

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
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
51 substances or preparations commonly known as "prescription" or
52 "legend" drugs which are required by federal or state law to be

53 dispensed only on a prescription, but shall not include patents
 54 or 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
 59 the provisions of the Florida Drug and Cosmetic Act.

60 (17)~~(10)~~ "Pharmacist" means any person licensed pursuant
 61 to 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

HB 1049

2015

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
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

HB 1049

2015

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
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,

HB 1049

2015

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
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.

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
 192 thereunder prohibit a veterinarian from dispensing a compounded
 193 drug to an 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).

203
 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
 221 of 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;

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

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

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

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

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

261 (rr) Applicable to a licensee who serves as the designated
 262 physician of a pain-management clinic as defined in s. 458.3265
 263 or s. 459.0137:

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

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

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

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

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

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

287 ability to practice, a licensed health care profession;

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

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

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

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

303 465.014 Pharmacy technician.—

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

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

322 Section 7. Paragraph (c) of subsection (2) of section
 323 465.015, Florida Statutes, is amended to read:

324 465.015 Violations and penalties.—

325 (2) It is unlawful for any person:

326 (c) To sell or dispense drugs as defined in s. 465.003 ~~s.~~
 327 ~~465.003(8)~~ without first being furnished with a prescription.

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

330 465.0156 Registration of nonresident pharmacies.—

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

337 Section 9. Paragraph (s) of subsection (1) of section
 338 465.016, Florida Statutes, is amended to read:

339 465.016 Disciplinary actions.—

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

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

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

349 465.0197 Internet pharmacy permits.—

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

356 Section 11. Paragraph (j) of subsection (5) of section
357 465.022, Florida Statutes, is amended to read:

358 465.022 Pharmacies; general requirements; fees.—

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

363 (j) Has dispensed any medicinal drug based upon a
364 communication that purports to be a prescription as defined by

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

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

379 Section 12. Paragraph (h) of subsection (1) of section
 380 465.023, Florida Statutes, is amended to read:

381 465.023 Pharmacy permittee; disciplinary action.—

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

388 (h) Dispensed any medicinal drug based upon a
 389 communication that purports to be a prescription as defined by
 390 s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows

391 or has reason to believe that the purported prescription is not
 392 based upon a valid practitioner-patient relationship that
 393 includes a documented patient evaluation, including history and
 394 a physical examination adequate to establish the diagnosis for
 395 which any drug is prescribed and any other requirement
 396 established by board rule under chapter 458, chapter 459,
 397 chapter 461, chapter 463, chapter 464, or chapter 466.

398 Section 13. Section 465.1901, Florida Statutes, is amended
 399 to read:

400 465.1901 Practice of orthotics and pedorthics.—The
 401 provisions of chapter 468 relating to orthotics or pedorthics do
 402 not apply to any licensed pharmacist or to any person acting
 403 under the supervision of a licensed pharmacist. The practice of
 404 orthotics or pedorthics by a pharmacist or any of the
 405 pharmacist's employees acting under the supervision of a
 406 pharmacist shall be construed to be within the meaning of the
 407 term "practice of the profession of pharmacy" as set forth in s.
 408 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in
 409 the same manner as any other pharmacy practice. The Board of
 410 Pharmacy shall develop rules regarding the practice of orthotics
 411 and pedorthics by a pharmacist. Any pharmacist or person under
 412 the supervision of a pharmacist engaged in the practice of
 413 orthotics or pedorthics is not precluded from continuing that
 414 practice pending adoption of these rules.

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

417 499.003 Definitions of terms used in this part.—As used in
 418 this part, the term:

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

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

430 893.02 Definitions.—The following words and phrases as
 431 used in this chapter shall have the following meanings, unless
 432 the context otherwise requires:

433 (22) "Prescription" means and includes an order for drugs
 434 or medicinal supplies written, signed, or transmitted by word of
 435 mouth, telephone, telegram, or other means of communication by a
 436 duly licensed practitioner licensed by the laws of the state to
 437 prescribe such drugs or medicinal supplies, issued in good faith
 438 and in the course of professional practice, intended to be
 439 filled, compounded, or dispensed by another person licensed by
 440 the laws of the state to do so, and meeting the requirements of
 441 s. 893.04. The term also includes an order for drugs or
 442 medicinal supplies so transmitted or written by a physician,

HB 1049

2015

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

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