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1 A bill to be entitled
2 An act relating to drugs, devices, and cosmetics;
3 amending s. 385.211, F.S.; authorizing a certain type
4 of specialty hospital to conduct research on
5 cannabidiol and low-THC cannabis if contracted with
6 the Department of Health to perform such research;
7 amending s. 499.003, F.S.; providing, revising, and
8 deleting definitions for purposes of the Florida Drug
9 and Cosmetic Act; requiring rulemaking; specifying a
10 default rule until the Department of Business and
11 Professional Regulation adopts a rule; amending s.
12 499.005, F.S.; revising prohibited acts related to the
13 distribution of prescription drugs; conforming a
14 cross-reference; amending s. 499.0051, F.S.;
15 prohibiting the distribution of prescription drugs
16 without delivering a transaction history, transaction
17 information, and transaction statement; providing
18 penalties; deleting provisions and revising
19 terminology related to pedigree papers, to conform to
20 changes made by the act; amending s. 499.006, F.S.;
21 conforming provisions; amending s. 499.01, F.S.;
22 requiring nonresident prescription drug repackagers to
23 obtain an operating permit; authorizing a manufacturer
24 to engage in the wholesale distribution of
25 prescription drugs; providing for the issuance of
26 virtual prescription drug manufacturer permits and
27 virtual nonresident prescription drug manufacturer
28 permits to certain persons; providing exceptions from
29 certain virtual manufacturer requirements; requiring a

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30 nonresident prescription drug repackager permit for
31 certain persons; deleting surety bond requirements for
32 prescription drug wholesale distributors; requiring
33 that certain persons obtain an out-of-state
34 prescription drug wholesale distributor permit;
35 providing that a restricted prescription drug
36 distributor permit is not required for distributions
37 between certain pharmacies; requiring the Department
38 of Business and Professional Regulation to establish
39 by rule when such distribution constitutes regular and
40 systematic supplying of a prescription drug; requiring
41 certain third party logistic providers to be licensed;
42 requiring research and development labeling on certain
43 prescription drug active pharmaceutical ingredient
44 packaging; requiring certain manufacturers to create
45 and maintain certain records; requiring certain
46 prescription drug distributors to provide certain
47 information to health care entities for which they
48 repackaged prescription drugs; requiring the department
49 to adopt rules concerning repackaged prescription drug
50 safety and integrity; amending s. 499.012, F.S.;
51 providing for issuance of a prescription drug
52 manufacturer permit or retail pharmacy drug wholesale
53 distributor permit when an applicant at the same
54 address is a licensed nuclear pharmacy or community
55 pharmacy; providing for the expiration of deficient
56 permit applications; requiring trade secret
57 information submitted by an applicant to be maintained
58 as a trade secret; authorizing the quadrennial renewal

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59 of permits; providing for calculation of fees for such
60 permit renewals; revising procedures and application
61 requirements for permit renewals; providing for late
62 renewal fees; allowing a permittee who submits a
63 renewal application to continue operations; removing
64 certain application requirements for renewal of a
65 permit; requiring bonds or other surety of a specified
66 amount; requiring proof of inspection of
67 establishments used in wholesale distribution;
68 authorizing the Department of Business and
69 Professional Regulation to contract for the collection
70 of electronic fingerprints under certain
71 circumstances; providing information that may be
72 submitted in lieu of certain application requirements
73 for specified permits and certifications; removing
74 provisions relating to annual renewal and expiration
75 of permits; conforming cross-references; amending s.
76 499.01201, F.S.; conforming provisions; amending s.
77 499.0121, F.S.; revising prescription drug
78 recordkeeping requirements; specifying recordkeeping
79 requirements for manufacturers and repackagers of
80 medical devices, over-the-counter drugs, and
81 cosmetics; increasing the quantity of unit doses of a
82 controlled substance that may be ordered in any given
83 month by a customer without triggering a requirement
84 that a wholesale distributor perform a reasonableness
85 assessment; conforming provisions; amending s.
86 499.015, F.S.; providing for the expiration, renewal,
87 and issuance of certain drug, device, and cosmetic

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88 product registrations; providing for product
89 registration fees; amending ss. 499.03, 499.05, and
90 499.051, F.S.; conforming provisions to changes made
91 by the act; amending s. 499.82, F.S.; revising the
92 definition of "wholesale distribution" for purposes of
93 medical gas requirements; amending s. 499.83, F.S.;
94 authorizing licensed hospices to obtain on behalf of,
95 and sell medical oxygen to, their patients without
96 obtaining a medical oxygen retail establishment permit
97 in certain circumstances; specifying recordkeeping
98 requirements; amending s. 499.89, F.S.; conforming
99 provisions; repealing s. 499.01212, F.S., relating to
100 pedigree papers; amending ss. 409.9201, 499.067,
101 794.075, and 921.0022, F.S.; conforming cross-
102 references; creating s. 893.30, F.S.; creating the
103 "Victoria Siegel Controlled Substances Safety
104 Education and Awareness Act"; requiring the Department
105 of Health to develop an educational pamphlet relating
106 to certain controlled substance issues; requiring the
107 department to encourage health care providers to
108 disseminate certain educational information; requiring
109 the department to encourage consumers to discuss
110 controlled substance risks with certain health care
111 providers; requiring the State Surgeon General to
112 provide certain educational resources on the
113 department's website; requiring the department to fund
114 controlled substance safety education and awareness
115 with certain grants; encouraging the department to
116 collaborate with other entities to create a systematic

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117 approach to increasing public awareness regarding
118 controlled substance safety; providing an effective
119 date.

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121 Be It Enacted by the Legislature of the State of Florida:

122

123 Section 1. Subsection (2) of section 385.211, Florida
124 Statutes, is amended to read:

125 385.211 Refractory and intractable epilepsy treatment and
126 research at recognized medical centers.—

127 (2) Notwithstanding chapter 893, medical centers recognized
128 pursuant to s. 381.925, or an academic medical research
129 institution legally affiliated with a licensed children's
130 specialty hospital as defined in s. 395.002(28) that contracts
131 with the Department of Health, may conduct research on
132 cannabidiol and low-THC cannabis. This research may include, but
133 is not limited to, the agricultural development, production,
134 clinical research, and use of liquid medical derivatives of
135 cannabidiol and low-THC cannabis for the treatment for
136 refractory or intractable epilepsy. The authority for recognized
137 medical centers to conduct this research is derived from 21
138 C.F.R. parts 312 and 316. Current state or privately obtained
139 research funds may be used to support the activities described
140 in this section.

141 Section 2. Section 499.003, Florida Statutes, is amended to
142 read:

143 499.003 Definitions of terms used in this part.—As used in
144 this part, the term:

145 (1) "Active pharmaceutical ingredient" includes any

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146 substance or mixture of substances intended, represented, or
147 labeled for use in drug manufacturing that furnishes or is
148 intended to furnish, in a finished dosage form, any
149 pharmacological activity or other direct effect in the
150 diagnosis, cure, mitigation, treatment, therapy, or prevention
151 of disease in humans or other animals, or to affect the
152 structure or any function of the body of humans or animals.

153 (2)~~(1)~~ "Advertisement" means any representation
154 disseminated in any manner or by any means, other than by
155 labeling, for the purpose of inducing, or which is likely to
156 induce, directly or indirectly, the purchase of drugs, devices,
157 or cosmetics.

158 (3) "Affiliate" means a business entity that has a
159 relationship with another business entity in which, directly or
160 indirectly:

161 (a) The business entity controls, or has the power to
162 control, the other business entity; or

163 (b) A third party controls, or has the power to control,
164 both business entities.

165 ~~(2) "Affiliated group" means an affiliated group as defined~~
166 ~~by s. 1504 of the Internal Revenue Code of 1986, as amended,~~
167 ~~which is composed of chain drug entities, including at least 50~~
168 ~~retail pharmacies, warehouses, or repackagers, which are members~~
169 ~~of the same affiliated group. The affiliated group must disclose~~
170 ~~the names of all its members to the department.~~

171 (4)~~(3)~~ "Affiliated party" means:

172 (a) A director, officer, trustee, partner, or committee
173 member of a permittee or applicant or a subsidiary or service
174 corporation of the permittee or applicant;

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175 (b) A person who, directly or indirectly, manages,
176 controls, or oversees the operation of a permittee or applicant,
177 regardless of whether such person is a partner, shareholder,
178 manager, member, officer, director, independent contractor, or
179 employee of the permittee or applicant;

180 (c) A person who has filed or is required to file a
181 personal information statement pursuant to s. 499.012(9) or is
182 required to be identified in an application for a permit or to
183 renew a permit pursuant to s. 499.012(8); or

184 (d) The five largest natural shareholders that own at least
185 5 percent of the permittee or applicant.

186 (5)~~(4)~~ "Applicant" means a person applying for a permit or
187 certification under this part.

188 ~~(5) "Authenticate" means to affirmatively verify upon
189 receipt of a prescription drug that each transaction listed on
190 the pedigree paper has occurred.~~

191 ~~(a) A wholesale distributor is not required to open a
192 sealed, medical convenience kit to authenticate a pedigree paper
193 for a prescription drug contained within the kit.~~

194 ~~(b) Authentication of a prescription drug included in a
195 sealed, medical convenience kit shall be limited to verifying
196 the transaction and pedigree information received.~~

197 (6) "Certificate of free sale" means a document prepared by
198 the department which certifies a drug, device, or cosmetic, that
199 is registered with the department, as one that can be legally
200 sold in the state.

201 (7) "Chain pharmacy warehouse" means a ~~wholesale~~
202 distributor permitted pursuant to s. 499.01 that maintains a
203 physical location for prescription drugs that functions solely

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204 as a central warehouse to perform intracompany transfers of such
205 drugs between members of an affiliate ~~to a member of its~~
206 ~~affiliated group.~~

207 (8) "Closed pharmacy" means a pharmacy that is licensed
208 under chapter 465 and purchases prescription drugs for use by a
209 limited patient population and not for wholesale distribution or
210 sale to the public. The term does not include retail pharmacies.

211 (9) "Color" includes black, white, and intermediate grays.

212 (10) "Color additive" means, with the exception of any
213 material that has been or hereafter is exempt under the federal
214 act, a material that:

215 (a) Is a dye pigment, or other substance, made by a process
216 of synthesis or similar artifice, or extracted, isolated, or
217 otherwise derived, with or without intermediate or final change
218 of identity from a vegetable, animal, mineral, or other source;
219 or

220 (b) When added or applied to a drug or cosmetic or to the
221 human body, or any part thereof, is capable alone, or through
222 reaction with other substances, of imparting color thereto.

223 (11) "Contraband prescription drug" means any adulterated
224 drug, as defined in s. 499.006, any counterfeit drug, as defined
225 in this section, and also means any prescription drug for which
226 a transaction history, transaction information, or transaction
227 statement ~~pedigree paper~~ does not exist, or for which the
228 transaction history, transaction information, or transaction
229 statement ~~pedigree paper~~ in existence has been forged,
230 counterfeited, falsely created, or contains any altered, false,
231 or misrepresented matter.

232 (12) "Cosmetic" means an article, with the exception of

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233 soap, that is:

234 (a) Intended to be rubbed, poured, sprinkled, or sprayed
235 on; introduced into; or otherwise applied to the human body or
236 any part thereof for cleansing, beautifying, promoting
237 attractiveness, or altering the appearance; or

238 (b) Intended for use as a component of any such article.

239 (13) "Counterfeit drug," "counterfeit device," or
240 "counterfeit cosmetic" means a drug, device, or cosmetic which,
241 or the container, seal, or labeling of which, without
242 authorization, bears the trademark, trade name, or other
243 identifying mark, imprint, or device, or any likeness thereof,
244 of a drug, device, or cosmetic manufacturer, processor, packer,
245 or distributor other than the person that in fact manufactured,
246 processed, packed, or distributed that drug, device, or cosmetic
247 and which thereby falsely purports or is represented to be the
248 product of, or to have been packed or distributed by, that other
249 drug, device, or cosmetic manufacturer, processor, packer, or
250 distributor.

251 (14) "Department" means the Department of Business and
252 Professional Regulation.

253 (15) "Device" means any instrument, apparatus, implement,
254 machine, contrivance, implant, in vitro reagent, or other
255 similar or related article, including its components, parts, or
256 accessories, which is:

257 (a) Recognized in the current edition of the United States
258 Pharmacopoeia and National Formulary, or any supplement thereof,

259 (b) Intended for use in the diagnosis, cure, mitigation,
260 treatment, therapy, or prevention of disease in humans or other
261 animals, or

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262 (c) Intended to affect the structure or any function of the
263 body of humans or other animals,
264

265 and that does not achieve any of its principal intended purposes
266 through chemical action within or on the body of humans or other
267 animals and which is not dependent upon being metabolized for
268 the achievement of any of its principal intended purposes.

269 (16) "Distribute" or "distribution" means to sell,
270 purchase, trade, deliver, handle, store, or receive to sell;
271 ~~offer to sell; give away; transfer, whether by passage of title,~~
272 ~~physical movement, or both; deliver; or offer to deliver.~~ The
273 term does not mean to administer or dispense and does not
274 include the billing and invoicing activities that commonly
275 follow a wholesale distribution transaction.

276 (17) ~~"Drop shipment" means the sale of a prescription drug~~
277 ~~from a manufacturer to a wholesale distributor, where the~~
278 ~~wholesale distributor takes title to, but not possession of, the~~
279 ~~prescription drug, and the manufacturer of the prescription drug~~
280 ~~ships the prescription drug directly to a chain pharmacy~~
281 ~~warehouse or a person authorized by law to purchase prescription~~
282 ~~drugs for the purpose of administering or dispensing the drug,~~
283 ~~as defined in s. 465.003.~~

284 (17) ~~(18)~~ "Drug" means an article that is:

285 (a) Recognized in the current edition of the United States
286 Pharmacopoeia and National Formulary, official Homeopathic
287 Pharmacopoeia of the United States, or any supplement to any of
288 those publications;

289 (b) Intended for use in the diagnosis, cure, mitigation,
290 treatment, therapy, or prevention of disease in humans or other

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291 animals;

292 (c) Intended to affect the structure or any function of the
293 body of humans or other animals; or

294 (d) Intended for use as a component of any article
295 specified in paragraph (a), paragraph (b), or paragraph (c), and
296 includes active pharmaceutical ingredients, but does not include
297 devices or their nondrug components, parts, or accessories. ~~For~~
298 ~~purposes of this paragraph, an "active pharmaceutical~~
299 ~~ingredient" includes any substance or mixture of substances~~
300 ~~intended, represented, or labeled for use in drug manufacturing~~
301 ~~that furnishes or is intended to furnish, in a finished dosage~~
302 ~~form, any pharmacological activity or other direct effect in the~~
303 ~~diagnosis, cure, mitigation, treatment, therapy, or prevention~~
304 ~~of disease in humans or other animals, or to affect the~~
305 ~~structure or any function of the body of humans or other~~
306 ~~animals.~~

307 (18)~~(19)~~ "Establishment" means a place of business which is
308 at one general physical location and may extend to one or more
309 contiguous suites, units, floors, or buildings operated and
310 controlled exclusively by entities under common operation and
311 control. Where multiple buildings are under common exclusive
312 ownership, operation, and control, an intervening thoroughfare
313 does not affect the contiguous nature of the buildings. For
314 purposes of permitting, each suite, unit, floor, or building
315 must be identified in the most recent permit application.

316 (19)~~(20)~~ "Federal act" means the Federal Food, Drug, and
317 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

318 (20)~~(21)~~ "Freight forwarder" means a person who receives
319 prescription drugs which are owned by another person and

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320 designated by that person for export, and exports those
321 prescription drugs.

322 (21)~~(22)~~ "Health care entity" means a closed pharmacy or
323 any person, organization, or business entity that provides
324 diagnostic, medical, surgical, or dental treatment or care, or
325 chronic or rehabilitative care, but does not include any
326 wholesale distributor or retail pharmacy licensed under state
327 law to deal in prescription drugs. However, a blood
328 establishment is a health care entity that may engage in the
329 wholesale distribution of prescription drugs under s.
330 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

331 (22)~~(23)~~ "Health care facility" means a health care
332 facility licensed under chapter 395.

333 (23)~~(24)~~ "Hospice" means a corporation licensed under part
334 IV of chapter 400.

335 (24)~~(25)~~ "Hospital" means a facility as defined in s.
336 395.002 and licensed under chapter 395.

337 (25)~~(26)~~ "Immediate container" does not include package
338 liners.

339 (26)~~(27)~~ "Label" means a display of written, printed, or
340 graphic matter upon the immediate container of any drug, device,
341 or cosmetic. A requirement made by or under authority of this
342 part or rules adopted under this part that any word, statement,
343 or other information appear on the label is not complied with
344 unless such word, statement, or other information also appears
345 on the outside container or wrapper, if any, of the retail
346 package of such drug, device, or cosmetic or is easily legible
347 through the outside container or wrapper.

348 (27)~~(28)~~ "Labeling" means all labels and other written,

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349 printed, or graphic matters:

350 (a) Upon a drug, device, or cosmetic, or any of its
351 containers or wrappers; or

352 (b) Accompanying or related to such drug, device, or
353 cosmetic.

354 ~~(28)~~(29) "Manufacture" means the preparation, deriving,
355 compounding, propagation, processing, producing, or fabrication
356 of any drug, device, or cosmetic.

357 ~~(29)~~(30) "Manufacturer" means:

358 (a) A person who holds a New Drug Application, an
359 Abbreviated New Drug Application, a Biologics License
360 Application, or a New Animal Drug Application approved under the
361 federal act or a license issued under s. 351 of the Public
362 Health Service Act, 42 U.S.C. s. 262, for such drug or
363 biologics, or if such drug or biologics are not the subject of
364 an approved application or license, the person who manufactured
365 the drug or biologics ~~prepares, derives, manufactures, or~~
366 ~~produces a drug, device, or cosmetic;~~

367 (b) A co-licensed partner of the person described in
368 paragraph (a) who obtains the drug or biologics directly from a
369 person described in paragraph (a), paragraph (c), or this
370 paragraph ~~The holder or holders of a New Drug Application (NDA),~~
371 ~~an Abbreviated New Drug Application (ANDA), a Biologics License~~
372 ~~Application (BLA), or a New Animal Drug Application (NADA),~~
373 ~~provided such application has become effective or is otherwise~~
374 ~~approved consistent with s. 499.023;~~

375 (c) An affiliate of a person described in paragraph (a),
376 paragraph (b), or this paragraph that receives the drug or
377 biologics directly from a person described in paragraph (a),

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378 ~~paragraph (b), or this paragraph~~ A private label distributor for
379 ~~whom the private label distributor's prescription drugs are~~
380 ~~originally manufactured and labeled for the distributor and have~~
381 ~~not been repackaged; or~~

382 (d) A person who manufactures a device or a cosmetic. A
383 ~~person registered under the federal act as a manufacturer of a~~
384 ~~prescription drug, who is described in paragraph (a), paragraph~~
385 ~~(b), or paragraph (c), who has entered into a written agreement~~
386 ~~with another prescription drug manufacturer that authorizes~~
387 ~~either manufacturer to distribute the prescription drug~~
388 ~~identified in the agreement as the manufacturer of that drug~~
389 ~~consistent with the federal act and its implementing~~
390 ~~regulations;~~

391 ~~(e) A member of an affiliated group that includes, but is~~
392 ~~not limited to, persons described in paragraph (a), paragraph~~
393 ~~(b), paragraph (c), or paragraph (d), which member distributes~~
394 ~~prescription drugs, whether or not obtaining title to the drugs,~~
395 ~~only for the manufacturer of the drugs who is also a member of~~
396 ~~the affiliated group. As used in this paragraph, the term~~
397 ~~"affiliated group" means an affiliated group as defined in s.~~
398 ~~1504 of the Internal Revenue Code of 1986, as amended. The~~
399 ~~manufacturer must disclose the names of all of its affiliated~~
400 ~~group members to the department; or~~

401 ~~(f) A person permitted as a third party logistics provider,~~
402 ~~only while providing warehousing, distribution, or other~~
403 ~~logistics services on behalf of a person described in paragraph~~
404 ~~(a), paragraph (b), paragraph (c), paragraph (d), or paragraph~~
405 ~~(e).~~

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407 The term does not include a pharmacy that is operating in
408 compliance with pharmacy practice standards as defined in
409 chapter 465 and rules adopted under that chapter.

410 (30)~~(31)~~ "Medical convenience kit" means packages or units
411 that contain combination products as defined in 21 C.F.R. s.
412 3.2(e) (2).

413 (31)~~(32)~~ "Medical gas" means any liquefied or vaporized gas
414 that is a prescription drug, whether alone or in combination
415 with other gases, and as defined in the federal act.

416 (32)~~(33)~~ "New drug" means:

417 (a) Any drug the composition of which is such that the drug
418 is not generally recognized, among experts qualified by
419 scientific training and experience to evaluate the safety and
420 effectiveness of drugs, as safe and effective for use under the
421 conditions prescribed, recommended, or suggested in the labeling
422 of that drug; or

423 (b) Any drug the composition of which is such that the
424 drug, as a result of investigations to determine its safety and
425 effectiveness for use under certain conditions, has been
426 recognized for use under such conditions, but which drug has
427 not, other than in those investigations, been used to a material
428 extent or for a material time under such conditions.

429 ~~(34) "Normal distribution chain" means a wholesale
430 distribution of a prescription drug in which the wholesale
431 distributor or its wholly owned subsidiary purchases and
432 receives the specific unit of the prescription drug directly
433 from the manufacturer and distributes the prescription drug
434 directly, or through up to two intracompany transfers, to a
435 chain pharmacy warehouse or a person authorized by law to~~

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436 ~~purchase prescription drugs for the purpose of administering or~~
437 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~
438 ~~this subsection, the term "intracompany" means any transaction~~
439 ~~or transfer between any parent, division, or subsidiary wholly~~
440 ~~owned by a corporate entity.~~

441 (33)~~(35)~~ "Nursing home" means a facility licensed under
442 part II of chapter 400.

443 (34)~~(36)~~ "Official compendium" means the current edition of
444 the official United States Pharmacopoeia and National Formulary,
445 or any supplement thereto.

446 ~~(37) "Pedigree paper" means a document in written or~~
447 ~~electronic form approved by the department which contains~~
448 ~~information required by s. 499.01212 regarding the sale and~~
449 ~~distribution of any given prescription drug.~~

450 (35)~~(38)~~ "Permittee" means any person holding a permit
451 issued under this chapter ~~pursuant to s. 499.012.~~

452 (36)~~(39)~~ "Person" means any individual, child, joint
453 venture, syndicate, fiduciary, partnership, corporation,
454 division of a corporation, firm, trust, business trust, company,
455 estate, public or private institution, association,
456 organization, group, city, county, city and county, political
457 subdivision of this state, other governmental agency within this
458 state, and any representative, agent, or agency of any of the
459 foregoing, or any other group or combination of the foregoing.

460 (37)~~(40)~~ "Pharmacist" means a person licensed under chapter
461 465.

462 (38)~~(41)~~ "Pharmacy" means an entity licensed under chapter
463 465.

464 (39)~~(42)~~ "Prepackaged drug product" means a drug that

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465 originally was in finished packaged form sealed by a
466 manufacturer and that is placed in a properly labeled container
467 by a pharmacy or practitioner authorized to dispense pursuant to
468 chapter 465 for the purpose of dispensing in the establishment
469 in which the prepackaging occurred.

470 (40)~~(43)~~ "Prescription drug" means a prescription,
471 medicinal, or legend drug, including, but not limited to,
472 finished dosage forms or active pharmaceutical ingredients
473 subject to, defined by, or described by s. 503(b) of the federal
474 act or s. 465.003(8), s. 499.007(13), subsection (31) ~~(32)~~, or
475 subsection (47) ~~(52)~~, except that an active pharmaceutical
476 ingredient is a prescription drug only if substantially all
477 finished dosage forms in which it may be lawfully dispensed or
478 administered in this state are also prescription drugs.

479 (41)~~(44)~~ "Prescription drug label" means any display of
480 written, printed, or graphic matter upon the immediate container
481 of any prescription drug before it is dispensed ~~prior to its~~
482 ~~dispensing~~ to an individual patient pursuant to a prescription
483 of a practitioner authorized by law to prescribe.

484 (42)~~(45)~~ "Prescription label" means any display of written,
485 printed, or graphic matter upon the immediate container of any
486 prescription drug dispensed pursuant to a prescription of a
487 practitioner authorized by law to prescribe.

488 ~~(46) "Primary wholesale distributor" means any wholesale~~
489 ~~distributor that:~~

490 ~~(a) Purchased 90 percent or more of the total dollar volume~~
491 ~~of its purchases of prescription drugs directly from~~
492 ~~manufacturers in the previous year; and~~

493 ~~(b)1. Directly purchased prescription drugs from not fewer~~

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494 ~~than 50 different prescription drug manufacturers in the~~
495 ~~previous year; or~~

496 ~~2. Has, or the affiliated group, as defined in s. 1504 of~~
497 ~~the Internal Revenue Code, of which the wholesale distributor is~~
498 ~~a member has, not fewer than 250 employees.~~

499 ~~(c) For purposes of this subsection, "directly from~~
500 ~~manufacturers" means:~~

501 ~~1. Purchases made by the wholesale distributor directly~~
502 ~~from the manufacturer of prescription drugs; and~~

503 ~~2. Transfers from a member of an affiliated group, as~~
504 ~~defined in s. 1504 of the Internal Revenue Code, of which the~~
505 ~~wholesale distributor is a member, if:~~

506 ~~a. The affiliated group purchases 90 percent or more of the~~
507 ~~total dollar volume of its purchases of prescription drugs from~~
508 ~~the manufacturer in the previous year; and~~

509 ~~b. The wholesale distributor discloses to the department~~
510 ~~the names of all members of the affiliated group of which the~~
511 ~~wholesale distributor is a member and the affiliated group~~
512 ~~agrees in writing to provide records on prescription drug~~
513 ~~purchases by the members of the affiliated group not later than~~
514 ~~48 hours after the department requests access to such records,~~
515 ~~regardless of the location where the records are stored.~~

516 ~~(43)(47)~~ "Proprietary drug," or "OTC drug," means a patent
517 or over-the-counter drug in its unbroken, original package,
518 which drug is sold to the public by, or under the authority of,
519 the manufacturer or primary distributor thereof, is not
520 misbranded under the provisions of this part, and can be
521 purchased without a prescription.

522 ~~(44)(48)~~ "Repackage" includes repacking or otherwise

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523 changing the container, wrapper, or labeling to further the
524 distribution of the drug, device, or cosmetic.

525 (45)~~(49)~~ "Repackager" means a person who repackages. The
526 term excludes pharmacies that are operating in compliance with
527 pharmacy practice standards as defined in chapter 465 and rules
528 adopted under that chapter.

529 (46)~~(50)~~ "Retail pharmacy" means a community pharmacy
530 licensed under chapter 465 that purchases prescription drugs at
531 fair market prices and provides prescription services to the
532 public.

533 ~~(51) "Secondary wholesale distributor" means a wholesale
534 distributor that is not a primary wholesale distributor.~~

535 (47)~~(52)~~ "Veterinary prescription drug" means a
536 prescription drug intended solely for veterinary use. The label
537 of the drug must bear the statement, "Caution: Federal law
538 restricts this drug to sale by or on the order of a licensed
539 veterinarian."

540 (48)~~(53)~~ "Wholesale distribution" means the distribution of
541 a prescription drug to a person ~~drugs to persons~~ other than a
542 consumer or patient, or the receipt of a prescription drug by a
543 person other than the consumer or patient, but does not include:

544 (a) Any of the following activities, which is not a
545 violation of s. 499.005(21) if such activity is conducted in
546 accordance with s. 499.01(2)(h) ~~499.01(2)(g)~~:

547 1. The purchase or other acquisition by a hospital or other
548 health care entity that is a member of a group purchasing
549 organization of a prescription drug for its own use from the
550 group purchasing organization or from other hospitals or health
551 care entities that are members of that organization.

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552 2. The distribution ~~sale, purchase, or trade~~ of a
553 prescription drug or an offer to distribute ~~sell, purchase, or~~
554 ~~trade~~ a prescription drug by a charitable organization described
555 in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended
556 and revised, to a nonprofit affiliate of the organization to the
557 extent otherwise permitted by law.

558 3. The distribution ~~sale, purchase, or trade~~ of a
559 prescription drug ~~or an offer to sell, purchase, or trade a~~
560 ~~prescription drug~~ among hospitals or other health care entities
561 that are under common control. For purposes of this
562 subparagraph, "common control" means the power to direct or
563 cause the direction of the management and policies of a person
564 or an organization, whether by ownership of stock, by voting
565 rights, by contract, or otherwise.

566 4. The distribution ~~sale, purchase, trade, or other~~
567 ~~transfer~~ of a prescription drug from or for any federal, state,
568 or local government agency or any entity eligible to purchase
569 prescription drugs at public health services prices pursuant to
570 Pub. L. No. 102-585, s. 602 to a contract provider or its
571 subcontractor for eligible patients of the agency or entity
572 under the following conditions:

573 a. The agency or entity must obtain written authorization
574 for the distribution ~~sale, purchase, trade, or other transfer~~ of
575 a prescription drug under this subparagraph from the Secretary
576 of Business and Professional Regulation or his or her designee.

577 b. The contract provider or subcontractor must be
578 authorized by law to administer or dispense prescription drugs.

579 c. In the case of a subcontractor, the agency or entity
580 must be a party to and execute the subcontract.

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581 d. The contract provider and subcontractor must maintain
582 and produce immediately for inspection all records of movement
583 or transfer of all the prescription drugs belonging to the
584 agency or entity, including, but not limited to, the records of
585 receipt and disposition of prescription drugs. Each contractor
586 and subcontractor dispensing or administering these drugs must
587 maintain and produce records documenting the dispensing or
588 administration. Records that are required to be maintained
589 include, but are not limited to, a perpetual inventory itemizing
590 drugs received and drugs dispensed by prescription number or
591 administered by patient identifier, which must be submitted to
592 the agency or entity quarterly.

593 e. The contract provider or subcontractor may administer or
594 dispense the prescription drugs only to the eligible patients of
595 the agency or entity or must return the prescription drugs for
596 or to the agency or entity. The contract provider or
597 subcontractor must require proof from each person seeking to
598 fill a prescription or obtain treatment that the person is an
599 eligible patient of the agency or entity and must, at a minimum,
600 maintain a copy of this proof as part of the records of the
601 contractor or subcontractor required under sub-subparagraph d.

602 f. In addition to the departmental inspection authority set
603 forth in s. 499.051, the establishment of the contract provider
604 and subcontractor and all records pertaining to prescription
605 drugs subject to this subparagraph shall be subject to
606 inspection by the agency or entity. All records relating to
607 prescription drugs of a manufacturer under this subparagraph
608 shall be subject to audit by the manufacturer of those drugs,
609 without identifying individual patient information.

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610 (b) Any of the following activities, which is not a
611 violation of s. 499.005(21) if such activity is conducted in
612 accordance with rules established by the department:

613 1. The distribution ~~sale, purchase, or trade~~ of a
614 prescription drug among federal, state, or local government
615 health care entities that are under common control and are
616 authorized to purchase such prescription drug.

617 2. The distribution ~~sale, purchase, or trade~~ of a
618 prescription drug or ~~an offer to~~ distribute ~~sell, purchase, or~~
619 ~~trade~~ a prescription drug for emergency medical reasons, which
620 may include. ~~For purposes of this subparagraph, The term~~
621 ~~"emergency medical reasons" includes~~ transfers of prescription
622 drugs by a retail pharmacy to another retail pharmacy to
623 alleviate a temporary shortage. For purposes of this
624 subparagraph, a drug shortage not caused by a public health
625 emergency does not constitute an emergency medical reason.

626 3. The distribution ~~transfer~~ of a prescription drug
627 acquired by a medical director on behalf of a licensed emergency
628 medical services provider to that emergency medical services
629 provider and its transport vehicles for use in accordance with
630 the provider's license under chapter 401.

631 ~~4. The revocation of a sale or the return of a prescription~~
632 ~~drug to the person's prescription drug wholesale supplier.~~

633 ~~4.5.~~ The donation of a prescription drug by a health care
634 entity to a charitable organization that has been granted an
635 exemption under s. 501(c)(3) of the Internal Revenue Code of
636 1986, as amended, and that is authorized to possess prescription
637 drugs.

638 ~~5.6.~~ The distribution ~~transfer~~ of a prescription drug by a

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639 person authorized to purchase or receive prescription drugs to a
640 person licensed or permitted to handle reverse distributions or
641 destruction under the laws of the jurisdiction in which the
642 person handling the reverse distribution or destruction receives
643 the drug.

644 6.7. The distribution ~~transfer~~ of a prescription drug by a
645 hospital or other health care entity to a person licensed under
646 this part to repackage prescription drugs for the purpose of
647 repackaging the prescription drug for use by that hospital, or
648 other health care entity and other health care entities that are
649 under common control, if ownership of the prescription drugs
650 remains with the hospital or other health care entity at all
651 times. In addition to the recordkeeping requirements of s.
652 499.0121(6), the hospital or health care entity that distributes
653 ~~transfers~~ prescription drugs pursuant to this subparagraph must
654 reconcile all drugs distributed ~~transferred~~ and returned and
655 resolve any discrepancies in a timely manner.

656 (c) Intracompany distribution of any drug between members
657 of an affiliate or within a manufacturer.

658 (d) The distribution of a prescription drug by the
659 manufacturer of the prescription drug.

660 (e)-(e) The distribution of prescription drug samples by
661 manufacturers' representatives or distributors' representatives
662 conducted in accordance with s. 499.028.

663 (f) The distribution of a prescription drug by a third-
664 party logistics provider permitted or licensed pursuant to and
665 operating in compliance with the laws of this state and federal
666 law if such third-party logistics provider does not take
667 ownership of the prescription drug.

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668 (g) The distribution of a prescription drug, or an offer to
669 distribute a prescription drug by a repackager registered as a
670 drug establishment with the United States Food and Drug
671 Administration that has taken ownership or possession of the
672 prescription drug and repacks it in accordance with this part.

673 (h) The purchase or other acquisition by a dispenser,
674 hospital, or other health care entity of a prescription drug for
675 use by such dispenser, hospital, or other health care entity.

676 (i) The distribution of a prescription drug by a hospital
677 or other health care entity, or by a wholesale distributor or
678 manufacturer operating at the direction of the hospital or other
679 health care entity, to a repackager for the purpose of
680 repackaging the prescription drug for use by that hospital, or
681 other health care entity and other health care entities that are
682 under common control, if ownership of the prescription drug
683 remains with the hospital or other health care entity at all
684 times.

685 (j)~~(d)~~ The distribution ~~sale, purchase, or trade~~ of blood
686 and blood components intended for transfusion. As used in this
687 paragraph, the term "blood" means whole blood collected from a
688 single donor and processed for transfusion or further
689 manufacturing, and the term "blood components" means that part
690 of the blood separated by physical or mechanical means.

691 (k)~~(e)~~ The lawful dispensing of a prescription drug in
692 accordance with chapter 465.

693 (l)~~(f)~~ The distribution ~~sale, purchase, or trade~~ of a
694 prescription drug between pharmacies as a result of a sale,
695 transfer, merger, or consolidation of all or part of the
696 business of the pharmacies from or with another pharmacy,

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697 whether accomplished as a purchase and sale of stock or of
698 business assets.

699 (m) The distribution of minimal quantities of prescription
700 drugs by a licensed retail pharmacy to a licensed practitioner
701 for office use in compliance with chapter 465 and rules adopted
702 thereunder. The department shall adopt rules specifying the
703 quantities of prescription drugs which are considered to be
704 minimal quantities. However, until such rules are adopted,
705 minimal quantities distributed may not exceed 3 percent of the
706 retail pharmacy's total annual purchases of prescription drugs.

707 (n) The distribution of an intravenous prescription drug
708 that, by its formulation, is intended for the replenishment of
709 fluids and electrolytes, such as sodium, chloride, and potassium
710 or calories, such as dextrose and amino acids.

711 (o) The distribution of an intravenous prescription drug
712 used to maintain the equilibrium of water and minerals in the
713 body, such as dialysis solutions.

714 (p) The distribution of a prescription drug that is
715 intended for irrigation or sterile water, whether intended for
716 such purposes or for injection.

717 (q) The distribution of an exempt medical convenience kit
718 pursuant to 21 U.S.C. s. 353(e) (4) (M).

719 (r) A common carrier that transports a prescription drug,
720 if the common carrier does not take ownership of the
721 prescription drug.

722 (s) Saleable drug returns when conducted by a dispenser.

723 (t) Facilitating the distribution of a prescription drug by
724 providing solely administrative services, including processing
725 of orders and payments.

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726 (u) The distribution by a charitable organization described
727 in s. 501(c)(3) of the Internal Revenue Code of prescription
728 drugs donated to or supplied at a reduced price to the
729 charitable organization to:

730 1. A licensed health care practitioner, as defined in s.
731 456.001, who is authorized under the appropriate practice act to
732 prescribe and administer prescription drugs;

733 2. A health care clinic establishment permitted pursuant to
734 chapter 499; or

735 3. The Department of Health or the licensed medical
736 director of a government agency health care entity, authorized
737 to possess prescription drugs, for storage and use in the
738 treatment of persons in need of emergency medical services,
739 including controlling communicable diseases or providing
740 protection from unsafe conditions that pose an imminent threat
741 to public health,

742
743 if the distributor and the receiving entity receive no direct or
744 indirect financial benefit other than tax benefits related to
745 charitable contributions. Distributions under this section that
746 involve controlled substances must comply with all state and
747 federal regulations pertaining to the handling of controlled
748 substances.

749 (v) The distribution of medical gas pursuant to part III of
750 this chapter.

751 (49)-(54) "Wholesale distributor" means a ~~any~~ person, other
752 than a manufacturer, a manufacturer's co-licensed partner, a
753 third-party logistics provider, or a repackager, who is engaged
754 in wholesale distribution of ~~prescription drugs in or into this~~

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755 ~~state, including, but not limited to, manufacturers;~~
756 ~~repackagers; own-label distributors; jobbers; private-label~~
757 ~~distributors; brokers; warehouses, including manufacturers' and~~
758 ~~distributors' warehouses, chain drug warehouses, and wholesale~~
759 ~~drug warehouses; independent wholesale drug traders; exporters;~~
760 ~~retail pharmacies; and the agents thereof that conduct wholesale~~
761 ~~distributions.~~

762 Section 3. Subsections (21), (28), and (29) of section
763 499.005, Florida Statutes, are amended to read:

764 499.005 Prohibited acts.—It is unlawful for a person to
765 perform or cause the performance of any of the following acts in
766 this state:

767 (21) The wholesale distribution of any prescription drug
768 that was:

769 (a) Purchased by a public or private hospital or other
770 health care entity; or

771 (b) Donated or supplied at a reduced price to a charitable
772 organization,

773

774 unless the wholesale distribution of the prescription drug is
775 authorized in s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.e.~~

776 (28) Failure to acquire or deliver a transaction history,
777 transaction information, or transaction statement ~~pedigree paper~~
778 as required under this part and rules adopted under this part.

779 ~~(29) The receipt of a prescription drug pursuant to a~~
780 ~~wholesale distribution without having previously received or~~
781 ~~simultaneously receiving a pedigree paper that was attested to~~
782 ~~as accurate and complete by the wholesale distributor as~~
783 ~~required under this part.~~

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784 Section 4. Subsections (4) through (17) of section
785 499.0051, Florida Statutes, are renumbered as subsections (3)
786 through (16), respectively, and subsections (1) and (2), present
787 subsection (3), paragraphs (h) and (i) of present subsection
788 (12), paragraph (d) of present subsection (13), and present
789 subsection (15) of that section are amended, to read:

790 499.0051 Criminal acts.—

791 (1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY,
792 TRANSACTION INFORMATION, OR TRANSACTION STATEMENT PEDIGREE
793 PAPERS.—

794 (a) A person, ~~other than a manufacturer,~~ engaged in the
795 ~~wholesale~~ distribution of prescription drugs who fails to
796 deliver to another person a complete and accurate transaction
797 history, transaction information, or transaction statement
798 pedigree papers concerning a prescription drug or contraband
799 prescription drug, as required by this chapter and rules adopted
800 under this chapter, before ~~prior to,~~ or simultaneous with, the
801 transfer of the prescription drug or contraband prescription
802 drug to another person commits a felony of the third degree,
803 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

804 (b) A person engaged in the ~~wholesale~~ distribution of
805 prescription drugs who fails to acquire a complete and accurate
806 transaction history, transaction information, or transaction
807 statement pedigree papers concerning a prescription drug or
808 contraband prescription drug, as required by this chapter and
809 rules adopted under this chapter, before ~~prior to,~~ or
810 simultaneous with, the receipt of the prescription drug or
811 contraband prescription drug from another person commits a
812 felony of the third degree, punishable as provided in s.

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813 775.082, s. 775.083, or s. 775.084.

814 (c) Any person who knowingly destroys, alters, conceals, or
815 fails to maintain a complete and accurate transaction history,
816 transaction information, or transaction statement pedigree
817 papers concerning any prescription drug or contraband
818 prescription drug, as required by this chapter and rules adopted
819 under this chapter, in his or her possession commits a felony of
820 the third degree, punishable as provided in s. 775.082, s.
821 775.083, or s. 775.084.

822 ~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July~~
823 ~~1, 2006:~~

824 ~~(a) A person engaged in the wholesale distribution of~~
825 ~~prescription drugs who is in possession of pedigree papers~~
826 ~~concerning prescription drugs or contraband prescription drugs~~
827 ~~and who fails to authenticate the matters contained in the~~
828 ~~pedigree papers and who nevertheless attempts to further~~
829 ~~distribute prescription drugs or contraband prescription drugs~~
830 ~~commits a felony of the third degree, punishable as provided in~~
831 ~~s. 775.082, s. 775.083, or s. 775.084.~~

832 ~~(b) A person in possession of pedigree papers concerning~~
833 ~~prescription drugs or contraband prescription drugs who falsely~~
834 ~~swears or certifies that he or she has authenticated the matters~~
835 ~~contained in the pedigree papers commits a felony of the third~~
836 ~~degree, punishable as provided in s. 775.082, s. 775.083, or s.~~
837 ~~775.084.~~

838 ~~(2)~~~~(3)~~ KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION
839 INFORMATION, OR TRANSACTION STATEMENT PEDIGREE PAPERS.—A person
840 who knowingly forges, counterfeits, or falsely creates any
841 transaction history, transaction information, or transaction

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842 statement ~~pedigree paper~~; who falsely represents any factual
843 matter contained on any transaction history, transaction
844 information, or transaction statement ~~pedigree paper~~; or who
845 knowingly omits to record material information required to be
846 recorded in a transaction history, transaction information, or
847 transaction statement ~~pedigree paper~~, commits a felony of the
848 second degree, punishable as provided in s. 775.082, s. 775.083,
849 or s. 775.084.

850 (11)~~(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE
851 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—
852 Any person who violates any of the following provisions commits
853 a misdemeanor of the second degree, punishable as provided in s.
854 775.082 or s. 775.083; but, if the violation is committed after
855 a conviction of such person under this subsection has become
856 final, such person commits a misdemeanor of the first degree,
857 punishable as provided in s. 775.082 or s. 775.083, or as
858 otherwise provided in this part:

859 (h) The failure to maintain records related to a drug as
860 required by this part and rules adopted under this part, except
861 for transaction histories, transaction information, or
862 transaction statements ~~pedigree papers~~, invoices, or shipping
863 documents related to prescription drugs.

864 (i) The possession of any drug in violation of this part,
865 except if the violation relates to a deficiency in transaction
866 histories, transaction information, or transaction statements
867 ~~pedigree papers~~.

868 (12)~~(13)~~ REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING,
869 OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
870 PRESCRIPTION DRUGS.—Any person who violates any of the following

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871 provisions commits a felony of the third degree, punishable as
872 provided in s. 775.082, s. 775.083, or s. 775.084, or as
873 otherwise provided in this part:

874 (d) The failure to receive, maintain, or provide invoices
875 and shipping documents, ~~other than pedigree papers,~~ if
876 applicable, related to the distribution of a prescription drug.

877 (14) ~~(15)~~ FALSE ADVERTISEMENT.—A publisher, radio broadcast
878 licensee, or agency or medium for the dissemination of an
879 advertisement, except the manufacturer, repackager, wholesale
880 distributor, or seller of the article to which a false
881 advertisement relates, is not liable under subsection (11) ~~(12)~~,
882 subsection (12) ~~(13)~~, or subsection (13) ~~(14)~~ by reason of the
883 dissemination by him or her of such false advertisement, unless
884 he or she has refused, on the request of the department, to
885 furnish to the department the name and post office address of
886 the manufacturer, repackager, wholesale distributor, seller, or
887 advertising agency that asked him or her to disseminate such
888 advertisement.

889 Section 5. Section 499.006, Florida Statutes, is amended to
890 read:

891 499.006 Adulterated drug or device.—A drug or device is
892 adulterated, if any of the following apply:

893 (1) ~~If~~ It consists in whole or in part of any filthy,
894 putrid, or decomposed substance. †

895 (2) ~~If~~ It has been produced, prepared, packed, or held
896 under conditions whereby it could have been contaminated with
897 filth or rendered injurious to health. †

898 (3) ~~If~~ It is a drug and the methods used in, or the
899 facilities or controls used for, its manufacture, processing,

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900 packing, or holding do not conform to, or are not operated or
901 administered in conformity with, current good manufacturing
902 practices to assure that the drug meets the requirements of this
903 part and that the drug has the identity and strength, and meets
904 the standard of quality and purity, which it purports or is
905 represented to possess.†

906 (4) ~~If~~ It is a drug and its container is composed, in whole
907 or in part, of any poisonous or deleterious substance which
908 could render the contents injurious to health.†

909 (5) ~~If~~ It is a drug and it bears or contains, for the
910 purpose of coloring only, a color additive that is unsafe within
911 the meaning of the federal act; or, if it is a color additive,
912 the intended use of which in or on drugs is for the purpose of
913 coloring only, and it is unsafe within the meaning of the
914 federal act.†

915 (6) ~~If~~ It purports to be, or is represented as, a drug the
916 name of which is recognized in the official compendium, and its
917 strength differs from, or its quality or purity falls below, the
918 standard set forth in such compendium. The determination as to
919 strength, quality, or purity must be made in accordance with the
920 tests or methods of assay set forth in such compendium, or, when
921 such tests or methods of assay are absent or inadequate, in
922 accordance with those tests or methods of assay prescribed under
923 authority of the federal act. A drug defined in the official
924 compendium is not adulterated under this subsection merely
925 because it differs from the standard of strength, quality, or
926 purity set forth for that drug in such compendium if its
927 difference in strength, quality, or purity from such standard is
928 plainly stated on its label.†

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929 (7) ~~If~~ It is not subject to subsection (6) and its strength
930 differs from, or its purity or quality falls below the standard
931 of, that which it purports or is represented to possess.~~†~~

932 (8) ~~If~~ It is a drug:

933 (a) With which any substance has been mixed or packed so as
934 to reduce the quality or strength of the drug; or

935 (b) For which any substance has been substituted wholly or
936 in part.~~†~~

937 (9) ~~If~~ It is a drug or device for which the expiration date
938 has passed.~~†~~

939 (10) ~~If~~ It is a prescription drug for which the required
940 transaction history, transaction information, or transaction
941 statement ~~pedigree paper~~ is nonexistent, fraudulent, or
942 incomplete under the requirements of this part or applicable
943 rules, or that has been purchased, held, sold, or distributed at
944 any time by a person not authorized under federal or state law
945 to do so.~~†~~ ~~or~~

946 (11) ~~If~~ It is a prescription drug subject to, defined by,
947 or described by s. 503(b) of the Federal Food, Drug, and
948 Cosmetic Act which has been returned by a veterinarian to a
949 limited prescription drug veterinary wholesale distributor.

950 Section 6. Section 499.01, Florida Statutes, is amended to
951 read:

952 499.01 Permits.—

953 (1) Before ~~Prior to~~ operating, a permit is required for
954 each person and establishment that intends to operate as:

955 (a) A prescription drug manufacturer;

956 (b) A prescription drug repackager;

957 (c) A nonresident prescription drug manufacturer;

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958 (d) A nonresident prescription drug repackager;
 959 (e)~~(d)~~ A prescription drug wholesale distributor;
 960 (f)~~(e)~~ An out-of-state prescription drug wholesale
 961 distributor;
 962 (g)~~(f)~~ A retail pharmacy drug wholesale distributor;
 963 (h)~~(g)~~ A restricted prescription drug distributor;
 964 (i)~~(h)~~ A complimentary drug distributor;
 965 (j)~~(i)~~ A freight forwarder;
 966 (k)~~(j)~~ A veterinary prescription drug retail establishment;
 967 (l)~~(k)~~ A veterinary prescription drug wholesale
 968 distributor;
 969 (m)~~(l)~~ A limited prescription drug veterinary wholesale
 970 distributor;
 971 (n)~~(m)~~ An over-the-counter drug manufacturer;
 972 (o)~~(n)~~ A device manufacturer;
 973 (p)~~(o)~~ A cosmetic manufacturer;
 974 (q)~~(p)~~ A third party logistics provider; or
 975 (r)~~(q)~~ A health care clinic establishment.
 976 (2) The following permits are established:
 977 (a) *Prescription drug manufacturer permit.*—A prescription
 978 drug manufacturer permit is required for any person that is a
 979 manufacturer of a prescription drug and that manufactures or
 980 distributes such prescription drugs in this state.
 981 1. A person that operates an establishment permitted as a
 982 prescription drug manufacturer may engage in ~~wholesale~~
 983 distribution of prescription drugs for which the person is the
 984 manufacturer ~~manufactured at that establishment~~ and must comply
 985 with s. 499.0121 and all other ~~of the~~ provisions of this part,
 986 ~~except s. 499.01212,~~ and the rules adopted under this part.

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987 ~~except s. 499.01212, which apply to a wholesale distributor. The~~
988 department shall adopt rules for issuing a virtual prescription
989 drug manufacturer permit to a person who engages in the
990 manufacture of prescription drugs but does not make or take
991 physical possession of any prescription drugs. The rules adopted
992 by the department under this section may exempt virtual
993 manufacturers from certain establishment, security, and storage
994 requirements set forth in s. 499.0121.

995 2. A prescription drug manufacturer must comply with all
996 appropriate state and federal good manufacturing practices.

997 3. A blood establishment, as defined in s. 381.06014,
998 operating in a manner consistent with the provisions of 21
999 C.F.R. parts 211 and 600-640, and manufacturing only the
1000 prescription drugs described in s. 499.003(48)(j) ~~499.003(53)(d)~~
1001 is not required to be permitted as a prescription drug
1002 manufacturer under this paragraph or to register products under
1003 s. 499.015.

1004 (b) *Prescription drug repackager permit.*—A prescription
1005 drug repackager permit is required for any person that
1006 repackages a prescription drug in this state.

1007 1. A person that operates an establishment permitted as a
1008 prescription drug repackager may engage in ~~wholesale~~
1009 distribution of prescription drugs repackaged at that
1010 establishment and must comply with all of the provisions of this
1011 part and the rules adopted under this part that apply to a
1012 prescription drug manufacturer ~~wholesale distributor~~.

1013 2. A prescription drug repackager must comply with all
1014 appropriate state and federal good manufacturing practices.

1015 (c) *Nonresident prescription drug manufacturer permit.*—A

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1016 nonresident prescription drug manufacturer permit is required
1017 for any person that is a manufacturer of prescription drugs,
1018 unless permitted as a third party logistics provider, located
1019 outside of this state or outside the United States and that
1020 engages in the ~~wholesale~~ distribution in this state of such
1021 prescription drugs. Each such manufacturer must be permitted by
1022 the department and comply with all of the provisions required of
1023 a prescription drug manufacturer ~~wholesale distributor~~ under
1024 this part, ~~except s. 499.01212~~. The department shall adopt rules
1025 for issuing a virtual nonresident prescription drug manufacturer
1026 permit to a person who engages in the manufacture of
1027 prescription drugs but does not make or take physical possession
1028 of any prescription drugs. The rules adopted by the department
1029 under this section may exempt virtual nonresident manufacturers
1030 from certain establishment, security, and storage requirements
1031 set forth in s. 499.0121.

1032 1. A person that distributes prescription drugs for which
1033 the person is not the manufacturer must also obtain an out-of-
1034 state prescription drug wholesale distributor permit or third
1035 party logistics provider permit pursuant to this section to
1036 engage in the ~~wholesale~~ distribution of such prescription drugs
1037 when required by this part. This subparagraph does not apply to
1038 a manufacturer that distributes prescription drugs only for the
1039 manufacturer of the prescription drugs where both manufacturers
1040 are affiliates ~~as defined in s. 499.003(30)(e)~~.

1041 2. Any such person must comply with the licensing or
1042 permitting requirements of the jurisdiction in which the
1043 establishment is located and the federal act, and any
1044 prescription drug distributed ~~product wholesaled~~ into this state

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1045 must comply with this part. If a person intends to import
1046 prescription drugs from a foreign country into this state, the
1047 nonresident prescription drug manufacturer must provide to the
1048 department a list identifying each prescription drug it intends
1049 to import and document approval by the United States Food and
1050 Drug Administration for such importation.

1051 (d) Nonresident prescription drug repackager permit.—A
1052 nonresident prescription drug repackager permit is required for
1053 any person located outside of this state, but within the United
1054 States or its territories, that repackages prescription drugs
1055 and engages in the distribution of such prescription drugs into
1056 this state.

1057 1. A nonresident prescription drug repackager must comply
1058 with all of the provisions of this section and the rules adopted
1059 under this section that apply to a prescription drug
1060 manufacturer.

1061 2. A nonresident prescription drug repackager must be
1062 permitted by the department and comply with all appropriate
1063 state and federal good manufacturing practices.

1064 3. A nonresident prescription drug repackager must be
1065 registered as a drug establishment with the United States Food
1066 and Drug Administration.

1067 (e)—~~(d)~~ Prescription drug wholesale distributor permit.—A
1068 prescription drug wholesale distributor permit is required for
1069 any person who is a wholesale distributor of prescription drugs
1070 and that may engage in the wholesale distributes such
1071 distribution of prescription drugs in this state. ~~A prescription~~
1072 ~~drug wholesale distributor that applies to the department for a~~
1073 ~~new permit or the renewal of a permit must submit a bond of~~

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1074 ~~\$100,000, or other equivalent means of security acceptable to~~
1075 ~~the department, such as an irrevocable letter of credit or a~~
1076 ~~deposit in a trust account or financial institution, payable to~~
1077 ~~the Professional Regulation Trust Fund. The purpose of the bond~~
1078 ~~is to secure payment of any administrative penalties imposed by~~
1079 ~~the department and any fees and costs incurred by the department~~
1080 ~~regarding that permit which are authorized under state law and~~
1081 ~~which the permittee fails to pay 30 days after the fine or costs~~
1082 ~~become final. The department may make a claim against such bond~~
1083 ~~or security until 1 year after the permittee's license ceases to~~
1084 ~~be valid or until 60 days after any administrative or legal~~
1085 ~~proceeding authorized in this part which involves the permittee~~
1086 ~~is concluded, including any appeal, whichever occurs later. The~~
1087 ~~department may adopt rules for issuing a prescription drug~~
1088 ~~wholesale distributor-broker permit to a person who engages in~~
1089 ~~the wholesale distribution of prescription drugs and does not~~
1090 ~~take physical possession of any prescription drugs.~~

1091 ~~(f)(e)~~ *Out-of-state prescription drug wholesale distributor*
1092 *permit.*—An out-of-state prescription drug wholesale distributor
1093 permit is required for any person that is a wholesale
1094 distributor located outside this state, but within the United
1095 States or its territories, which engages in the wholesale
1096 distribution of prescription drugs into this state ~~and which~~
1097 ~~must be permitted by the department and comply with all the~~
1098 ~~provisions required of a wholesale distributor under this part.~~
1099 ~~An out-of-state prescription drug wholesale distributor that~~
1100 ~~applies to the department for a new permit or the renewal of a~~
1101 ~~permit must submit a bond of \$100,000, or other equivalent means~~
1102 ~~of security acceptable to the department, such as an irrevocable~~

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1103 ~~letter of credit or a deposit in a trust account or financial~~
1104 ~~institution, payable to the Professional Regulation Trust Fund.~~
1105 ~~The purpose of the bond is to secure payment of any~~
1106 ~~administrative penalties imposed by the department and any fees~~
1107 ~~and costs incurred by the department regarding that permit which~~
1108 ~~are authorized under state law and which the permittee fails to~~
1109 ~~pay 30 days after the fine or costs become final. The department~~
1110 ~~may make a claim against such bond or security until 1 year~~
1111 ~~after the permittee's license ceases to be valid or until 60~~
1112 ~~days after any administrative or legal proceeding authorized in~~
1113 ~~this part which involves the permittee is concluded, including~~
1114 ~~any appeal, whichever occurs later. The out-of-state~~
1115 ~~prescription drug wholesale distributor must maintain at all~~
1116 ~~times a license or permit to engage in the wholesale~~
1117 ~~distribution of prescription drugs in compliance with laws of~~
1118 ~~the state in which it is a resident. If the state from which the~~
1119 ~~wholesale distributor distributes prescription drugs does not~~
1120 ~~require a license to engage in the wholesale distribution of~~
1121 ~~prescription drugs, the distributor must be licensed as a~~
1122 ~~wholesale distributor as required by the federal act.~~

1123 ~~(g)(f)~~ *Retail pharmacy drug wholesale distributor permit.*-A
1124 retail pharmacy drug wholesale distributor is a retail pharmacy
1125 engaged in wholesale distribution of prescription drugs within
1126 this state under the following conditions:

1127 1. The pharmacy must obtain a retail pharmacy drug
1128 wholesale distributor permit pursuant to this part and ~~the~~ rules
1129 adopted under this part.

1130 2. The wholesale distribution activity does not exceed 30
1131 percent of the total annual purchases of prescription drugs. If

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1132 the wholesale distribution activity exceeds the 30-percent
1133 maximum, the pharmacy must obtain a prescription drug wholesale
1134 distributor permit.

1135 3. The transfer of prescription drugs that appear in any
1136 schedule contained in chapter 893 is subject to chapter 893 and
1137 the federal Comprehensive Drug Abuse Prevention and Control Act
1138 of 1970.

1139 4. The transfer is between a retail pharmacy and another
1140 retail pharmacy, or a Modified Class II institutional pharmacy,
1141 or a health care practitioner licensed in this state and
1142 authorized by law to dispense or prescribe prescription drugs.

1143 5. All records of sales of prescription drugs subject to
1144 this section must be maintained separate and distinct from other
1145 records and comply with the recordkeeping requirements of this
1146 part.

1147 (h)~~(g)~~ *Restricted prescription drug distributor permit.*—

1148 1. A restricted prescription drug distributor permit is
1149 required for:

1150 a. Any person located in this state who engages in the
1151 distribution of a prescription drug, which distribution is not
1152 considered "wholesale distribution" under s. 499.003(48)(a)
1153 ~~499.003(53)(a)~~.

1154 b. Any person located in this state who engages in the
1155 receipt or distribution of a prescription drug in this state for
1156 the purpose of processing its return or its destruction if such
1157 person is not the person initiating the return, the prescription
1158 drug wholesale supplier of the person initiating the return, or
1159 the manufacturer of the drug.

1160 c. A blood establishment located in this state which

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1161 collects blood and blood components only from volunteer donors
1162 as defined in s. 381.06014 or pursuant to an authorized
1163 practitioner's order for medical treatment or therapy and
1164 engages in the wholesale distribution of a prescription drug not
1165 described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care
1166 entity. A mobile blood unit operated by a blood establishment
1167 permitted under this sub-subparagraph is not required to be
1168 separately permitted. The health care entity receiving a
1169 prescription drug distributed under this sub-subparagraph must
1170 be licensed as a closed pharmacy or provide health care services
1171 at that establishment. The blood establishment must operate in
1172 accordance with s. 381.06014 and may distribute only:

1173 (I) Prescription drugs indicated for a bleeding or clotting
1174 disorder or anemia;

1175 (II) Blood-collection containers approved under s. 505 of
1176 the federal act;

1177 (III) Drugs that are blood derivatives, or a recombinant or
1178 synthetic form of a blood derivative;

1179 (IV) Prescription drugs that are identified in rules
1180 adopted by the department and that are essential to services
1181 performed or provided by blood establishments and authorized for
1182 distribution by blood establishments under federal law; or

1183 (V) To the extent authorized by federal law, drugs
1184 necessary to collect blood or blood components from volunteer
1185 blood donors; for blood establishment personnel to perform
1186 therapeutic procedures under the direction and supervision of a
1187 licensed physician; and to diagnose, treat, manage, and prevent
1188 any reaction of a volunteer blood donor or a patient undergoing
1189 a therapeutic procedure performed under the direction and

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1190 supervision of a licensed physician,
1191
1192 as long as all of the health care services provided by the blood
1193 establishment are related to its activities as a registered
1194 blood establishment or the health care services consist of
1195 collecting, processing, storing, or administering human
1196 hematopoietic stem cells or progenitor cells or performing
1197 diagnostic testing of specimens if such specimens are tested
1198 together with specimens undergoing routine donor testing. The
1199 blood establishment may purchase and possess the drugs described
1200 in this sub-subparagraph without a health care clinic
1201 establishment permit.

1202 2. Storage, handling, and recordkeeping of these
1203 distributions by a person required to be permitted as a
1204 restricted prescription drug distributor must be in accordance
1205 with the requirements for wholesale distributors under s.
1206 ~~499.0121, but not those set forth in s. 499.01212 if the~~
1207 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~
1208 ~~subparagraph 1.b.~~

1209 3. A person who applies for a permit as a restricted
1210 prescription drug distributor, or for the renewal of such a
1211 permit, must provide to the department the information required
1212 under s. 499.012.

1213 4. The department may adopt rules regarding the
1214 distribution of prescription drugs by hospitals, health care
1215 entities, charitable organizations, other persons not involved
1216 in wholesale distribution, and blood establishments, which rules
1217 are necessary for the protection of the public health, safety,
1218 and welfare.

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1219 5. A restricted prescription drug distributor permit is not
1220 required for distributions between pharmacies that each hold an
1221 active permit under chapter 465, have a common ownership, and
1222 are operating in a freestanding end-stage renal dialysis clinic,
1223 if such distributions are made to meet the immediate emergency
1224 medical needs of specifically identified patients and do not
1225 occur with such frequency as to amount to the regular and
1226 systematic supplying of that drug between the pharmacies. The
1227 department shall adopt rules establishing when the distribution
1228 of a prescription drug under this subparagraph amounts to the
1229 regular and systematic supplying of that drug.

1230 (i)~~(h)~~ *Complimentary drug distributor permit.*—A
1231 complimentary drug distributor permit is required for any person
1232 that engages in the distribution of a complimentary drug,
1233 subject to the requirements of s. 499.028.

1234 (j)~~(i)~~ *Freight forwarder permit.*—A freight forwarder permit
1235 is required for any person that engages in the distribution of a
1236 prescription drug as a freight forwarder unless the person is a
1237 common carrier. The storage, handling, and recordkeeping of such
1238 distributions must comply with the requirements for wholesale
1239 distributors under s. 499.0121, ~~but not those set forth in s.~~
1240 ~~499.01212.~~ A freight forwarder must provide the source of the
1241 prescription drugs with a validated airway bill, bill of lading,
1242 or other appropriate documentation to evidence the exportation
1243 of the product.

1244 (k)~~(j)~~ *Veterinary prescription drug retail establishment*
1245 *permit.*—A veterinary prescription drug retail establishment
1246 permit is required for any person that sells veterinary
1247 prescription drugs to the public but does not include a pharmacy

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1248 licensed under chapter 465.

1249 1. The sale to the public must be based on a valid written
1250 order from a veterinarian licensed in this state who has a valid
1251 client-veterinarian relationship with the purchaser's animal.

1252 2. Veterinary prescription drugs may not be sold in excess
1253 of the amount clearly indicated on the order or beyond the date
1254 indicated on the order.

1255 3. An order may not be valid for more than 1 year.

1256 4. A veterinary prescription drug retail establishment may
1257 not purchase, sell, trade, or possess human prescription drugs
1258 or any controlled substance as defined in chapter 893.

1259 5. A veterinary prescription drug retail establishment must
1260 sell a veterinary prescription drug in the original, sealed
1261 manufacturer's container with all labeling intact and legible.
1262 The department may adopt by rule additional labeling
1263 requirements for the sale of a veterinary prescription drug.

1264 6. A veterinary prescription drug retail establishment must
1265 comply with all of the wholesale distribution requirements of s.
1266 499.0121.

1267 7. Prescription drugs sold by a veterinary prescription
1268 drug retail establishment pursuant to a practitioner's order may
1269 not be returned into the retail establishment's inventory.

1270 (1) ~~(*)~~ *Veterinary prescription drug wholesale distributor*
1271 *permit.*—A veterinary prescription drug wholesale distributor
1272 permit is required for any person that engages in the
1273 distribution of veterinary prescription drugs in or into this
1274 state. A veterinary prescription drug wholesale distributor that
1275 also distributes prescription drugs subject to, defined by, or
1276 described by s. 503(b) of the Federal Food, Drug, and Cosmetic

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1277 Act which it did not manufacture must obtain a permit as a
1278 prescription drug wholesale distributor, an out-of-state
1279 prescription drug wholesale distributor, or a limited
1280 prescription drug veterinary wholesale distributor in lieu of
1281 the veterinary prescription drug wholesale distributor permit. A
1282 veterinary prescription drug wholesale distributor must comply
1283 with the requirements for wholesale distributors under s.
1284 499.0121, ~~but not those set forth in s. 499.01212.~~

1285 (m) ~~(l)~~ *Limited prescription drug veterinary wholesale*
1286 *distributor permit.*—Unless engaging in the activities of and
1287 permitted as a prescription drug manufacturer, nonresident
1288 prescription drug manufacturer, prescription drug wholesale
1289 distributor, or out-of-state prescription drug wholesale
1290 distributor, a limited prescription drug veterinary wholesale
1291 distributor permit is required for any person that engages in
1292 the distribution in or into this state of veterinary
1293 prescription drugs and prescription drugs subject to, defined
1294 by, or described by s. 503(b) of the Federal Food, Drug, and
1295 Cosmetic Act under the following conditions:

- 1296 1. The person is engaged in the business of wholesaling
1297 prescription and veterinary prescription drugs to persons:
- 1298 a. Licensed as veterinarians practicing on a full-time
1299 basis;
 - 1300 b. Regularly and lawfully engaged in instruction in
1301 veterinary medicine;
 - 1302 c. Regularly and lawfully engaged in law enforcement
1303 activities;
 - 1304 d. For use in research not involving clinical use; or
1305 e. For use in chemical analysis or physical testing or for

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1306 purposes of instruction in law enforcement activities, research,
1307 or testing.

1308 2. No more than 30 percent of total annual prescription
1309 drug sales may be prescription drugs approved for human use
1310 which are subject to, defined by, or described by s. 503(b) of
1311 the Federal Food, Drug, and Cosmetic Act.

1312 3. The person does not distribute in any jurisdiction
1313 prescription drugs subject to, defined by, or described by s.
1314 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
1315 who is authorized to sell, distribute, purchase, trade, or use
1316 these drugs on or for humans.

1317 4. A limited prescription drug veterinary wholesale
1318 distributor that applies to the department for a new permit or
1319 the renewal of a permit must submit a bond of \$20,000, or other
1320 equivalent means of security acceptable to the department, such
1321 as an irrevocable letter of credit or a deposit in a trust
1322 account or financial institution, payable to the Professional
1323 Regulation Trust Fund. The purpose of the bond is to secure
1324 payment of any administrative penalties imposed by the
1325 department and any fees and costs incurred by the department
1326 regarding that permit which are authorized under state law and
1327 which the permittee fails to pay 30 days after the fine or costs
1328 become final. The department may make a claim against such bond
1329 or security until 1 year after the permittee's license ceases to
1330 be valid or until 60 days after any administrative or legal
1331 proceeding authorized in this part which involves the permittee
1332 is concluded, including any appeal, whichever occurs later.

1333 5. A limited prescription drug veterinary wholesale
1334 distributor must maintain at all times a license or permit to

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1335 engage in the wholesale distribution of prescription drugs in
1336 compliance with laws of the state in which it is a resident.

1337 6. A limited prescription drug veterinary wholesale
1338 distributor must comply with the requirements for wholesale
1339 distributors under s. ss. 499.0121 and ~~499.01212~~, ~~except that a~~
1340 ~~limited prescription drug veterinary wholesale distributor is~~
1341 ~~not required to provide a pedigree paper as required by s.~~
1342 ~~499.01212 upon the wholesale distribution of a prescription drug~~
1343 ~~to a veterinarian.~~

1344 7. A limited prescription drug veterinary wholesale
1345 distributor may not return to inventory for subsequent wholesale
1346 distribution any prescription drug subject to, defined by, or
1347 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1348 Act which has been returned by a veterinarian.

1349 8. A limited prescription drug veterinary wholesale
1350 distributor permit is not required for an intracompany sale or
1351 transfer of a prescription drug from an out-of-state
1352 establishment that is duly licensed to engage in the wholesale
1353 distribution of prescription drugs in its state of residence to
1354 a licensed limited prescription drug veterinary wholesale
1355 distributor in this state if both wholesale distributors conduct
1356 wholesale distributions of prescription drugs under the same
1357 business name. The recordkeeping requirements of s. ss.
1358 499.0121(6) and ~~499.01212~~ must be followed for this transaction.

1359 (n) ~~(m)~~ *Over-the-counter drug manufacturer permit.*—An over-
1360 the-counter drug manufacturer permit is required for any person
1361 that engages in the manufacture or repackaging of an over-the-
1362 counter drug.

1363 1. An over-the-counter drug manufacturer may not possess or

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1364 purchase prescription drugs.

1365 2. A pharmacy is exempt from obtaining an over-the-counter
1366 drug manufacturer permit if it is operating in compliance with
1367 pharmacy practice standards as defined in chapter 465 and ~~the~~
1368 rules adopted under that chapter.

1369 3. An over-the-counter drug manufacturer must comply with
1370 all appropriate state and federal good manufacturing practices.

1371 (o) ~~(n)~~ *Device manufacturer permit.*—

1372 1. A device manufacturer permit is required for any person
1373 that engages in the manufacture, repackaging, or assembly of
1374 medical devices for human use in this state, except that a
1375 permit is not required if:

1376 a. The person is engaged only in manufacturing,
1377 repackaging, or assembling a medical device pursuant to a
1378 practitioner's order for a specific patient; or

1379 b. The person does not manufacture, repackage, or assemble
1380 any medical devices or components for such devices, except those
1381 devices or components which are exempt from registration
1382 pursuant to s. 499.015(8).

1383 2. A manufacturer or repackager of medical devices in this
1384 state must comply with all appropriate state and federal good
1385 manufacturing practices and quality system rules.

1386 3. The department shall adopt rules related to storage,
1387 handling, and recordkeeping requirements for manufacturers of
1388 medical devices for human use.

1389 (p) ~~(e)~~ *Cosmetic manufacturer permit.*—A cosmetic
1390 manufacturer permit is required for any person that manufactures
1391 or repackages cosmetics in this state. A person that only labels
1392 or changes the labeling of a cosmetic but does not open the

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1393 container sealed by the manufacturer of the product is exempt
1394 from obtaining a permit under this paragraph.

1395 (q)~~(p)~~ *Third party logistics provider permit.*—A third party
1396 logistics provider permit is required for any person that
1397 contracts with a prescription drug wholesale distributor or
1398 prescription drug manufacturer to provide warehousing,
1399 distribution, or other logistics services on behalf of a
1400 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who
1401 does not take title to the prescription drug or have
1402 responsibility to direct the sale or disposition of the
1403 prescription drug. A third party logistics provider located
1404 outside of this state, must be licensed in the state or
1405 territory from which the prescription drug is distributed by the
1406 third party logistics provider. If the state or territory from
1407 which the third party logistics provider originates does not
1408 require a license to operate as a third party logistics
1409 provider, the third party logistics provider must be licensed as
1410 a third party logistics provider as required by the federal act.
1411 Each third party logistics provider permittee shall comply with
1412 ~~s. the requirements for wholesale distributors under ss.~~
1413 ~~499.0121 and 499.01212, with the exception of those wholesale~~
1414 ~~distributions described in s. 499.01212(3)(a), and other rules~~
1415 that the department requires.

1416 (r)~~(q)~~ *Health care clinic establishment permit.*—~~Effective~~
1417 ~~January 1, 2009,~~ A health care clinic establishment permit is
1418 required for the purchase of a prescription drug by a place of
1419 business at one general physical location that provides health
1420 care or veterinary services, which is owned and operated by a
1421 business entity that has been issued a federal employer tax

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1422 identification number. For the purpose of this paragraph, the
1423 term "qualifying practitioner" means a licensed health care
1424 practitioner defined in s. 456.001, or a veterinarian licensed
1425 under chapter 474, who is authorized under the appropriate
1426 practice act to prescribe and administer a prescription drug.

1427 1. An establishment must provide, as part of the
1428 application required under s. 499.012, designation of a
1429 qualifying practitioner who will be responsible for complying
1430 with all legal and regulatory requirements related to the
1431 purchase, recordkeeping, storage, and handling of the
1432 prescription drugs. In addition, the designated qualifying
1433 practitioner shall be the practitioner whose name, establishment
1434 address, and license number is used on all distribution
1435 documents for prescription drugs purchased or returned by the
1436 health care clinic establishment. Upon initial appointment of a
1437 qualifying practitioner, the qualifying practitioner and the
1438 health care clinic establishment shall notify the department on
1439 a form furnished by the department within 10 days after such
1440 employment. In addition, the qualifying practitioner and health
1441 care clinic establishment shall notify the department within 10
1442 days after any subsequent change.

1443 2. The health care clinic establishment must employ a
1444 qualifying practitioner at each establishment.

1445 3. In addition to the remedies and penalties provided in
1446 this part, a violation of this chapter by the health care clinic
1447 establishment or qualifying practitioner constitutes grounds for
1448 discipline of the qualifying practitioner by the appropriate
1449 regulatory board.

1450 4. The purchase of prescription drugs by the health care

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1451 clinic establishment is prohibited during any period of time
1452 when the establishment does not comply with this paragraph.

1453 5. A health care clinic establishment permit is not a
1454 pharmacy permit or otherwise subject to chapter 465. A health
1455 care clinic establishment that meets the criteria of a modified
1456 Class II institutional pharmacy under s. 465.019 is not eligible
1457 to be permitted under this paragraph.

1458 6. This paragraph does not apply to the purchase of a
1459 prescription drug by a licensed practitioner under his or her
1460 license.

1461 (3) A nonresident prescription drug manufacturer permit is
1462 not required for a manufacturer to distribute a prescription
1463 drug active pharmaceutical ingredient that it manufactures to a
1464 prescription drug manufacturer permitted in this state ~~in~~
1465 ~~limited quantities~~ intended for research and development and not
1466 for resale or human use other than lawful clinical trials and
1467 biostudies authorized and regulated by federal law. A
1468 manufacturer claiming to be exempt from the permit requirements
1469 of this subsection and the prescription drug manufacturer
1470 purchasing and receiving the active pharmaceutical ingredient
1471 shall comply with the recordkeeping requirements of s.
1472 499.0121(6), ~~but not the requirements of s. 499.01212.~~ The
1473 prescription drug manufacturer purchasing and receiving the
1474 active pharmaceutical ingredient shall maintain on file a record
1475 of the FDA registration number; if available, the out-of-state
1476 license, permit, or registration number; and, if available, a
1477 copy of the most current FDA inspection report, for all
1478 manufacturers from whom they purchase active pharmaceutical
1479 ingredients under this section. ~~The department shall define the~~

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1480 ~~term "limited quantities" by rule, and may include the allowable~~
1481 ~~number of transactions within a given period of time and the~~
1482 ~~amount of prescription drugs distributed into the state for~~
1483 ~~purposes of this exemption.~~ The failure to comply with the
1484 requirements of this subsection, or rules adopted by the
1485 department to administer this subsection, for the purchase of
1486 prescription drug active pharmaceutical ingredients is a
1487 violation of s. 499.005(14), and a knowing failure is a
1488 violation of s. 499.0051(3) ~~499.0051(4)~~.

1489 (a) The immediate package or container of a prescription
1490 drug active pharmaceutical ingredient distributed into the state
1491 that is intended for research and development under this
1492 subsection shall bear a label prominently displaying the
1493 statement: "Caution: Research and Development Only—Not for
1494 Manufacturing, Compounding, or Resale."

1495 (b) A prescription drug manufacturer that obtains a
1496 prescription drug active pharmaceutical ingredient under this
1497 subsection for use in clinical trials and or biostudies
1498 authorized and regulated by federal law must create and maintain
1499 records detailing the specific clinical trials or biostudies for
1500 which the prescription drug active pharmaceutical ingredient was
1501 obtained.

1502 (4) (a) A permit issued under this part is not required to
1503 distribute a prescription drug active pharmaceutical ingredient
1504 from an establishment located in the United States to an
1505 establishment located in this state permitted as a prescription
1506 drug manufacturer under this part for use by the recipient in
1507 preparing, deriving, processing, producing, or fabricating a
1508 prescription drug finished dosage form at the establishment in

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1509 this state where the product is received under an approved and
1510 otherwise valid New Drug Approval Application, Abbreviated New
1511 Drug Application, New Animal Drug Application, or Therapeutic
1512 Biologic Application, provided that the application, active
1513 pharmaceutical ingredient, or finished dosage form has not been
1514 withdrawn or removed from the market in this country for public
1515 health reasons.

1516 1. Any distributor claiming exemption from permitting
1517 requirements pursuant to this paragraph shall maintain a
1518 license, permit, or registration to engage in the wholesale
1519 distribution of prescription drugs under the laws of the state
1520 from which the product is distributed. If the state from which
1521 the prescription drugs are distributed does not require a
1522 license to engage in the wholesale distribution of prescription
1523 drugs, the distributor must be licensed as a wholesale
1524 distributor as required by the federal act.

1525 2. Any distributor claiming exemption from permitting
1526 requirements pursuant to this paragraph and the prescription
1527 drug manufacturer purchasing and receiving the active
1528 pharmaceutical ingredient shall comply with the recordkeeping
1529 requirements of s. 499.0121(6), ~~but not the requirements of s.~~
1530 ~~499.01212.~~

1531 (b) A permit issued under this part is not required to
1532 distribute ~~limited quantities of~~ a prescription drug that has
1533 not been repackaged from an establishment located in the United
1534 States to an establishment located in this state permitted as a
1535 prescription drug manufacturer under this part for research and
1536 development or to a holder of a letter of exemption issued by
1537 the department under s. 499.03(4) for research, teaching, or

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1538 testing. ~~The department shall define "limited quantities" by~~
1539 ~~rule and may include the allowable number of transactions within~~
1540 ~~a given period of time and the amounts of prescription drugs~~
1541 ~~distributed into the state for purposes of this exemption.~~

1542 1. Any distributor claiming exemption from permitting
1543 requirements pursuant to this paragraph shall maintain a
1544 license, permit, or registration to engage in the wholesale
1545 distribution of prescription drugs under the laws of the state
1546 from which the product is distributed. If the state from which
1547 the prescription drugs are distributed does not require a
1548 license to engage in the wholesale distribution of prescription
1549 drugs, the distributor must be licensed as a wholesale
1550 distributor as required by the federal act.

1551 2. All purchasers and recipients of any prescription drugs
1552 distributed pursuant to this paragraph shall ensure that the
1553 products are not resold or used, directly or indirectly, on
1554 humans except in lawful clinical trials and biostudies
1555 authorized and regulated by federal law.

1556 3. Any distributor claiming exemption from permitting
1557 requirements pursuant to this paragraph, and the purchaser and
1558 recipient of the prescription drug, shall comply with the
1559 recordkeeping requirements of s. 499.0121(6), ~~but not the~~
1560 ~~requirements of s. 499.01212.~~

1561 4. The immediate package or container of any active
1562 pharmaceutical ingredient distributed into the state that is
1563 intended for teaching, testing, research, and development shall
1564 bear a label prominently displaying the statement: "Caution:
1565 Research, Teaching, or Testing Only - Not for Manufacturing,
1566 Compounding, or Resale."

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1567 (c) An out-of-state prescription drug wholesale distributor
1568 permit is not required for an intracompany sale or transfer of a
1569 prescription drug from an out-of-state establishment that is
1570 duly licensed as a prescription drug wholesale distributor in
1571 its state of residence to a licensed prescription drug wholesale
1572 distributor in this state, if both wholesale distributors
1573 conduct wholesale distributions of prescription drugs under the
1574 same business name. The recordkeeping requirements of s. ss.
1575 499.0121(6) ~~and 499.01212~~ must be followed for such
1576 transactions.

1577 (d) Persons receiving prescription drugs from a source
1578 claimed to be exempt from permitting requirements under this
1579 subsection shall maintain on file:

1580 1. A record of the FDA establishment registration number,
1581 if any;

1582 2. The resident state or federal license, registration, or
1583 permit that authorizes the source to distribute prescription
1584 drugs ~~drug wholesale distribution license, permit, or~~
1585 ~~registration number~~; and

1586 3. A copy of the most recent resident state or FDA
1587 inspection report, for all distributors and establishments from
1588 whom they purchase or receive prescription drugs under this
1589 subsection.

1590 (e) All persons claiming exemption from permitting
1591 requirements pursuant to this subsection who engage in the
1592 distribution of prescription drugs within or into the state are
1593 subject to this part, including ss. 499.005 and 499.0051, and
1594 shall make available, within 48 hours, to the department on
1595 request all records related to any prescription drugs

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1596 distributed under this subsection, including those records
1597 described in s. 499.051(4), regardless of the location where the
1598 records are stored.

1599 (f) A person purchasing and receiving a prescription drug
1600 from a person claimed to be exempt from licensing requirements
1601 pursuant to this subsection shall report to the department in
1602 writing within 14 days after receiving any product that is
1603 misbranded or adulterated or that fails to meet minimum
1604 standards set forth in the official compendium or state or
1605 federal good manufacturing practices for identity, purity,
1606 potency, or sterility, regardless of whether the product is
1607 thereafter rehabilitated, quarantined, returned, or destroyed.

1608 (g) The department may adopt rules to administer this
1609 subsection which are necessary for the protection of the public
1610 health, safety, and welfare. Failure to comply with the
1611 requirements of this subsection, or rules adopted by the
1612 department to administer this subsection, is a violation of s.
1613 499.005(14), and a knowing failure is a violation of s.
1614 499.0051(3) ~~499.0051(4)~~.

1615 (h) This subsection does not relieve any person from any
1616 requirement prescribed by law with respect to controlled
1617 substances as defined in the applicable federal and state laws.

1618 (5) A prescription drug repackager permit issued under this
1619 part is not required for a restricted prescription drug
1620 distributor permitholder that is a health care entity to
1621 repackaging prescription drugs in this state for its own use or
1622 for distribution to hospitals or other health care entities in
1623 the state for their own use, pursuant to s. 499.003(48)(a)3.
1624 ~~499.003(53)(a)3.~~, if:

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1625 (a) The prescription drug distributor notifies the
1626 department, in writing, of its intention to engage in
1627 repackaging under this exemption, 30 days before engaging in the
1628 repackaging of prescription drugs at the permitted
1629 establishment;

1630 (b) The prescription drug distributor is under common
1631 control with the hospitals or other health care entities to
1632 which the prescription drug distributor is distributing
1633 prescription drugs. As used in this paragraph, "common control"
1634 means the power to direct or cause the direction of the
1635 management and policies of a person or an organization, whether
1636 by ownership of stock, voting rights, contract, or otherwise;

1637 (c) The prescription drug distributor repackages the
1638 prescription drugs in accordance with current state and federal
1639 good manufacturing practices; and

1640 (d) The prescription drug distributor labels the
1641 prescription drug it repackages in accordance with state and
1642 federal laws and rules.

1643
1644 The prescription drug distributor is exempt from the product
1645 registration requirements of s. 499.015 with regard to the
1646 prescription drugs that it repackages and distributes under this
1647 subsection. A prescription drug distributor that repackages and
1648 distributes prescription drugs under this subsection to a not-
1649 for-profit rural hospital, as defined in s. 395.602, is not
1650 required to comply with paragraph (c) or paragraph (d), but must
1651 provide to each health care entity for which it repackages, for
1652 each prescription drug that is repackaged and distributed, the
1653 information required by department rule for labeling

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1654 prescription drugs. The department shall adopt rules to ensure
1655 the safety and integrity of prescription drugs repackaged and
1656 distributed under this subsection, including rules regarding
1657 prescription drug manufacturing and labeling requirements.

1658 Section 7. Section 499.012, Florida Statutes, is amended to
1659 read:

1660 499.012 Permit application requirements.—

1661 (1) (a) A permit issued pursuant to this part may be issued
1662 only to a natural person who is at least 18 years of age or to
1663 an applicant that is not a natural person if each person who,
1664 directly or indirectly, manages, controls, or oversees the
1665 operation of that applicant is at least 18 years of age.

1666 (b) An establishment that is a place of residence may not
1667 receive a permit and may not operate under this part.

1668 (c) A person that applies for or renews a permit to
1669 manufacture or distribute prescription drugs may not use a name
1670 identical to the name used by any other establishment or
1671 licensed person authorized to purchase prescription drugs in
1672 this state, except that a restricted drug distributor permit
1673 issued to a health care entity will be issued in the name in
1674 which the institutional pharmacy permit is issued and a retail
1675 pharmacy drug wholesale distributor will be issued a permit in
1676 the name of its retail pharmacy permit.

1677 (d) A permit for a prescription drug manufacturer,
1678 prescription drug repackager, prescription drug wholesale
1679 distributor, limited prescription drug veterinary wholesale
1680 distributor, or retail pharmacy drug wholesale distributor may
1681 not be issued to the address of a health care entity or to a
1682 pharmacy licensed under chapter 465, except as provided in this

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1683 paragraph. The department may issue a prescription drug
1684 manufacturer permit to an applicant at the same address as a
1685 licensed nuclear pharmacy, which is a health care entity, even
1686 if the nuclear pharmacy holds a special sterile compounding
1687 permit under chapter 465, for the purpose of manufacturing
1688 prescription drugs used in positron emission tomography or other
1689 radiopharmaceuticals, as listed in a rule adopted by the
1690 department pursuant to this paragraph. The purpose of this
1691 exemption is to assure availability of state-of-the-art
1692 pharmaceuticals that would pose a significant danger to the
1693 public health if manufactured at a separate establishment
1694 address from the nuclear pharmacy from which the prescription
1695 drugs are dispensed. The department may also issue a retail
1696 pharmacy drug wholesale distributor permit to the address of a
1697 community pharmacy licensed under chapter 465, even if the
1698 community pharmacy holds a special sterile compounding permit
1699 under chapter 465, as long as the community pharmacy ~~which~~ does
1700 not meet the definition of a closed pharmacy in s. 499.003.

1701 (e) A county or municipality may not issue an occupational
1702 license for ~~any licensing period beginning on or after October~~
1703 ~~1, 2003, for~~ any establishment that requires a permit pursuant
1704 to this part, unless the establishment exhibits a current permit
1705 issued by the department for the establishment. Upon
1706 presentation of the requisite permit issued by the department,
1707 an occupational license may be issued by the municipality or
1708 county in which application is made. The department shall
1709 furnish to local agencies responsible for issuing occupational
1710 licenses a current list of all establishments licensed pursuant
1711 to this part.

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1712 (2) Notwithstanding subsection (6), a permitted person in
1713 good standing may change the type of permit issued to that
1714 person by completing a new application for the requested permit,
1715 paying the amount of the difference in the permit fees if the
1716 fee for the new permit is more than the fee for the original
1717 permit, and meeting the applicable permitting conditions for the
1718 new permit type. The new permit expires on the expiration date
1719 of the original permit being changed; however, a new permit for
1720 a prescription drug wholesale distributor, an out-of-state
1721 prescription drug wholesale distributor, or a retail pharmacy
1722 drug wholesale distributor shall expire on the expiration date
1723 of the original permit or 1 year after the date of issuance of
1724 the new permit, whichever is earlier. A refund may not be issued
1725 if the fee for the new permit is less than the fee that was paid
1726 for the original permit.

1727 (3) (a) A written application for a permit or to renew a
1728 permit must be filed with the department on forms furnished by
1729 the department. The department shall establish, by rule, the
1730 form and content of the application to obtain or renew a permit.
1731 The applicant must submit to the department with the application
1732 a statement that swears or affirms that the information is true
1733 and correct.

1734 (b) Upon a determination that 2 years have elapsed since
1735 the department notified an applicant for permit, certification,
1736 or product registration of a deficiency in the application and
1737 that the applicant has failed to cure the deficiency, the
1738 application shall expire. The determination regarding the 2-year
1739 lapse of time shall be based on documentation that the
1740 department notified the applicant of the deficiency in

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1741 accordance with s. 120.60.

1742 (c) Information submitted by an applicant on an application
1743 required pursuant to this subsection which is a trade secret, as
1744 defined in s. 812.081, shall be maintained by the department as
1745 trade secret information pursuant to s. 499.051(7).

1746 (4) (a) Except for a permit for a prescription drug
1747 wholesale distributor or an out-of-state prescription drug
1748 wholesale distributor, an application for a permit must include:

1749 1. The name, full business address, and telephone number of
1750 the applicant;

1751 2. All trade or business names used by the applicant;

1752 3. The address, telephone numbers, and the names of contact
1753 persons for each facility used by the applicant for the storage,
1754 handling, and distribution of prescription drugs;

1755 4. The type of ownership or operation, such as a
1756 partnership, corporation, or sole proprietorship; and

1757 5. The names of the owner and the operator of the
1758 establishment, including:

1759 a. If an individual, the name of the individual;

1760 b. If a partnership, the name of each partner and the name
1761 of the partnership;

1762 c. If a corporation, the name and title of each corporate
1763 officer and director, the corporate names, and the name of the
1764 state of incorporation;

1765 d. If a sole proprietorship, the full name of the sole
1766 proprietor and the name of the business entity;

1767 e. If a limited liability company, the name of each member,
1768 the name of each manager, the name of the limited liability
1769 company, and the name of the state in which the limited

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1770 liability company was organized; and

1771 f. Any other relevant information that the department
1772 requires.

1773 (b) Upon approval of the application by the department and
1774 payment of the required fee, the department shall issue a permit
1775 to the applicant, if the applicant meets the requirements of
1776 this part and rules adopted under this part.

1777 (c) Any change in information required under paragraph (a)
1778 must be submitted to the department before the change occurs.

1779 (d) The department shall consider, at a minimum, the
1780 following factors in reviewing the qualifications of persons to
1781 be permitted under this part:

1782 1. The applicant's having been found guilty, regardless of
1783 adjudication, in a court of this state or other jurisdiction, of
1784 a violation of a law that directly relates to a drug, device, or
1785 cosmetic. A plea of nolo contendere constitutes a finding of
1786 guilt for purposes of this subparagraph.

1787 2. The applicant's having been disciplined by a regulatory
1788 agency in any state for any offense that would constitute a
1789 violation of this part.

1790 3. Any felony conviction of the applicant under a federal,
1791 state, or local law;

1792 4. The applicant's past experience in manufacturing or
1793 distributing drugs, devices, or cosmetics;

1794 5. The furnishing by the applicant of false or fraudulent
1795 material in any application made in connection with
1796 manufacturing or distributing drugs, devices, or cosmetics;

1797 6. Suspension or revocation by a federal, state, or local
1798 government of any permit currently or previously held by the

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1799 applicant for the manufacture or distribution of any drugs,
1800 devices, or cosmetics;

1801 7. Compliance with permitting requirements under any
1802 previously granted permits;

1803 8. Compliance with requirements to maintain or make
1804 available to the state permitting authority or to federal,
1805 state, or local law enforcement officials those records required
1806 under this section; and

1807 9. Any other factors or qualifications the department
1808 considers relevant to and consistent with the public health and
1809 safety.

1810 (5) ~~Except for a permit for a prescription drug wholesale~~
1811 ~~distributor or an out-of-state prescription drug wholesale~~
1812 ~~distributor:~~

1813 (a) The department shall adopt rules for the biennial
1814 renewal of permits; however, the department may issue up to a 4-
1815 year permit to selected permittees notwithstanding any other
1816 provision of law. Fees for such renewal may not exceed the fee
1817 caps set forth in s. 499.041 on an annualized basis as
1818 authorized by law.

1819 (b) The department shall renew a permit upon receipt of the
1820 renewal application and renewal fee if the applicant meets the
1821 requirements established under this part and ~~the~~ rules adopted
1822 under this part.

1823 (c) At least 90 days before the expiration date of a
1824 permit, the department shall forward a permit renewal
1825 notification to the permittee at the mailing address of the
1826 permitted establishment on file with the department. The permit
1827 renewal notification must state conspicuously the date on which

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1828 the permit for the establishment will expire and that the
1829 establishment may not operate unless the permit for the
1830 establishment is renewed timely. A permit, unless sooner
1831 suspended or revoked, automatically expires 2 years after the
1832 last day of the anniversary month in which the permit was
1833 originally issued.

1834 (d) A permit issued under this part may be renewed by
1835 making application for renewal on forms furnished by the
1836 department and paying the appropriate fees.

1837 1. If a prescription drug wholesale distributor or an out-
1838 of-state prescription drug wholesale distributor renewal
1839 application and fee are submitted and postmarked later than 45
1840 days before the expiration date of the permit, the permit may be
1841 renewed only upon payment of a late renewal fee of \$100, plus
1842 the required renewal fee.

1843 2. If any other a renewal application and fee are submitted
1844 and postmarked after the expiration date of the permit, the
1845 permit may be renewed only upon payment of a late renewal
1846 delinquent fee of \$100, plus the required renewal fee, not later
1847 than 60 days after the expiration date.

1848 3. A permittee who submits a renewal application in
1849 accordance with this paragraph may continue to operate under its
1850 permit, unless the permit is suspended or revoked, until final
1851 disposition of the renewal application.

1852 4.-(d) Failure to renew a permit in accordance with this
1853 section precludes any future renewal of that permit. If a permit
1854 issued pursuant to this part has expired and cannot be renewed,
1855 before an establishment may engage in activities that require a
1856 permit under this part, the establishment must submit an

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1857 application for a new permit, pay the applicable application
1858 fee, the initial permit fee, and all applicable penalties, and
1859 be issued a new permit by the department.

1860 (6) A permit issued by the department is nontransferable.
1861 Each permit is valid only for the person or governmental unit to
1862 which it is issued and is not subject to sale, assignment, or
1863 other transfer, voluntarily or involuntarily; nor is a permit
1864 valid for any establishment other than the establishment for
1865 which it was originally issued.

1866 (a) A person permitted under this part must notify the
1867 department before making a change of address. The department
1868 shall set a change of location fee not to exceed \$100.

1869 (b)1. An application for a new permit is required when a
1870 majority of the ownership or controlling interest of a permitted
1871 establishment is transferred or assigned or when a lessee agrees
1872 to undertake or provide services to the extent that legal
1873 liability for operation of the establishment will rest with the
1874 lessee. The application for the new permit must be made before
1875 the date of the sale, transfer, assignment, or lease.

1876 2. A permittee that is authorized to distribute
1877 prescription drugs may transfer such drugs to the new owner or
1878 lessee under subparagraph 1. only after the new owner or lessee
1879 has been approved for a permit to distribute prescription drugs.

1880 (c) If an establishment permitted under this part closes,
1881 the owner must notify the department in writing before the
1882 effective date of closure and must:

1883 1. Return the permit to the department;

1884 2. If the permittee is authorized to distribute
1885 prescription drugs, indicate the disposition of such drugs,

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1886 including the name, address, and inventory, and provide the name
1887 and address of a person to contact regarding access to records
1888 that are required to be maintained under this part. Transfer of
1889 ownership of prescription drugs may be made only to persons
1890 authorized to possess prescription drugs under this part.

1891
1892 The department may revoke the permit of any person that fails to
1893 comply with the requirements of this subsection.

1894 (7) A permit must be posted in a conspicuous place on the
1895 licensed premises.

1896 (8) An application for a permit or to renew a permit for a
1897 prescription drug wholesale distributor or an out-of-state
1898 prescription drug wholesale distributor submitted to the
1899 department must include:

1900 (a) The name, full business address, and telephone number
1901 of the applicant.

1902 (b) All trade or business names used by the applicant.

1903 (c) The address, telephone numbers, and the names of
1904 contact persons for each facility used by the applicant for the
1905 storage, handling, and distribution of prescription drugs.

1906 (d) The type of ownership or operation, such as a
1907 partnership, corporation, or sole proprietorship.

1908 (e) The names of the owner and the operator of the
1909 establishment, including:

1910 1. If an individual, the name of the individual.

1911 2. If a partnership, the name of each partner and the name
1912 of the partnership.

1913 3. If a corporation:

1914 a. The name, address, and title of each corporate officer

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1915 and director.

1916 b. The name and address of the corporation, resident agent
1917 of the corporation, the resident agent's address, and the
1918 corporation's state of incorporation.

1919 c. The name and address of each shareholder of the
1920 corporation that owns 5 percent or more of the outstanding stock
1921 of the corporation.

1922 4. If a sole proprietorship, the full name of the sole
1923 proprietor and the name of the business entity.

1924 5. If a limited liability company:

1925 a. The name and address of each member.

1926 b. The name and address of each manager.

1927 c. The name and address of the limited liability company,
1928 the resident agent of the limited liability company, and the
1929 name of the state in which the limited liability company was
1930 organized.

1931 (f) If applicable, the name and address of each affiliate
1932 ~~of member of the affiliated group of which the applicant is a~~
1933 ~~member.~~

1934 (g) ~~1. The applicant's gross annual receipts attributable to~~
1935 ~~prescription drug wholesale distribution activities for the~~
1936 ~~previous tax year. For an application for a new permit, the~~
1937 ~~estimated annual dollar volume of prescription drug sales of the~~
1938 ~~applicant, the estimated annual percentage of the applicant's~~
1939 ~~total company sales that are prescription drugs, the applicant's~~
1940 ~~estimated annual total dollar volume of purchases of~~
1941 ~~prescription drugs, and the applicant's estimated annual total~~
1942 ~~dollar volume of prescription drug purchases directly from~~
1943 ~~manufacturers.~~

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1944 ~~2. For an application to renew a permit, the total dollar~~
1945 ~~volume of prescription drug sales in the previous year, the~~
1946 ~~total dollar volume of prescription drug sales made in the~~
1947 ~~previous 6 months, the percentage of total company sales that~~
1948 ~~were prescription drugs in the previous year, the total dollar~~
1949 ~~volume of purchases of prescription drugs in the previous year,~~
1950 ~~and the total dollar volume of prescription drug purchases~~
1951 ~~directly from manufacturers in the previous year.~~

1952
1953 ~~Such portions of the information required pursuant to this~~
1954 ~~paragraph which are a trade secret, as defined in s. 812.081,~~
1955 ~~shall be maintained by the department as trade secret~~
1956 ~~information is required to be maintained under s. 499.051.~~

1957 (h) The tax year of the applicant.

1958 (i) A copy of the deed for the property on which
1959 applicant's establishment is located, if the establishment is
1960 owned by the applicant, or a copy of the applicant's lease for
1961 the property on which applicant's establishment is located that
1962 has an original term of not less than 1 calendar year, if the
1963 establishment is not owned by the applicant.

1964 (j) A list of all licenses and permits issued to the
1965 applicant by any other state which authorize the applicant to
1966 purchase or possess prescription drugs.

1967 (k) The name of the manager of the establishment that is
1968 applying for the permit or to renew the permit, the next four
1969 highest ranking employees responsible for prescription drug
1970 wholesale operations for the establishment, and the name of all
1971 affiliated parties for the establishment, together with the
1972 personal information statement and fingerprints required

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1973 pursuant to subsection (9) for each of such persons.

1974 (l) The name of each of the applicant's designated
1975 representatives as required by subsection (15) ~~(16)~~, together
1976 with the personal information statement and fingerprints
1977 required pursuant to subsection (9) for each such person.

1978 (m) Evidence of a surety bond in this state or any other
1979 state in the United States in the amount of \$100,000. If the
1980 annual gross receipts of the applicant's previous tax year is
1981 \$10 million or less, evidence of a surety bond in the amount of
1982 \$25,000. The specific language of the surety bond must include
1983 the State of Florida as a beneficiary, payable to the
1984 Professional Regulation Trust Fund. In lieu of the surety bond,
1985 the applicant may provide other equivalent security such as an
1986 irrevocable letter of credit, or a deposit in a trust account or
1987 financial institution, which includes the State of Florida as a
1988 beneficiary, payable to the Professional Regulation Trust Fund.
1989 The purpose of the bond or other security is to secure payment
1990 of any administrative penalties imposed by the department and
1991 any fees and costs incurred by the department regarding that
1992 permit which are authorized under state law and which the
1993 permittee fails to pay 30 days after the fine or costs become
1994 final. The department may make a claim against such bond or
1995 security until 1 year after the permittee's license ceases to be
1996 valid or until 60 days after any administrative or legal
1997 proceeding authorized in this part which involves the permittee
1998 is concluded, including any appeal, whichever occurs later. For
1999 ~~an applicant that is a secondary wholesale distributor, each of~~
2000 ~~the following:~~

2001 ~~1. A personal background information statement containing~~

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2002 ~~the background information and fingerprints required pursuant to~~
2003 ~~subsection (9) for each person named in the applicant's response~~
2004 ~~to paragraphs (k) and (l) and for each affiliated party of the~~
2005 ~~applicant.~~

2006 ~~2. If any of the five largest shareholders of the~~
2007 ~~corporation seeking the permit is a corporation, the name,~~
2008 ~~address, and title of each corporate officer and director of~~
2009 ~~each such corporation; the name and address of such corporation;~~
2010 ~~the name of such corporation's resident agent, such~~
2011 ~~corporation's resident agent's address, and such corporation's~~
2012 ~~state of its incorporation; and the name and address of each~~
2013 ~~shareholder of such corporation that owns 5 percent or more of~~
2014 ~~the stock of such corporation.~~

2015 ~~3. The name and address of all financial institutions in~~
2016 ~~which the applicant has an account which is used to pay for the~~
2017 ~~operation of the establishment or to pay for drugs purchased for~~
2018 ~~the establishment, together with the names of all persons that~~
2019 ~~are authorized signatories on such accounts. The portions of the~~
2020 ~~information required pursuant to this subparagraph which are a~~
2021 ~~trade secret, as defined in s. 812.081, shall be maintained by~~
2022 ~~the department as trade secret information is required to be~~
2023 ~~maintained under s. 499.051.~~

2024 ~~4. The sources of all funds and the amounts of such funds~~
2025 ~~used to purchase or finance purchases of prescription drugs or~~
2026 ~~to finance the premises on which the establishment is to be~~
2027 ~~located.~~

2028 ~~5. If any of the funds identified in subparagraph 4. were~~
2029 ~~borrowed, copies of all promissory notes or loans used to obtain~~
2030 ~~such funds.~~

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2031 (n) For establishments used in wholesale distribution,
2032 proof of an inspection conducted by the department, the United
2033 States Food and Drug Administration, or another governmental
2034 entity charged with the regulation of good manufacturing
2035 practices related to wholesale distribution of prescription
2036 drugs, within timeframes set forth by the department in
2037 departmental rules, which demonstrates substantial compliance
2038 with current good manufacturing practices applicable to
2039 wholesale distribution of prescription drugs. The department may
2040 recognize another state's inspection of a wholesale distributor
2041 located in that state if such state's laws are deemed to be
2042 substantially equivalent to the law of this state by the
2043 department. The department may accept an inspection by a third-
2044 party accreditation or inspection service which meets the
2045 criteria set forth in department rule.

2046 (o)~~(n)~~ Any other relevant information that the department
2047 requires, ~~including, but not limited to, any information related~~
2048 ~~to whether the applicant satisfies the definition of a primary~~
2049 ~~wholesale distributor or a secondary wholesale distributor.~~

2050 (p)~~(e)~~ Documentation of the credentialing policies and
2051 procedures required by s. 499.0121(15).

2052 (9) (a) Each person required by subsection (8) or subsection
2053 (15) to provide a personal information statement and
2054 fingerprints shall provide the following information to the
2055 department on forms prescribed by the department:

- 2056 1. The person's places of residence for the past 7 years.
- 2057 2. The person's date and place of birth.
- 2058 3. The person's occupations, positions of employment, and
2059 offices held during the past 7 years.

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2060 4. The principal business and address of any business,
2061 corporation, or other organization in which each such office of
2062 the person was held or in which each such occupation or position
2063 of employment was carried on.

2064 5. Whether the person has been, during the past 7 years,
2065 the subject of any proceeding for the revocation of any license
2066 and, if so, the nature of the proceeding and the disposition of
2067 the proceeding.

2068 6. Whether, during the past 7 years, the person has been
2069 enjoined, temporarily or permanently, by a court of competent
2070 jurisdiction from violating any federal or state law regulating
2071 the possession, control, or distribution of prescription drugs,
2072 together with details concerning any such event.

2073 7. A description of any involvement by the person with any
2074 business, including any investments, other than the ownership of
2075 stock in a publicly traded company or mutual fund, during the
2076 past 4 7 years, which manufactured, administered, prescribed,
2077 distributed, or stored pharmaceutical products and any lawsuits
2078 in which such businesses were named as a party.

2079 8. A description of any felony criminal offense of which
2080 the person, as an adult, was found guilty, regardless of whether
2081 adjudication of guilt was withheld or whether the person pled
2082 guilty or nolo contendere. A criminal offense committed in
2083 another jurisdiction which would have been a felony in this
2084 state must be reported. If the person indicates that a criminal
2085 conviction is under appeal and submits a copy of the notice of
2086 appeal of that criminal offense, the applicant must, within 15
2087 days after the disposition of the appeal, submit to the
2088 department a copy of the final written order of disposition.

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2089 9. A photograph of the person taken in the previous 180 ~~30~~
2090 days.

2091 10. A set of fingerprints for the person on a form and
2092 under procedures specified by the department, together with
2093 payment of an amount equal to the costs incurred by the
2094 department for the criminal record check of the person.

2095 11. The name, address, occupation, and date and place of
2096 birth for each member of the person's immediate family who is 18
2097 years of age or older. As used in this subparagraph, the term
2098 "member of the person's immediate family" includes the person's
2099 spouse, children, parents, siblings, the spouses of the person's
2100 children, and the spouses of the person's siblings.

2101 12. Any other relevant information that the department
2102 requires.

2103 (b) The information required pursuant to paragraph (a)
2104 shall be provided under oath.

2105 (c) The department shall submit the fingerprints provided
2106 by a person for initial licensure to the Department of Law
2107 Enforcement for a statewide criminal record check and for
2108 forwarding to the Federal Bureau of Investigation for a national
2109 criminal record check of the person. The department shall submit
2110 the fingerprints provided by a person as a part of a renewal
2111 application to the Department of Law Enforcement for a statewide
2112 criminal record check, and for forwarding to the Federal Bureau
2113 of Investigation for a national criminal record check, for the
2114 initial renewal of a permit after January 1, 2004; for any
2115 subsequent renewal of a permit, the department shall submit the
2116 required information for a statewide and national criminal
2117 record check of the person. Any person who as a part of an

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2118 initial permit application or initial permit renewal after
2119 January 1, 2004, submits to the department a set of fingerprints
2120 required for the criminal record check required in this
2121 paragraph ~~are shall~~ not ~~be~~ required to provide a subsequent set
2122 of fingerprints for a criminal record check to the department,
2123 if the person has undergone a criminal record check as a
2124 condition of the issuance of an initial permit or the initial
2125 renewal of a permit of an applicant after January 1, 2004. The
2126 department is authorized to contract with private vendors, or
2127 enter into interagency agreements, to collect electronic
2128 fingerprints where fingerprints are required for registration,
2129 certification, or the licensure process or where criminal
2130 history record checks are required.

2131 (d) For purposes of applying for renewal of a permit under
2132 subsection (8) or certification under subsection (16), a person
2133 may submit the following in lieu of satisfying the requirements
2134 of paragraphs (a), (b), and (c):

2135 1. A photograph of the individual taken within 180 days;
2136 and

2137 2. A copy of the personal information statement form most
2138 recently submitted to the department and a certification under
2139 oath, on a form specified by the department, that the individual
2140 has reviewed the previously submitted personal information
2141 statement form and that the information contained therein
2142 remains unchanged.

2143 (10) The department may deny an application for a permit or
2144 refuse to renew a permit for a prescription drug wholesale
2145 distributor or an out-of-state prescription drug wholesale
2146 distributor if:

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2147 (a) The applicant has not met the requirements for the
2148 permit.

2149 (b) The management, officers, or directors of the applicant
2150 or any affiliated party are found by the department to be
2151 incompetent or untrustworthy.

2152 (c) The applicant is so lacking in experience in managing a
2153 wholesale distributor as to make the issuance of the proposed
2154 permit hazardous to the public health.

2155 (d) The applicant is so lacking in experience in managing a
2156 wholesale distributor as to jeopardize the reasonable promise of
2157 successful operation of the wholesale distributor.

2158 (e) The applicant is lacking in experience in the
2159 distribution of prescription drugs.

2160 (f) The applicant's past experience in manufacturing or
2161 distributing prescription drugs indicates that the applicant
2162 poses a public health risk.

2163 (g) The applicant is affiliated directly or indirectly
2164 through ownership, control, or other business relations, with
2165 any person or persons whose business operations are or have been
2166 detrimental to the public health.

2167 (h) The applicant, or any affiliated party, has been found
2168 guilty of or has pleaded guilty or nolo contendere to any felony
2169 or crime punishable by imprisonment for 1 year or more under the
2170 laws of the United States, any state, or any other country,
2171 regardless of whether adjudication of guilt was withheld.

2172 (i) The applicant or any affiliated party has been charged
2173 with a felony in a state or federal court and the disposition of
2174 that charge is pending during the application review or renewal
2175 review period.

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2176 (j) The applicant has furnished false or fraudulent
2177 information or material in any application made in this state or
2178 any other state in connection with obtaining a permit or license
2179 to manufacture or distribute drugs, devices, or cosmetics.

2180 (k) That a federal, state, or local government permit
2181 currently or previously held by the applicant, or any affiliated
2182 party, for the manufacture or distribution of any drugs,
2183 devices, or cosmetics has been disciplined, suspended, or
2184 revoked and has not been reinstated.

2185 (l) The applicant does not possess the financial or
2186 physical resources to operate in compliance with the permit
2187 being sought, this chapter, and the rules adopted under this
2188 chapter.

2189 (m) The applicant or any affiliated party receives,
2190 directly or indirectly, financial support and assistance from a
2191 person who was an affiliated party of a permittee whose permit
2192 was subject to discipline or was suspended or revoked, other
2193 than through the ownership of stock in a publicly traded company
2194 or a mutual fund.

2195 (n) The applicant or any affiliated party receives,
2196 directly or indirectly, financial support and assistance from a
2197 person who has been found guilty of any violation of this part
2198 or chapter 465, chapter 501, or chapter 893, any rules adopted
2199 under this part or those chapters, any federal or state drug
2200 law, or any felony where the underlying facts related to drugs,
2201 regardless of whether the person has been pardoned, had her or
2202 his civil rights restored, or had adjudication withheld, other
2203 than through the ownership of stock in a publicly traded company
2204 or a mutual fund.

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2205 (o) The applicant for renewal of a permit under s.
2206 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged
2207 in the wholesale distribution of prescription drugs, as
2208 demonstrated by the regular and systematic distribution of
2209 prescription drugs throughout the year as evidenced by not fewer
2210 than 12 wholesale distributions in the previous year and not
2211 fewer than three wholesale distributions in the previous 6
2212 months.

2213 (p) Information obtained in response to s. 499.01(2)(e) or
2214 (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best
2215 interest of the public health, safety, and welfare to issue a
2216 permit.

2217 (q) The applicant does not possess the financial standing
2218 and business experience for the successful operation of the
2219 applicant.

2220 (r) The applicant or any affiliated party has failed to
2221 comply with the requirements for manufacturing or distributing
2222 prescription drugs under this part, similar federal laws,
2223 similar laws in other states, or the rules adopted under such
2224 laws.

2225 (11) Upon approval of the application by the department and
2226 payment of the required fee, the department shall issue or renew
2227 a prescription drug wholesale distributor or an out-of-state
2228 prescription drug wholesale distributor permit to the applicant.

2229 ~~(12) For a permit for a prescription drug wholesale~~
2230 ~~distributor or an out-of-state prescription drug wholesale~~
2231 ~~distributor:~~

2232 ~~(a) The department shall adopt rules for the annual renewal~~
2233 ~~of permits. At least 90 days before the expiration of a permit,~~

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2234 ~~the department shall forward a permit renewal notification and~~
2235 ~~renewal application to the prescription drug wholesale~~
2236 ~~distributor or out-of-state prescription drug wholesale~~
2237 ~~distributor at the mailing address of the permitted~~
2238 ~~establishment on file with the department. The permit renewal~~
2239 ~~notification must state conspicuously the date on which the~~
2240 ~~permit for the establishment will expire and that the~~
2241 ~~establishment may not operate unless the permit for the~~
2242 ~~establishment is renewed timely.~~

2243 ~~(b) A permit, unless sooner suspended or revoked,~~
2244 ~~automatically expires 1 year after the last day of the~~
2245 ~~anniversary month in which the permit was originally issued. A~~
2246 ~~permit may be renewed by making application for renewal on forms~~
2247 ~~furnished by the department and paying the appropriate fees. If~~
2248 ~~a renewal application and fee are submitted and postmarked after~~
2249 ~~45 days prior to the expiration date of the permit, the permit~~
2250 ~~may be renewed only upon payment of a late renewal fee of \$100,~~
2251 ~~plus the required renewal fee. A permittee that has submitted a~~
2252 ~~renewal application in accordance with this paragraph may~~
2253 ~~continue to operate under its permit, unless the permit is~~
2254 ~~suspended or revoked, until final disposition of the renewal~~
2255 ~~application.~~

2256 ~~(c) Failure to renew a permit in accordance with this~~
2257 ~~section precludes any future renewal of that permit. If a permit~~
2258 ~~issued pursuant to this section has expired and cannot be~~
2259 ~~renewed, before an establishment may engage in activities that~~
2260 ~~require a permit under this part, the establishment must submit~~
2261 ~~an application for a new permit; pay the applicable application~~
2262 ~~fee, initial permit fee, and all applicable penalties; and be~~

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2263 ~~issued a new permit by the department.~~

2264 (12)~~(13)~~ A person that engages in wholesale distribution of
2265 prescription drugs in this state must have a wholesale
2266 distributor's permit issued by the department, except as noted
2267 in this section. Each establishment must be separately permitted
2268 except as noted in this subsection.

2269 (a) A separate establishment permit is not required when a
2270 permitted prescription drug wholesale distributor consigns a
2271 prescription drug to a pharmacy that is permitted under chapter
2272 465 and located in this state, provided that:

2273 1. The consignor wholesale distributor notifies the
2274 department in writing of the contract to consign prescription
2275 drugs to a pharmacy along with the identity and location of each
2276 consignee pharmacy;

2277 2. The pharmacy maintains its permit under chapter 465;

2278 3. The consignor wholesale distributor, which has no legal
2279 authority to dispense prescription drugs, complies with all
2280 wholesale distribution requirements of s. ss. 499.0121 ~~and~~
2281 ~~499.01212~~ with respect to the consigned drugs and maintains
2282 records documenting the transfer of title or other completion of
2283 the wholesale distribution of the consigned prescription drugs;

2284 4. The distribution of the prescription drug is otherwise
2285 lawful under this chapter and other applicable law;

2286 5. Open packages containing prescription drugs within a
2287 pharmacy are the responsibility of the pharmacy, regardless of
2288 how the drugs are titled; and

2289 6. The pharmacy dispenses the consigned prescription drug
2290 in accordance with the limitations of its permit under chapter
2291 465 or returns the consigned prescription drug to the consignor

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2292 wholesale distributor. In addition, a person who holds title to
2293 prescription drugs may transfer the drugs to a person permitted
2294 or licensed to handle the reverse distribution or destruction of
2295 drugs. Any other distribution by and means of the consigned
2296 prescription drug by any person, not limited to the consignor
2297 wholesale distributor or consignee pharmacy, to any other person
2298 is prohibited.

2299 (b) A wholesale distributor's permit is not required for
2300 the one-time transfer of title of a pharmacy's lawfully acquired
2301 prescription drug inventory by a pharmacy with a valid permit
2302 issued under chapter 465 to a consignor prescription drug
2303 wholesale distributor, permitted under this chapter, in
2304 accordance with a written consignment agreement between the
2305 pharmacy and that wholesale distributor if the permitted
2306 pharmacy and the permitted prescription drug wholesale
2307 distributor comply with all of the provisions of paragraph (a)
2308 and the prescription drugs continue to be within the permitted
2309 pharmacy's inventory for dispensing in accordance with the
2310 limitations of the pharmacy permit under chapter 465. A
2311 consignor drug wholesale distributor may not use the pharmacy as
2312 a wholesale distributor through which it distributes the
2313 prescription drugs to other pharmacies. Nothing in this section
2314 is intended to prevent a wholesale distributor from obtaining
2315 this inventory in the event of nonpayment by the pharmacy.

2316 (c) A separate establishment permit is not required when a
2317 permitted prescription drug wholesale distributor operates
2318 temporary transit storage facilities for the sole purpose of
2319 storage, for up to 16 hours, of a delivery of prescription drugs
2320 when the wholesale distributor was temporarily unable to

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2321 complete the delivery to the recipient.

2322 (d) The department shall require information from each
2323 wholesale distributor as part of the permit and renewal of such
2324 permit, as required under this section.

2325 (13)~~(14)~~ Personnel employed in wholesale distribution must
2326 have appropriate education and experience to enable them to
2327 perform their duties in compliance with state permitting
2328 requirements.

2329 (14)~~(15)~~ The name of a permittee or establishment on a
2330 prescription drug wholesale distributor permit or an out-of-
2331 state prescription drug wholesale distributor permit may not
2332 include any indicia of attainment of any educational degree, any
2333 indicia that the permittee or establishment possesses a
2334 professional license, or any name or abbreviation that the
2335 department determines is likely to cause confusion or mistake or
2336 that the department determines is deceptive, including that of
2337 any other entity authorized to purchase prescription drugs.

2338 (15)~~(16)~~ (a) Each establishment that is issued an initial or
2339 renewal permit as a prescription drug wholesale distributor or
2340 an out-of-state prescription drug wholesale distributor must
2341 designate in writing to the department at least one natural
2342 person to serve as the designated representative of the
2343 wholesale distributor. Such person must have an active
2344 certification as a designated representative from the
2345 department.

2346 (b) To be certified as a designated representative, a
2347 natural person must:

2348 1. Submit an application on a form furnished by the
2349 department and pay the appropriate fees.

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2350 2. Be at least 18 years of age.

2351 3. Have at least 2 years of verifiable full-time:

2352 a. Work experience in a pharmacy licensed in this state or
2353 another state, where the person's responsibilities included, but
2354 were not limited to, recordkeeping for prescription drugs;

2355 b. Managerial experience with a prescription drug wholesale
2356 distributor licensed in this state or in another state; or

2357 c. Managerial experience with the United States Armed
2358 Forces, where the person's responsibilities included, but were
2359 not limited to, recordkeeping, warehousing, distributing, or
2360 other logistics services pertaining to prescription drugs.

2361 4. Receive a passing score of at least 75 percent on an
2362 examination given by the department regarding federal laws
2363 governing distribution of prescription drugs and this part and
2364 the rules adopted by the department governing the wholesale
2365 distribution of prescription drugs. This requirement shall be
2366 effective 1 year after the results of the initial examination
2367 are mailed to the persons that took the examination. The
2368 department shall offer such examinations at least four times
2369 each calendar year.

2370 5. Provide the department with a personal information
2371 statement and fingerprints pursuant to subsection (9).

2372 (c) The department may deny an application for
2373 certification as a designated representative or may suspend or
2374 revoke a certification of a designated representative pursuant
2375 to s. 499.067.

2376 (d) A designated representative:

2377 1. Must be actively involved in and aware of the actual
2378 daily operation of the wholesale distributor.

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2379 2. Must be employed full time in a managerial position by
2380 the wholesale distributor.

2381 3. Must be physically present at the establishment during
2382 normal business hours, except for time periods when absent due
2383 to illness, family illness or death, scheduled vacation, or
2384 other authorized absence.

2385 4. May serve as a designated representative for only one
2386 wholesale distributor at any one time.

2387 (e) A wholesale distributor must notify the department when
2388 a designated representative leaves the employ of the wholesale
2389 distributor. Such notice must be provided to the department
2390 within 10 business days after the last day of designated
2391 representative's employment with the wholesale distributor.

2392 (f) A wholesale distributor may not operate under a
2393 prescription drug wholesale distributor permit or an out-of-
2394 state prescription drug wholesale distributor permit for more
2395 than 10 business days after the designated representative leaves
2396 the employ of the wholesale distributor, unless the wholesale
2397 distributor employs another designated representative and
2398 notifies the department within 10 business days of the identity
2399 of the new designated representative.

2400 Section 8. Section 499.01201, Florida Statutes, is amended
2401 to read:

2402 499.01201 Agency for Health Care Administration review and
2403 use of statute and rule violation or compliance data.—

2404 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~
2405 ~~contrary~~, the Agency for Health Care Administration may not:

2406 (1) Review or use any violation or alleged violation of s.
2407 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that

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2408 section ~~these sections~~, as a ground for denying or withholding
2409 any payment of a Medicaid reimbursement to a pharmacy licensed
2410 under chapter 465; or

2411 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~
2412 ~~499.01212~~, or any rules adopted under that section ~~these~~
2413 ~~sections~~, as the subject of any audit of Medicaid-related
2414 records held by a pharmacy licensed under chapter 465.

2415 Section 9. Paragraph (d) of subsection (4), subsection (6),
2416 and paragraph (b) of subsection (15) of section 499.0121,
2417 Florida Statutes, are amended to read:

2418 499.0121 Storage and handling of prescription drugs;
2419 recordkeeping.—The department shall adopt rules to implement
2420 this section as necessary to protect the public health, safety,
2421 and welfare. Such rules shall include, but not be limited to,
2422 requirements for the storage and handling of prescription drugs
2423 and for the establishment and maintenance of prescription drug
2424 distribution records.

2425 (4) EXAMINATION OF MATERIALS AND RECORDS.—

2426 (d) Upon receipt, a wholesale distributor must review
2427 records required under this section for the acquisition of
2428 prescription drugs for accuracy and completeness, considering
2429 the total facts and circumstances surrounding the transactions
2430 and the wholesale distributors involved. ~~This includes~~
2431 ~~authenticating each transaction listed on a pedigree paper, as~~
2432 ~~defined in s. 499.003(37).~~

2433 (6) RECORDKEEPING.—The department shall adopt rules that
2434 require keeping such records of prescription drugs, including
2435 active pharmaceutical ingredients, as are necessary for the
2436 protection of the public health.

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2437 (a) The following persons must maintain business records
2438 that include the information specified in paragraph (b)
2439 ~~Wholesale distributors must establish and maintain inventories~~
2440 ~~and records of all transactions regarding the receipt and~~
2441 ~~distribution or other disposition of prescription drugs. These~~
2442 ~~records must provide a complete audit trail from receipt to sale~~
2443 ~~or other disposition, be readily retrievable for inspection, and~~
2444 ~~include, at a minimum, the following information:~~

2445 1. Persons permitted or required to be permitted under
2446 chapter 499 to engage in the manufacture, repackaging, or
2447 distribution of active pharmaceutical ingredients or
2448 prescription drugs. The source of the drugs, including the name
2449 and principal address of the seller or transferor, and the
2450 address of the location from which the drugs were shipped;

2451 2. Persons other than those set forth in subparagraph 1.
2452 that engage in the receipt of active pharmaceutical ingredients
2453 or prescription drugs. The name, principal address, and state
2454 license permit or registration number of the person authorized
2455 to purchase prescription drugs;

2456 3. ~~The name, strength, dosage form, and quantity of the~~
2457 ~~drugs received and distributed or disposed of;~~

2458 4. ~~The dates of receipt and distribution or other~~
2459 ~~disposition of the drugs; and~~

2460 5. ~~Any financial documentation supporting the transaction.~~

2461 (b) Business records for persons specified in paragraph (a)
2462 must include:

2463 1. The name and address of the seller, and the Florida
2464 permit number of the seller if such seller is not exempt from
2465 Florida permitting requirements, of the active pharmaceutical

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- 2466 ingredient or prescription drug.
- 2467 2. The address of the location the active pharmaceutical
2468 ingredient or prescription drug was shipped from.
- 2469 3. The distribution date of the active pharmaceutical
2470 ingredient or prescription drug.
- 2471 4. The name, strength, and quantity, and the National Drug
2472 Code if such code has been assigned, of the distributed active
2473 pharmaceutical ingredient or prescription drug.
- 2474 5. The name and Florida permit number of the person that
2475 purchased the active pharmaceutical ingredient or prescription
2476 drug.
- 2477 6. The financial data, including the unit type and unit
2478 price, for the distributions involving active pharmaceutical
2479 ingredients or prescription drugs.
- 2480 7. The date and method of disposition of the active
2481 pharmaceutical ingredient or prescription drug. ~~Inventories and~~
2482 ~~records must be made available for inspection and photocopying~~
2483 ~~by authorized federal, state, or local officials for a period of~~
2484 ~~2 years following disposition of the drugs or 3 years after the~~
2485 ~~creation of the records, whichever period is longer.~~
- 2486 (c) Each manufacturer or repackager of medical devices,
2487 over-the-counter drugs, or cosmetics must maintain business
2488 records that include:
- 2489 1. The name and address of the seller or transferor of the
2490 product.
- 2491 2. The address of the location the product was shipped
2492 from.
- 2493 3. The date of the sale or distribution of the product.
- 2494 4. The name and quantity of the product involved.

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2495 5. The name and address of the person who purchased the
2496 product ~~Records described in this section that are kept at the~~
2497 ~~inspection site or that can be immediately retrieved by computer~~
2498 ~~or other electronic means must be readily available for~~
2499 ~~authorized inspection during the retention period. Records that~~
2500 ~~are kept at a central location outside of this state and that~~
2501 ~~are not electronically retrievable must be made available for~~
2502 ~~inspection within 2 working days after a request by an~~
2503 ~~authorized official of a federal, state, or local law~~
2504 ~~enforcement agency. Records that are maintained at a central~~
2505 ~~location within this state must be maintained at an~~
2506 ~~establishment that is permitted pursuant to this part and must~~
2507 ~~be readily available.~~

2508 (d) Persons permitted, or required to be permitted, under
2509 this chapter to engage in the manufacture, repackaging, or
2510 distribution of active pharmaceutical ingredients or
2511 prescription drugs; or the manufacture or repackaging of medical
2512 devices, over-the-counter drugs, and cosmetics; must establish,
2513 maintain, or have the capability to create a current inventory
2514 of the active pharmaceutical ingredients, prescription drugs,
2515 over-the-counter drugs, cosmetics, and devices at an
2516 establishment where activities specified in this paragraph are
2517 undertaken and must be able to produce such inventory for
2518 inspection by the department within 2 business days ~~Each~~
2519 ~~manufacturer or repackager of medical devices, over-the-counter~~
2520 ~~drugs, or cosmetics must maintain records that include the name~~
2521 ~~and principal address of the seller or transferor of the~~
2522 ~~product, the address of the location from which the product was~~
2523 ~~shipped, the date of the transaction, the name and quantity of~~

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2524 ~~the product involved, and the name and principal address of the~~
2525 ~~person who purchased the product.~~

2526 (e) Business records required to be kept pursuant to this
2527 section, and that are kept at the inspection site or can be
2528 immediately retrieved by computer or other electronic means,
2529 must be readily available for authorized inspection during the
2530 retention period. Records kept at a central location outside of
2531 this state which are not electronically retrievable must be made
2532 available for inspection within 2 working days after a request
2533 by an authorized official of a federal, state, or local law
2534 enforcement agency. Records maintained at a central location
2535 within this state must be maintained at an establishment that is
2536 permitted pursuant to this part and such records must be readily
2537 available for inspection ~~When pedigree papers are required by~~
2538 ~~this part, a wholesale distributor must maintain the pedigree~~
2539 ~~papers separate and distinct from other records required under~~
2540 ~~this part.~~

2541 (f) Records required to be kept pursuant to this subsection
2542 must be maintained as specified for a period of not less than 6
2543 years from the date of disposition of the active pharmaceutical
2544 ingredients, prescription drugs, over-the-counter drugs, medical
2545 devices, or cosmetics.

2546 (g) To the extent that prescription drugs are also products
2547 as defined in the federal act, as amended, and the information
2548 required by the business records requirements of this section
2549 are also included in the tracking and tracing requirements of
2550 the federal act, as amended, and departmental rules, the
2551 manufacturer, wholesale distributor, repackager, or dispenser
2552 must follow both the requirements of the federal act, as

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2553 amended, and departmental rules.

2554 (15) DUE DILIGENCE OF PURCHASERS.—

2555 (b) A wholesale distributor must take reasonable measures
2556 to identify its customers, understand the normal and expected
2557 transactions conducted by those customers, and identify those
2558 transactions that are suspicious in nature. A wholesale
2559 distributor must establish internal policies and procedures for
2560 identifying suspicious orders and preventing suspicious
2561 transactions. A wholesale distributor must assess orders for
2562 more ~~greater~~ than 7,500 ~~5,000~~ unit doses of any one controlled
2563 substance in any one month to determine whether the purchase is
2564 reasonable. In making such assessments, a wholesale distributor
2565 may consider the purchasing entity's clinical business needs,
2566 location, and population served, in addition to other factors
2567 established in the distributor's policies and procedures. A
2568 wholesale distributor must report to the department any
2569 regulated transaction involving an extraordinary quantity of a
2570 listed chemical, an uncommon method of payment or delivery, or
2571 any other circumstance that the regulated person believes may
2572 indicate that the listed chemical will be used in violation of
2573 the law. The wholesale distributor shall maintain records that
2574 document the report submitted to the department in compliance
2575 with this paragraph.

2576 Section 10. Subsection (4) of section 499.015, Florida
2577 Statutes, is amended to read:

2578 499.015 Registration of drugs, devices, and cosmetics;
2579 issuance of certificates of free sale.—

2580 (4) Unless a registration is renewed, it expires 2 years
2581 after the last day of the month in which it was issued. Any

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2582 product registration issued or renewed on or after July 1, 2016,
2583 shall expire on the same date as the manufacturer or repackager
2584 permit of the person seeking to register the product. If the
2585 first product registration issued to a person on or after July
2586 1, 2016, expires less than 366 days after issuance, the fee for
2587 product registration shall be \$15. If the first product
2588 registration issued to a person on or after July 1, 2016,
2589 expires more than 365 days after issuance, the fee for product
2590 registration shall be \$30. The department may issue a stop-sale
2591 notice or order against a person that is subject to the
2592 requirements of this section and that fails to comply with this
2593 section within 31 days after the date the registration expires.
2594 The notice or order shall prohibit such person from selling or
2595 causing to be sold any drugs, devices, or cosmetics covered by
2596 this part until he or she complies with the requirements of this
2597 section.

2598 Section 11. Subsection (1) of section 499.03, Florida
2599 Statutes, is amended to read:

2600 499.03 Possession of certain drugs without prescriptions
2601 unlawful; exemptions and exceptions.—

2602 (1) A person may not possess, or possess with intent to
2603 sell, dispense, or deliver, any habit-forming, toxic, harmful,
2604 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or
2605 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,
2606 unless the possession of the drug has been obtained by a valid
2607 prescription of a practitioner licensed by law to prescribe the
2608 drug. However, this section does not apply to the delivery of
2609 such drugs to persons included in any of the classes named in
2610 this subsection, or to the agents or employees of such persons,

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2611 for use in the usual course of their businesses or practices or
2612 in the performance of their official duties, as the case may be;
2613 nor does this section apply to the possession of such drugs by
2614 those persons or their agents or employees for such use:

2615 (a) A licensed pharmacist or any person under the licensed
2616 pharmacist's supervision while acting within the scope of the
2617 licensed pharmacist's practice;

2618 (b) A licensed practitioner authorized by law to prescribe
2619 prescription drugs or any person under the licensed
2620 practitioner's supervision while acting within the scope of the
2621 licensed practitioner's practice;

2622 (c) A qualified person who uses prescription drugs for
2623 lawful research, teaching, or testing, and not for resale;

2624 (d) A licensed hospital or other institution that procures
2625 such drugs for lawful administration or dispensing by
2626 practitioners;

2627 (e) An officer or employee of a federal, state, or local
2628 government; or

2629 (f) A person that holds a valid permit issued by the
2630 department pursuant to this part which authorizes that person to
2631 possess prescription drugs.

2632 Section 12. Paragraphs (i) through (p) of subsection (1) of
2633 section 499.05, Florida Statutes, are amended to read:

2634 499.05 Rules.—

2635 (1) The department shall adopt rules to implement and
2636 enforce this chapter with respect to:

2637 (i) Additional conditions that qualify as an emergency
2638 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.
2639 499.82.

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2640 ~~(j) Procedures and forms relating to the pedigree paper~~
2641 ~~requirement of s. 499.01212.~~

2642 (j)~~(k)~~ The protection of the public health, safety, and
2643 welfare regarding good manufacturing practices that
2644 manufacturers and repackagers must follow to ensure the safety
2645 of the products.

2646 (k)~~(l)~~ Information required from each retail establishment
2647 pursuant to s. 499.012(3) or s. 499.83(2)(c), including
2648 requirements for prescriptions or orders.

2649 (l)~~(m)~~ The recordkeeping, storage, and handling with
2650 respect to each of the distributions of prescription drugs
2651 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.
2652 499.82(14).

2653 ~~(n) Alternatives to compliance with s. 499.01212 for a~~
2654 ~~prescription drug in the inventory of a permitted prescription~~
2655 ~~drug wholesale distributor as of June 30, 2006, and the return~~
2656 ~~of a prescription drug purchased prior to July 1, 2006. The~~
2657 ~~department may specify time limits for such alternatives.~~

2658 (m)~~(o)~~ Wholesale distributor reporting requirements of s.
2659 499.0121(14).

2660 (n)~~(p)~~ Wholesale distributor credentialing and distribution
2661 requirements of s. 499.0121(15).

2662 Section 13. Subsection (7) of section 499.051, Florida
2663 Statutes, is amended to read:

2664 499.051 Inspections and investigations.—

2665 (7) The complaint and all information obtained pursuant to
2666 the investigation by the department are confidential and exempt
2667 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution
2668 until the investigation and the enforcement action are

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2669 completed. However, trade secret information contained therein
2670 as defined by s. 812.081(1)(c) shall remain confidential and
2671 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I
2672 of the State Constitution, as long as the information is
2673 retained by the department. This subsection does not prohibit
2674 the department from using such information for regulatory or
2675 enforcement proceedings under this chapter or from providing
2676 such information to any law enforcement agency or any other
2677 regulatory agency. However, the receiving agency shall keep such
2678 records confidential and exempt as provided in this subsection.
2679 ~~In addition, this subsection is not intended to prevent~~
2680 ~~compliance with the provisions of s. 499.01212, and the pedigree~~
2681 ~~papers required in that section shall not be deemed a trade~~
2682 ~~secret.~~

2683 Section 14. Subsection (14) of section 499.82, Florida
2684 Statutes, is amended to read:

2685 499.82 Definitions.—As used in this part, the term:

2686 (14) "Wholesale distribution" means the distribution of
2687 medical gas to a person other than a consumer or patient.

2688 Wholesale distribution of medical gases does not include:

2689 (a) The sale, purchase, or trade of a medical gas; an offer
2690 to sell, purchase, or trade a medical gas; or the dispensing of
2691 a medical gas pursuant to a prescription;

2692 (b) Activities exempt from the definition of wholesale
2693 distribution in s. 499.003; or

2694 (c) The sale, purchase, or trade of a medical gas or an
2695 offer to sell, purchase, or trade a medical gas for emergency
2696 medical reasons; ~~or~~

2697 ~~(d) Other transactions excluded from the definition of~~

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2698 ~~wholesale distribution under the federal act or regulations~~
2699 ~~implemented under the federal act related to medical gas.~~

2700 Section 15. Subsection (6) of section 499.83, Florida
2701 Statutes, is created to read:

2702 499.83 Permits.—

2703 (6) A hospice licensed by the Agency for Health Care
2704 Administration pursuant to part IV of chapter 400 is not
2705 required to obtain medical oxygen retail establishment permit to
2706 purchase on behalf of and sell medical oxygen to its hospice
2707 patients, if the hospice contracts for the purchase and delivery
2708 of medical oxygen from an establishment permitted pursuant to
2709 this part. Sale and delivery to patients by hospices pursuant to
2710 this subsection must be based upon on a prescription or an order
2711 from a practitioner authorized by law to prescribe medical
2712 oxygen. For sales to hospices pursuant to this subsection, the
2713 medical gas wholesale distributor or the medical gas
2714 manufacturer selling medical oxygen to a hospice shall reflect
2715 on its invoice the hospice license number provided by the Agency
2716 for Health Care Administration and shall maintain such record
2717 pursuant to s. 499.89. Both the hospice and the medical oxygen
2718 retailer delivering medical oxygen to the patient must maintain
2719 a copy of a valid order or prescription for medical oxygen in
2720 accordance with s. 499.89 and department rule, which copy must
2721 be readily available for inspection.

2722 Section 16. Subsection (4) of section 499.89, Florida
2723 Statutes, is amended to read:

2724 499.89 Recordkeeping.—

2725 ~~(4) A pedigree paper is not required for distributing or~~
2726 ~~dispensing medical gas.~~

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2727 Section 17. Section 499.01212, Florida Statutes, is
2728 repealed.

2729 Section 18. Paragraph (a) of subsection (1) of section
2730 409.9201, Florida Statutes, is amended to read:

2731 409.9201 Medicaid fraud.—

2732 (1) As used in this section, the term:

2733 (a) "Prescription drug" means any drug, including, but not
2734 limited to, finished dosage forms or active ingredients that are
2735 subject to, defined in, or described in s. 503(b) of the Federal
2736 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)
2737 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2738
2739 The value of individual items of the legend drugs or goods or
2740 services involved in distinct transactions committed during a
2741 single scheme or course of conduct, whether involving a single
2742 person or several persons, may be aggregated when determining
2743 the punishment for the offense.

2744 Section 19. Paragraph (b) of subsection (1) of section
2745 499.067, Florida Statutes, is amended to read:

2746 499.067 Denial, suspension, or revocation of permit,
2747 certification, or registration.—

2748 (1)

2749 (b) The department may deny an application for a permit or
2750 certification, or suspend or revoke a permit or certification,
2751 if the department finds that:

2752 1. The applicant is not of good moral character or that it
2753 would be a danger or not in the best interest of the public
2754 health, safety, and welfare if the applicant were issued a
2755 permit or certification.

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2756 2. The applicant has not met the requirements for the
2757 permit or certification.

2758 3. The applicant is not eligible for a permit or
2759 certification for any of the reasons enumerated in s. 499.012.

2760 4. The applicant, permittee, or person certified under s.
2761 499.012(15) ~~s. 499.012(16)~~ demonstrates any of the conditions
2762 enumerated in s. 499.012.

2763 5. The applicant, permittee, or person certified under s.
2764 499.012(15) ~~s. 499.012(16)~~ has committed any violation of this
2765 chapter.

2766 Section 20. Subsection (1) of section 794.075, Florida
2767 Statutes, is amended to read:

2768 794.075 Sexual predators; erectile dysfunction drugs.—

2769 (1) A person may not possess a prescription drug, as
2770 defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of
2771 treating erectile dysfunction if the person is designated as a
2772 sexual predator under s. 775.21.

2773 Section 21. Paragraphs (d), (f), (i), and (j) of subsection
2774 (3) of section 921.0022, Florida Statutes, are amended to read:

2775 921.0022 Criminal Punishment Code; offense severity ranking
2776 chart.—

2777 (3) OFFENSE SEVERITY RANKING CHART

2778 (d) LEVEL 4

2779

2780

Florida	Felony	Description
Statute	Degree	

2781

316.1935(3)(a)	2nd	Driving at high speed or with
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			wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
2782	499.0051 (1)	3rd	Failure to maintain or deliver <u>transaction history,</u> <u>transaction information, or</u> <u>transaction statements</u> pedigree papers.
2783	499.0051 (2)	3rd	Failure to authenticate pedigree papers.
2784	<u>499.0051 (5)</u> 499.0051 (6)	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
2785	517.07 (1)	3rd	Failure to register securities.
2786	517.12 (1)	3rd	Failure of dealer, associated person, or issuer of securities to register.
2787	784.07 (2) (b)	3rd	Battery of law enforcement officer, firefighter, etc.
2788	784.074 (1) (c)	3rd	Battery of sexually violent

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2789			predators facility staff.
2790	784.075	3rd	Battery on detention or commitment facility staff.
2791	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
2792	784.08 (2) (c)	3rd	Battery on a person 65 years of age or older.
2793	784.081 (3)	3rd	Battery on specified official or employee.
2794	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
2795	784.083 (3)	3rd	Battery on code inspector.
2796	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
2797	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.

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2798	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
2799	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
2800	787.07	3rd	Human smuggling.
2801	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
2802	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
2803	790.115 (2) (c)	3rd	Possessing firearm on school property.
2804	800.04 (7) (c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied

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			structure; unarmed; no assault or battery.
2805	810.02(4)(b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
2806	810.06	3rd	Burglary; possession of tools.
2807	810.08(2)(c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
2808	812.014(2)(c)3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
2809	812.014 (2)(c)4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
2810	812.0195(2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
2811	817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.

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2812	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
2813	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
2814	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
2815	837.02 (1)	3rd	Perjury in official proceedings.
2816	837.021 (1)	3rd	Make contradictory statements in official proceedings.
2817	838.022	3rd	Official misconduct.
2818	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
2819	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Families.
2820	843.021	3rd	Possession of a concealed

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2821			handcuff key by a person in custody.
2822	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
2823	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
2824	847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
2825	874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
2826	893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
2827	914.14(2)	3rd	Witnesses accepting bribes.
	914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.

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2828 914.23(2) 3rd Retaliation against a witness,
victim, or informant, no bodily
injury.

2829 918.12 3rd Tampering with jurors.

2830 934.215 3rd Use of two-way communications
device to facilitate commission
of a crime.

2831
2832
2833 (f) LEVEL 6

2834
2835
Florida Felony Description
Statute Degree

2836 316.027(2)(b) 2nd Leaving the scene of a crash
involving serious bodily
injury.

2837 316.193(2)(b) 3rd Felony DUI, 4th or subsequent
conviction.

2838 400.9935(4)(c) 2nd Operating a clinic, or offering
services requiring licensure,
without a license.

2839

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2840	<u>499.0051(2)</u> 499.0051(3)	2nd	Knowing forgery of <u>transaction history, transaction information, or transaction statement</u> pedigree papers.
2841	<u>499.0051(3)</u> 499.0051(4)	2nd	Knowing purchase or receipt of prescription drug from unauthorized person.
2842	<u>499.0051(4)</u> 499.0051(5)	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
2843	775.0875(1)	3rd	Taking firearm from law enforcement officer.
2844	784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
2845	784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
2846	784.041	3rd	Felony battery; domestic battery by strangulation.
2847	784.048(3)	3rd	Aggravated stalking; credible threat.
	784.048(5)	3rd	Aggravated stalking of person

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2848			under 16.
2849	784.07(2)(c)	2nd	Aggravated assault on law enforcement officer.
2850	784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
2851	784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
2852	784.081(2)	2nd	Aggravated assault on specified official or employee.
2853	784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
2854	784.083(2)	2nd	Aggravated assault on code inspector.
2855	787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
2856	790.115(2)(d)	2nd	Discharging firearm or weapon on school property.

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2857	790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
2858	790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
2859	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
2860	794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
2861	794.05(1)	2nd	Unlawful sexual activity with specified minor.
2862	800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; offender less than 18 years.
	800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.

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2863	806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
2864	810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
2865	810.145(8)(b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
2866	812.014(2)(b)1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
2867	812.014(6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.
2868	812.015(9)(a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
2869	812.015(9)(b)	2nd	Retail theft; property stolen \$3,000 or more; coordination of others.
2870	812.13(2)(c)	2nd	Robbery, no firearm or other

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2871			weapon (strong-arm robbery).
	817.4821 (5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
2872			
	825.102 (1)	3rd	Abuse of an elderly person or disabled adult.
2873			
	825.102 (3) (c)	3rd	Neglect of an elderly person or disabled adult.
2874			
	825.1025 (3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
2875			
	825.103 (3) (c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$10,000.
2876			
	827.03 (2) (c)	3rd	Abuse of a child.
2877			
	827.03 (2) (d)	3rd	Neglect of a child.
2878			
	827.071 (2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
2879			
	836.05	2nd	Threats; extortion.

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2880	836.10	2nd	Written threats to kill or do bodily injury.
2881	843.12	3rd	Aids or assists person to escape.
2882	847.011	3rd	Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.
2883	847.012	3rd	Knowingly using a minor in the production of materials harmful to minors.
2884	847.0135 (2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
2885	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
2886	944.35 (3) (a) 2.	3rd	Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great

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2887			bodily harm.
2888	944.40	2nd	Escapes.
2889	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
2890	944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
2891	951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
2892			
2893	(i) LEVEL 9		
2894			
2895	Florida Statute	Felony Degree	Description
2896	316.193 (3)(c)3.b.	1st	DUI manslaughter; failing to render aid or give information.
2897	327.35 (3)(c)3.b.	1st	BUI manslaughter; failing to render aid or give information.

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2898	409.920 (2) (b) 1.c.	1st	Medicaid provider fraud; \$50,000 or more.
2899	<u>499.0051 (8)</u> 499.0051 (9)	1st	Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.
2900	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
2901	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
2902	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
	775.0844	1st	Aggravated white collar

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2903			crime.
	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
2904			
	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, aggravated fleeing or eluding with serious bodily injury or death, and other specified felonies.
2905			
	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
2906			
	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
2907			
	787.01 (1) (a) 1.	1st, PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
2908			

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2909	787.01 (1) (a) 2.	1st, PBL	Kidnapping with intent to commit or facilitate commission of any felony.
2910	787.01 (1) (a) 4.	1st, PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
2911	787.02 (3) (a)	1st, PBL	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
2912	787.06 (3) (c) 1.	1st	Human trafficking for labor and services of an unauthorized alien child.
2913	787.06 (3) (d)	1st	Human trafficking using coercion for commercial sexual activity of an unauthorized adult alien.
	787.06 (3) (f) 1.	1st, PBL	Human trafficking for

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2914	790.161	1st	commercial sexual activity by the transfer or transport of any child from outside Florida to within the state. Attempted capital destructive device offense.
2915	790.166 (2)	1st, PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
2916	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
2917	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
2918	794.011 (4) (a)	1st, PBL	Sexual battery, certain circumstances; victim 12 years of age or older but younger than 18 years;

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2919	794.011 (4) (b)	1st	Sexual battery, certain circumstances; victim and offender 18 years of age or older.
2920	794.011 (4) (c)	1st	Sexual battery, certain circumstances; victim 12 years of age or older; offender younger than 18 years.
2921	794.011 (4) (d)	1st, PBL	Sexual battery, certain circumstances; victim 12 years of age or older; prior conviction for specified sex offenses.
2922	794.011 (8) (b)	1st, PBL	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
2923	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of

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2924			age.
	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
2925			
	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
2926			
	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
2927			
	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
2928			
	817.535 (3) (b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; property owner is a public officer or employee.
2929			
	817.535 (4) (a) 2.	1st	Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.

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2930	817.535 (5) (b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; owner of the property incurs financial loss as a result of the false instrument.
2931	817.568 (7)	2nd, PBL	Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.
2932	827.03 (2) (a)	1st	Aggravated child abuse.
2933	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
2934	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
2935			

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2936	859.01	1st	Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.
2937	893.135	1st	Attempted capital trafficking offense.
2938	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
2939	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
2940	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
2941	893.135 (1) (c) 2.d.	1st	Trafficking in hydrocodone, 200 grams or more, less than 30 kilograms.
	893.135	1st	Trafficking in oxycodone,

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2942	(1) (c) 3.d.		100 grams or more, less than 30 kilograms.
	893.135	1st	Trafficking in
	(1) (d) 1.c.		phencyclidine, more than 400 grams.
2943			
	893.135	1st	Trafficking in
	(1) (e) 1.c.		methaqualone, more than 25 kilograms.
2944			
	893.135	1st	Trafficking in
	(1) (f) 1.c.		amphetamine, more than 200 grams.
2945			
	893.135	1st	Trafficking in gamma-
	(1) (h) 1.c.		hydroxybutyric acid (GHB), 10 kilograms or more.
2946			
	893.135	1st	Trafficking in 1,4-
	(1) (j) 1.c.		Butanediol, 10 kilograms or more.
2947			
	893.135	1st	Trafficking in
	(1) (k) 2.c.		Phenethylamines, 400 grams or more.
2948			
	896.101 (5) (c)	1st	Money laundering,

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2949			financial instruments totaling or exceeding \$100,000.
	896.104 (4) (a) 3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
2950			
2951			
2952	(j) LEVEL 10		
2953			
	Florida Statute	Felony Degree	Description
2954	<u>499.0051 (9)</u> 499.0051 (10)	1st	Knowing sale or purchase of contraband prescription drugs resulting in death.
2955	782.04 (2)	1st, PBL	Unlawful killing of human; act is homicide, unpremeditated.
2956	782.07 (3)	1st	Aggravated manslaughter of a child.
2957			

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2958	787.01 (1) (a) 3.	1st, PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
2959	787.01 (3) (a)	Life	Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
2960	787.06 (3) (g)	Life	Human trafficking for commercial sexual activity of a child under the age of 18 or mentally defective or incapacitated person.
2961	787.06 (4) (a)	Life	Selling or buying of minors into human trafficking.
	794.011 (3)	Life	Sexual battery; victim 12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.

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2962

812.135(2)(a) 1st, PBL Home-invasion robbery
with firearm or other
deadly weapon.

2963

876.32 1st Treason against the
state.

2964

2965 Section 22. Section 893.30, Florida Statutes, is created to
2966 read:

2967

893.30 Controlled substance safety education and
2968 awareness.—

2969

(1) This section may be cited as the "Victoria Siegel
2970 Controlled Substance Safety Education and Awareness Act."

2971

(2) The department shall develop a written pamphlet
2972 relating to controlled substances which includes educational
2973 information about the following:

2974

(a) Precautions regarding the use of pain management
2975 prescriptions.

2976

(b) The potential for misuse and abuse of controlled
2977 substances by adults and children.

2978

(c) The risk of controlled substance dependency and
2979 addiction.

2980

(d) The proper storage and disposal of controlled
2981 substances.

2982

(e) Controlled substance addiction support and treatment
2983 resources.

2984

(f) Telephone helplines and website links that provide
2985 counseling and emergency assistance for individuals dealing with

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2986 substance abuse.

2987 (3) The department shall encourage health care providers,
2988 including, but not limited to, hospitals, county health
2989 departments, physicians, and nurses, to disseminate and display
2990 information about controlled substance safety, including, but
2991 not limited to, the pamphlet created pursuant to subsection (2).

2992 (4) The department shall encourage consumers to discuss the
2993 risks of controlled substance use with their health care
2994 providers.

2995 (5) The State Surgeon General shall make publicly
2996 available, by posting on the department's website, the pamphlet
2997 created pursuant to subsection (2) and additional resources as
2998 appropriate.

2999 (6) The department shall fund the promotion of controlled
3000 substance safety education and awareness under this section
3001 through grants from private or federal sources.

3002 (7) The department is encouraged to collaborate with other
3003 agencies, organizations, and institutions to create a systematic
3004 approach to increasing public awareness regarding controlled
3005 substance safety.

3006 Section 23. This act shall take effect July 1, 2016.