

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

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

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

17 465.003 Definitions.—As used in this chapter, the term:

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

21 (3)~~(2)~~ "Board" means the Board of Pharmacy.

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

25 (8)~~(4)~~ "Data communication device" means an electronic
 26 device that receives electronic information from one source and

27 | transmits or routes it to another, including, but not limited
28 | to, any such bridge, router, switch, or gateway.

29 | (9)~~(5)~~ "Department" means the Department of Health.

30 | (10)~~(6)~~ "Dispense" means the transfer of possession of one
31 | or more doses of a medicinal drug by a pharmacist to the
32 | ultimate consumer or her or his agent. As an element of
33 | dispensing, the pharmacist shall, prior to the actual physical
34 | transfer, interpret and assess the prescription order for
35 | potential adverse reactions, interactions, and dosage regimen
36 | she or he deems appropriate in the exercise of her or his
37 | professional judgment, and the pharmacist shall certify that the
38 | medicinal drug called for by the prescription is ready for
39 | transfer. The pharmacist shall also provide counseling on proper
40 | drug usage, either orally or in writing, if in the exercise of
41 | her or his professional judgment counseling is necessary. The
42 | actual sales transaction and delivery of such drug shall not be
43 | considered dispensing. The administration shall not be
44 | considered dispensing.

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

51 | (12)~~(8)~~ "Medicinal drugs" or "drugs" means those
52 | substances or preparations commonly known as "prescription" or

53 "legend" drugs which are required by federal or state law to be
54 dispensed only on a prescription, but shall not include patents
55 or proprietary preparations as hereafter defined.

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

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

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

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

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

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

79 | under chapter 395 or the nuclear medicine facilities of such
80 | hospitals.

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

84 | 5. The term "Internet pharmacy" includes locations not
85 | otherwise licensed or issued a permit under this chapter, within
86 | or outside this state, which use the Internet to communicate
87 | with or obtain information from consumers in this state and use
88 | such communication or information to fill or refill
89 | prescriptions or to dispense, distribute, or otherwise engage in
90 | the practice of pharmacy in this state. Any act described in
91 | this definition constitutes the practice of pharmacy as defined
92 | in subsection (20) ~~(13)~~.

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

104 | (19) ~~(12)~~ "Pharmacy intern" means a person who is currently

105 registered in, and attending, a duly accredited college or
106 school of pharmacy, or who is a graduate of such a school or
107 college of pharmacy, and who is duly and properly registered
108 with the department as provided for under its rules.

109 (20)~~(13)~~ "Practice of the profession of pharmacy" includes
110 compounding, dispensing, and consulting concerning contents,
111 therapeutic values, and uses of any medicinal drug; consulting
112 concerning therapeutic values and interactions of patent or
113 proprietary preparations, whether pursuant to prescriptions or
114 in the absence and entirely independent of such prescriptions or
115 orders; and other pharmaceutical services. For purposes of this
116 subsection, "other pharmaceutical services" means the monitoring
117 of the patient's drug therapy and assisting the patient in the
118 management of his or her drug therapy, and includes review of
119 the patient's drug therapy and communication with the patient's
120 prescribing health care provider as licensed under chapter 458,
121 chapter 459, chapter 461, or chapter 466, or similar statutory
122 provision in another jurisdiction, or such provider's agent or
123 such other persons as specifically authorized by the patient,
124 regarding the drug therapy. However, nothing in this subsection
125 may be interpreted to permit an alteration of a prescriber's
126 directions, the diagnosis or treatment of any disease, the
127 initiation of any drug therapy, the practice of medicine, or the
128 practice of osteopathic medicine, unless otherwise permitted by
129 law. "Practice of the profession of pharmacy" also includes any
130 other act, service, operation, research, or transaction

131 incidental to, or forming a part of, any of the foregoing acts,
132 requiring, involving, or employing the science or art of any
133 branch of the pharmaceutical profession, study, or training, and
134 shall expressly permit a pharmacist to transmit information from
135 persons authorized to prescribe medicinal drugs to their
136 patients. The practice of the profession of pharmacy also
137 includes the administration of vaccines to adults pursuant to s.
138 465.189.

139 (21)~~(14)~~ "Prescription" includes any order for drugs or
140 medicinal supplies written or transmitted by any means of
141 communication by a duly licensed practitioner authorized by the
142 laws of the state to prescribe such drugs or medicinal supplies
143 and intended to be dispensed by a pharmacist. The term also
144 includes an orally transmitted order by the lawfully designated
145 agent of such practitioner. The term also includes an order
146 written or transmitted by a practitioner licensed to practice in
147 a jurisdiction other than this state, but only if the pharmacist
148 called upon to dispense such order determines, in the exercise
149 of her or his professional judgment, that the order is valid and
150 necessary for the treatment of a chronic or recurrent illness.
151 The term "prescription" also includes a pharmacist's order for a
152 product selected from the formulary created pursuant to s.
153 465.186. Prescriptions may be retained in written form or the
154 pharmacist may cause them to be recorded in a data processing
155 system, provided that such order can be produced in printed form
156 upon lawful request.

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

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

166 (4)~~(16)~~ "Centralized prescription filling" means the
 167 filling of a prescription by one pharmacy upon request by
 168 another pharmacy to fill or refill the prescription. The term
 169 includes the performance by one pharmacy for another pharmacy of
 170 other pharmacy duties such as drug utilization review,
 171 therapeutic drug utilization review, claims adjudication, and
 172 the obtaining of refill authorizations.

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

176 (6)~~(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 (15)~~(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 (5)~~(20)~~ "Compounded sterile product" means a drug that is
 184 intended for parenteral administration, an ophthalmic or oral
 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 Section 2. A new subsection (6) is added to section
 190 465.0276, Florida Statutes, to read:

191 465.0276 Dispensing practitioner.—

192 (6) This chapter and the rules adopted thereunder do not
 193 prohibit an animal health practitioner from dispensing a
 194 compounded drug to an animal patient or its owner or caretaker.

195 Section 3. Paragraph (a) of subsection (1) of section
 196 409.9201, Florida Statutes, is amended to read:

197 409.9201 Medicaid fraud.—

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

199 (a) "Prescription drug" means any drug, including, but not
 200 limited to, finished dosage forms or active ingredients that are
 201 subject to, defined in, or described in s. 503(b) of the Federal
 202 Food, Drug, and Cosmetic Act or in s. 465.003 ~~s. 465.003(8)~~, s.
 203 499.003(52), s. 499.007(13), or s. 499.82(10).

204
 205 The value of individual items of the legend drugs or goods or
 206 services involved in distinct transactions committed during a
 207 single scheme or course of conduct, whether involving a single
 208 person or several persons, may be aggregated when determining

209 the punishment for the offense.

210 Section 4. Paragraph (pp) of subsection (1) of section
211 458.331, Florida Statutes, is amended to read:

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

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

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

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

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

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

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

234 5. Being convicted of, or disciplined by a regulatory

235 agency of the Federal Government or a regulatory agency of
 236 another state for, any offense that would constitute a violation
 237 of this chapter;

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

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

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

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

256 Section 5. Paragraph (rr) of subsection (1) of section
 257 459.015, Florida Statutes, is amended to read:

258 459.015 Grounds for disciplinary action; action by the
 259 board and department.—

260 (1) The following acts constitute grounds for denial of a

261 license or disciplinary action, as specified in s. 456.072(2):
 262 (rr) Applicable to a licensee who serves as the designated
 263 physician of a pain-management clinic as defined in s. 458.3265
 264 or s. 459.0137:

- 265 1. Registering a pain-management clinic through
 266 misrepresentation or fraud;
- 267 2. Procuring, or attempting to procure, the registration
 268 of a pain-management clinic for any other person by making or
 269 causing to be made, any false representation;
- 270 3. Failing to comply with any requirement of chapter 499,
 271 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
 272 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
 273 the Drug Abuse Prevention and Control Act; or chapter 893, the
 274 Florida Comprehensive Drug Abuse Prevention and Control Act;
- 275 4. Being convicted or found guilty of, regardless of
 276 adjudication to, a felony or any other crime involving moral
 277 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
 278 the courts of this state, of any other state, or of the United
 279 States;
- 280 5. Being convicted of, or disciplined by a regulatory
 281 agency of the Federal Government or a regulatory agency of
 282 another state for, any offense that would constitute a violation
 283 of this chapter;
- 284 6. Being convicted of, or entering a plea of guilty or
 285 nolo contendere to, regardless of adjudication, a crime in any
 286 jurisdiction of the courts of this state, of any other state, or

287 of the United States which relates to the practice of, or the
 288 ability to practice, a licensed health care profession;

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

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

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

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

304 465.014 Pharmacy technician.—

305 (1) A person other than a licensed pharmacist or pharmacy
 306 intern may not engage in the practice of the profession of
 307 pharmacy, except that a licensed pharmacist may delegate to
 308 pharmacy technicians who are registered pursuant to this section
 309 those duties, tasks, and functions that do not fall within the
 310 purview of the practice of the profession of pharmacy as defined
 311 in s. 465.003 ~~s. 465.003(13)~~. All such delegated acts must be
 312 performed under the direct supervision of a licensed pharmacist

313 who is responsible for all such acts performed by persons under
 314 his or her supervision. A registered pharmacy technician, under
 315 the supervision of a pharmacist, may initiate or receive
 316 communications with a practitioner or his or her agent, on
 317 behalf of a patient, regarding refill authorization requests. A
 318 licensed pharmacist may not supervise more than one registered
 319 pharmacy technician unless otherwise permitted by the guidelines
 320 adopted by the board. The board shall establish guidelines to be
 321 followed by licensees or permittees in determining the
 322 circumstances under which a licensed pharmacist may supervise
 323 more than one pharmacy technician.

324 Section 7. Paragraph (c) of subsection (2) of section
 325 465.015, Florida Statutes, is amended to read:

326 465.015 Violations and penalties.—

327 (2) It is unlawful for any person:

328 (c) To sell or dispense drugs as defined in s. 465.003 ~~s.~~
 329 ~~465.003(8)~~ without first being furnished with a prescription.

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

332 465.0156 Registration of nonresident pharmacies.—

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

339 Section 9. Paragraph (s) of subsection (1) of section
 340 465.016, Florida Statutes, is amended to read:

341 465.016 Disciplinary actions.—

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

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

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

351 465.0197 Internet pharmacy permits.—

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

358 Section 11. Paragraph (j) of subsection (5) of section
 359 465.022, Florida Statutes, is amended to read:

360 465.022 Pharmacies; general requirements; fees.—

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

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

375

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

381 Section 12. Paragraph (h) of subsection (1) of section
382 465.023, Florida Statutes, is amended to read:

383 465.023 Pharmacy permittee; disciplinary action.—

384 (1) The department or the board may revoke or suspend the
385 permit of any pharmacy permittee, and may fine, place on
386 probation, or otherwise discipline any pharmacy permittee if the
387 permittee, or any affiliated person, partner, officer, director,
388 or agent of the permittee, including a person fingerprinted
389 under s. 465.022(3), has:

390 (h) Dispensed any medicinal drug based upon a

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

400 Section 13. Section 465.1901, Florida Statutes, is amended
 401 to read:

402 465.1901 Practice of orthotics and pedorthics.—The
 403 provisions of chapter 468 relating to orthotics or pedorthics do
 404 not apply to any licensed pharmacist or to any person acting
 405 under the supervision of a licensed pharmacist. The practice of
 406 orthotics or pedorthics by a pharmacist or any of the
 407 pharmacist's employees acting under the supervision of a
 408 pharmacist shall be construed to be within the meaning of the
 409 term "practice of the profession of pharmacy" as set forth in s.
 410 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in
 411 the same manner as any other pharmacy practice. The Board of
 412 Pharmacy shall develop rules regarding the practice of orthotics
 413 and pedorthics by a pharmacist. Any pharmacist or person under
 414 the supervision of a pharmacist engaged in the practice of
 415 orthotics or pedorthics is not precluded from continuing that
 416 practice pending adoption of these rules.

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

419 499.003 Definitions of terms used in this part.—As used in
 420 this part, the term:

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

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

432 893.02 Definitions.—The following words and phrases as
 433 used in this chapter shall have the following meanings, unless
 434 the context otherwise requires:

435 (22) "Prescription" means and includes an order for drugs
 436 or medicinal supplies written, signed, or transmitted by word of
 437 mouth, telephone, telegram, or other means of communication by a
 438 duly licensed practitioner licensed by the laws of the state to
 439 prescribe such drugs or medicinal supplies, issued in good faith
 440 and in the course of professional practice, intended to be
 441 filled, compounded, or dispensed by another person licensed by
 442 the laws of the state to do so, and meeting the requirements of

443 s. 893.04. The term also includes an order for drugs or
444 medicinal supplies so transmitted or written by a physician,
445 dentist, veterinarian, or other practitioner licensed to
446 practice in a state other than Florida, but only if the
447 pharmacist called upon to fill such an order determines, in the
448 exercise of his or her professional judgment, that the order was
449 issued pursuant to a valid patient-physician relationship, that
450 it is authentic, and that the drugs or medicinal supplies so
451 ordered are considered necessary for the continuation of
452 treatment of a chronic or recurrent illness. However, if the
453 physician writing the prescription is not known to the
454 pharmacist, the pharmacist shall obtain proof to a reasonable
455 certainty of the validity of said prescription. A prescription
456 order for a controlled substance shall not be issued on the same
457 prescription blank with another prescription order for a
458 controlled substance which is named or described in a different
459 schedule, nor shall any prescription order for a controlled
460 substance be issued on the same prescription blank as a
461 prescription order for a medicinal drug, as defined in s.
462 465.003 ~~s. 465.003(8)~~, which does not fall within the definition
463 of a controlled substance as defined in this act.

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