

By Senator Latvala

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1 A bill to be entitled
2 An act relating to the practice of pharmacy; amending
3 s. 465.003, F.S.; defining a term; amending s.
4 465.0276, F.S.; providing that the Florida Pharmacy
5 Act does not prohibit the dispensing of a compounded
6 drug by a veterinarian; amending ss. 409.9201,
7 458.331, 459.015, 465.014, 465.015, 465.0156, 465.016,
8 465.0197, 465.022, 465.023, 465.1901, 499.003, and
9 893.02; conforming cross references; providing an
10 effective date.

11
12 Be It Enacted by the Legislature of the State of Florida:

13
14 Section 1. Section 465.003, Florida Statutes, is reordered
15 and amended, to read:

16 465.003 Definitions.—As used in this chapter, the term:

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

20 (3)~~(2)~~ "Board" means the Board of Pharmacy.

21 (7)~~(3)~~ "Consultant pharmacist" means a pharmacist licensed
22 by the department and certified as a consultant pharmacist
23 pursuant to s. 465.0125.

24 (8)~~(4)~~ "Data communication device" means an electronic
25 device that receives electronic information from one source and
26 transmits or routes it to another, including, but not limited
27 to, any such bridge, router, switch, or gateway.

28 (9)~~(5)~~ "Department" means the Department of Health.

29 (10)~~(6)~~ "Dispense" means the transfer of possession of one

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30 or more doses of a medicinal drug by a pharmacist to the
31 ultimate consumer or her or his agent. As an element of
32 dispensing, the pharmacist shall, prior to the actual physical
33 transfer, interpret and assess the prescription order for
34 potential adverse reactions, interactions, and dosage regimen
35 she or he deems appropriate in the exercise of her or his
36 professional judgment, and the pharmacist shall certify that the
37 medicinal drug called for by the prescription is ready for
38 transfer. The pharmacist shall also provide counseling on proper
39 drug usage, either orally or in writing, if in the exercise of
40 her or his professional judgment counseling is necessary. The
41 actual sales transaction and delivery of such drug shall not be
42 considered dispensing. The administration shall not be
43 considered dispensing.

44 (11)~~(7)~~ "Institutional formulary system" means a method
45 whereby the medical staff evaluates, appraises, and selects
46 those medicinal drugs or proprietary preparations which in the
47 medical staff's clinical judgment are most useful in patient
48 care, and which are available for dispensing by a practicing
49 pharmacist in a Class II institutional pharmacy.

50 (12)~~(8)~~ "Medicinal drugs" or "drugs" means those substances
51 or preparations commonly known as "prescription" or "legend"
52 drugs which are required by federal or state law to be dispensed
53 only on a prescription, but shall not include patents or
54 proprietary preparations as hereafter defined.

55 (16)~~(9)~~ "Patent or proprietary preparation" means a
56 medicine in its unbroken, original package which is sold to the
57 public by, or under the authority of, the manufacturer or
58 primary distributor thereof and which is not misbranded under

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59 the provisions of the Florida Drug and Cosmetic Act.

60 (17)~~(10)~~ "Pharmacist" means any person licensed pursuant to
61 this chapter to practice the profession of pharmacy.

62 (18)~~(11)~~(a) "Pharmacy" includes a community pharmacy, an
63 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
64 and an Internet pharmacy.

65 1. The term "community pharmacy" includes every location
66 where medicinal drugs are compounded, dispensed, stored, or sold
67 or where prescriptions are filled or dispensed on an outpatient
68 basis.

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

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

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

83 5. The term "Internet pharmacy" includes locations not
84 otherwise licensed or issued a permit under this chapter, within
85 or outside this state, which use the Internet to communicate
86 with or obtain information from consumers in this state and use
87 such communication or information to fill or refill

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88 prescriptions or to dispense, distribute, or otherwise engage in
89 the practice of pharmacy in this state. Any act described in
90 this definition constitutes the practice of pharmacy as defined
91 in subsection (20) ~~(13)~~.

92 (b) The pharmacy department of any permittee shall be
93 considered closed whenever a Florida licensed pharmacist is not
94 present and on duty. The term "not present and on duty" shall
95 not be construed to prevent a pharmacist from exiting the
96 prescription department for the purposes of consulting or
97 responding to inquiries or providing assistance to patients or
98 customers, attending to personal hygiene needs, or performing
99 any other function for which the pharmacist is responsible,
100 provided that such activities are conducted in a manner
101 consistent with the pharmacist's responsibility to provide
102 pharmacy services.

103 (19) ~~(12)~~ "Pharmacy intern" means a person who is currently
104 registered in, and attending, a duly accredited college or
105 school of pharmacy, or who is a graduate of such a school or
106 college of pharmacy, and who is duly and properly registered
107 with the department as provided for under its rules.

108 (20) ~~(13)~~ "Practice of the profession of pharmacy" includes
109 compounding, dispensing, and consulting concerning contents,
110 therapeutic values, and uses of any medicinal drug; consulting
111 concerning therapeutic values and interactions of patent or
112 proprietary preparations, whether pursuant to prescriptions or
113 in the absence and entirely independent of such prescriptions or
114 orders; and other pharmaceutical services. For purposes of this
115 subsection, "other pharmaceutical services" means the monitoring
116 of the patient's drug therapy and assisting the patient in the

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117 management of his or her drug therapy, and includes review of
118 the patient's drug therapy and communication with the patient's
119 prescribing health care provider as licensed under chapter 458,
120 chapter 459, chapter 461, or chapter 466, or similar statutory
121 provision in another jurisdiction, or such provider's agent or
122 such other persons as specifically authorized by the patient,
123 regarding the drug therapy. However, nothing in this subsection
124 may be interpreted to permit an alteration of a prescriber's
125 directions, the diagnosis or treatment of any disease, the
126 initiation of any drug therapy, the practice of medicine, or the
127 practice of osteopathic medicine, unless otherwise permitted by
128 law. "Practice of the profession of pharmacy" also includes any
129 other act, service, operation, research, or transaction
130 incidental to, or forming a part of, any of the foregoing acts,
131 requiring, involving, or employing the science or art of any
132 branch of the pharmaceutical profession, study, or training, and
133 shall expressly permit a pharmacist to transmit information from
134 persons authorized to prescribe medicinal drugs to their
135 patients. The practice of the profession of pharmacy also
136 includes the administration of vaccines to adults pursuant to s.
137 465.189.

138 (21) ~~(14)~~ "Prescription" includes any order for drugs or
139 medicinal supplies written or transmitted by any means of
140 communication by a duly licensed practitioner authorized by the
141 laws of the state to prescribe such drugs or medicinal supplies
142 and intended to be dispensed by a pharmacist. The term also
143 includes an orally transmitted order by the lawfully designated
144 agent of such practitioner. The term also includes an order
145 written or transmitted by a practitioner licensed to practice in

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146 a jurisdiction other than this state, but only if the pharmacist
147 called upon to dispense such order determines, in the exercise
148 of her or his professional judgment, that the order is valid and
149 necessary for the treatment of a chronic or recurrent illness.
150 The term "prescription" also includes a pharmacist's order for a
151 product selected from the formulary created pursuant to s.
152 465.186. Prescriptions may be retained in written form or the
153 pharmacist may cause them to be recorded in a data processing
154 system, provided that such order can be produced in printed form
155 upon lawful request.

156 (13)~~(15)~~ "Nuclear pharmacist" means a pharmacist licensed
157 by the department and certified as a nuclear pharmacist pursuant
158 to s. 465.0126.

159 (14) "Office use compounding" means the provision and
160 administration of a compounded drug to a patient by a
161 practitioner in the practitioner's office or other treatment
162 setting. In the case of veterinary drugs, office use compounding
163 includes compounding for a veterinarian to dispense to the owner
164 or caretaker of the animal patient.

165 (4)~~(16)~~ "Centralized prescription filling" means the
166 filling of a prescription by one pharmacy upon request 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 pharmacy and maintains related transaction information.

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175 (6)~~(18)~~ "Compounding" means combining, mixing, or altering
176 the ingredients of one or more drugs or products to create
177 another drug or product.

178 (15)~~(19)~~ "Outsourcing facility" means a single physical
179 location registered as an outsourcing facility under the federal
180 Drug Quality and Security Act, Pub. L. No. 113-54, at which
181 sterile compounding of a drug or product is conducted.

182 (5)~~(20)~~ "Compounded sterile product" means a drug that is
183 intended for parenteral administration, an ophthalmic or oral
184 inhalation drug in aqueous format, or a drug or product that is
185 required to be sterile under federal or state law or rule, which
186 is produced through compounding, but is not approved by the
187 United States Food and Drug Administration.

188 Section 2. A new subsection (6) is added to section
189 465.0276, Florida Statutes, to read:

190 465.0276 Dispensing practitioner.—

191 (6) Nothing in this chapter or the rules adopted thereunder
192 prohibit a veterinarian from dispensing a compounded drug to an
193 animal patient or its owner or caretaker.

194 Section 3. Paragraph (a) of subsection (1) of section
195 409.9201, Florida Statutes, is amended to read:

196 409.9201 Medicaid fraud.—

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

198 (a) "Prescription drug" means any drug, including, but not
199 limited to, finished dosage forms or active ingredients that are
200 subject to, defined in, or described in s. 503(b) of the Federal
201 Food, Drug, and Cosmetic Act or in s. 465.003 ~~s. 465.003(8)~~, s.
202 499.003(52), s. 499.007(13), or s. 499.82(10).
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204 The value of individual items of the legend drugs or goods or
205 services involved in distinct transactions committed during a
206 single scheme or course of conduct, whether involving a single
207 person or several persons, may be aggregated when determining
208 the punishment for the offense.

209 Section 4. Paragraph (pp) of subsection (1) of section
210 458.331, Florida Statutes, is amended to read:

211 458.331 Grounds for disciplinary action; action by the
212 board and department.—

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

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

218 1. Registering a pain-management clinic through
219 misrepresentation or fraud;

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

223 3. Failing to comply with any requirement of chapter 499,
224 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
225 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
226 the Drug Abuse Prevention and Control Act; or chapter 893, the
227 Florida Comprehensive Drug Abuse Prevention and Control Act;

228 4. Being convicted or found guilty of, regardless of
229 adjudication to, a felony or any other crime involving moral
230 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
231 the courts of this state, of any other state, or of the United
232 States;

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233 5. Being convicted of, or disciplined by a regulatory
234 agency of the Federal Government or a regulatory agency of
235 another state for, any offense that would constitute a violation
236 of this chapter;

237 6. Being convicted of, or entering a plea of guilty or nolo
238 contendere to, regardless of adjudication, a crime in any
239 jurisdiction of the courts of this state, of any other state, or
240 of the United States which relates to the practice of, or the
241 ability to practice, a licensed health care profession;

242 7. Being convicted of, or entering a plea of guilty or nolo
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 health care fraud;

246 8. Dispensing any medicinal drug based upon a communication
247 that purports to be a prescription as defined in s. 465.003 ~~s.~~
248 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
249 has reason to believe that the purported prescription is not
250 based upon a valid practitioner-patient relationship; or

251 9. Failing to timely notify the board of the date of his or
252 her termination from a pain-management clinic as required by s.
253 458.3265(2).

254 Section 5. Paragraph (rr) of subsection (1) of section
255 459.015, Florida Statutes, is amended to read:

256 459.015 Grounds for disciplinary action; action by the
257 board and department.—

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

260 (rr) Applicable to a licensee who serves as the designated
261 physician of a pain-management clinic as defined in s. 458.3265

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262 or s. 459.0137:

263 1. Registering a pain-management clinic through
264 misrepresentation or fraud;

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

268 3. Failing to comply with any requirement of chapter 499,
269 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
270 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
271 the Drug Abuse Prevention and Control Act; or chapter 893, the
272 Florida Comprehensive Drug Abuse Prevention and Control Act;

273 4. Being convicted or found guilty of, regardless of
274 adjudication to, a felony or any other crime involving moral
275 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
276 the courts of this state, of any other state, or of the United
277 States;

278 5. Being convicted of, or disciplined by a regulatory
279 agency of the Federal Government or a regulatory agency of
280 another state for, any offense that would constitute a violation
281 of this chapter;

282 6. Being convicted of, or entering a plea of guilty or nolo
283 contendere to, regardless of adjudication, a crime in any
284 jurisdiction of the courts of this state, of any other state, or
285 of the United States which relates to the practice of, or the
286 ability to practice, a licensed health care profession;

287 7. 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 health care fraud;

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291 8. Dispensing any medicinal drug based upon a communication
292 that purports to be a prescription as defined in s. 465.003 ~~s.~~
293 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
294 has reason to believe that the purported prescription is not
295 based upon a valid practitioner-patient relationship; or

296 9. Failing to timely notify the board of the date of his or
297 her termination from a pain-management clinic as required by s.
298 459.0137(2).

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

301 465.014 Pharmacy technician.—

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

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320 Section 7. Paragraph (c) of subsection (2) of section
321 465.015, Florida Statutes, is amended to read:

322 465.015 Violations and penalties.—

323 (2) It is unlawful for any person:

324 (c) To sell or dispense drugs as defined in s. 465.003 ~~s.~~
325 ~~465.003(8)~~ without first being furnished with a prescription.

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

328 465.0156 Registration of nonresident pharmacies.—

329 (9) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes
330 of this section, the registered pharmacy and the pharmacist
331 designated by the registered pharmacy as the prescription
332 department manager or the equivalent must be licensed in the
333 state of location in order to dispense into this state.

334 Section 9. Paragraph (s) of subsection (1) of section
335 465.016, Florida Statutes, is amended to read:

336 465.016 Disciplinary actions.—

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

339 (s) Dispensing any medicinal drug based upon a
340 communication that purports to be a prescription as defined by
341 s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows
342 or has reason to believe that the purported prescription is not
343 based upon a valid practitioner-patient relationship.

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

346 465.0197 Internet pharmacy permits.—

347 (4) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes
348 of this section, the Internet pharmacy and the pharmacist

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349 designated by the Internet pharmacy as the prescription
350 department manager or the equivalent must be licensed in the
351 state of location in order to dispense into this state.

352 Section 11. Paragraph (j) of subsection (5) of section
353 465.022, Florida Statutes, is amended to read:

354 465.022 Pharmacies; general requirements; fees.—

355 (5) The department or board shall deny an application for a
356 pharmacy permit if the applicant or an affiliated person,
357 partner, officer, director, or prescription department manager
358 or consultant pharmacist of record of the applicant:

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

369
370 For felonies in which the defendant entered a plea of guilty or
371 nolo contendere in an agreement with the court to enter a
372 pretrial intervention or drug diversion program, the department
373 shall deny the application if upon final resolution of the case
374 the licensee has failed to successfully complete the program.

375 Section 12. Paragraph (h) of subsection (1) of section
376 465.023, Florida Statutes, is amended to read:

377 465.023 Pharmacy permittee; disciplinary action.—

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378 (1) The department or the board may revoke or suspend the
379 permit of any pharmacy permittee, and may fine, place on
380 probation, or otherwise discipline any pharmacy permittee if the
381 permittee, or any affiliated person, partner, officer, director,
382 or agent of the permittee, including a person fingerprinted
383 under s. 465.022(3), has:

384 (h) Dispensed any medicinal drug based upon a communication
385 that purports to be a prescription as defined by s. 465.003 ~~s.~~
386 ~~465.003(14)~~ or s. 893.02 when the pharmacist knows or has reason
387 to believe that the purported prescription is not based upon a
388 valid practitioner-patient relationship that includes a
389 documented patient evaluation, including history and a physical
390 examination adequate to establish the diagnosis for which any
391 drug is prescribed and any other requirement established by
392 board rule under chapter 458, chapter 459, chapter 461, chapter
393 463, chapter 464, or chapter 466.

394 Section 13. Section 465.1901, Florida Statutes, is amended
395 to read:

396 465.1901 Practice of orthotics and pedorthics.—The
397 provisions of chapter 468 relating to orthotics or pedorthics do
398 not apply to any licensed pharmacist or to any person acting
399 under the supervision of a licensed pharmacist. The practice of
400 orthotics or pedorthics by a pharmacist or any of the
401 pharmacist's employees acting under the supervision of a
402 pharmacist shall be construed to be within the meaning of the
403 term "practice of the profession of pharmacy" as set forth in s.
404 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in
405 the same manner as any other pharmacy practice. The Board of
406 Pharmacy shall develop rules regarding the practice of orthotics

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407 and pedorthics by a pharmacist. Any pharmacist or person under
408 the supervision of a pharmacist engaged in the practice of
409 orthotics or pedorthics is not precluded from continuing that
410 practice pending adoption of these rules.

411 Section 14. Subsection (43) of section 499.003, Florida
412 Statutes, is amended to read:

413 499.003 Definitions of terms used in this part.—As used in
414 this part, the term:

415 (43) "Prescription drug" means a prescription, medicinal,
416 or legend drug, including, but not limited to, finished dosage
417 forms or active pharmaceutical ingredients subject to, defined
418 by, or described by s. 503(b) of the federal act or s. 465.003
419 ~~s. 465.003(8)~~, s. 499.007(13), subsection (32), or subsection
420 (52), except that an active pharmaceutical ingredient is a
421 prescription drug only if substantially all finished dosage
422 forms in which it may be lawfully dispensed or administered in
423 this state are also prescription drugs.

424 Section 15. Subsection (22) of section 893.02, Florida
425 Statutes, is amended to read:

426 893.02 Definitions.—The following words and phrases as used
427 in this chapter shall have the following meanings, unless the
428 context otherwise requires:

429 (22) "Prescription" means and includes an order for drugs
430 or medicinal supplies written, signed, or transmitted by word of
431 mouth, telephone, telegram, or other means of communication by a
432 duly licensed practitioner licensed by the laws of the state to
433 prescribe such drugs or medicinal supplies, issued in good faith
434 and in the course of professional practice, intended to be
435 filled, compounded, or dispensed by another person licensed by

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436 the laws of the state to do so, and meeting the requirements of
437 s. 893.04. The term also includes an order for drugs or
438 medicinal supplies so transmitted or written by a physician,
439 dentist, veterinarian, or other practitioner licensed to
440 practice in a state other than Florida, but only if the
441 pharmacist called upon to fill such an order determines, in the
442 exercise of his or her professional judgment, that the order was
443 issued pursuant to a valid patient-physician relationship, that
444 it is authentic, and that the drugs or medicinal supplies so
445 ordered are considered necessary for the continuation of
446 treatment of a chronic or recurrent illness. However, if the
447 physician writing the prescription is not known to the
448 pharmacist, the pharmacist shall obtain proof to a reasonable
449 certainty of the validity of said prescription. A prescription
450 order for a controlled substance shall not be issued on the same
451 prescription blank with another prescription order for a
452 controlled substance which is named or described in a different
453 schedule, nor shall any prescription order for a controlled
454 substance be issued on the same prescription blank as a
455 prescription order for a medicinal drug, as defined in s.
456 465.003 ~~s. 465.003(8)~~, which does not fall within the definition
457 of a controlled substance as defined in this act.

458 Section 16. This act shall take effect July 1, 2015.