this state, which use the Internet to communicate
88 with or obtain information from consumers in this state and use
89 such communication or information to fill or refill
90 prescriptions or to dispense, distribute, or otherwise engage in
91 the practice of pharmacy in this state. Any act described in
92 this definition constitutes the practice of pharmacy as defined
93 in subsection (22) ~~(13)~~.

94 (b) The pharmacy department of any permittee is ~~shall be~~
95 considered closed whenever a Florida licensed pharmacist is not
96 present and on duty. The term "not present and on duty" may
97 ~~shall~~ not be construed to prevent a pharmacist from exiting the



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98 prescription department for the purposes of consulting or
99 responding to inquiries or providing assistance to patients or
100 customers, attending to personal hygiene needs, or performing
101 any other function for which the pharmacist is responsible,
102 provided that such activities are conducted in a manner
103 consistent with the pharmacist's responsibility to provide
104 pharmacy services.

105 (21)~~(12)~~ "Pharmacy intern" means a person who is currently
106 registered in, and attending, a duly accredited college or
107 school of pharmacy, or who is a graduate of such a school or
108 college of pharmacy, and who is duly and properly registered
109 with the department as provided by department rule ~~for under its~~
110 ~~rules~~.

111 (22)~~(13)~~ "Practice of the profession of pharmacy" includes
112 compounding, dispensing, and consulting concerning contents,
113 therapeutic values, and uses of any medicinal drug; consulting
114 concerning therapeutic values and interactions of patent or
115 proprietary preparations, whether pursuant to prescriptions or
116 in the absence and entirely independent of such prescriptions or
117 orders; and conducting other pharmaceutical services. For
118 purposes of this subsection, "other pharmaceutical services"
119 means the monitoring of the patient's drug therapy and assisting
120 the patient in the management of his or her drug therapy, and
121 includes review of the patient's drug therapy and communication
122 with the patient's prescribing health care provider as licensed
123 under chapter 458, chapter 459, chapter 461, or chapter 466, or
124 similar statutory provision in another jurisdiction, or such
125 provider's agent or such other persons as specifically
126 authorized by the patient, regarding the drug therapy. However,



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127 ~~nothing in~~ this subsection may not be interpreted to permit an
128 alteration of a prescriber's directions, the diagnosis or
129 treatment of any disease, the initiation of any drug therapy,
130 the practice of medicine, or the practice of osteopathic
131 medicine, unless otherwise permitted by law. The term "practice
132 of the profession of pharmacy" also includes any other act,
133 service, operation, research, or transaction incidental to, or
134 forming a part of, any of the foregoing acts, requiring,
135 involving, or employing the science or art of any branch of the
136 pharmaceutical profession, study, or training, and ~~shall~~
137 expressly authorizes ~~permit~~ a pharmacist to transmit information
138 from persons authorized to prescribe medicinal drugs to their
139 patients. The practice of the profession of pharmacy also
140 includes the administration of vaccines to adults pursuant to s.
141 465.189 and the preparation of prepackaged drug products in
142 facilities holding Class III institutional pharmacy permits.

143 (23)-(14) "Prescription" includes any order for drugs or
144 medicinal supplies written or transmitted by any means of
145 communication by a duly licensed practitioner authorized by the
146 laws of this ~~the~~ state to prescribe such drugs or medicinal
147 supplies and which drugs or medicinal supplies are intended to
148 be dispensed by a pharmacist. The term also includes an orally
149 transmitted order by the lawfully designated agent of such a
150 practitioner. The term also includes an order written or
151 transmitted by a practitioner licensed to practice in a
152 jurisdiction other than this state, but only if the pharmacist
153 called upon to dispense such order determines, in the exercise
154 of her or his professional judgment, that the order is valid and
155 necessary for the treatment of a chronic or recurrent illness;



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156 ~~and. The term "prescription" also includes~~ a pharmacist's order
157 for a product selected from the formulary created pursuant to s.
158 465.186. Prescriptions may be retained in written form or the
159 pharmacist may cause them to be recorded in a data processing
160 system, provided that such order can be produced in printed form
161 upon lawful request.

162 ~~(16)-(15)~~ "Nuclear pharmacist" means a pharmacist licensed
163 by the department and certified as a nuclear pharmacist pursuant
164 to s. 465.0126.

165 ~~(5)-(16)~~ "Centralized prescription filling" means the
166 filling of a prescription by one pharmacy upon the request of ~~by~~
167 another pharmacy to fill or refill the prescription. The term
168 includes the performance by one pharmacy for another pharmacy of
169 other pharmacy duties, such as drug utilization review,
170 therapeutic drug utilization review, claims adjudication, and
171 the obtaining of refill authorizations.

172 ~~(2)-(17)~~ "Automated pharmacy system" means a mechanical
173 system that delivers prescription drugs received from a Florida-
174 licensed ~~Florida-licensed~~ pharmacy and maintains related
175 transaction information.

176 ~~(8)-(18)~~ "Compounding" means combining, mixing, or altering
177 the ingredients of one or more drugs or products to create
178 another drug or product.

179 ~~(17)-(19)~~ "Outsourcing facility" means a single physical
180 location registered as an outsourcing facility under the federal
181 Drug Quality and Security Act, Pub. L. No. 113-54, at which
182 sterile compounding of a drug or product is conducted.

183 ~~(7)-(20)~~ "Compounded sterile product" means a drug that is
184 intended for parenteral administration, an ophthalmic or oral



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185 inhalation drug in aqueous format, or a drug or product that is
186 required to be sterile under federal or state law or rule, which
187 is produced through compounding, but is not approved by the
188 United States Food and Drug Administration.

189 (4)~~(21)~~ "Central distribution facility" means a facility
190 under common control with a hospital holding a Class III
191 institutional pharmacy permit that may dispense, distribute,
192 compound, or fill prescriptions for medicinal drugs; prepare
193 prepackaged drug products; and conduct other pharmaceutical
194 services.

195 (6)~~(22)~~ "Common control" means the power to direct or cause
196 the direction of the management and policies of a person or an
197 organization, whether by ownership of stock, voting rights,
198 contract, or otherwise.

199 Section 3. Paragraph (a) of subsection (1) of section
200 409.9201, Florida Statutes, is amended to read:

201 409.9201 Medicaid fraud.—

202 (1) As used in this section, the term:

203 (a) "Prescription drug" means any drug, including, but not
204 limited to, finished dosage forms or active ingredients that are
205 subject to, defined in, or described in s. 503(b) of the Federal
206 Food, Drug, and Cosmetic Act or in s. 465.003(15) ~~s. 465.003(8)~~,
207 s. 499.003(17), s. 499.007(13), or s. 499.82(10).

208
209 The value of individual items of the legend drugs or goods or
210 services involved in distinct transactions committed during a
211 single scheme or course of conduct, whether involving a single
212 person or several persons, may be aggregated when determining
213 the punishment for the offense.



214 Section 4. Paragraph (pp) of subsection (1) of section
215 458.331, Florida Statutes, is amended to read:

216 458.331 Grounds for disciplinary action; action by the
217 board and department.—

218 (1) The following acts constitute grounds for denial of a
219 license or disciplinary action, as specified in s. 456.072(2):

220 (pp) Applicable to a licensee who serves as the designated
221 physician of a pain-management clinic as defined in s. 458.3265
222 or s. 459.0137:

223 1. Registering a pain-management clinic through
224 misrepresentation or fraud;

225 2. Procuring, or attempting to procure, the registration of
226 a pain-management clinic for any other person by making or
227 causing to be made, any false representation;

228 3. Failing to comply with any requirement of chapter 499,
229 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
230 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
231 the Drug Abuse Prevention and Control Act; or chapter 893, the
232 Florida Comprehensive Drug Abuse Prevention and Control Act;

233 4. Being convicted or found guilty of, regardless of
234 adjudication to, a felony or any other crime involving moral
235 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
236 the courts of this state, of any other state, or of the United
237 States;

238 5. Being convicted of, or disciplined by a regulatory
239 agency of the Federal Government or a regulatory agency of
240 another state for, any offense that would constitute a violation
241 of this chapter;

242 6. Being convicted of, or entering a plea of guilty or nolo



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243 | contendere to, regardless of adjudication, a crime in any
244 | jurisdiction of the courts of this state, of any other state, or
245 | of the United States which relates to the practice of, or the
246 | ability to practice, a licensed health care profession;

247 | 7. Being convicted of, or entering a plea of guilty or nolo
248 | contendere to, regardless of adjudication, a crime in any
249 | jurisdiction of the courts of this state, of any other state, or
250 | of the United States which relates to health care fraud;

251 | 8. Dispensing any medicinal drug based upon a communication
252 | that purports to be a prescription as defined in s. 465.003 ~~s.~~
253 | ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
254 | has reason to believe that the purported prescription is not
255 | based upon a valid practitioner-patient relationship; or

256 | 9. Failing to timely notify the board of the date of his or
257 | her termination from a pain-management clinic as required by s.
258 | 458.3265(3).

259 | Section 5. Paragraph (rr) of subsection (1) of section
260 | 459.015, Florida Statutes, is amended to read:

261 | 459.015 Grounds for disciplinary action; action by the
262 | board and department.—

263 | (1) The following acts constitute grounds for denial of a
264 | license or disciplinary action, as specified in s. 456.072(2):

265 | (rr) Applicable to a licensee who serves as the designated
266 | physician of a pain-management clinic as defined in s. 458.3265
267 | or s. 459.0137:

268 | 1. Registering a pain-management clinic through
269 | misrepresentation or fraud;

270 | 2. Procuring, or attempting to procure, the registration of
271 | a pain-management clinic for any other person by making or



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272 causing to be made, any false representation;

273 3. Failing to comply with any requirement of chapter 499,
274 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
275 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
276 the Drug Abuse Prevention and Control Act; or chapter 893, the
277 Florida Comprehensive Drug Abuse Prevention and Control Act;

278 4. Being convicted or found guilty of, regardless of
279 adjudication to, a felony or any other crime involving moral
280 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
281 the courts of this state, of any other state, or of the United
282 States;

283 5. Being convicted of, or disciplined by a regulatory
284 agency of the Federal Government or a regulatory agency of
285 another state for, any offense that would constitute a violation
286 of this chapter;

287 6. Being convicted of, or entering a plea of guilty or nolo
288 contendere to, regardless of adjudication, a crime in any
289 jurisdiction of the courts of this state, of any other state, or
290 of the United States which relates to the practice of, or the
291 ability to practice, a licensed health care profession;

292 7. Being convicted of, or entering a plea of guilty or nolo
293 contendere to, regardless of adjudication, a crime in any
294 jurisdiction of the courts of this state, of any other state, or
295 of the United States which relates to health care fraud;

296 8. Dispensing any medicinal drug based upon a communication
297 that purports to be a prescription as defined in s. 465.003 ~~s.~~
298 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
299 has reason to believe that the purported prescription is not
300 based upon a valid practitioner-patient relationship; or



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301 9. Failing to timely notify the board of the date of his or
302 her termination from a pain-management clinic as required by s.
303 459.0137(3).

304 Section 6. Subsection (1) of section 465.014, Florida
305 Statutes, is amended to read:

306 465.014 Pharmacy technician.—

307 (1) A person other than a licensed pharmacist or pharmacy
308 intern may not engage in the practice of the profession of
309 pharmacy, except that a licensed pharmacist may delegate to
310 pharmacy technicians who are registered pursuant to this section
311 those duties, tasks, and functions that do not fall within the
312 purview of s. 456.003(22) ~~s. 465.003(13)~~. All such delegated
313 acts must be performed under the direct supervision of a
314 licensed pharmacist who is responsible for all such acts
315 performed by persons under his or her supervision. A registered
316 pharmacy technician, under the supervision of a pharmacist, may
317 initiate or receive communications with a practitioner or his or
318 her agent, on behalf of a patient, regarding refill
319 authorization requests. A licensed pharmacist may not supervise
320 more than one registered pharmacy technician unless otherwise
321 permitted by the guidelines adopted by the board. The board
322 shall establish guidelines to be followed by licensees or
323 permittees in determining the circumstances under which a
324 licensed pharmacist may supervise more than one pharmacy
325 technician.

326 Section 7. Paragraph (c) of subsection (2) of section
327 465.015, Florida Statutes, is amended to read:

328 465.015 Violations and penalties.—

329 (2) It is unlawful for any person:



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330 (c) To sell or dispense drugs as defined in s. 465.003(15)
331 ~~s. 465.003(8)~~ without first being furnished with a prescription.

332 Section 8. Subsection (9) of section 465.0156, Florida
333 Statutes, is amended to read:

334 465.0156 Registration of nonresident pharmacies.—

335 (9) Notwithstanding s. 465.003(19) ~~s. 465.003(10)~~, for
336 purposes of this section, the registered pharmacy and the
337 pharmacist designated by the registered pharmacy as the
338 prescription department manager or the equivalent must be
339 licensed in the state of location in order to dispense into this
340 state.

341 Section 9. Paragraph (s) of subsection (1) of section
342 465.016, Florida Statutes, is amended to read:

343 465.016 Disciplinary actions.—

344 (1) The following acts constitute grounds for denial of a
345 license or disciplinary action, as specified in s. 456.072(2):

346 (s) Dispensing any medicinal drug based upon a
347 communication that purports to be a prescription as defined in
348 s. 465.003 ~~by s. 465.003(14)~~ or s. 893.02 when the pharmacist
349 knows or has reason to believe that the purported prescription
350 is not based upon a valid practitioner-patient relationship.

351 Section 10. Subsection (4) of section 465.0197, Florida
352 Statutes, is amended to read:

353 465.0197 Internet pharmacy permits.—

354 (4) Notwithstanding s. 465.003(19) ~~s. 465.003(10)~~, for
355 purposes of this section, the Internet pharmacy and the
356 pharmacist designated by the Internet pharmacy as the
357 prescription department manager or the equivalent must be
358 licensed in the state of location in order to dispense into this



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359 state.

360 Section 11. Paragraph (j) of subsection (5) of section
361 465.022, Florida Statutes, is amended to read:

362 465.022 Pharmacies; general requirements; fees.—

363 (5) The department or board shall deny an application for a
364 pharmacy permit if the applicant or an affiliated person,
365 partner, officer, director, or prescription department manager
366 or consultant pharmacist of record of the applicant:

367 (j) Has dispensed any medicinal drug based upon a
368 communication that purports to be a prescription as defined in
369 s. 465.003 ~~by s. 465.003(14)~~ or s. 893.02 when the pharmacist
370 knows or has reason to believe that the purported prescription
371 is not based upon a valid practitioner-patient relationship that
372 includes a documented patient evaluation, including history and
373 a physical examination adequate to establish the diagnosis for
374 which any drug is prescribed and any other requirement
375 established by board rule under chapter 458, chapter 459,
376 chapter 461, chapter 463, chapter 464, or chapter 466.

377
378 For felonies in which the defendant entered a plea of guilty or
379 nolo contendere in an agreement with the court to enter a
380 pretrial intervention or drug diversion program, the department
381 shall deny the application if upon final resolution of the case
382 the licensee has failed to successfully complete the program.

383 Section 12. Paragraph (h) of subsection (1) of section
384 465.023, Florida Statutes, is amended to read:

385 465.023 Pharmacy permittee; disciplinary action.—

386 (1) The department or the board may revoke or suspend the
387 permit of any pharmacy permittee, and may fine, place on



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388 probation, or otherwise discipline any pharmacy permittee if the
389 permittee, or any affiliated person, partner, officer, director,
390 or agent of the permittee, including a person fingerprinted
391 under s. 465.022(3), has:

392 (h) Dispensed any medicinal drug based upon a communication
393 that purports to be a prescription as defined in s. 465.003 ~~by~~
394 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows or has
395 reason to believe that the purported prescription is not based
396 upon a valid practitioner-patient relationship that includes a
397 documented patient evaluation, including history and a physical
398 examination adequate to establish the diagnosis for which any
399 drug is prescribed and any other requirement established by
400 board rule under chapter 458, chapter 459, chapter 461, chapter
401 463, chapter 464, or chapter 466.

402 Section 13. Section 465.1901, Florida Statutes, is amended
403 to read:

404 465.1901 Practice of orthotics and pedorthics.—The
405 provisions of chapter 468 relating to orthotics or pedorthics do
406 not apply to any licensed pharmacist or to any person acting
407 under the supervision of a licensed pharmacist. The practice of
408 orthotics or pedorthics by a pharmacist or any of the
409 pharmacist's employees acting under the supervision of a
410 pharmacist shall be construed to be within the meaning of the
411 term "practice of the profession of pharmacy" as defined in s.
412 465.003 ~~set forth in s. 465.003(13)~~, and shall be subject to
413 regulation in the same manner as any other pharmacy practice.
414 The Board of Pharmacy shall develop rules regarding the practice
415 of orthotics and pedorthics by a pharmacist. Any pharmacist or
416 person under the supervision of a pharmacist engaged in the



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417 practice of orthotics or pedorthics is not precluded from
418 continuing that practice pending adoption of these rules.

419 Section 14. Subsection (40) of section 499.003, Florida
420 Statutes, is amended to read:

421 499.003 Definitions of terms used in this part.—As used in
422 this part, the term:

423 (40) "Prescription drug" means a prescription, medicinal,
424 or legend drug, including, but not limited to, finished dosage
425 forms or active pharmaceutical ingredients subject to, defined
426 by, or described by s. 503(b) of the federal act or s.
427 465.003(15) ~~s. 465.003(8)~~, s. 499.007(13), subsection (31), or
428 subsection (47), except that an active pharmaceutical ingredient
429 is a prescription drug only if substantially all finished dosage
430 forms in which it may be lawfully dispensed or administered in
431 this state are also prescription drugs.

432 Section 15. Paragraph (c) of subsection (24) of section
433 893.02, Florida Statutes, is amended to read:

434 893.02 Definitions.—The following words and phrases as used
435 in this chapter shall have the following meanings, unless the
436 context otherwise requires:

437 (24) "Prescription" includes any order for drugs or
438 medicinal supplies which is written or transmitted by any means
439 of communication by a licensed practitioner authorized by the
440 laws of this state to prescribe such drugs or medicinal
441 supplies, is issued in good faith and in the course of
442 professional practice, is intended to be dispensed by a person
443 authorized by the laws of this state to do so, and meets the
444 requirements of s. 893.04.

445 (c) A prescription for a controlled substance may not be



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446 issued on the same prescription blank with another prescription
447 for a controlled substance that is named or described in a
448 different schedule or with another prescription for a medicinal
449 drug, as defined in s. 465.003 ~~s. 465.003(8)~~, that is not a
450 controlled substance.

451
452 ===== T I T L E A M E N D M E N T =====

453 And the title is amended as follows:

454 Between lines 9 and 10

455 insert:

456 reordering and amending s. 465.003, F.S.; defining the
457 term "establishment"; amending ss. 409.9201, 458.331,
458 459.015, 465.014, 465.015, 465.0156, 465.016,
459 465.0197, 465.022, 465.023, 465.1901, 499.003, and
460 893.02, F.S.; conforming cross-references;