

By Senator Grimsley

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1 A bill to be entitled
2 An act relating to drugs, devices, and cosmetics;
3 amending s. 499.003, F.S.; providing, revising, and
4 deleting definitions for purposes of the Florida Drug
5 and Cosmetic Act; amending s. 499.005, F.S.; revising
6 prohibited acts related to the distribution of
7 prescription drugs; conforming a cross-reference;
8 amending s. 499.0051, F.S.; prohibiting the
9 distribution of prescription drugs without delivering
10 a transaction history, transaction information, and
11 transaction statement; providing penalties; deleting
12 provisions and revising terminology related to
13 pedigree papers, to conform to changes made by the
14 act; amending s. 499.006, F.S.; conforming provisions;
15 amending s. 499.01, F.S.; requiring nonresident
16 prescription drug repackagers to obtain an operating
17 permit; authorizing a manufacturer to engage in the
18 wholesale distribution of prescription drugs;
19 providing for the issuance of virtual prescription
20 drug manufacturer permits and virtual nonresident
21 prescription drug manufacturer permits to certain
22 persons; providing exceptions from certain virtual
23 manufacturer requirements; requiring a nonresident
24 prescription drug repackager permit for certain
25 persons; deleting surety bond requirements for
26 prescription drug wholesale distributors; requiring
27 that certain persons obtain an out-of-state
28 prescription drug wholesale distributor permit
29 requiring certain third party logistic providers to be
30 licensed; requiring research and development labeling
31 on certain prescription drug active pharmaceutical
32 ingredient packaging; requiring certain manufacturers

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33 to create and maintain certain records; requiring
34 certain prescription drug distributors to provide
35 certain information to health care entities for which
36 they repackage prescription drugs; amending s.
37 499.012, F.S.; providing for issuance of a
38 prescription drug manufacturer permit or retail
39 pharmacy drug wholesale distributor permit when an
40 applicant at the same address is a licensed nuclear
41 pharmacy or community pharmacy; providing for the
42 expiration of deficient permit applications; requiring
43 trade secret information submitted by an applicant to
44 be maintained as a trade secret; authorizing the
45 quadrennial renewal of permits; providing for
46 calculation of fees for such permit renewals; revising
47 procedures and application requirements for permit
48 renewals; providing for late renewal fees; allowing a
49 permittee who submits a renewal application to
50 continue operations; removing certain application
51 requirements for renewal of a permit; requiring bonds
52 or other surety of a specified amount; requiring proof
53 of inspection of establishments used in wholesale
54 distribution; authorizing the Department of Business
55 and Professional Regulation to contract for the
56 collection of electronic fingerprints under certain
57 circumstances; providing information that may be
58 submitted in lieu of certain application requirements
59 for specified permits and certifications; removing
60 provisions relating to annual renewal and expiration
61 of permits; conforming cross-references; amending s.

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62 499.01201, F.S.; conforming provisions; amending s.
63 499.0121, F.S.; revising prescription drug
64 recordkeeping requirements; requiring inventories and
65 records of transactions for active pharmaceutical
66 ingredients; conforming provisions; amending s.
67 499.015, F.S.; removing cosmetics from registration
68 requirements; authorizing voluntary registration of
69 cosmetics; providing application and fee requirements
70 for cosmetics; restricting those persons who may
71 register a product with the department; providing for
72 the expiration, renewal, and issuance of certain
73 product registrations; providing for product
74 registration fees; amending ss. 499.03, 499.05, and
75 499.051, F.S.; conforming provisions to changes made
76 by the act; amending s. 499.066, F.S.; authorizing the
77 issuance of nondisciplinary citations; authorizing the
78 department to adopt rules designating violations for
79 which a citation may be issued; authorizing the
80 department to recover investigative costs pursuant to
81 the citation; specifying a time limitation for
82 issuance of a citation; providing for service of a
83 citation; amending s. 499.82, F.S.; revising the
84 definition of "wholesale distribution" for purposes of
85 medical gas requirements; amending s. 499.89, F.S.;
86 conforming provisions; repealing s. 499.01212, F.S.,
87 relating to pedigree papers; amending ss. 409.9201,
88 499.067, 794.075, and 921.0022, F.S.; conforming
89 cross-references; providing an effective date.
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91 Be It Enacted by the Legislature of the State of Florida:

92
93 Section 1. Section 499.003, Florida Statutes, is amended to
94 read:

95 499.003 Definitions of terms used in this part.—As used in
96 this part, the term:

97 (1) "Active pharmaceutical ingredient" includes any
98 substance or mixture of substances intended, represented, or
99 labeled for use in drug manufacturing that furnishes or is
100 intended to furnish, in a finished dosage form, any
101 pharmacological activity or other direct effect in the
102 diagnosis, cure, mitigation, treatment, therapy, or prevention
103 of disease in humans or other animals, or to affect the
104 structure or any function of the body of humans or animals.

105 (2)(1) "Advertisement" means any representation
106 disseminated in any manner or by any means, other than by
107 labeling, for the purpose of inducing, or which is likely to
108 induce, directly or indirectly, the purchase of drugs, devices,
109 or cosmetics.

110 (3) "Affiliate" means a business entity that has a
111 relationship with another business entity in which, directly or
112 indirectly:

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

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

117 ~~(2) "Affiliated group" means an affiliated group as defined~~
118 ~~by s. 1504 of the Internal Revenue Code of 1986, as amended,~~
119 ~~which is composed of chain drug entities, including at least 50~~

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120 ~~retail pharmacies, warehouses, or repackagers, which are members~~
121 ~~of the same affiliated group. The affiliated group must disclose~~
122 ~~the names of all its members to the department.~~

123 (4)~~(3)~~ "Affiliated party" means:

124 (a) A director, officer, trustee, partner, or committee
125 member of a permittee or applicant or a subsidiary or service
126 corporation of the permittee or applicant;

127 (b) A person who, directly or indirectly, manages,
128 controls, or oversees the operation of a permittee or applicant,
129 regardless of whether such person is a partner, shareholder,
130 manager, member, officer, director, independent contractor, or
131 employee of the permittee or applicant;

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

136 (d) The five largest natural shareholders that own at least
137 5 percent of the permittee or applicant.

138 (5)~~(4)~~ "Applicant" means a person applying for a permit or
139 certification under this part.

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

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

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

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

153 (7) "Chain pharmacy warehouse" means a ~~wholesale~~
154 distributor permitted pursuant to s. 499.01 that maintains a
155 physical location for prescription drugs that functions solely
156 as a central warehouse to perform intracompany transfers of such
157 drugs between members of an affiliate ~~to a member of its~~
158 ~~affiliated group~~.

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

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

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

167 (a) Is a dye pigment, or other substance, made by a process
168 of synthesis or similar artifice, or extracted, isolated, or
169 otherwise derived, with or without intermediate or final change
170 of identity from a vegetable, animal, mineral, or other source;
171 or

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

175 (11) "Contraband prescription drug" means any adulterated
176 drug, as defined in s. 499.006, any counterfeit drug, as defined
177 in this section, and also means any prescription drug for which

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178 a transaction history, transaction information, or transaction
179 statement ~~pedigree paper~~ does not exist, or for which the
180 transaction history, transaction information, or transaction
181 statement ~~pedigree paper~~ in existence has been forged,
182 counterfeited, falsely created, or contains any altered, false,
183 or misrepresented matter.

184 (12) "Cosmetic" means an article, with the exception of
185 soap, that is:

186 (a) Intended to be rubbed, poured, sprinkled, or sprayed
187 on; introduced into; or otherwise applied to the human body or
188 any part thereof for cleansing, beautifying, promoting
189 attractiveness, or altering the appearance; or

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

191 (13) "Counterfeit drug," "counterfeit device," or
192 "counterfeit cosmetic" means a drug, device, or cosmetic which,
193 or the container, seal, or labeling of which, without
194 authorization, bears the trademark, trade name, or other
195 identifying mark, imprint, or device, or any likeness thereof,
196 of a drug, device, or cosmetic manufacturer, processor, packer,
197 or distributor other than the person that in fact manufactured,
198 processed, packed, or distributed that drug, device, or cosmetic
199 and which thereby falsely purports or is represented to be the
200 product of, or to have been packed or distributed by, that other
201 drug, device, or cosmetic manufacturer, processor, packer, or
202 distributor.

203 (14) "Department" means the Department of Business and
204 Professional Regulation.

205 (15) "Device" means any instrument, apparatus, implement,
206 machine, contrivance, implant, in vitro reagent, or other

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207 similar or related article, including its components, parts, or
208 accessories, which is:

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

211 (b) Intended for use in the diagnosis, cure, mitigation,
212 treatment, therapy, or prevention of disease in humans or other
213 animals, or

214 (c) Intended to affect the structure or any function of the
215 body of humans or other animals,

216

217 and that does not achieve any of its principal intended purposes
218 through chemical action within or on the body of humans or other
219 animals and which is not dependent upon being metabolized for
220 the achievement of any of its principal intended purposes.

221 (16) "Distribute" or "distribution" means to sell,
222 purchase, trade, deliver, handle, store, or receive to sell;
223 ~~offer to sell; give away; transfer, whether by passage of title,~~
224 ~~physical movement, or both; deliver; or offer to deliver.~~ The
225 term does not mean to administer or dispense and does not
226 include the billing and invoicing activities that commonly
227 follow a wholesale distribution transaction.

228 ~~(17) "Drop shipment" means the sale of a prescription drug~~
229 ~~from a manufacturer to a wholesale distributor, where the~~
230 ~~wholesale distributor takes title to, but not possession of, the~~
231 ~~prescription drug, and the manufacturer of the prescription drug~~
232 ~~ships the prescription drug directly to a chain pharmacy~~
233 ~~warehouse or a person authorized by law to purchase prescription~~
234 ~~drugs for the purpose of administering or dispensing the drug,~~
235 ~~as defined in s. 465.003.~~

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236 (17)~~(18)~~ "Drug" means an article that is:

237 (a) Recognized in the current edition of the United States
238 Pharmacopoeia and National Formulary, official Homeopathic
239 Pharmacopoeia of the United States, or any supplement to any of
240 those publications;

241 (b) Intended for use in the diagnosis, cure, mitigation,
242 treatment, therapy, or prevention of disease in humans or other
243 animals;

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

246 (d) Intended for use as a component of any article
247 specified in paragraph (a), paragraph (b), or paragraph (c), and
248 includes active pharmaceutical ingredients, but does not include
249 devices or their nondrug components, parts, or accessories. ~~For~~
250 ~~purposes of this paragraph, an "active pharmaceutical~~
251 ~~ingredient" includes any substance or mixture of substances~~
252 ~~intended, represented, or labeled for use in drug manufacturing~~
253 ~~that furnishes or is intended to furnish, in a finished dosage~~
254 ~~form, any pharmacological activity or other direct effect in the~~
255 ~~diagnosis, cure, mitigation, treatment, therapy, or prevention~~
256 ~~of disease in humans or other animals, or to affect the~~
257 ~~structure or any function of the body of humans or other~~
258 ~~animals.~~

259 (18)~~(19)~~ "Establishment" means a place of business which is
260 at one general physical location and may extend to one or more
261 contiguous suites, units, floors, or buildings operated and
262 controlled exclusively by entities under common operation and
263 control. Where multiple buildings are under common exclusive
264 ownership, operation, and control, an intervening thoroughfare

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265 does not affect the contiguous nature of the buildings. For
266 purposes of permitting, each suite, unit, floor, or building
267 must be identified in the most recent permit application.

268 (19)~~(20)~~ "Federal act" means the Federal Food, Drug, and
269 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

270 (20)~~(21)~~ "Freight forwarder" means a person who receives
271 prescription drugs which are owned by another person and
272 designated by that person for export, and exports those
273 prescription drugs.

274 (21)~~(22)~~ "Health care entity" means a closed pharmacy or
275 any person, organization, or business entity that provides
276 diagnostic, medical, surgical, or dental treatment or care, or
277 chronic or rehabilitative care, but does not include any
278 wholesale distributor or retail pharmacy licensed under state
279 law to deal in prescription drugs. However, a blood
280 establishment is a health care entity that may engage in the
281 wholesale distribution of prescription drugs under s.
282 499.01(2)(h)1.c. ~~499.01(2)(g)1.e.~~

283 (22)~~(23)~~ "Health care facility" means a health care
284 facility licensed under chapter 395.

285 (23)~~(24)~~ "Hospice" means a corporation licensed under part
286 IV of chapter 400.

287 (24)~~(25)~~ "Hospital" means a facility as defined in s.
288 395.002 and licensed under chapter 395.

289 (25)~~(26)~~ "Immediate container" does not include package
290 liners.

291 (26)~~(27)~~ "Label" means a display of written, printed, or
292 graphic matter upon the immediate container of any drug, device,
293 or cosmetic. A requirement made by or under authority of this

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294 part or rules adopted under this part that any word, statement,
295 or other information appear on the label is not complied with
296 unless such word, statement, or other information also appears
297 on the outside container or wrapper, if any, of the retail
298 package of such drug, device, or cosmetic or is easily legible
299 through the outside container or wrapper.

300 ~~(27)~~~~(28)~~ "Labeling" means all labels and other written,
301 printed, or graphic matters:

302 (a) Upon a drug, device, or cosmetic, or any of its
303 containers or wrappers; or

304 (b) Accompanying or related to such drug, device, or
305 cosmetic.

306 ~~(28)~~~~(29)~~ "Manufacture" means the preparation, deriving,
307 compounding, propagation, processing, producing, or fabrication
308 of any drug, device, or cosmetic.

309 ~~(29)~~~~(30)~~ "Manufacturer" means:

310 (a) A person who holds a New Drug Application, an
311 Abbreviated New Drug Application, a Biologics License
312 Application, or a New Animal Drug Application approved under the
313 federal act or a license issued under s. 351 of the Public
314 Health Service Act, 42 U.S.C. s. 262, for such drug or
315 biologics, or if such drug or biologics is not the subject of an
316 approved application or license, the person who manufactured the
317 drug or biologics prepares, derives, manufactures, or produces a
318 drug, device, or cosmetic;

319 (b) A co-licensed partner of the person described in
320 paragraph (a) who obtains the drug or biologics directly from a
321 person described in paragraph (a), paragraph (c), or this
322 paragraph ~~The holder or holders of a New Drug Application (NDA),~~

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323 ~~an Abbreviated New Drug Application (ANDA), a Biologics License~~
324 ~~Application (BLA), or a New Animal Drug Application (NADA),~~
325 ~~provided such application has become effective or is otherwise~~
326 ~~approved consistent with s. 499.023;~~

327 (c) An affiliate of a person described in paragraph (a),
328 paragraph (b), or this paragraph that receives the drug or
329 biologics directly from a person described in paragraph (a),
330 paragraph (b), or this paragraph ~~A private label distributor for~~
331 ~~whom the private label distributor's prescription drugs are~~
332 ~~originally manufactured and labeled for the distributor and have~~
333 ~~not been repackaged; or~~

334 (d) A person who manufactures a device or a cosmetic. ~~A~~
335 ~~person registered under the federal act as a manufacturer of a~~
336 ~~prescription drug, who is described in paragraph (a), paragraph~~
337 ~~(b), or paragraph (c), who has entered into a written agreement~~
338 ~~with another prescription drug manufacturer that authorizes~~
339 ~~either manufacturer to distribute the prescription drug~~
340 ~~identified in the agreement as the manufacturer of that drug~~
341 ~~consistent with the federal act and its implementing~~
342 ~~regulations;~~

343 ~~(e) A member of an affiliated group that includes, but is~~
344 ~~not limited to, persons described in paragraph (a), paragraph~~
345 ~~(b), paragraph (c), or paragraph (d), which member distributes~~
346 ~~prescription drugs, whether or not obtaining title to the drugs,~~
347 ~~only for the manufacturer of the drugs who is also a member of~~
348 ~~the affiliated group. As used in this paragraph, the term~~
349 ~~"affiliated group" means an affiliated group as defined in s.~~
350 ~~1504 of the Internal Revenue Code of 1986, as amended. The~~
351 ~~manufacturer must disclose the names of all of its affiliated~~

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352 ~~group members to the department; or~~

353 ~~(f) A person permitted as a third party logistics provider,~~
354 ~~only while providing warehousing, distribution, or other~~
355 ~~logistics services on behalf of a person described in paragraph~~
356 ~~(a), paragraph (b), paragraph (c), paragraph (d), or paragraph~~
357 ~~(e).~~

358
359 The term does not include a pharmacy that is operating in
360 compliance with pharmacy practice standards as defined in
361 chapter 465 and rules adopted under that chapter.

362 (30)~~(31)~~ "Medical convenience kit" means packages or units
363 that contain combination products as defined in 21 C.F.R. s.
364 3.2(e)(2).

365 (31)~~(32)~~ "Medical gas" means any liquefied or vaporized gas
366 that is a prescription drug, whether alone or in combination
367 with other gases, and as defined in the federal act.

368 (32)~~(33)~~ "New drug" means:

369 (a) Any drug the composition of which is such that the drug
370 is not generally recognized, among experts qualified by
371 scientific training and experience to evaluate the safety and
372 effectiveness of drugs, as safe and effective for use under the
373 conditions prescribed, recommended, or suggested in the labeling
374 of that drug; or

375 (b) Any drug the composition of which is such that the
376 drug, as a result of investigations to determine its safety and
377 effectiveness for use under certain conditions, has been
378 recognized for use under such conditions, but which drug has
379 not, other than in those investigations, been used to a material
380 extent or for a material time under such conditions.

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381 ~~(34) "Normal distribution chain" means a wholesale~~
382 ~~distribution of a prescription drug in which the wholesale~~
383 ~~distributor or its wholly owned subsidiary purchases and~~
384 ~~receives the specific unit of the prescription drug directly~~
385 ~~from the manufacturer and distributes the prescription drug~~
386 ~~directly, or through up to two intracompany transfers, to a~~
387 ~~chain pharmacy warehouse or a person authorized by law to~~
388 ~~purchase prescription drugs for the purpose of administering or~~
389 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~
390 ~~this subsection, the term "intracompany" means any transaction~~
391 ~~or transfer between any parent, division, or subsidiary wholly~~
392 ~~owned by a corporate entity.~~

393 (33)~~(35)~~ "Nursing home" means a facility licensed under
394 part II of chapter 400.

395 (34)~~(36)~~ "Official compendium" means the current edition of
396 the official United States Pharmacopoeia and National Formulary,
397 or any supplement thereto.

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

402 (35)~~(38)~~ "Permittee" means any person holding a permit
403 issued under this chapter ~~pursuant to s. 499.012.~~

404 (36)~~(39)~~ "Person" means any individual, child, joint
405 venture, syndicate, fiduciary, partnership, corporation,
406 division of a corporation, firm, trust, business trust, company,
407 estate, public or private institution, association,
408 organization, group, city, county, city and county, political
409 subdivision of this state, other governmental agency within this

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410 state, and any representative, agent, or agency of any of the
411 foregoing, or any other group or combination of the foregoing.

412 (37)~~(40)~~ "Pharmacist" means a person licensed under chapter
413 465.

414 (38)~~(41)~~ "Pharmacy" means an entity licensed under chapter
415 465.

416 (39)~~(42)~~ "Prepackaged drug product" means a drug that
417 originally was in finished packaged form sealed by a
418 manufacturer and that is placed in a properly labeled container
419 by a pharmacy or practitioner authorized to dispense pursuant to
420 chapter 465 for the purpose of dispensing in the establishment
421 in which the prepackaging occurred.

422 (40)~~(43)~~ "Prescription drug" means a prescription,
423 medicinal, or legend drug, including, but not limited to,
424 finished dosage forms or active pharmaceutical ingredients
425 subject to, defined by, or described by s. 503(b) of the federal
426 act or s. 465.003(8), s. 499.007(13), subsection (31) ~~(32)~~, or
427 subsection (47) ~~(52)~~, except that an active pharmaceutical
428 ingredient is a prescription drug only if substantially all
429 finished dosage forms in which it may be lawfully dispensed or
430 administered in this state are also prescription drugs.

431 (41)~~(44)~~ "Prescription drug label" means any display of
432 written, printed, or graphic matter upon the immediate container
433 of any prescription drug before it is dispensed ~~prior to its~~
434 ~~dispensing~~ to an individual patient pursuant to a prescription
435 of a practitioner authorized by law to prescribe.

436 (42)~~(45)~~ "Prescription label" means any display of written,
437 printed, or graphic matter upon the immediate container of any
438 prescription drug dispensed pursuant to a prescription of a

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439 practitioner authorized by law to prescribe.

440 ~~(46) "Primary wholesale distributor" means any wholesale~~
441 ~~distributor that:~~

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

445 ~~(b)1. Directly purchased prescription drugs from not fewer~~
446 ~~than 50 different prescription drug manufacturers in the~~
447 ~~previous year; or~~

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

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

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

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

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

461 ~~b. The wholesale distributor discloses to the department~~
462 ~~the names of all members of the affiliated group of which the~~
463 ~~wholesale distributor is a member and the affiliated group~~
464 ~~agrees in writing to provide records on prescription drug~~
465 ~~purchases by the members of the affiliated group not later than~~
466 ~~48 hours after the department requests access to such records,~~
467 ~~regardless of the location where the records are stored.~~

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468 ~~(43)(47)~~ "Proprietary drug," or "OTC drug," means a patent
469 or over-the-counter drug in its unbroken, original package,
470 which drug is sold to the public by, or under the authority of,
471 the manufacturer or primary distributor thereof, is not
472 misbranded under the provisions of this part, and can be
473 purchased without a prescription.

474 ~~(44)(48)~~ "Repackage" includes repacking or otherwise
475 changing the container, wrapper, or labeling to further the
476 distribution of the drug, device, or cosmetic.

477 ~~(45)(49)~~ "Repackager" means a person who repackages. The
478 term excludes pharmacies that are operating in compliance with
479 pharmacy practice standards as defined in chapter 465 and rules
480 adopted under that chapter.

481 ~~(46)(50)~~ "Retail pharmacy" means a community pharmacy
482 licensed under chapter 465 that purchases prescription drugs at
483 fair market prices and provides prescription services to the
484 public.

485 ~~(51) "Secondary wholesale distributor" means a wholesale~~
486 ~~distributor that is not a primary wholesale distributor.~~

487 ~~(47)(52)~~ "Veterinary prescription drug" means a
488 prescription drug intended solely for veterinary use. The label
489 of the drug must bear the statement, "Caution: Federal law
490 restricts this drug to sale by or on the order of a licensed
491 veterinarian."

492 ~~(48)(53)~~ "Wholesale distribution" means the distribution of
493 a prescription drug to a person ~~drugs to persons~~ other than a
494 consumer or patient, or the receipt of a prescription drug by a
495 person other than the consumer or patient, but does not include:

496 (a) Any of the following activities, which is not a

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497 violation of s. 499.005(21) if such activity is conducted in
498 accordance with s. 499.01(2)(h) ~~499.01(2)(g)~~:

499 1. The purchase or other acquisition by a hospital or other
500 health care entity that is a member of a group purchasing
501 organization of a prescription drug for its own use from the
502 group purchasing organization or from other hospitals or health
503 care entities that are members of that organization.

504 2. The distribution ~~sale, purchase, or trade~~ of a
505 prescription drug or an offer to distribute ~~sell, purchase, or~~
506 ~~trade~~ a prescription drug by a charitable organization described
507 in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended
508 and revised, to a nonprofit affiliate of the organization to the
509 extent otherwise permitted by law.

510 3. The distribution ~~sale, purchase, or trade~~ of a
511 prescription drug ~~or an offer to sell, purchase, or trade a~~
512 ~~prescription drug~~ among hospitals or other health care entities
513 that are under common control. For purposes of this
514 subparagraph, "common control" means the power to direct or
515 cause the direction of the management and policies of a person
516 or an organization, whether by ownership of stock, by voting
517 rights, by contract, or otherwise.

518 4. The distribution ~~sale, purchase, trade, or other~~
519 ~~transfer~~ of a prescription drug from or for any federal, state,
520 or local government agency or any entity eligible to purchase
521 prescription drugs at public health services prices pursuant to
522 Pub. L. No. 102-585, s. 602 to a contract provider or its
523 subcontractor for eligible patients of the agency or entity
524 under the following conditions:

525 a. The agency or entity must obtain written authorization

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526 for the distribution ~~sale, purchase, trade, or other transfer~~ of
527 a prescription drug under this subparagraph from the Secretary
528 of Business and Professional Regulation or his or her designee.

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

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

533 d. The contract provider and subcontractor must maintain
534 and produce immediately for inspection all records of movement
535 or transfer of all the prescription drugs belonging to the
536 agency or entity, including, but not limited to, the records of
537 receipt and disposition of prescription drugs. Each contractor
538 and subcontractor dispensing or administering these drugs must
539 maintain and produce records documenting the dispensing or
540 administration. Records that are required to be maintained
541 include, but are not limited to, a perpetual inventory itemizing
542 drugs received and drugs dispensed by prescription number or
543 administered by patient identifier, which must be submitted to
544 the agency or entity quarterly.

545 e. The contract provider or subcontractor may administer or
546 dispense the prescription drugs only to the eligible patients of
547 the agency or entity or must return the prescription drugs for
548 or to the agency or entity. The contract provider or
549 subcontractor must require proof from each person seeking to
550 fill a prescription or obtain treatment that the person is an
551 eligible patient of the agency or entity and must, at a minimum,
552 maintain a copy of this proof as part of the records of the
553 contractor or subcontractor required under sub-subparagraph d.

554 f. In addition to the departmental inspection authority set

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555 forth in s. 499.051, the establishment of the contract provider
556 and subcontractor and all records pertaining to prescription
557 drugs subject to this subparagraph shall be subject to
558 inspection by the agency or entity. All records relating to
559 prescription drugs of a manufacturer under this subparagraph
560 shall be subject to audit by the manufacturer of those drugs,
561 without identifying individual patient information.

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

565 1. The distribution ~~sale, purchase, or trade~~ of a
566 prescription drug among federal, state, or local government
567 health care entities that are under common control and are
568 authorized to purchase such prescription drug.

569 2. The distribution ~~sale, purchase, or trade~~ of a
570 prescription drug or ~~an~~ offer to distribute ~~sell, purchase, or~~
571 ~~trade~~ a prescription drug for emergency medical reasons, which
572 may include. ~~For purposes of this subparagraph, The term~~
573 ~~"emergency medical reasons" includes~~ transfers of prescription
574 drugs by a retail pharmacy to another retail pharmacy to
575 alleviate a temporary shortage. For purposes of this
576 subparagraph, a drug shortage not caused by a public health
577 emergency does not constitute an emergency medical reason.

578 3. The distribution ~~transfer~~ of a prescription drug
579 acquired by a medical director on behalf of a licensed emergency
580 medical services provider to that emergency medical services
581 provider and its transport vehicles for use in accordance with
582 the provider's license under chapter 401.

583 ~~4. The revocation of a sale or the return of a prescription~~

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584 ~~drug to the person's prescription drug wholesale supplier.~~

585 ~~4.5.~~ The donation of a prescription drug by a health care
586 entity to a charitable organization that has been granted an
587 exemption under s. 501(c)(3) of the Internal Revenue Code of
588 1986, as amended, and that is authorized to possess prescription
589 drugs.

590 ~~5.6.~~ The distribution ~~transfer~~ of a prescription drug by a
591 person authorized to purchase or receive prescription drugs to a
592 person licensed or permitted to handle reverse distributions or
593 destruction under the laws of the jurisdiction in which the
594 person handling the reverse distribution or destruction receives
595 the drug.

596 ~~6.7.~~ The distribution ~~transfer~~ of a prescription drug by a
597 hospital or other health care entity to a person licensed under
598 this part to repackage prescription drugs for the purpose of
599 repackaging the prescription drug for use by that hospital, or
600 other health care entity and other health care entities that are
601 under common control, if ownership of the prescription drugs
602 remains with the hospital or other health care entity at all
603 times. In addition to the recordkeeping requirements of s.
604 499.0121(6), the hospital or health care entity that distributes
605 ~~transfers~~ prescription drugs pursuant to this subparagraph must
606 reconcile all drugs distributed ~~transferred~~ and returned and
607 resolve any discrepancies in a timely manner.

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

610 (d) The distribution of a prescription drug by the
611 manufacturer of the prescription drug.

612 (e) ~~(e)~~ The distribution of prescription drug samples by

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613 manufacturers' representatives or distributors' representatives
614 conducted in accordance with s. 499.028.

615 (f) The distribution of a prescription drug by a third-
616 party logistics provider permitted or licensed pursuant to and
617 operating in compliance with the laws of this state and federal
618 law if such third-party logistics provider does not take
619 ownership of the prescription drug.

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

625 (h) The purchase or other acquisition by a dispenser,
626 hospital, or other health care entity of a prescription drug for
627 use by such dispenser, hospital, or other health care entity.

628 (i) The distribution of a prescription drug by a hospital
629 or other health care entity, or by a wholesale distributor or
630 manufacturer operating at the direction of the hospital or other
631 health care entity, to a repackager for the purpose of
632 repackaging the prescription drug for use by that hospital, or
633 other health care entity and other health care entities that are
634 under common control, if ownership of the prescription drug
635 remains with the hospital or other health care entity at all
636 times.

637 (j)~~(d)~~ The distribution ~~sale, purchase, or trade~~ of blood
638 and blood components intended for transfusion. As used in this
639 paragraph, the term "blood" means whole blood collected from a
640 single donor and processed for transfusion or further
641 manufacturing, and the term "blood components" means that part

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642 of the blood separated by physical or mechanical means.

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

645 (l)~~(f)~~ The distribution sale, purchase, or trade of a
646 prescription drug between pharmacies as a result of a sale,
647 transfer, merger, or consolidation of all or part of the
648 business of the pharmacies from or with another pharmacy,
649 whether accomplished as a purchase and sale of stock or of
650 business assets.

651 (m) The distribution of minimal quantities of prescription
652 drugs by a licensed retail pharmacy to a licensed practitioner
653 for office use in compliance with chapter 465 and rules adopted
654 thereunder.

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

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

662 (p) The distribution of a prescription drug that is
663 intended for irrigation or sterile water, whether intended for
664 such purposes or for injection.

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

667 (r) A common carrier that transports a prescription drug,
668 if the common carrier does not take ownership of the
669 prescription drug.

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

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671 (t) Facilitating the distribution of a prescription drug by
672 providing solely administrative services, including processing
673 of orders and payments.

674 (u) The distribution by a charitable organization described
675 in s. 501(c) (3) of the Internal Revenue Code of prescription
676 drugs donated to or supplied at a reduced price to the
677 charitable organization to:

678 1. A licensed health care practitioner, as defined in s.
679 456.001, who is authorized under the appropriate practice act to
680 prescribe and administer prescription drugs;

681 2. A health care clinic establishment permitted pursuant to
682 chapter 499; or

683 3. The Department of Health or the licensed medical
684 director of a government agency health care entity, authorized
685 to possess prescription drugs, for storage and use in the
686 treatment of persons in need of emergency medical services,
687 including controlling communicable diseases or providing
688 protection from unsafe conditions that pose an imminent threat
689 to public health,

690
691 if the distributor and the receiving entity receive no direct or
692 indirect financial benefit other than tax benefits related to
693 charitable contributions. Distributions under this section that
694 involve controlled substances must comply with all state and
695 federal regulations pertaining to the handling of controlled
696 substances.

697 (v) The distribution of medical gas pursuant to part III of
698 this chapter.

699 (49) ~~(54)~~ "Wholesale distributor" means a ~~any~~ any person, other

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700 than a manufacturer, a manufacturer's co-licensed partner, a
 701 third-party logistics provider, or a repackager, who is engaged
 702 in wholesale distribution of prescription drugs in or into this
 703 state, including, but not limited to, manufacturers;
 704 repackagers; own-label distributors; jobbers; private-label
 705 distributors; brokers; warehouses, including manufacturers' and
 706 distributors' warehouses, chain drug warehouses, and wholesale
 707 drug warehouses; independent wholesale drug traders; exporters;
 708 retail pharmacies; and the agents thereof that conduct wholesale
 709 distributions.

710 Section 2. Subsections (21), (28), and (29) of section
 711 499.005, Florida Statutes, are amended to read:

712 499.005 Prohibited acts.—It is unlawful for a person to
 713 perform or cause the performance of any of the following acts in
 714 this state:

715 (21) The wholesale distribution of any prescription drug
 716 that was:

717 (a) Purchased by a public or private hospital or other
 718 health care entity; or

719 (b) Donated or supplied at a reduced price to a charitable
 720 organization,

721
 722 unless the wholesale distribution of the prescription drug is
 723 authorized in s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

724 (28) Failure to acquire or deliver a transaction history,
 725 transaction information, or transaction statement pedigree paper
 726 as required under this part and rules adopted under this part.

727 ~~(29) The receipt of a prescription drug pursuant to a~~
 728 ~~wholesale distribution without having previously received or~~

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729 ~~simultaneously receiving a pedigree paper that was attested to~~
 730 ~~as accurate and complete by the wholesale distributor as~~
 731 ~~required under this part.~~

732 Section 3. Subsections (4) through (17) of section
 733 499.0051, Florida Statutes, are renumbered as subsections (3)
 734 through (16), respectively, and subsections (1) and (2), present
 735 subsection (3), paragraphs (h) and (i) of present subsection
 736 (12), paragraph (d) of present subsection (13), and present
 737 subsection (15) of that section are amended, to read:

738 499.0051 Criminal acts.—

739 (1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY,
 740 TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE~~
 741 ~~PAPERS.~~—

742 (a) A person, ~~other than a manufacturer,~~ engaged in the
 743 ~~wholesale~~ distribution of prescription drugs who fails to
 744 deliver to another person a complete and accurate transaction
 745 history, transaction information, or transaction statement
 746 ~~pedigree papers~~ concerning a prescription drug or contraband
 747 prescription drug, as required by this chapter and rules adopted
 748 under this chapter, before ~~prior to,~~ or simultaneous with, the
 749 transfer of the prescription drug or contraband prescription
 750 drug to another person commits a felony of the third degree,
 751 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

752 (b) A person engaged in the ~~wholesale~~ distribution of
 753 prescription drugs who fails to acquire a complete and accurate
 754 transaction history, transaction information, or transaction
 755 statement ~~pedigree papers~~ concerning a prescription drug or
 756 contraband prescription drug, as required by this chapter and
 757 rules adopted under this chapter, before ~~prior to,~~ or

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758 simultaneous with, the receipt of the prescription drug or
759 contraband prescription drug from another person commits a
760 felony of the third degree, punishable as provided in s.
761 775.082, s. 775.083, or s. 775.084.

762 (c) Any person who knowingly destroys, alters, conceals, or
763 fails to maintain a complete and accurate transaction history,
764 transaction information, or transaction statement ~~pedigree~~
765 ~~papers~~ concerning any prescription drug or contraband
766 prescription drug, as required by this chapter and rules adopted
767 under this chapter, in his or her possession commits a felony of
768 the third degree, punishable as provided in s. 775.082, s.
769 775.083, or s. 775.084.

770 ~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July~~
771 ~~1, 2006:~~

772 ~~(a) A person engaged in the wholesale distribution of~~
773 ~~prescription drugs who is in possession of pedigree papers~~
774 ~~concerning prescription drugs or contraband prescription drugs~~
775 ~~and who fails to authenticate the matters contained in the~~
776 ~~pedigree papers and who nevertheless attempts to further~~
777 ~~distribute prescription drugs or contraband prescription drugs~~
778 ~~commits a felony of the third degree, punishable as provided in~~
779 ~~s. 775.082, s. 775.083, or s. 775.084.~~

780 ~~(b) A person in possession of pedigree papers concerning~~
781 ~~prescription drugs or contraband prescription drugs who falsely~~
782 ~~swears or certifies that he or she has authenticated the matters~~
783 ~~contained in the pedigree papers commits a felony of the third~~
784 ~~degree, punishable as provided in s. 775.082, s. 775.083, or s.~~
785 ~~775.084.~~

786 (2)(3) KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION

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787 INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS~~.—A person
 788 who knowingly forges, counterfeits, or falsely creates any
 789 transaction history, transaction information, or transaction
 790 statement ~~pedigree paper~~; who falsely represents any factual
 791 matter contained on any transaction history, transaction
 792 information, or transaction statement ~~pedigree paper~~; or who
 793 knowingly omits to record material information required to be
 794 recorded in a transaction history, transaction information, or
 795 transaction statement ~~pedigree paper~~, commits a felony of the
 796 second degree, punishable as provided in s. 775.082, s. 775.083,
 797 or s. 775.084.

798 (11)~~(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE
 799 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—
 800 Any person who violates any of the following provisions commits
 801 a misdemeanor of the second degree, punishable as provided in s.
 802 775.082 or s. 775.083; but, if the violation is committed after
 803 a conviction of such person under this subsection has become
 804 final, such person commits a misdemeanor of the first degree,
 805 punishable as provided in s. 775.082 or s. 775.083, or as
 806 otherwise provided in this part:

807 (h) The failure to maintain records related to a drug as
 808 required by this part and rules adopted under this part, except
 809 for transaction histories, transaction information, or
 810 transaction statements ~~pedigree papers~~, invoices, or shipping
 811 documents related to prescription drugs.

812 (i) The possession of any drug in violation of this part,
 813 except if the violation relates to a deficiency in transaction
 814 histories, transaction information, or transaction statements
 815 ~~pedigree papers~~.

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816 (12) ~~(13)~~ REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING,
817 OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
818 PRESCRIPTION DRUGS.—Any person who violates any of the following
819 provisions commits a felony of the third degree, punishable as
820 provided in s. 775.082, s. 775.083, or s. 775.084, or as
821 otherwise provided in this part:

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

825 (15) FALSE ADVERTISEMENT.—A publisher, radio broadcast
826 licensee, or agency or medium for the dissemination of an
827 advertisement, except the manufacturer, repackager, wholesale
828 distributor, or seller of the article to which a false
829 advertisement relates, is not liable under subsection (11) ~~(12)~~,
830 subsection (12) ~~(13)~~, or subsection (13) ~~(14)~~ by reason of the
831 dissemination by him or her of such false advertisement, unless
832 he or she has refused, on the request of the department, to
833 furnish to the department the name and post office address of
834 the manufacturer, repackager, wholesale distributor, seller, or
835 advertising agency that asked him or her to disseminate such
836 advertisement.

837 Section 4. Section 499.006, Florida Statutes, is amended to
838 read:

839 499.006 Adulterated drug or device.—A drug or device is
840 adulterated, if any of the following apply:

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

843 (2) ~~If~~ It has been produced, prepared, packed, or held
844 under conditions whereby it could have been contaminated with

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845 filth or rendered injurious to health.†

846 (3) ~~If~~ It is a drug and the methods used in, or the
847 facilities or controls used for, its manufacture, processing,
848 packing, or holding do not conform to, or are not operated or
849 administered in conformity with, current good manufacturing
850 practices to assure that the drug meets the requirements of this
851 part and that the drug has the identity and strength, and meets
852 the standard of quality and purity, which it purports or is
853 represented to possess.†

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

857 (5) ~~If~~ It is a drug and it bears or contains, for the
858 purpose of coloring only, a color additive that is unsafe within
859 the meaning of the federal act; or, if it is a color additive,
860 the intended use of which in or on drugs is for the purpose of
861 coloring only, and it is unsafe within the meaning of the
862 federal act.†

863 (6) ~~If~~ It purports to be, or is represented as, a drug the
864 name of which is recognized in the official compendium, and its
865 strength differs from, or its quality or purity falls below, the
866 standard set forth in such compendium. The determination as to
867 strength, quality, or purity must be made in accordance with the
868 tests or methods of assay set forth in such compendium, or, when
869 such tests or methods of assay are absent or inadequate, in
870 accordance with those tests or methods of assay prescribed under
871 authority of the federal act. A drug defined in the official
872 compendium is not adulterated under this subsection merely
873 because it differs from the standard of strength, quality, or

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874 purity set forth for that drug in such compendium if its
 875 difference in strength, quality, or purity from such standard is
 876 plainly stated on its label.~~†~~

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

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

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

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

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

887 (10) ~~If~~ It is a prescription drug for which the required
 888 transaction history, transaction information, or transaction
 889 statement ~~pedigree paper~~ is nonexistent, fraudulent, or
 890 incomplete under the requirements of this part or applicable
 891 rules, or that has been purchased, held, sold, or distributed at
 892 any time by a person not authorized under federal or state law
 893 to do so.~~†~~~~or~~

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

898 Section 5. Section 499.01, Florida Statutes, is amended to
 899 read:

900 499.01 Permits.—

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

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- 903 (a) A prescription drug manufacturer;
- 904 (b) A prescription drug repackager;
- 905 (c) A nonresident prescription drug manufacturer;
- 906 (d) A nonresident prescription drug repackager;
- 907 (e)~~(d)~~ A prescription drug wholesale distributor;
- 908 (f)~~(e)~~ An out-of-state prescription drug wholesale
- 909 distributor;
- 910 (g)~~(f)~~ A retail pharmacy drug wholesale distributor;
- 911 (h)~~(g)~~ A restricted prescription drug distributor;
- 912 (i)~~(h)~~ A complimentary drug distributor;
- 913 (j)~~(i)~~ A freight forwarder;
- 914 (k)~~(j)~~ A veterinary prescription drug retail establishment;
- 915 (l)~~(k)~~ A veterinary prescription drug wholesale
- 916 distributor;
- 917 (m)~~(l)~~ A limited prescription drug veterinary wholesale
- 918 distributor;
- 919 (n)~~(m)~~ An over-the-counter drug manufacturer;
- 920 (o)~~(n)~~ A device manufacturer;
- 921 (p)~~(o)~~ A cosmetic manufacturer;
- 922 (q)~~(p)~~ A third party logistics provider; or
- 923 (r)~~(q)~~ A health care clinic establishment.
- 924 (2) The following permits are established:
- 925 (a) *Prescription drug manufacturer permit.*—A prescription
- 926 drug manufacturer permit is required for any person that is a
- 927 manufacturer of a prescription drug and that manufactures or
- 928 distributes such prescription drugs in this state.
- 929 1. A person that operates an establishment permitted as a
- 930 prescription drug manufacturer may engage in wholesale
- 931 distribution of prescription drugs for which the person is the

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932 ~~manufacturer manufactured at that establishment~~ and must comply
 933 with s. 499.0121 and all other ~~of the~~ provisions of this part,
 934 ~~except s. 499.01212,~~ and the rules adopted under this part,
 935 ~~except s. 499.01212,~~ which apply to a ~~wholesale distributor~~. The
 936 department shall adopt rules for issuing a virtual prescription
 937 drug manufacturer permit to a person who engages in the
 938 manufacture of prescription drugs but does not make or take
 939 physical possession of any prescription drugs. The rules adopted
 940 by the department under this section may exempt virtual
 941 manufacturers from certain establishment, security, and storage
 942 requirements set forth in s. 499.0121.

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

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

952 (b) *Prescription drug repackager permit.*—A prescription
 953 drug repackager permit is required for any person that
 954 repackages a prescription drug in this state.

955 1. A person that operates an establishment permitted as a
 956 prescription drug repackager may engage in ~~wholesale~~
 957 distribution of prescription drugs repackaged at that
 958 establishment and must comply with all of the provisions of this
 959 part and the rules adopted under this part that apply to a
 960 prescription drug manufacturer ~~wholesale distributor~~.

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

963 (c) *Nonresident prescription drug manufacturer permit.*—A
964 nonresident prescription drug manufacturer permit is required
965 for any person that is a manufacturer of prescription drugs,
966 unless permitted as a third party logistics provider, located
967 outside of this state or outside the United States and that
968 engages in the ~~wholesale~~ distribution in this state of such
969 prescription drugs. Each such manufacturer must be permitted by
970 the department and comply with all of the provisions required of
971 a prescription drug manufacturer ~~wholesale distributor~~ under
972 this part, ~~except s. 499.01212.~~ The department shall adopt rules
973 for issuing a virtual nonresident prescription drug manufacturer
974 permit to a person who engages in the manufacture of
975 prescription drugs but does not make or take physical possession
976 of any prescription drugs. The rules adopted by the department
977 under this section may exempt virtual nonresident manufacturers
978 from certain establishment, security, and storage requirements
979 set forth in s. 499.0121.

980 1. A person that distributes prescription drugs for which
981 the person is not the manufacturer must also obtain an out-of-
982 state prescription drug wholesale distributor permit or third
983 party logistics provider permit pursuant to this section to
984 engage in the ~~wholesale~~ distribution of such prescription drugs
985 when required by this part. This subparagraph does not apply to
986 a manufacturer that distributes prescription drugs only for the
987 manufacturer of the prescription drugs where both manufacturers
988 are affiliates ~~as defined in s. 499.003(30)(e).~~

989 2. Any such person must comply with the licensing or

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990 permitting requirements of the jurisdiction in which the
991 establishment is located and the federal act, and any
992 prescription drug distributed ~~product-wholesaled~~ into this state
993 must comply with this part. If a person intends to import
994 prescription drugs from a foreign country into this state, the
995 nonresident prescription drug manufacturer must provide to the
996 department a list identifying each prescription drug it intends
997 to import and document approval by the United States Food and
998 Drug Administration for such importation.

999 (d) Nonresident prescription drug repackager permit.-A
1000 nonresident prescription drug repackager permit is required for
1001 any person located outside of this state, but within the United
1002 States or its territories, that repackages prescription drugs
1003 and engages in the distribution of such prescription drugs into
1004 this state.

1005 1. A nonresident prescription drug repackager must comply
1006 with all of the provisions of this section and the rules adopted
1007 under this section that apply to a prescription drug
1008 manufacturer.

1009 2. A nonresident prescription drug repackager must be
1010 permitted by the department and comply with all appropriate
1011 state and federal good manufacturing practices.

1012 3. A nonresident prescription drug repackager must be
1013 registered as a drug establishment with the United States Food
1014 and Drug Administration.

1015 (e) ~~(d)~~ Prescription drug wholesale distributor permit.-A
1016 prescription drug wholesale distributor permit is required for
1017 any person who is a wholesale distributor of prescription drugs
1018 and that may engage in the wholesale distributes such

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1019 ~~distribution of prescription drugs in this state. A prescription~~
1020 ~~drug wholesale distributor that applies to the department for a~~
1021 ~~new permit or the renewal of a permit must submit a bond of~~
1022 ~~\$100,000, or other equivalent means of security acceptable to~~
1023 ~~the department, such as an irrevocable letter of credit or a~~
1024 ~~deposit in a trust account or financial institution, payable to~~
1025 ~~the Professional Regulation Trust Fund. The purpose of the bond~~
1026 ~~is to secure payment of any administrative penalties imposed by~~
1027 ~~the department and any fees and costs incurred by the department~~
1028 ~~regarding that permit which are authorized under state law and~~
1029 ~~which the permittee fails to pay 30 days after the fine or costs~~
1030 ~~become final. The department may make a claim against such bond~~
1031 ~~or security until 1 year after the permittee's license ceases to~~
1032 ~~be valid or until 60 days after any administrative or legal~~
1033 ~~proceeding authorized in this part which involves the permittee~~
1034 ~~is concluded, including any appeal, whichever occurs later. The~~
1035 ~~department may adopt rules for issuing a prescription drug~~
1036 ~~wholesale distributor-broker permit to a person who engages in~~
1037 ~~the wholesale distribution of prescription drugs and does not~~
1038 ~~take physical possession of any prescription drugs.~~

1039 (f) ~~(e)~~ *Out-of-state prescription drug wholesale distributor*
1040 *permit.* ~~An out-of-state prescription drug wholesale distributor~~
1041 ~~permit is required for any person that is a wholesale~~
1042 ~~distributor located outside this state, but within the United~~
1043 ~~States or its territories, which engages in the wholesale~~
1044 ~~distribution of prescription drugs into this state ~~and which~~~~
1045 ~~must be permitted by the department and comply with all the~~
1046 ~~provisions required of a wholesale distributor under this part.~~
1047 ~~An out-of-state prescription drug wholesale distributor that~~

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1048 ~~applies to the department for a new permit or the renewal of a~~
1049 ~~permit must submit a bond of \$100,000, or other equivalent means~~
1050 ~~of security acceptable to the department, such as an irrevocable~~
1051 ~~letter of credit or a deposit in a trust account or financial~~
1052 ~~institution, payable to the Professional Regulation Trust Fund.~~
1053 ~~The purpose of the bond is to secure payment of any~~
1054 ~~administrative penalties imposed by the department and any fees~~
1055 ~~and costs incurred by the department regarding that permit which~~
1056 ~~are authorized under state law and which the permittee fails to~~
1057 ~~pay 30 days after the fine or costs become final. The department~~
1058 ~~may make a claim against such bond or security until 1 year~~
1059 ~~after the permittee's license ceases to be valid or until 60~~
1060 ~~days after any administrative or legal proceeding authorized in~~
1061 ~~this part which involves the permittee is concluded, including~~
1062 ~~any appeal, whichever occurs later. The out-of-state~~
1063 ~~prescription drug wholesale distributor must maintain at all~~
1064 ~~times a license or permit to engage in the wholesale~~
1065 ~~distribution of prescription drugs in compliance with laws of~~
1066 ~~the state in which it is a resident. If the state from which the~~
1067 ~~wholesale distributor distributes prescription drugs does not~~
1068 ~~require a license to engage in the wholesale distribution of~~
1069 ~~prescription drugs, the distributor must be licensed as a~~
1070 ~~wholesale distributor as required by the federal act.~~

1071 ~~(g)~~ ~~(f)~~ *Retail pharmacy drug wholesale distributor permit.*—A
1072 retail pharmacy drug wholesale distributor is a retail pharmacy
1073 engaged in wholesale distribution of prescription drugs within
1074 this state under the following conditions:

1075 1. The pharmacy must obtain a retail pharmacy drug
1076 wholesale distributor permit pursuant to this part and ~~the~~ rules

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1077 adopted under this part.

1078 2. The wholesale distribution activity does not exceed 30
1079 percent of the total annual purchases of prescription drugs. If
1080 the wholesale distribution activity exceeds the 30-percent
1081 maximum, the pharmacy must obtain a prescription drug wholesale
1082 distributor permit.

1083 3. The transfer of prescription drugs that appear in any
1084 schedule contained in chapter 893 is subject to chapter 893 and
1085 the federal Comprehensive Drug Abuse Prevention and Control Act
1086 of 1970.

1087 4. The transfer is between a retail pharmacy and another
1088 retail pharmacy, or a Modified Class II institutional pharmacy,
1089 or a health care practitioner licensed in this state and
1090 authorized by law to dispense or prescribe prescription drugs.

1091 5. All records of sales of prescription drugs subject to
1092 this section must be maintained separate and distinct from other
1093 records and comply with the recordkeeping requirements of this
1094 part.

1095 (h)~~(g)~~ *Restricted prescription drug distributor permit.*—

1096 1. A restricted prescription drug distributor permit is
1097 required for:

1098 a. Any person located in this state who engages in the
1099 distribution of a prescription drug, which distribution is not
1100 considered "wholesale distribution" under s. 499.003(48)(a)
1101 ~~499.003(53)(a)~~.

1102 b. Any person located in this state who engages in the
1103 receipt or distribution of a prescription drug in this state for
1104 the purpose of processing its return or its destruction if such
1105 person is not the person initiating the return, the prescription

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1106 drug wholesale supplier of the person initiating the return, or
1107 the manufacturer of the drug.

1108 c. A blood establishment located in this state which
1109 collects blood and blood components only from volunteer donors
1110 as defined in s. 381.06014 or pursuant to an authorized
1111 practitioner's order for medical treatment or therapy and
1112 engages in the wholesale distribution of a prescription drug not
1113 described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care
1114 entity. A mobile blood unit operated by a blood establishment
1115 permitted under this sub-subparagraph is not required to be
1116 separately permitted. The health care entity receiving a
1117 prescription drug distributed under this sub-subparagraph must
1118 be licensed as a closed pharmacy or provide health care services
1119 at that establishment. The blood establishment must operate in
1120 accordance with s. 381.06014 and may distribute only:

1121 (I) Prescription drugs indicated for a bleeding or clotting
1122 disorder or anemia;

1123 (II) Blood-collection containers approved under s. 505 of
1124 the federal act;

1125 (III) Drugs that are blood derivatives, or a recombinant or
1126 synthetic form of a blood derivative;

1127 (IV) Prescription drugs that are identified in rules
1128 adopted by the department and that are essential to services
1129 performed or provided by blood establishments and authorized for
1130 distribution by blood establishments under federal law; or

1131 (V) To the extent authorized by federal law, drugs
1132 necessary to collect blood or blood components from volunteer
1133 blood donors; for blood establishment personnel to perform
1134 therapeutic procedures under the direction and supervision of a

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1135 licensed physician; and to diagnose, treat, manage, and prevent
1136 any reaction of a volunteer blood donor or a patient undergoing
1137 a therapeutic procedure performed under the direction and
1138 supervision of a licensed physician,

1139
1140 as long as all of the health care services provided by the blood
1141 establishment are related to its activities as a registered
1142 blood establishment or the health care services consist of
1143 collecting, processing, storing, or administering human
1144 hematopoietic stem cells or progenitor cells or performing
1145 diagnostic testing of specimens if such specimens are tested
1146 together with specimens undergoing routine donor testing. The
1147 blood establishment may purchase and possess the drugs described
1148 in this sub-subparagraph without a health care clinic
1149 establishment permit.

1150 2. Storage, handling, and recordkeeping of these
1151 distributions by a person required to be permitted as a
1152 restricted prescription drug distributor must be in accordance
1153 with the requirements for wholesale distributors under s.
1154 499.0121, ~~but not those set forth in s. 499.0122 if the~~
1155 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~
1156 ~~subparagraph 1.b.~~

1157 3. A person who applies for a permit as a restricted
1158 prescription drug distributor, or for the renewal of such a
1159 permit, must provide to the department the information required
1160 under s. 499.012.

1161 4. The department may adopt rules regarding the
1162 distribution of prescription drugs by hospitals, health care
1163 entities, charitable organizations, other persons not involved

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1164 in wholesale distribution, and blood establishments, which rules
1165 are necessary for the protection of the public health, safety,
1166 and welfare.

1167 (i)~~(h)~~ *Complimentary drug distributor permit.*—A
1168 complimentary drug distributor permit is required for any person
1169 that engages in the distribution of a complimentary drug,
1170 subject to the requirements of s. 499.028.

1171 (j)~~(i)~~ *Freight forwarder permit.*—A freight forwarder permit
1172 is required for any person that engages in the distribution of a
1173 prescription drug as a freight forwarder unless the person is a
1174 common carrier. The storage, handling, and recordkeeping of such
1175 distributions must comply with the requirements for wholesale
1176 distributors under s. 499.0121, ~~but not those set forth in s.~~
1177 ~~499.01212.~~ A freight forwarder must provide the source of the
1178 prescription drugs with a validated airway bill, bill of lading,
1179 or other appropriate documentation to evidence the exportation
1180 of the product.

1181 (k)~~(j)~~ *Veterinary prescription drug retail establishment*
1182 *permit.*—A veterinary prescription drug retail establishment
1183 permit is required for any person that sells veterinary
1184 prescription drugs to the public but does not include a pharmacy
1185 licensed under chapter 465.

1186 1. The sale to the public must be based on a valid written
1187 order from a veterinarian licensed in this state who has a valid
1188 client-veterinarian relationship with the purchaser's animal.

1189 2. Veterinary prescription drugs may not be sold in excess
1190 of the amount clearly indicated on the order or beyond the date
1191 indicated on the order.

1192 3. An order may not be valid for more than 1 year.

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1193 4. A veterinary prescription drug retail establishment may
1194 not purchase, sell, trade, or possess human prescription drugs
1195 or any controlled substance as defined in chapter 893.

1196 5. A veterinary prescription drug retail establishment must
1197 sell a veterinary prescription drug in the original, sealed
1198 manufacturer's container with all labeling intact and legible.
1199 The department may adopt by rule additional labeling
1200 requirements for the sale of a veterinary prescription drug.

1201 6. A veterinary prescription drug retail establishment must
1202 comply with all of the wholesale distribution requirements of s.
1203 499.0121.

1204 7. Prescription drugs sold by a veterinary prescription
1205 drug retail establishment pursuant to a practitioner's order may
1206 not be returned into the retail establishment's inventory.

1207 (1)~~(*)~~ *Veterinary prescription drug wholesale distributor*
1208 *permit.*—A veterinary prescription drug wholesale distributor
1209 permit is required for any person that engages in the
1210 distribution of veterinary prescription drugs in or into this
1211 state. A veterinary prescription drug wholesale distributor that
1212 also distributes prescription drugs subject to, defined by, or
1213 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1214 Act which it did not manufacture must obtain a permit as a
1215 prescription drug wholesale distributor, an out-of-state
1216 prescription drug wholesale distributor, or a limited
1217 prescription drug veterinary wholesale distributor in lieu of
1218 the veterinary prescription drug wholesale distributor permit. A
1219 veterinary prescription drug wholesale distributor must comply
1220 with the requirements for wholesale distributors under s.
1221 499.0121, ~~but not those set forth in s. 499.01212.~~

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1222 (m)~~(l)~~ *Limited prescription drug veterinary wholesale*
1223 *distributor permit.*—Unless engaging in the activities of and
1224 permitted as a prescription drug manufacturer, nonresident
1225 prescription drug manufacturer, prescription drug wholesale
1226 distributor, or out-of-state prescription drug wholesale
1227 distributor, a limited prescription drug veterinary wholesale
1228 distributor permit is required for any person that engages in
1229 the distribution in or into this state of veterinary
1230 prescription drugs and prescription drugs subject to, defined
1231 by, or described by s. 503(b) of the Federal Food, Drug, and
1232 Cosmetic Act under the following conditions:

1233 1. The person is engaged in the business of wholesaling
1234 prescription and veterinary prescription drugs to persons:
1235 a. Licensed as veterinarians practicing on a full-time
1236 basis;
1237 b. Regularly and lawfully engaged in instruction in
1238 veterinary medicine;
1239 c. Regularly and lawfully engaged in law enforcement
1240 activities;
1241 d. For use in research not involving clinical use; or
1242 e. For use in chemical analysis or physical testing or for
1243 purposes of instruction in law enforcement activities, research,
1244 or testing.

1245 2. No more than 30 percent of total annual prescription
1246 drug sales may be prescription drugs approved for human use
1247 which are subject to, defined by, or described by s. 503(b) of
1248 the Federal Food, Drug, and Cosmetic Act.

1249 3. The person does not distribute in any jurisdiction
1250 prescription drugs subject to, defined by, or described by s.

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1251 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
1252 who is authorized to sell, distribute, purchase, trade, or use
1253 these drugs on or for humans.

1254 4. A limited prescription drug veterinary wholesale
1255 distributor that applies to the department for a new permit or
1256 the renewal of a permit must submit a bond of \$20,000, or other
1257 equivalent means of security acceptable to the department, such
1258 as an irrevocable letter of credit or a deposit in a trust
1259 account or financial institution, payable to the Professional
1260 Regulation Trust Fund. The purpose of the bond is to secure
1261 payment of any administrative penalties imposed by the
1262 department and any fees and costs incurred by the department
1263 regarding that permit which are authorized under state law and
1264 which the permittee fails to pay 30 days after the fine or costs
1265 become final. The department may make a claim against such bond
1266 or security until 1 year after the permittee's license ceases to
1267 be valid or until 60 days after any administrative or legal
1268 proceeding authorized in this part which involves the permittee
1269 is concluded, including any appeal, whichever occurs later.

1270 5. A limited prescription drug veterinary wholesale
1271 distributor must maintain at all times a license or permit to
1272 engage in the wholesale distribution of prescription drugs in
1273 compliance with laws of the state in which it is a resident.

1274 6. A limited prescription drug veterinary wholesale
1275 distributor must comply with the requirements for wholesale
1276 distributors under s. ss. 499.0121 and 499.01212, except that a
1277 ~~limited prescription drug veterinary wholesale distributor is~~
1278 ~~not required to provide a pedigree paper as required by s.~~
1279 ~~499.01212 upon the wholesale distribution of a prescription drug~~

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1280 ~~to a veterinarian.~~

1281 7. A limited prescription drug veterinary wholesale
1282 distributor may not return to inventory for subsequent wholesale
1283 distribution any prescription drug subject to, defined by, or
1284 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1285 Act which has been returned by a veterinarian.

1286 8. A limited prescription drug veterinary wholesale
1287 distributor permit is not required for an intracompany sale or
1288 transfer of a prescription drug from an out-of-state
1289 establishment that is duly licensed to engage in the wholesale
1290 distribution of prescription drugs in its state of residence to
1291 a licensed limited prescription drug veterinary wholesale
1292 distributor in this state if both wholesale distributors conduct
1293 wholesale distributions of prescription drugs under the same
1294 business name. The recordkeeping requirements of s. ss.
1295 499.0121(6) ~~and 499.01212~~ must be followed for this transaction.

1296 (n) ~~(m)~~ *Over-the-counter drug manufacturer permit.*—An over-
1297 the-counter drug manufacturer permit is required for any person
1298 that engages in the manufacture or repackaging of an over-the-
1299 counter drug.

1300 1. An over-the-counter drug manufacturer may not possess or
1301 purchase prescription drugs.

1302 2. A pharmacy is exempt from obtaining an over-the-counter
1303 drug manufacturer permit if it is operating in compliance with
1304 pharmacy practice standards as defined in chapter 465 and ~~the~~
1305 rules adopted under that chapter.

1306 3. An over-the-counter drug manufacturer must comply with
1307 all appropriate state and federal good manufacturing practices.

1308 (o) ~~(n)~~ *Device manufacturer permit.*—

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1309 1. A device manufacturer permit is required for any person
 1310 that engages in the manufacture, repackaging, or assembly of
 1311 medical devices for human use in this state, except that a
 1312 permit is not required if:

1313 a. The person is engaged only in manufacturing,
 1314 repackaging, or assembling a medical device pursuant to a
 1315 practitioner's order for a specific patient; or

1316 b. The person does not manufacture, repackage, or assemble
 1317 any medical devices or components for such devices, except those
 1318 devices or components which are exempt from registration
 1319 pursuant to s. 499.015(8).

1320 2. A manufacturer or repackager of medical devices in this
 1321 state must comply with all appropriate state and federal good
 1322 manufacturing practices and quality system rules.

1323 3. The department shall adopt rules related to storage,
 1324 handling, and recordkeeping requirements for manufacturers of
 1325 medical devices for human use.

1326 (p) ~~(e)~~ *Cosmetic manufacturer permit.*—A cosmetic
 1327 manufacturer permit is required for any person that manufactures
 1328 or repackages cosmetics in this state. A person that only labels
 1329 or changes the labeling of a cosmetic but does not open the
 1330 container sealed by the manufacturer of the product is exempt
 1331 from obtaining a permit under this paragraph.

1332 (q) ~~(e)~~ *Third party logistics provider permit.*—A third party
 1333 logistics provider permit is required for any person that
 1334 contracts with a prescription drug wholesale distributor or
 1335 prescription drug manufacturer to provide warehousing,
 1336 distribution, or other logistics services on behalf of a
 1337 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who

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1338 does not take title to the prescription drug or have
1339 responsibility to direct the sale or disposition of the
1340 prescription drug. A third party logistics provider located
1341 outside of this state, must be licensed in the state or
1342 territory from which the prescription drug is distributed by the
1343 third party logistics provider. If the state or territory from
1344 which the third party logistics provider originates does not
1345 require a license to operate as a third party logistics
1346 provider, the third party logistic provider must be licensed as
1347 a third party logistics provider as required by the federal act.
1348 Each third party logistics provider permittee shall comply with
1349 s. the requirements for wholesale distributors under ss.
1350 499.0121 and 499.01212, with the exception of those wholesale
1351 distributions described in s. 499.01212(3)(a), and other rules
1352 that the department requires.

1353 (r)(g) Health care clinic establishment permit. ~~Effective~~
1354 ~~January 1, 2009,~~ A health care clinic establishment permit is
1355 required for the purchase of a prescription drug by a place of
1356 business at one general physical location that provides health
1357 care or veterinary services, which is owned and operated by a
1358 business entity that has been issued a federal employer tax
1359 identification number. For the purpose of this paragraph, the
1360 term "qualifying practitioner" means a licensed health care
1361 practitioner defined in s. 456.001, or a veterinarian licensed
1362 under chapter 474, who is authorized under the appropriate
1363 practice act to prescribe and administer a prescription drug.

1364 1. An establishment must provide, as part of the
1365 application required under s. 499.012, designation of a
1366 qualifying practitioner who will be responsible for complying

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1367 with all legal and regulatory requirements related to the
1368 purchase, recordkeeping, storage, and handling of the
1369 prescription drugs. In addition, the designated qualifying
1370 practitioner shall be the practitioner whose name, establishment
1371 address, and license number is used on all distribution
1372 documents for prescription drugs purchased or returned by the
1373 health care clinic establishment. Upon initial appointment of a
1374 qualifying practitioner, the qualifying practitioner and the
1375 health care clinic establishment shall notify the department on
1376 a form furnished by the department within 10 days after such
1377 employment. In addition, the qualifying practitioner and health
1378 care clinic establishment shall notify the department within 10
1379 days after any subsequent change.

1380 2. The health care clinic establishment must employ a
1381 qualifying practitioner at each establishment.

1382 3. In addition to the remedies and penalties provided in
1383 this part, a violation of this chapter by the health care clinic
1384 establishment or qualifying practitioner constitutes grounds for
1385 discipline of the qualifying practitioner by the appropriate
1386 regulatory board.

1387 4. The purchase of prescription drugs by the health care
1388 clinic establishment is prohibited during any period of time
1389 when the establishment does not comply with this paragraph.

1390 5. A health care clinic establishment permit is not a
1391 pharmacy permit or otherwise subject to chapter 465. A health
1392 care clinic establishment that meets the criteria of a modified
1393 Class II institutional pharmacy under s. 465.019 is not eligible
1394 to be permitted under this paragraph.

1395 6. This paragraph does not apply to the purchase of a

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1396 prescription drug by a licensed practitioner under his or her
1397 license.

1398 (3) A nonresident prescription drug manufacturer permit is
1399 not required for a manufacturer to distribute a prescription
1400 drug active pharmaceutical ingredient that it manufactures to a
1401 prescription drug manufacturer permitted in this state ~~in~~
1402 ~~limited quantities~~ intended for research and development and not
1403 for resale or human use other than lawful clinical trials and
1404 biostudies authorized and regulated by federal law. A
1405 manufacturer claiming to be exempt from the permit requirements
1406 of this subsection and the prescription drug manufacturer
1407 purchasing and receiving the active pharmaceutical ingredient
1408 shall comply with the recordkeeping requirements of s.
1409 ~~499.0121(6), but not the requirements of s. 499.01212.~~ The
1410 prescription drug manufacturer purchasing and receiving the
1411 active pharmaceutical ingredient shall maintain on file a record
1412 of the FDA registration number; if available, the out-of-state
1413 license, permit, or registration number; and, if available, a
1414 copy of the most current FDA inspection report, for all
1415 manufacturers from whom they purchase active pharmaceutical
1416 ingredients under this section. ~~The department shall define the~~
1417 ~~term "limited quantities" by rule, and may include the allowable~~
1418 ~~number of transactions within a given period of time and the~~
1419 ~~amount of prescription drugs distributed into the state for~~
1420 ~~purposes of this exemption.~~ The failure to comply with the
1421 requirements of this subsection, or rules adopted by the
1422 department to administer this subsection, for the purchase of
1423 prescription drug active pharmaceutical ingredients is a
1424 violation of s. 499.005(14), and a knowing failure is a

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1425 violation of s. 499.0051(3) ~~499.0051(4)~~.

1426 (a) The immediate package or container of a prescription
1427 drug active pharmaceutical ingredient distributed into the state
1428 that is intended for research and development under this
1429 subsection shall bear a label prominently displaying the
1430 statement: "Caution: Research and Development Only-Not for
1431 Manufacturing, Compounding, or Resale."

1432 (b) A prescription drug manufacturer that obtains a
1433 prescription drug active pharmaceutical ingredient under this
1434 subsection for use in clinical trials and or biostudies
1435 authorized and regulated by federal law must create and maintain
1436 records detailing the specific clinical trials or biostudies for
1437 which the prescription drug active pharmaceutical ingredient was
1438 obtained.

1439 (4) (a) A permit issued under this part is not required to
1440 distribute a prescription drug active pharmaceutical ingredient
1441 from an establishment located in the United States to an
1442 establishment located in this state permitted as a prescription
1443 drug manufacturer under this part for use by the recipient in
1444 preparing, deriving, processing, producing, or fabricating a
1445 prescription drug finished dosage form at the establishment in
1446 this state where the product is received under an approved and
1447 otherwise valid New Drug Approval Application, Abbreviated New
1448 Drug Application, New Animal Drug Application, or Therapeutic
1449 Biologic Application, provided that the application, active
1450 pharmaceutical ingredient, or finished dosage form has not been
1451 withdrawn or removed from the market in this country for public
1452 health reasons.

1453 1. Any distributor claiming exemption from permitting

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1454 requirements pursuant to this paragraph shall maintain a
1455 license, permit, or registration to engage in the wholesale
1456 distribution of prescription drugs under the laws of the state
1457 from which the product is distributed. If the state from which
1458 the prescription drugs are distributed does not require a
1459 license to engage in the wholesale distribution of prescription
1460 drugs, the distributor must be licensed as a wholesale
1461 distributor as required by the federal act.

1462 2. Any distributor claiming exemption from permitting
1463 requirements pursuant to this paragraph and the prescription
1464 drug manufacturer purchasing and receiving the active
1465 pharmaceutical ingredient shall comply with the recordkeeping
1466 requirements of s. 499.0121(6), ~~but not the requirements of s.~~
1467 ~~499.01212.~~

1468 (b) A permit issued under this part is not required to
1469 distribute ~~limited quantities of~~ a prescription drug that has
1470 not been repackaged from an establishment located in the United
1471 States to an establishment located in this state permitted as a
1472 prescription drug manufacturer under this part for research and
1473 development or to a holder of a letter of exemption issued by
1474 the department under s. 499.03(4) for research, teaching, or
1475 testing. ~~The department shall define "limited quantities" by~~
1476 ~~rule and may include the allowable number of transactions within~~
1477 ~~a given period of time and the amounts of prescription drugs~~
1478 ~~distributed into the state for purposes of this exemption.~~

1479 1. Any distributor claiming exemption from permitting
1480 requirements pursuant to this paragraph shall maintain a
1481 license, permit, or registration to engage in the wholesale
1482 distribution of prescription drugs under the laws of the state

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1483 from which the product is distributed. If the state from which
1484 the prescription drugs are distributed does not require a
1485 license to engage in the wholesale distribution of prescription
1486 drugs, the distributor must be licensed as a wholesale
1487 distributor as required by the federal act.

1488 2. All purchasers and recipients of any prescription drugs
1489 distributed pursuant to this paragraph shall ensure that the
1490 products are not resold or used, directly or indirectly, on
1491 humans except in lawful clinical trials and biostudies
1492 authorized and regulated by federal law.

1493 3. Any distributor claiming exemption from permitting
1494 requirements pursuant to this paragraph, and the purchaser and
1495 recipient of the prescription drug, shall comply with the
1496 recordkeeping requirements of s. 499.0121(6), ~~but not the~~
1497 ~~requirements of s. 499.01212.~~

1498 4. The immediate package or container of any active
1499 pharmaceutical ingredient distributed into the state that is
1500 intended for teaching, testing, research, and development shall
1501 bear a label prominently displaying the statement: "Caution:
1502 Research, Teaching, or Testing Only - Not for Manufacturing,
1503 Compounding, or Resale."

1504 (c) An out-of-state prescription drug wholesale distributor
1505 permit is not required for an intracompany sale or transfer of a
1506 prescription drug from an out-of-state establishment that is
1507 duly licensed as a prescription drug wholesale distributor in
1508 its state of residence to a licensed prescription drug wholesale
1509 distributor in this state, if both wholesale distributors
1510 conduct wholesale distributions of prescription drugs under the
1511 same business name. The recordkeeping requirements of s. ~~ss.~~

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1512 499.0121(6) ~~and 499.01212~~ must be followed for such
1513 transactions.

1514 (d) Persons receiving prescription drugs from a source
1515 claimed to be exempt from permitting requirements under this
1516 subsection shall maintain on file:

1517 1. A record of the FDA establishment registration number,
1518 if any;

1519 2. The resident state or federal license, registration, or
1520 permit that authorizes the source to distribute prescription
1521 drugs ~~drug wholesale distribution license, permit, or~~
1522 ~~registration number~~; and

1523 3. A copy of the most recent resident state or FDA
1524 inspection report, for all distributors and establishments from
1525 whom they purchase or receive prescription drugs under this
1526 subsection.

1527 (e) All persons claiming exemption from permitting
1528 requirements pursuant to this subsection who engage in the
1529 distribution of prescription drugs within or into the state are
1530 subject to this part, including ss. 499.005 and 499.0051, and
1531 shall make available, within 48 hours, to the department on
1532 request all records related to any prescription drugs
1533 distributed under this subsection, including those records
1534 described in s. 499.051(4), regardless of the location where the
1535 records are stored.

1536 (f) A person purchasing and receiving a prescription drug
1537 from a person claimed to be exempt from licensing requirements
1538 pursuant to this subsection shall report to the department in
1539 writing within 14 days after receiving any product that is
1540 misbranded or adulterated or that fails to meet minimum

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1541 standards set forth in the official compendium or state or
1542 federal good manufacturing practices for identity, purity,
1543 potency, or sterility, regardless of whether the product is
1544 thereafter rehabilitated, quarantined, returned, or destroyed.

1545 (g) The department may adopt rules to administer this
1546 subsection which are necessary for the protection of the public
1547 health, safety, and welfare. Failure to comply with the
1548 requirements of this subsection, or rules adopted by the
1549 department to administer this subsection, is a violation of s.
1550 499.005(14), and a knowing failure is a violation of s.
1551 499.0051(3) ~~499.0051(4)~~.

1552 (h) This subsection does not relieve any person from any
1553 requirement prescribed by law with respect to controlled
1554 substances as defined in the applicable federal and state laws.

1555 (5) A prescription drug repackager permit issued under this
1556 part is not required for a restricted prescription drug
1557 distributor permitholder that is a health care entity to
1558 repackaging prescription drugs in this state for its own use or
1559 for distribution to hospitals or other health care entities in
1560 the state for their own use, pursuant to s. 499.003(48)(a)3.
1561 ~~499.003(53)(a)3.~~, if:

1562 (a) The prescription drug distributor notifies the
1563 department, in writing, of its intention to engage in
1564 repackaging under this exemption, 30 days before engaging in the
1565 repackaging of prescription drugs at the permitted
1566 establishment;

1567 (b) The prescription drug distributor is under common
1568 control with the hospitals or other health care entities to
1569 which the prescription drug distributor is distributing

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1570 prescription drugs. As used in this paragraph, "common control"
1571 means the power to direct or cause the direction of the
1572 management and policies of a person or an organization, whether
1573 by ownership of stock, voting rights, contract, or otherwise;

1574 (c) The prescription drug distributor repackages the
1575 prescription drugs in accordance with current state and federal
1576 good manufacturing practices; and

1577 (d) The prescription drug distributor labels the
1578 prescription drug it repackages in accordance with state and
1579 federal laws and rules.

1580
1581 The prescription drug distributor is exempt from the product
1582 registration requirements of s. 499.015 with regard to the
1583 prescription drugs that it repackages and distributes under this
1584 subsection. A prescription drug distributor that repackages and
1585 distributes prescription drugs under this subsection to a not-
1586 for-profit rural hospital, as defined in s. 395.602, is not
1587 required to comply with paragraph (c) or paragraph (d), but must
1588 provide to each health care entity for which it repackages, for
1589 each prescription drug that is repackaged and distributed, the
1590 information required by department rule for labeling
1591 prescription drugs. The prescription drug distributor shall also
1592 provide the additional current packaging and label information
1593 for the prescription drug by hard copy or by electronic means.

1594 Section 6. Section 499.012, Florida Statutes, is amended to
1595 read:

1596 499.012 Permit application requirements.—

1597 (1) (a) A permit issued pursuant to this part may be issued
1598 only to a natural person who is at least 18 years of age or to

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1599 an applicant that is not a natural person if each person who,
1600 directly or indirectly, manages, controls, or oversees the
1601 operation of that applicant is at least 18 years of age.

1602 (b) An establishment that is a place of residence may not
1603 receive a permit and may not operate under this part.

1604 (c) A person that applies for or renews a permit to
1605 manufacture or distribute prescription drugs may not use a name
1606 identical to the name used by any other establishment or
1607 licensed person authorized to purchase prescription drugs in
1608 this state, except that a restricted drug distributor permit
1609 issued to a health care entity will be issued in the name in
1610 which the institutional pharmacy permit is issued and a retail
1611 pharmacy drug wholesale distributor will be issued a permit in
1612 the name of its retail pharmacy permit.

1613 (d) A permit for a prescription drug manufacturer,
1614 prescription drug repackager, prescription drug wholesale
1615 distributor, limited prescription drug veterinary wholesale
1616 distributor, or retail pharmacy drug wholesale distributor may
1617 not be issued to the address of a health care entity or to a
1618 pharmacy licensed under chapter 465, except as provided in this
1619 paragraph. The department may issue a prescription drug
1620 manufacturer permit to an applicant at the same address as a
1621 licensed nuclear pharmacy, which is a health care entity, even
1622 if the nuclear pharmacy holds a special sterile compounding
1623 permit under chapter 465, for the purpose of manufacturing
1624 prescription drugs used in positron emission tomography or other
1625 radiopharmaceuticals, as listed in a rule adopted by the
1626 department pursuant to this paragraph. The purpose of this
1627 exemption is to assure availability of state-of-the-art

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1628 pharmaceuticals that would pose a significant danger to the
1629 public health if manufactured at a separate establishment
1630 address from the nuclear pharmacy from which the prescription
1631 drugs are dispensed. The department may also issue a retail
1632 pharmacy drug wholesale distributor permit to the address of a
1633 community pharmacy licensed under chapter 465, even if the
1634 community pharmacy holds a special sterile compounding permit
1635 under chapter 465, as long as the community pharmacy ~~which~~ does
1636 not meet the definition of a closed pharmacy in s. 499.003.

1637 (e) A county or municipality may not issue an occupational
1638 license for ~~any licensing period beginning on or after October~~
1639 ~~1, 2003, for~~ any establishment that requires a permit pursuant
1640 to this part, unless the establishment exhibits a current permit
1641 issued by the department for the establishment. Upon
1642 presentation of the requisite permit issued by the department,
1643 an occupational license may be issued by the municipality or
1644 county in which application is made. The department shall
1645 furnish to local agencies responsible for issuing occupational
1646 licenses a current list of all establishments licensed pursuant
1647 to this part.

1648 (2) Notwithstanding subsection (6), a permitted person in
1649 good standing may change the type of permit issued to that
1650 person by completing a new application for the requested permit,
1651 paying the amount of the difference in the permit fees if the
1652 fee for the new permit is more than the fee for the original
1653 permit, and meeting the applicable permitting conditions for the
1654 new permit type. The new permit expires on the expiration date
1655 of the original permit being changed; however, a new permit for
1656 a prescription drug wholesale distributor, an out-of-state

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1657 prescription drug wholesale distributor, or a retail pharmacy
1658 drug wholesale distributor shall expire on the expiration date
1659 of the original permit or 1 year after the date of issuance of
1660 the new permit, whichever is earlier. A refund may not be issued
1661 if the fee for the new permit is less than the fee that was paid
1662 for the original permit.

1663 (3) (a) A written application for a permit or to renew a
1664 permit must be filed with the department on forms furnished by
1665 the department. The department shall establish, by rule, the
1666 form and content of the application to obtain or renew a permit.
1667 The applicant must submit to the department with the application
1668 a statement that swears or affirms that the information is true
1669 and correct.

1670 (b) Upon a determination that 2 years have elapsed since
1671 the department notified an applicant for permit, certification,
1672 or product registration of a deficiency in the application and
1673 that the applicant has failed to cure the deficiency, the
1674 application shall expire. The determination regarding the 2-year
1675 lapse of time shall be based on documentation that the
1676 department notified the applicant of the deficiency in
1677 accordance with s. 120.60.

1678 (c) Information submitted by an applicant on an application
1679 required pursuant to this subsection which is a trade secret, as
1680 defined in s. 812.081, shall be maintained by the department as
1681 trade secret information pursuant to s. 499.051(7).

1682 (4) (a) Except for a permit for a prescription drug
1683 wholesale distributor or an out-of-state prescription drug
1684 wholesale distributor, an application for a permit must include:
1685 1. The name, full business address, and telephone number of

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1686 the applicant;

1687 2. All trade or business names used by the applicant;

1688 3. The address, telephone numbers, and the names of contact
1689 persons for each facility used by the applicant for the storage,
1690 handling, and distribution of prescription drugs;

1691 4. The type of ownership or operation, such as a
1692 partnership, corporation, or sole proprietorship; and

1693 5. The names of the owner and the operator of the
1694 establishment, including:

1695 a. If an individual, the name of the individual;

1696 b. If a partnership, the name of each partner and the name
1697 of the partnership;

1698 c. If a corporation, the name and title of each corporate
1699 officer and director, the corporate names, and the name of the
1700 state of incorporation;

1701 d. If a sole proprietorship, the full name of the sole
1702 proprietor and the name of the business entity;

1703 e. If a limited liability company, the name of each member,
1704 the name of each manager, the name of the limited liability
1705 company, and the name of the state in which the limited
1706 liability company was organized; and

1707 f. Any other relevant information that the department
1708 requires.

1709 (b) Upon approval of the application by the department and
1710 payment of the required fee, the department shall issue a permit
1711 to the applicant, if the applicant meets the requirements of
1712 this part and rules adopted under this part.

1713 (c) Any change in information required under paragraph (a)
1714 must be submitted to the department before the change occurs.

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1715 (d) The department shall consider, at a minimum, the
1716 following factors in reviewing the qualifications of persons to
1717 be permitted under this part:

1718 1. The applicant's having been found guilty, regardless of
1719 adjudication, in a court of this state or other jurisdiction, of
1720 a violation of a law that directly relates to a drug, device, or
1721 cosmetic. A plea of nolo contendere constitutes a finding of
1722 guilt for purposes of this subparagraph.

1723 2. The applicant's having been disciplined by a regulatory
1724 agency in any state for any offense that would constitute a
1725 violation of this part.

1726 3. Any felony conviction of the applicant under a federal,
1727 state, or local law;

1728 4. The applicant's past experience in manufacturing or
1729 distributing drugs, devices, or cosmetics;

1730 5. The furnishing by the applicant of false or fraudulent
1731 material in any application made in connection with
1732 manufacturing or distributing drugs, devices, or cosmetics;

1733 6. Suspension or revocation by a federal, state, or local
1734 government of any permit currently or previously held by the
1735 applicant for the manufacture or distribution of any drugs,
1736 devices, or cosmetics;

1737 7. Compliance with permitting requirements under any
1738 previously granted permits;

1739 8. Compliance with requirements to maintain or make
1740 available to the state permitting authority or to federal,
1741 state, or local law enforcement officials those records required
1742 under this section; and

1743 9. Any other factors or qualifications the department

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1744 considers relevant to and consistent with the public health and
1745 safety.

1746 ~~(5) Except for a permit for a prescription drug wholesale~~
1747 ~~distributor or an out-of-state prescription drug wholesale~~
1748 ~~distributor.~~

1749 (a) The department shall adopt rules for the biennial
1750 renewal of permits; however, the department may issue up to a 4-
1751 year permit to selected permittees notwithstanding any other
1752 provision of law. Fees for such renewal may not exceed the fee
1753 caps set forth in s. 499.041 on an annualized basis as
1754 authorized by law.

1755 (b) The department shall renew a permit upon receipt of the
1756 renewal application and renewal fee if the applicant meets the
1757 requirements established under this part and ~~the~~ rules adopted
1758 under this part.

1759 (c) At least 90 days before the expiration date of a
1760 permit, the department shall forward a permit renewal
1761 notification to the permittee at the mailing address of the
1762 permitted establishment on file with the department. The permit
1763 renewal notification must state conspicuously the date on which
1764 the permit for the establishment will expire and that the
1765 establishment may not operate unless the permit for the
1766 establishment is renewed timely. ~~A permit, unless sooner~~
1767 ~~suspended or revoked, automatically expires 2 years after the~~
1768 ~~last day of the anniversary month in which the permit was~~
1769 ~~originally issued.~~

1770 (d) A permit issued under this part may be renewed by
1771 making application for renewal on forms furnished by the
1772 department and paying the appropriate fees.

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1773 1. If a prescription drug wholesale distributor or an out-
1774 of-state prescription drug wholesale distributor renewal
1775 application and fee are submitted and postmarked later than 45
1776 days before the expiration date of the permit, the permit may be
1777 renewed only upon payment of a late renewal fee of \$100, plus
1778 the required renewal fee.

1779 2. If any other a renewal application and fee are submitted
1780 and postmarked after the expiration date of the permit, the
1781 permit may be renewed only upon payment of a late renewal
1782 delinquent fee of \$100, plus the required renewal fee, not later
1783 than 60 days after the expiration date.

1784 3. A permittee submits a renewal application in accordance
1785 with this paragraph may continue to operate under its permit,
1786 unless the permit is suspended or revoked, until final
1787 disposition of the renewal application.

1788 4.~~(d)~~ Failure to renew a permit in accordance with this
1789 section precludes any future renewal of that permit. If a permit
1790 issued pursuant to this part has expired and cannot be renewed,
1791 before an establishment may engage in activities that require a
1792 permit under this part, the establishment must submit an
1793 application for a new permit, pay the applicable application
1794 fee, the initial permit fee, and all applicable penalties, and
1795 be issued a new permit by the department.

1796 (6) A permit issued by the department is nontransferable.
1797 Each permit is valid only for the person or governmental unit to
1798 which it is issued and is not subject to sale, assignment, or
1799 other transfer, voluntarily or involuntarily; nor is a permit
1800 valid for any establishment other than the establishment for
1801 which it was originally issued.

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1802 (a) A person permitted under this part must notify the
1803 department before making a change of address. The department
1804 shall set a change of location fee not to exceed \$100.

1805 (b)1. An application for a new permit is required when a
1806 majority of the ownership or controlling interest of a permitted
1807 establishment is transferred or assigned or when a lessee agrees
1808 to undertake or provide services to the extent that legal
1809 liability for operation of the establishment will rest with the
1810 lessee. The application for the new permit must be made before
1811 the date of the sale, transfer, assignment, or lease.

1812 2. A permittee that is authorized to distribute
1813 prescription drugs may transfer such drugs to the new owner or
1814 lessee under subparagraph 1. only after the new owner or lessee
1815 has been approved for a permit to distribute prescription drugs.

1816 (c) If an establishment permitted under this part closes,
1817 the owner must notify the department in writing before the
1818 effective date of closure and must:

1819 1. Return the permit to the department;

1820 2. If the permittee is authorized to distribute
1821 prescription drugs, indicate the disposition of such drugs,
1822 including the name, address, and inventory, and provide the name
1823 and address of a person to contact regarding access to records
1824 that are required to be maintained under this part. Transfer of
1825 ownership of prescription drugs may be made only to persons
1826 authorized to possess prescription drugs under this part.

1827
1828 The department may revoke the permit of any person that fails to
1829 comply with the requirements of this subsection.

1830 (7) A permit must be posted in a conspicuous place on the

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1831 licensed premises.

1832 (8) An application for a permit or to renew a permit for a
1833 prescription drug wholesale distributor or an out-of-state
1834 prescription drug wholesale distributor submitted to the
1835 department must include:

1836 (a) The name, full business address, and telephone number
1837 of the applicant.

1838 (b) All trade or business names used by the applicant.

1839 (c) The address, telephone numbers, and the names of
1840 contact persons for each facility used by the applicant for the
1841 storage, handling, and distribution of prescription drugs.

1842 (d) The type of ownership or operation, such as a
1843 partnership, corporation, or sole proprietorship.

1844 (e) The names of the owner and the operator of the
1845 establishment, including:

1846 1. If an individual, the name of the individual.

1847 2. If a partnership, the name of each partner and the name
1848 of the partnership.

1849 3. If a corporation:

1850 a. The name, address, and title of each corporate officer
1851 and director.

1852 b. The name and address of the corporation, resident agent
1853 of the corporation, the resident agent's address, and the
1854 corporation's state of incorporation.

1855 c. The name and address of each shareholder of the
1856 corporation that owns 5 percent or more of the outstanding stock
1857 of the corporation.

1858 4. If a sole proprietorship, the full name of the sole
1859 proprietor and the name of the business entity.

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- 1860 5. If a limited liability company:
- 1861 a. The name and address of each member.
- 1862 b. The name and address of each manager.
- 1863 c. The name and address of the limited liability company,
- 1864 the resident agent of the limited liability company, and the
- 1865 name of the state in which the limited liability company was
- 1866 organized.
- 1867 (f) If applicable, the name and address of each affiliate
- 1868 ~~of member of the affiliated group of which the applicant is a~~
- 1869 ~~member.~~
- 1870 (g) ~~1.~~ The applicant's gross annual receipts attributable to
- 1871 prescription drug wholesale distribution activities for the
- 1872 previous tax year. ~~For an application for a new permit, the~~
- 1873 ~~estimated annual dollar volume of prescription drug sales of the~~
- 1874 ~~applicant, the estimated annual percentage of the applicant's~~
- 1875 ~~total company sales that are prescription drugs, the applicant's~~
- 1876 ~~estimated annual total dollar volume of purchases of~~
- 1877 ~~prescription drugs, and the applicant's estimated annual total~~
- 1878 ~~dollar volume of prescription drug purchases directly from~~
- 1879 ~~manufacturers.~~
- 1880 2. ~~For an application to renew a permit, the total dollar~~
- 1881 ~~volume of prescription drug sales in the previous year, the~~
- 1882 ~~total dollar volume of prescription drug sales made in the~~
- 1883 ~~previous 6 months, the percentage of total company sales that~~
- 1884 ~~were prescription drugs in the previous year, the total dollar~~
- 1885 ~~volume of purchases of prescription drugs in the previous year,~~
- 1886 ~~and the total dollar volume of prescription drug purchases~~
- 1887 ~~directly from manufacturers in the previous year.~~
- 1888

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1889 ~~Such portions of the information required pursuant to this~~
1890 ~~paragraph which are a trade secret, as defined in s. 812.081,~~
1891 ~~shall be maintained by the department as trade secret~~
1892 ~~information is required to be maintained under s. 499.051.~~

1893 (h) The tax year of the applicant.

1894 (i) A copy of the deed for the property on which
1895 applicant's establishment is located, if the establishment is
1896 owned by the applicant, or a copy of the applicant's lease for
1897 the property on which applicant's establishment is located that
1898 has an original term of not less than 1 calendar year, if the
1899 establishment is not owned by the applicant.

1900 (j) A list of all licenses and permits issued to the
1901 applicant by any other state which authorize the applicant to
1902 purchase or possess prescription drugs.

1903 (k) The name of the manager of the establishment that is
1904 applying for the permit or to renew the permit, the next four
1905 highest ranking employees responsible for prescription drug
1906 wholesale operations for the establishment, and the name of all
1907 affiliated parties for the establishment, together with the
1908 personal information statement and fingerprints required
1909 pursuant to subsection (9) for each of such persons.

1910 (l) The name of each of the applicant's designated
1911 representatives as required by subsection (15) ~~(16)~~, together
1912 with the personal information statement and fingerprints
1913 required pursuant to subsection (9) for each such person.

1914 (m) Evidence of a surety bond in this state or any other
1915 state in the United States in the amount of \$100,000. If the
1916 annual gross receipts of the applicant's previous tax year is
1917 \$10 million or less, evidence of a surety bond in the amount of

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1918 \$25,000. The specific language of the surety bond must include
1919 the State of Florida as a beneficiary, payable to the
1920 Professional Regulation Trust Fund. In lieu of the surety bond,
1921 the applicant may provide other equivalent security such as an
1922 irrevocable letter of credit or a deposit in a trust account or
1923 financial institution payable to the Professional Regulation
1924 Trust Fund. The purpose of the bond or other security is to
1925 secure payment of any administrative penalties imposed by the
1926 department and any fees and costs incurred by the department
1927 regarding that permit which are authorized under state law and
1928 which the permittee fails to pay 30 days after the fine or costs
1929 become final. The department may make a claim against such bond
1930 or security until 1 year after the permittee's license ceases to
1931 be valid or until 60 days after any administrative or legal
1932 proceeding authorized in this part which involves the permittee
1933 is concluded, including any appeal, whichever occurs later. For
1934 an applicant that is a secondary wholesale distributor, each of
1935 the following:

1936 1. ~~A personal background information statement containing~~
1937 ~~the background information and fingerprints required pursuant to~~
1938 ~~subsection (9) for each person named in the applicant's response~~
1939 ~~to paragraphs (k) and (l) and for each affiliated party of the~~
1940 ~~applicant.~~

1941 2. ~~If any of the five largest shareholders of the~~
1942 ~~corporation seeking the permit is a corporation, the name,~~
1943 ~~address, and title of each corporate officer and director of~~
1944 ~~each such corporation; the name and address of such corporation;~~
1945 ~~the name of such corporation's resident agent, such~~
1946 ~~corporation's resident agent's address, and such corporation's~~

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1947 ~~state of its incorporation; and the name and address of each~~
1948 ~~shareholder of such corporation that owns 5 percent or more of~~
1949 ~~the stock of such corporation.~~

1950 ~~3. The name and address of all financial institutions in~~
1951 ~~which the applicant has an account which is used to pay for the~~
1952 ~~operation of the establishment or to pay for drugs purchased for~~
1953 ~~the establishment, together with the names of all persons that~~
1954 ~~are authorized signatories on such accounts. The portions of the~~
1955 ~~information required pursuant to this subparagraph which are a~~
1956 ~~trade secret, as defined in s. 812.081, shall be maintained by~~
1957 ~~the department as trade secret information is required to be~~
1958 ~~maintained under s. 499.051.~~

1959 ~~4. The sources of all funds and the amounts of such funds~~
1960 ~~used to purchase or finance purchases of prescription drugs or~~
1961 ~~to finance the premises on which the establishment is to be~~
1962 ~~located.~~

1963 ~~5. If any of the funds identified in subparagraph 4. were~~
1964 ~~borrowed, copies of all promissory notes or loans used to obtain~~
1965 ~~such funds.~~

1966 (n) For establishments used in wholesale distribution,
1967 proof of an inspection conducted by the department, the United
1968 States Food and Drug Administration, or another governmental
1969 entity charged with the regulation of good manufacturing
1970 practices related to wholesale distribution of prescription
1971 drugs, within timeframes set forth by the department in
1972 departmental rules, which demonstrates substantial compliance
1973 with current good manufacturing practices applicable to
1974 wholesale distribution of prescription drugs. The department may
1975 recognize another state's inspection of a wholesale distributor

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1976 located in that state if such state's laws are deemed to be
1977 substantially equivalent to the law of this state by the
1978 department. The department may accept an inspection by a third-
1979 party accreditation or inspection service which meets the
1980 criteria set forth in department rule.

1981 ~~(o) (n)~~ Any other relevant information that the department
1982 requires, including, but not limited to, any information related
1983 to whether the applicant satisfies the definition of a primary
1984 wholesale distributor or a secondary wholesale distributor.

1985 ~~(p) (e)~~ Documentation of the credentialing policies and
1986 procedures required by s. 499.0121(15).

1987 (9) (a) Each person required by subsection (8) or subsection
1988 (15) to provide a personal information statement and
1989 fingerprints shall provide the following information to the
1990 department on forms prescribed by the department:

1991 1. The person's places of residence for the past 7 years.

1992 2. The person's date and place of birth.

1993 3. The person's occupations, positions of employment, and
1994 offices held during the past 7 years.

1995 4. The principal business and address of any business,
1996 corporation, or other organization in which each such office of
1997 the person was held or in which each such occupation or position
1998 of employment was carried on.

1999 5. Whether the person has been, during the past 7 years,
2000 the subject of any proceeding for the revocation of any license
2001 and, if so, the nature of the proceeding and the disposition of
2002 the proceeding.

2003 6. Whether, during the past 7 years, the person has been
2004 enjoined, temporarily or permanently, by a court of competent

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jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning any such event.

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

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

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

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

11. The name, address, occupation, and date and place of birth for each member of the person's immediate family who is 18 years of age or older. As used in this subparagraph, the term "member of the person's immediate family" includes the person's

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2034 spouse, children, parents, siblings, the spouses of the person's
2035 children, and the spouses of the person's siblings.

2036 12. Any other relevant information that the department
2037 requires.

2038 (b) The information required pursuant to paragraph (a)
2039 shall be provided under oath.

2040 (c) The department shall submit the fingerprints provided
2041 by a person for initial licensure to the Department of Law
2042 Enforcement for a statewide criminal record check and for
2043 forwarding to the Federal Bureau of Investigation for a national
2044 criminal record check of the person. The department shall submit
2045 the fingerprints provided by a person as a part of a renewal
2046 application to the Department of Law Enforcement for a statewide
2047 criminal record check, and for forwarding to the Federal Bureau
2048 of Investigation for a national criminal record check, for the
2049 initial renewal of a permit after January 1, 2004; for any
2050 subsequent renewal of a permit, the department shall submit the
2051 required information for a statewide and national criminal
2052 record check of the person. Any person who as a part of an
2053 initial permit application or initial permit renewal after
2054 January 1, 2004, submits to the department a set of fingerprints
2055 required for the criminal record check required in this
2056 paragraph are ~~shall~~ not ~~be~~ required to provide a subsequent set
2057 of fingerprints for a criminal record check to the department,
2058 if the person has undergone a criminal record check as a
2059 condition of the issuance of an initial permit or the initial
2060 renewal of a permit of an applicant after January 1, 2004. The
2061 department is authorized to contract with private vendors, or
2062 enter into interagency agreements, to collect electronic

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2063 fingerprints where fingerprints are required for registration,
2064 certification, or the licensure process or where criminal
2065 history record checks are required.

2066 (d) For purposes of applying for renewal of a permit under
2067 subsection (8) or certification under subsection (16), a person
2068 may submit the following in lieu of satisfying the requirements
2069 of paragraphs (a), (b), and (c):

2070 1. A photograph of the individual taken within 180 days;
2071 and

2072 2. A copy of the personal information statement form most
2073 recently submitted to the department and a certification under
2074 oath, on a form specified by the department, that the individual
2075 has reviewed the previously submitted personal information
2076 statement form and that the information contained therein
2077 remains unchanged.

2078 (10) The department may deny an application for a permit or
2079 refuse to renew a permit for a prescription drug wholesale
2080 distributor or an out-of-state prescription drug wholesale
2081 distributor if:

2082 (a) The applicant has not met the requirements for the
2083 permit.

2084 (b) The management, officers, or directors of the applicant
2085 or any affiliated party are found by the department to be
2086 incompetent or untrustworthy.

2087 (c) The applicant is so lacking in experience in managing a
2088 wholesale distributor as to make the issuance of the proposed
2089 permit hazardous to the public health.

2090 (d) The applicant is so lacking in experience in managing a
2091 wholesale distributor as to jeopardize the reasonable promise of

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2092 successful operation of the wholesale distributor.

2093 (e) The applicant is lacking in experience in the
2094 distribution of prescription drugs.

2095 (f) The applicant's past experience in manufacturing or
2096 distributing prescription drugs indicates that the applicant
2097 poses a public health risk.

2098 (g) The applicant is affiliated directly or indirectly
2099 through ownership, control, or other business relations, with
2100 any person or persons whose business operations are or have been
2101 detrimental to the public health.

2102 (h) The applicant, or any affiliated party, has been found
2103 guilty of or has pleaded guilty or nolo contendere to any felony
2104 or crime punishable by imprisonment for 1 year or more under the
2105 laws of the United States, any state, or any other country,
2106 regardless of whether adjudication of guilt was withheld.

2107 (i) The applicant or any affiliated party has been charged
2108 with a felony in a state or federal court and the disposition of
2109 that charge is pending during the application review or renewal
2110 review period.

2111 (j) The applicant has furnished false or fraudulent
2112 information or material in any application made in this state or
2113 any other state in connection with obtaining a permit or license
2114 to manufacture or distribute drugs, devices, or cosmetics.

2115 (k) That a federal, state, or local government permit
2116 currently or previously held by the applicant, or any affiliated
2117 party, for the manufacture or distribution of any drugs,
2118 devices, or cosmetics has been disciplined, suspended, or
2119 revoked and has not been reinstated.

2120 (l) The applicant does not possess the financial or

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2121 physical resources to operate in compliance with the permit
2122 being sought, this chapter, and the rules adopted under this
2123 chapter.

2124 (m) The applicant or any affiliated party receives,
2125 directly or indirectly, financial support and assistance from a
2126 person who was an affiliated party of a permittee whose permit
2127 was subject to discipline or was suspended or revoked, other
2128 than through the ownership of stock in a publicly traded company
2129 or a mutual fund.

2130 (n) The applicant or any affiliated party receives,
2131 directly or indirectly, financial support and assistance from a
2132 person who has been found guilty of any violation of this part
2133 or chapter 465, chapter 501, or chapter 893, any rules adopted
2134 under this part or those chapters, any federal or state drug
2135 law, or any felony where the underlying facts related to drugs,
2136 regardless of whether the person has been pardoned, had her or
2137 his civil rights restored, or had adjudication withheld, other
2138 than through the ownership of stock in a publicly traded company
2139 or a mutual fund.

2140 (o) The applicant for renewal of a permit under s.
2141 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged
2142 in the wholesale distribution of prescription drugs, as
2143 demonstrated by the regular and systematic distribution of
2144 prescription drugs throughout the year as evidenced by not fewer
2145 than 12 wholesale distributions in the previous year and not
2146 fewer than three wholesale distributions in the previous 6
2147 months.

2148 (p) Information obtained in response to s. 499.01(2)(e) or
2149 (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best

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2150 interest of the public health, safety, and welfare to issue a
2151 permit.

2152 (q) The applicant does not possess the financial standing
2153 and business experience for the successful operation of the
2154 applicant.

2155 (r) The applicant or any affiliated party has failed to
2156 comply with the requirements for manufacturing or distributing
2157 prescription drugs under this part, similar federal laws,
2158 similar laws in other states, or the rules adopted under such
2159 laws.

2160 (11) Upon approval of the application by the department and
2161 payment of the required fee, the department shall issue or renew
2162 a prescription drug wholesale distributor or an out-of-state
2163 prescription drug wholesale distributor permit to the applicant.

2164 ~~(12) For a permit for a prescription drug wholesale~~
2165 ~~distributor or an out-of-state prescription drug wholesale~~
2166 ~~distributor:~~

2167 ~~(a) The department shall adopt rules for the annual renewal~~
2168 ~~of permits. At least 90 days before the expiration of a permit,~~
2169 ~~the department shall forward a permit renewal notification and~~
2170 ~~renewal application to the prescription drug wholesale~~
2171 ~~distributor or out-of-state prescription drug wholesale~~
2172 ~~distributor at the mailing address of the permitted~~
2173 ~~establishment on file with the department. The permit renewal~~
2174 ~~notification must state conspicuously the date on which the~~
2175 ~~permit for the establishment will expire and that the~~
2176 ~~establishment may not operate unless the permit for the~~
2177 ~~establishment is renewed timely.~~

2178 ~~(b) A permit, unless sooner suspended or revoked,~~

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2179 automatically expires 1 year after the last day of the
2180 anniversary month in which the permit was originally issued. A
2181 permit may be renewed by making application for renewal on forms
2182 furnished by the department and paying the appropriate fees. If
2183 a renewal application and fee are submitted and postmarked after
2184 45 days prior to the expiration date of the permit, the permit
2185 may be renewed only upon payment of a late renewal fee of \$100,
2186 plus the required renewal fee. A permittee that has submitted a
2187 renewal application in accordance with this paragraph may
2188 continue to operate under its permit, unless the permit is
2189 suspended or revoked, until final disposition of the renewal
2190 application.

2191 (c) Failure to renew a permit in accordance with this
2192 section precludes any future renewal of that permit. If a permit
2193 issued pursuant to this section has expired and cannot be
2194 renewed, before an establishment may engage in activities that
2195 require a permit under this part, the establishment must submit
2196 an application for a new permit; pay the applicable application
2197 fee, initial permit fee, and all applicable penalties; and be
2198 issued a new permit by the department.

2199 (12)~~(13)~~ A person that engages in wholesale distribution of
2200 prescription drugs in this state must have a wholesale
2201 distributor's permit issued by the department, except as noted
2202 in this section. Each establishment must be separately permitted
2203 except as noted in this subsection.

2204 (a) A separate establishment permit is not required when a
2205 permitted prescription drug wholesale distributor consigns a
2206 prescription drug to a pharmacy that is permitted under chapter
2207 465 and located in this state, provided that:

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2208 1. The consignor wholesale distributor notifies the
2209 department in writing of the contract to consign prescription
2210 drugs to a pharmacy along with the identity and location of each
2211 consignee pharmacy;

2212 2. The pharmacy maintains its permit under chapter 465;

2213 3. The consignor wholesale distributor, which has no legal
2214 authority to dispense prescription drugs, complies with all
2215 wholesale distribution requirements of s. ss. 499.0121 ~~and~~
2216 ~~499.01212~~ with respect to the consigned drugs and maintains
2217 records documenting the transfer of title or other completion of
2218 the wholesale distribution of the consigned prescription drugs;

2219 4. The distribution of the prescription drug is otherwise
2220 lawful under this chapter and other applicable law;

2221 5. Open packages containing prescription drugs within a
2222 pharmacy are the responsibility of the pharmacy, regardless of
2223 how the drugs are titled; and

2224 6. The pharmacy dispenses the consigned prescription drug
2225 in accordance with the limitations of its permit under chapter
2226 465 or returns the consigned prescription drug to the consignor
2227 wholesale distributor. In addition, a person who holds title to
2228 prescription drugs may transfer the drugs to a person permitted
2229 or licensed to handle the reverse distribution or destruction of
2230 drugs. Any other distribution by and means of the consigned
2231 prescription drug by any person, not limited to the consignor
2232 wholesale distributor or consignee pharmacy, to any other person
2233 is prohibited.

2234 (b) A wholesale distributor's permit is not required for
2235 the one-time transfer of title of a pharmacy's lawfully acquired
2236 prescription drug inventory by a pharmacy with a valid permit

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2237 issued under chapter 465 to a consignor prescription drug
2238 wholesale distributor, permitted under this chapter, in
2239 accordance with a written consignment agreement between the
2240 pharmacy and that wholesale distributor if the permitted
2241 pharmacy and the permitted prescription drug wholesale
2242 distributor comply with all of the provisions of paragraph (a)
2243 and the prescription drugs continue to be within the permitted
2244 pharmacy's inventory for dispensing in accordance with the
2245 limitations of the pharmacy permit under chapter 465. A
2246 consignor drug wholesale distributor may not use the pharmacy as
2247 a wholesale distributor through which it distributes the
2248 prescription drugs to other pharmacies. Nothing in this section
2249 is intended to prevent a wholesale distributor from obtaining
2250 this inventory in the event of nonpayment by the pharmacy.

2251 (c) A separate establishment permit is not required when a
2252 permitted prescription drug wholesale distributor operates
2253 temporary transit storage facilities for the sole purpose of
2254 storage, for up to 16 hours, of a delivery of prescription drugs
2255 when the wholesale distributor was temporarily unable to
2256 complete the delivery to the recipient.

2257 (d) The department shall require information from each
2258 wholesale distributor as part of the permit and renewal of such
2259 permit, as required under this section.

2260 (13)~~(14)~~ Personnel employed in wholesale distribution must
2261 have appropriate education and experience to enable them to
2262 perform their duties in compliance with state permitting
2263 requirements.

2264 (14)~~(15)~~ The name of a permittee or establishment on a
2265 prescription drug wholesale distributor permit or an out-of-

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2266 state prescription drug wholesale distributor permit may not
2267 include any indicia of attainment of any educational degree, any
2268 indicia that the permittee or establishment possesses a
2269 professional license, or any name or abbreviation that the
2270 department determines is likely to cause confusion or mistake or
2271 that the department determines is deceptive, including that of
2272 any other entity authorized to purchase prescription drugs.

2273 (15)~~(16)~~(a) Each establishment that is issued an initial or
2274 renewal permit as a prescription drug wholesale distributor or
2275 an out-of-state prescription drug wholesale distributor must
2276 designate in writing to the department at least one natural
2277 person to serve as the designated representative of the
2278 wholesale distributor. Such person must have an active
2279 certification as a designated representative from the
2280 department.

2281 (b) To be certified as a designated representative, a
2282 natural person must:

2283 1. Submit an application on a form furnished by the
2284 department and pay the appropriate fees.

2285 2. Be at least 18 years of age.

2286 3. Have at least 2 years of verifiable full-time:

2287 a. Work experience in a pharmacy licensed in this state or
2288 another state, where the person's responsibilities included, but
2289 were not limited to, recordkeeping for prescription drugs;

2290 b. Managerial experience with a prescription drug wholesale
2291 distributor licensed in this state or in another state; or

2292 c. Managerial experience with the United States Armed
2293 Forces, where the person's responsibilities included, but were
2294 not limited to, recordkeeping, warehousing, distributing, or

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2295 other logistics services pertaining to prescription drugs.

2296 4. Receive a passing score of at least 75 percent on an
2297 examination given by the department regarding federal laws
2298 governing distribution of prescription drugs and this part and
2299 the rules adopted by the department governing the wholesale
2300 distribution of prescription drugs. This requirement shall be
2301 effective 1 year after the results of the initial examination
2302 are mailed to the persons that took the examination. The
2303 department shall offer such examinations at least four times
2304 each calendar year.

2305 5. Provide the department with a personal information
2306 statement and fingerprints pursuant to subsection (9).

2307 (c) The department may deny an application for
2308 certification as a designated representative or may suspend or
2309 revoke a certification of a designated representative pursuant
2310 to s. 499.067.

2311 (d) A designated representative:

2312 1. Must be actively involved in and aware of the actual
2313 daily operation of the wholesale distributor.

2314 2. Must be employed full time in a managerial position by
2315 the wholesale distributor.

2316 3. Must be physically present at the establishment during
2317 normal business hours, except for time periods when absent due
2318 to illness, family illness or death, scheduled vacation, or
2319 other authorized absence.

2320 4. May serve as a designated representative for only one
2321 wholesale distributor at any one time.

2322 (e) A wholesale distributor must notify the department when
2323 a designated representative leaves the employ of the wholesale

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2324 distributor. Such notice must be provided to the department
2325 within 10 business days after the last day of designated
2326 representative's employment with the wholesale distributor.

2327 (f) A wholesale distributor may not operate under a
2328 prescription drug wholesale distributor permit or an out-of-
2329 state prescription drug wholesale distributor permit for more
2330 than 10 business days after the designated representative leaves
2331 the employ of the wholesale distributor, unless the wholesale
2332 distributor employs another designated representative and
2333 notifies the department within 10 business days of the identity
2334 of the new designated representative.

2335 Section 7. Section 499.01201, Florida Statutes, is amended
2336 to read:

2337 499.01201 Agency for Health Care Administration review and
2338 use of statute and rule violation or compliance data.-
2339 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~
2340 ~~contrary~~, the Agency for Health Care Administration may not:

2341 (1) Review or use any violation or alleged violation of s.
2342 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that
2343 section ~~those sections~~, as a ground for denying or withholding
2344 any payment of a Medicaid reimbursement to a pharmacy licensed
2345 under chapter 465; or

2346 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~
2347 ~~499.01212~~, or any rules adopted under that section ~~these~~
2348 ~~sections~~, as the subject of any audit of Medicaid-related
2349 records held by a pharmacy licensed under chapter 465.

2350 Section 8. Paragraph (d) of subsection (4) and subsection
2351 (6) of section 499.0121, Florida Statutes, are amended to read:

2352 499.0121 Storage and handling of prescription drugs;

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2353 recordkeeping.—The department shall adopt rules to implement
2354 this section as necessary to protect the public health, safety,
2355 and welfare. Such rules shall include, but not be limited to,
2356 requirements for the storage and handling of prescription drugs
2357 and for the establishment and maintenance of prescription drug
2358 distribution records.

2359 (4) EXAMINATION OF MATERIALS AND RECORDS.—

2360 (d) Upon receipt, a wholesale distributor must review
2361 records required under this section for the acquisition of
2362 prescription drugs for accuracy and completeness, considering
2363 the total facts and circumstances surrounding the transactions
2364 and the wholesale distributors involved. ~~This includes~~
2365 ~~authenticating each transaction listed on a pedigree paper, as~~
2366 ~~defined in s. 499.003(37).~~

2367 (6) RECORDKEEPING.—The department shall adopt rules that
2368 require keeping such records of prescription drugs, including
2369 active pharmaceutical ingredients, as are necessary for the
2370 protection of the public health.

2371 (a) ~~Wholesale Distributors~~ of prescription drugs and active
2372 pharmaceutical ingredients must establish and maintain
2373 inventories and records of all transactions regarding the
2374 receipt and distribution or other disposition of prescription
2375 drugs and active pharmaceutical ingredients. These records must
2376 provide a complete audit trail from receipt to sale or other
2377 disposition, be readily retrievable for inspection, and include,
2378 at a minimum, the following information:

2379 1. The source of the prescription drugs or active
2380 pharmaceutical ingredients, including the name and principal
2381 address of the seller or transferor, and the address of the

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2382 location from which the prescription drugs were shipped;

2383 2. The name, principal address, and state license permit or
2384 registration number of the person authorized to purchase
2385 prescription drugs or active pharmaceutical ingredients;

2386 3. The name, strength, dosage form, and quantity of the
2387 prescription drugs received and distributed or disposed of;

2388 4. The dates of receipt and distribution or other
2389 disposition of the prescription drugs or active pharmaceutical
2390 ingredients; and

2391 5. Any financial documentation supporting the transaction.

2392 (b) Inventories and records must be made available for
2393 inspection and photocopying by authorized federal, state, or
2394 local officials for a period of 2 years following disposition of
2395 the drugs or 3 years after the creation of the records,
2396 whichever period is longer.

2397 (c) Records described in this section that are kept at the
2398 inspection site or that can be immediately retrieved by computer
2399 or other electronic means must be readily available for
2400 authorized inspection during the retention period. Records that
2401 are kept at a central location outside of this state and that
2402 are not electronically retrievable must be made available for
2403 inspection within 2 working days after a request by an
2404 authorized official of a federal, state, or local law
2405 enforcement agency. Records that are maintained at a central
2406 location within this state must be maintained at an
2407 establishment that is permitted pursuant to this part and must
2408 be readily available.

2409 (d) Each manufacturer or repackager of medical devices,
2410 over-the-counter drugs, or cosmetics must maintain records that

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2411 include the name and principal address of the seller or
2412 transferor of the product, the address of the location from
2413 which the product was shipped, the date of the transaction, the
2414 name and quantity of the product involved, and the name and
2415 principal address of the person who purchased the product.

2416 ~~(c) When pedigree papers are required by this part, a~~
2417 ~~wholesale distributor must maintain the pedigree papers separate~~
2418 ~~and distinct from other records required under this part.~~

2419 Section 9. Subsections (1), (3), (4), and (6) of section
2420 499.015, Florida Statutes, are amended to read:

2421 499.015 Registration of drugs, devices, and cosmetics;
2422 issuance of certificates of free sale.—

2423 (1) (a) Except for those persons exempted from the
2424 definition of manufacturer in s. 499.003, any person who
2425 manufactures, packages, repackages, labels, or relabels a drug
2426 or a ~~device, or cosmetic~~ in this state must register such drug
2427 or ~~device, or cosmetic~~ biennially with the department; pay a
2428 fee in accordance with the fee schedule provided by s. 499.041;
2429 and comply with this section. The registrant must list each
2430 separate and distinct drug or ~~device, or cosmetic~~ at the time
2431 of registration.

2432 (b) Any person who manufactures, packages, repackages,
2433 labels, or relabels a cosmetic in this state may voluntarily
2434 register such cosmetic biennially with the department. A person
2435 registering a cosmetic must submit a completed application to
2436 register the cosmetic, pay a fee in accordance with the fee
2437 schedule provided by s. 499.041, comply with the provisions of
2438 this section, and must list each separate and distinct cosmetic
2439 at the time of registration.

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2440 (c) ~~(b)~~ The department may not register any product that
2441 does not comply with the Federal Food, Drug, and Cosmetic Act,
2442 as amended, or Title 21 C.F.R. Registration of a product by the
2443 department does not mean that the product does in fact comply
2444 with all provisions of the Federal Food, Drug, and Cosmetic Act,
2445 as amended.

2446 (d) A person may not register a product with the department
2447 if that person is not legally authorized to manufacture,
2448 package, repackage, label, or relabel the product in this state.

2449 (3) Except for those persons exempted from the definition
2450 of manufacturer in s. 499.003, a person may not sell any product
2451 that he or she has failed to register in conformity with this
2452 section. Such failure to register subjects such drug or ~~device~~
2453 ~~or cosmetic product~~ to seizure and condemnation as provided in
2454 s. 499.062, and subjects such person to the penalties and
2455 remedies provided in this part.

2456 (4) Unless a registration is renewed, it expires 2 years
2457 after the last day of the month in which it was issued. Any
2458 product registration issued or renewed on or after July 1, 2016,
2459 shall expire on the same date as the manufacturer or repackager
2460 permit of the person seeking to register the product. If the
2461 first product registration issued to a person on or after July
2462 1, 2016, expires less than 366 days after issuance, the fee for
2463 product registration shall be \$15. If the first product
2464 registration issued to a person on or after July 1, 2016,
2465 expires more than 365 days after issuance, the fee for product
2466 registration shall be \$30. The department may issue a stop-sale
2467 notice or order against a person that is subject to the
2468 requirements of this section and that fails to comply with this

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2469 section within 31 days after the date the registration expires.
2470 The notice or order shall prohibit such person from selling or
2471 causing to be sold any drugs, devices, or cosmetics covered by
2472 this part until he or she complies with the requirements of this
2473 section.

2474 (6) The department may only issue a certificate of free
2475 sale for any product that is ~~required to be~~ registered under
2476 this part.

2477 Section 10. Subsection (1) of section 499.03, Florida
2478 Statutes, is amended to read:

2479 499.03 Possession of certain drugs without prescriptions
2480 unlawful; exemptions and exceptions.—

2481 (1) A person may not possess, or possess with intent to
2482 sell, dispense, or deliver, any habit-forming, toxic, harmful,
2483 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or
2484 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,
2485 unless the possession of the drug has been obtained by a valid
2486 prescription of a practitioner licensed by law to prescribe the
2487 drug. However, this section does not apply to the delivery of
2488 such drugs to persons included in any of the classes named in
2489 this subsection, or to the agents or employees of such persons,
2490 for use in the usual course of their businesses or practices or
2491 in the performance of their official duties, as the case may be;
2492 nor does this section apply to the possession of such drugs by
2493 those persons or their agents or employees for such use:

2494 (a) A licensed pharmacist or any person under the licensed
2495 pharmacist's supervision while acting within the scope of the
2496 licensed pharmacist's practice;

2497 (b) A licensed practitioner authorized by law to prescribe

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2498 prescription drugs or any person under the licensed
 2499 practitioner's supervision while acting within the scope of the
 2500 licensed practitioner's practice;

2501 (c) A qualified person who uses prescription drugs for
 2502 lawful research, teaching, or testing, and not for resale;

2503 (d) A licensed hospital or other institution that procures
 2504 such drugs for lawful administration or dispensing by
 2505 practitioners;

2506 (e) An officer or employee of a federal, state, or local
 2507 government; or

2508 (f) A person that holds a valid permit issued by the
 2509 department pursuant to this part which authorizes that person to
 2510 possess prescription drugs.

2511 Section 11. Paragraphs (i) through (p) of subsection (1) of
 2512 section 499.05, Florida Statutes, are amended to read:

2513 499.05 Rules.—

2514 (1) The department shall adopt rules to implement and
 2515 enforce this chapter with respect to:

2516 (i) Additional conditions that qualify as an emergency
 2517 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.
 2518 499.82.

2519 ~~(j) Procedures and forms relating to the pedigree paper~~
 2520 ~~requirement of s. 499.01212.~~

2521 (j) ~~(k)~~ The protection of the public health, safety, and
 2522 welfare regarding good manufacturing practices that
 2523 manufacturers and repackagers must follow to ensure the safety
 2524 of the products.

2525 (k) ~~(l)~~ Information required from each retail establishment
 2526 pursuant to s. 499.012(3) or s. 499.83(2)(c), including

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2527 requirements for prescriptions or orders.

2528 (l)~~(m)~~ The recordkeeping, storage, and handling with
2529 respect to each of the distributions of prescription drugs
2530 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.
2531 499.82(14).

2532 ~~(n) Alternatives to compliance with s. 499.01212 for a~~
2533 ~~prescription drug in the inventory of a permitted prescription~~
2534 ~~drug wholesale distributor as of June 30, 2006, and the return~~
2535 ~~of a prescription drug purchased prior to July 1, 2006. The~~
2536 ~~department may specify time limits for such alternatives.~~

2537 (m)~~(o)~~ Wholesale distributor reporting requirements of s.
2538 499.0121(14).

2539 (n)~~(p)~~ Wholesale distributor credentialing and distribution
2540 requirements of s. 499.0121(15).

2541 Section 12. Subsection (7) of section 499.051, Florida
2542 Statutes, is amended to read:

2543 499.051 Inspections and investigations.—

2544 (7) The complaint and all information obtained pursuant to
2545 the investigation by the department are confidential and exempt
2546 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution
2547 until the investigation and the enforcement action are
2548 completed. However, trade secret information contained therein
2549 as defined by s. 812.081(1)(c) shall remain confidential and
2550 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I
2551 of the State Constitution, as long as the information is
2552 retained by the department. This subsection does not prohibit
2553 the department from using such information for regulatory or
2554 enforcement proceedings under this chapter or from providing
2555 such information to any law enforcement agency or any other

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2556 regulatory agency. However, the receiving agency shall keep such
2557 records confidential and exempt as provided in this subsection.
2558 ~~In addition, this subsection is not intended to prevent~~
2559 ~~compliance with the provisions of s. 499.01212, and the pedigree~~
2560 ~~papers required in that section shall not be deemed a trade~~
2561 ~~secret.~~

2562 Section 13. Subsection (8) is added to section 499.066,
2563 Florida Statutes, to read:

2564 499.066 Penalties; remedies.—In addition to other penalties
2565 and other enforcement provisions:

2566 (8) (a) The department shall adopt rules to permit the
2567 issuance of remedial, nondisciplinary citations. A citation
2568 shall be issued to the person alleged to have committed a
2569 violation and contain the person's name, address, and license
2570 number, if applicable, a brief factual statement, the sections
2571 of the law allegedly violated, and the monetary assessment and
2572 or other remedial measures imposed. The citation must clearly
2573 state that the person may choose, in lieu of accepting the
2574 citation, to have the department rescind the citation and
2575 conduct an investigation pursuant to s. 499.051. If the person
2576 does not dispute the matter in the citation with the department
2577 within 30 days after the citation is served, the citation
2578 becomes a final order and does not constitute discipline.

2579 (b) The department shall adopt rules designating violations
2580 for which a citation may be issued. The rules shall designate as
2581 citable those violations for which there is no substantial
2582 threat to the public health, safety, or welfare.

2583 (c) The department is entitled to recover the costs of
2584 investigation, in addition to any penalty provided according to

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2585 department rule, as part of the penalty levied pursuant to the
2586 citation.

2587 (d) A citation must be issued within 12 months after the
2588 filing of the complaint that is the basis for the citation.

2589 (e) Service of a citation may be made by personal service
2590 or certified mail, restricted delivery, to the person at the
2591 person's last known address of record with the department or to
2592 the person's Florida registered agent.

2593 (f) The department has authority to, and shall adopt rules
2594 to, designate those violations for which a person is subject to
2595 the issuance of a citation and designate the monetary
2596 assessments and or other remedial measures that must be taken
2597 for those violations. The department has continuous authority to
2598 amend its rules adopted pursuant to this section.

2599 Section 14. Subsection (14) of section 499.82, Florida
2600 Statutes, is amended to read:

2601 499.82 Definitions.—As used in this part, the term:

2602 (14) "Wholesale distribution" means the distribution of
2603 medical gas to a person other than a consumer or patient.
2604 Wholesale distribution of medical gases does not include:

2605 (a) The sale, purchase, or trade of a medical gas; an offer
2606 to sell, purchase, or trade a medical gas; or the dispensing of
2607 a medical gas pursuant to a prescription;

2608 (b) Activities exempt from the definition of wholesale
2609 distribution in s. 499.003; or

2610 (c) The sale, purchase, or trade of a medical gas or an
2611 offer to sell, purchase, or trade a medical gas for emergency
2612 medical reasons; ~~or~~

2613 ~~(d) Other transactions excluded from the definition of~~

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2614 ~~wholesale distribution under the federal act or regulations~~
2615 ~~implemented under the federal act related to medical gas.~~

2616 Section 15. Subsection (4) of section 499.89, Florida
2617 Statutes, is amended to read:

2618 499.89 Recordkeeping.—

2619 ~~(4) A pedigree paper is not required for distributing or~~
2620 ~~dispensing medical gas.~~

2621 Section 16. Section 499.01212, Florida Statutes, is
2622 repealed.

2623 Section 17. Paragraph (a) of subsection (1) of section
2624 409.9201, Florida Statutes, is amended to read:

2625 409.9201 Medicaid fraud.—

2626 (1) As used in this section, the term:

2627 (a) "Prescription drug" means any drug, including, but not
2628 limited to, finished dosage forms or active ingredients that are
2629 subject to, defined in, or described in s. 503(b) of the Federal
2630 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)
2631 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2632
2633 The value of individual items of the legend drugs or goods or
2634 services involved in distinct transactions committed during a
2635 single scheme or course of conduct, whether involving a single
2636 person or several persons, may be aggregated when determining
2637 the punishment for the offense.

2638 Section 18. Paragraph (b) of subsection (1) of section
2639 499.067, Florida Statutes, is amended to read:

2640 499.067 Denial, suspension, or revocation of permit,
2641 certification, or registration.—

2642 (1)

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2643 (b) The department may deny an application for a permit or
2644 certification, or suspend or revoke a permit or certification,
2645 if the department finds that:

2646 1. The applicant is not of good moral character or that it
2647 would be a danger or not in the best interest of the public
2648 health, safety, and welfare if the applicant were issued a
2649 permit or certification.

2650 2. The applicant has not met the requirements for the
2651 permit or certification.

2652 3. The applicant is not eligible for a permit or
2653 certification for any of the reasons enumerated in s. 499.012.

2654 4. The applicant, permittee, or person certified under s.
2655 499.012(15) ~~s. 499.012(16)~~ demonstrates any of the conditions
2656 enumerated in s. 499.012.

2657 5. The applicant, permittee, or person certified under s.
2658 499.012(15) ~~s. 499.012(16)~~ has committed any violation of this
2659 chapter.

2660 Section 19. Subsection (1) of section 794.075, Florida
2661 Statutes, is amended to read:

2662 794.075 Sexual predators; erectile dysfunction drugs.—

2663 (1) A person may not possess a prescription drug, as
2664 defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of
2665 treating erectile dysfunction if the person is designated as a
2666 sexual predator under s. 775.21.

2667 Section 20. Paragraphs (d), (f), (i), and (j) of subsection
2668 (3) of section 921.0022, Florida Statutes, are amended to read:

2669 921.0022 Criminal Punishment Code; offense severity ranking
2670 chart.—

2671 (3) OFFENSE SEVERITY RANKING CHART

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2672 (d) LEVEL 4

2673

2674

Florida Statute	Felony Degree	Description
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2675

316.1935 (3) (a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
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2676

499.0051 (1)	3rd	Failure to maintain or deliver <u>transaction history,</u> <u>transaction information,</u> or <u>transaction statements</u> pedigree papers.
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2677

499.0051 (2)	3rd	Failure to authenticate pedigree papers.
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2678

<u>499.0051 (5)</u> 499.0051 (6)	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
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2679

517.07 (1)	3rd	Failure to register securities.
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2680

517.12 (1)	3rd	Failure of dealer, associated
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			person, or issuer of securities to register.
2681	784.07 (2) (b)	3rd	Battery of law enforcement officer, firefighter, etc.
2682	784.074 (1) (c)	3rd	Battery of sexually violent predators facility staff.
2683	784.075	3rd	Battery on detention or commitment facility staff.
2684	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
2685	784.08 (2) (c)	3rd	Battery on a person 65 years of age or older.
2686	784.081 (3)	3rd	Battery on specified official or employee.
2687	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
2688	784.083 (3)	3rd	Battery on code inspector.
2689	784.085	3rd	Battery of child by throwing, tossing, projecting, or

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2690

expelling certain fluids or materials.

787.03(1)

3rd

Interference with custody; wrongly takes minor from appointed guardian.

2691

787.04(2)

3rd

Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.

2692

787.04(3)

3rd

Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.

2693

787.07

3rd

Human smuggling.

2694

790.115(1)

3rd

Exhibiting firearm or weapon within 1,000 feet of a school.

2695

790.115(2)(b)

3rd

Possessing electric weapon or device, destructive device, or other weapon on school property.

2696

790.115(2)(c)

3rd

Possessing firearm on school

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			property.
2697	800.04 (7) (c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
2698	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
2699	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
2700	810.06	3rd	Burglary; possession of tools.
2701	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
2702	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
2703	812.014 (2) (c) 4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
2704	812.0195 (2)	3rd	Dealing in stolen property by

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2705			use of the Internet; property stolen \$300 or more.
	817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
2706			
	817.568(2)(a)	3rd	Fraudulent use of personal identification information.
2707			
	817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
2708			
	828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
2709			
	837.02(1)	3rd	Perjury in official proceedings.
2710			
	837.021(1)	3rd	Make contradictory statements in official proceedings.
2711			
	838.022	3rd	Official misconduct.
2712			
	839.13(2)(a)	3rd	Falsifying records of an individual in the care and

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2713			custody of a state agency.
	839.13(2)(c)	3rd	Falsifying records of the Department of Children and Families.
2714			
	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
2715			
	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
2716			
	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
2717			
	847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
2718			
	874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
2719			
	893.13(2)(a)1.	2nd	Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d),

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(2) (a), (2) (b), or (2) (c) 4.
drugs).

2720

914.14 (2) 3rd Witnesses accepting bribes.

2721

914.22 (1) 3rd Force, threaten, etc., witness,
victim, or informant.

2722

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

2723

918.12 3rd Tampering with jurors.

2724

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

2725

2726 (f) LEVEL 6

2727

2728

Florida	Felony	Description
Statute	Degree	

2729

316.027 (2) (b)	2nd	Leaving the scene of a crash involving serious bodily injury.
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2730

316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent
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2731			conviction.
	400.9935 (4) (c)	2nd	Operating a clinic, or offering services requiring licensure, without a license.
2732	<u>499.0051 (2)</u> 499.0051 (3)	2nd	Knowing forgery of <u>transaction history, transaction information, or transaction statement</u> pedigree papers .
2733	<u>499.0051 (3)</u> 499.0051 (4)	2nd	Knowing purchase or receipt of prescription drug from unauthorized person.
2734	<u>499.0051 (4)</u> 499.0051 (5)	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
2735	775.0875 (1)	3rd	Taking firearm from law enforcement officer.
2736	784.021 (1) (a)	3rd	Aggravated assault; deadly weapon without intent to kill.
2737	784.021 (1) (b)	3rd	Aggravated assault; intent to commit felony.
2738	784.041	3rd	Felony battery; domestic

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			battery by strangulation.
2739	784.048 (3)	3rd	Aggravated stalking; credible threat.
2740	784.048 (5)	3rd	Aggravated stalking of person under 16.
2741	784.07 (2) (c)	2nd	Aggravated assault on law enforcement officer.
2742	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
2743	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
2744	784.081 (2)	2nd	Aggravated assault on specified official or employee.
2745	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
2746	784.083 (2)	2nd	Aggravated assault on code inspector.
2747	787.02 (2)	3rd	False imprisonment; restraining

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			with purpose other than those in s. 787.01.
2748	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
2749	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
2750	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
2751	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
2752	794.011 (8) (a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
2753	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
2754	800.04 (5) (d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older

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2755			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.
2756			
	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
2757			
	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
2758			
	810.145 (8) (b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
2759			
	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
2760			
	812.014 (6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.
2761			
	812.015 (9) (a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.

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2762

812.015 (9) (b) 2nd Retail theft; property stolen
\$3,000 or more; coordination of
others.

2763

812.13 (2) (c) 2nd Robbery, no firearm or other
weapon (strong-arm robbery).

2764

817.4821 (5) 2nd Possess cloning paraphernalia
with intent to create cloned
cellular telephones.

2765

825.102 (1) 3rd Abuse of an elderly person or
disabled adult.

2766

825.102 (3) (c) 3rd Neglect of an elderly person or
disabled adult.

2767

825.1025 (3) 3rd Lewd or lascivious molestation
of an elderly person or
disabled adult.

2768

825.103 (3) (c) 3rd Exploiting an elderly person or
disabled adult and property is
valued at less than \$10,000.

2769

827.03 (2) (c) 3rd Abuse of a child.

2770

827.03 (2) (d) 3rd Neglect of a child.

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2771

827.071(2) & (3) 2nd Use or induce a child in a sexual performance, or promote or direct such performance.

2772

836.05 2nd Threats; extortion.

2773

836.10 2nd Written threats to kill or do bodily injury.

2774

843.12 3rd Aids or assists person to escape.

2775

847.011 3rd Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.

2776

847.012 3rd Knowingly using a minor in the production of materials harmful to minors.

2777

847.0135(2) 3rd Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.

2778

914.23 2nd Retaliation against a witness, victim, or informant, with bodily injury.

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2779

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 bodily harm.

2780

944.40 2nd Escapes.

2781

944.46 3rd Harboring, concealing, aiding escaped prisoners.

2782

944.47 (1) (a) 5. 2nd Introduction of contraband (firearm, weapon, or explosive) into correctional facility.

2783

951.22 (1) 3rd Intoxicating drug, firearm, or weapon introduced into county facility.

2784

2785 (i) LEVEL 9

2786

Florida	Felony	
Statute	Degree	Description

2787

316.193	1st	DUI manslaughter; failing to render aid or give information.
(3) (c) 3.b.		

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2788	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
2789	409.920 (2) (b) 1.c.	1st	Medicaid provider fraud; \$50,000 or more.
2790	<u>499.0051 (8)</u> 499.0051 (9)	1st	Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.
2791	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
2792	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
2793	655.50 (10) (b) 3.	1st	Failure to report financial transactions

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2794	775.0844	1st	totaling or exceeding \$100,000 by financial institution.
2795	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
2796	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.
2797	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3).
2798	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.

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2799

787.01 (1) (a) 1. 1st, PBL Kidnapping; hold for
ransom or reward or as a
shield or hostage.

2800

787.01 (1) (a) 2. 1st, PBL Kidnapping with intent to
commit or facilitate
commission of any felony.

2801

787.01 (1) (a) 4. 1st, PBL Kidnapping with intent to
interfere with
performance of any
governmental or political
function.

2802

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.

2803

787.06 (3) (c) 1. 1st Human trafficking for
labor and services of an
unauthorized alien child.

2804

787.06 (3) (d) 1st Human trafficking using

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2805

787.06(3)(f)1.

1st,PBL

coercion for commercial sexual activity of an unauthorized adult alien.

2806

790.161

1st

Human trafficking for commercial sexual activity by the transfer or transport of any child from outside Florida to within the state.

2807

790.166(2)

1st,PBL

Attempted capital destructive device offense.

2808

794.011(2)

1st

Possessing, selling, using, or attempting to use a weapon of mass destruction.

2809

794.011(2)

Life

Attempted sexual battery; victim less than 12 years of age.
Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.

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2810

794.011 (4) (a) 1st, PBL Sexual battery, certain
circumstances; victim 12
years of age or older but
younger than 18 years;
offender 18 years or
older.

2811

794.011 (4) (b) 1st Sexual battery, certain
circumstances; victim and
offender 18 years of age
or older.

2812

794.011 (4) (c) 1st Sexual battery, certain
circumstances; victim 12
years of age or older;
offender younger than 18
years.

2813

794.011 (4) (d) 1st, PBL Sexual battery, certain
circumstances; victim 12
years of age or older;
prior conviction for
specified sex offenses.

2814

794.011 (8) (b) 1st, PBL Sexual battery; engage in
sexual conduct with minor
12 to 18 years by person
in familial or custodial

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2815			authority.
	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
2816			
	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
2817			
	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
2818			
	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
2819			
	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
2820			
	817.535 (3) (b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; property owner is a public officer or employee.
2821			

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2822	817.535 (4) (a) 2.	1st	Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.
2823	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.
2824	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.
2825	827.03 (2) (a)	1st	Aggravated child abuse.
2825	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.

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2826	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
2827	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.
2828	893.135	1st	Attempted capital trafficking offense.
2829	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
2830	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
2831	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
2832	893.135	1st	Trafficking in

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	(1) (c) 2.d.		hydrocodone, 200 grams or more, less than 30 kilograms.
2833	893.135	1st	Trafficking in oxycodone, 100 grams or more, less than 30 kilograms.
	(1) (c) 3.d.		
2834	893.135	1st	Trafficking in phencyclidine, more than 400 grams.
	(1) (d) 1.c.		
2835	893.135	1st	Trafficking in methaqualone, more than 25 kilograms.
	(1) (e) 1.c.		
2836	893.135	1st	Trafficking in amphetamine, more than 200 grams.
	(1) (f) 1.c.		
2837	893.135	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
	(1) (h) 1.c.		
2838	893.135	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
	(1) (j) 1.c.		
2839			

2840	21-01087-16	20161604__	1st	Trafficking in Phenethylamines, 400 grams or more.
	893.135 (1) (k) 2.c.			
2841	896.101 (5) (c)		1st	Money laundering, financial instruments totaling or exceeding \$100,000.
2842	896.104 (4) (a) 3.		1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
2843	(j) LEVEL 10			
2844	Florida Statute		Felony Degree	Description
2845	<u>499.0051 (9)</u> 499.0051 (10)		1st	Knowing sale or purchase of contraband prescription drugs resulting in death.
2846	782.04 (2)		1st, PBL	Unlawful killing of human; act is homicide, unpremeditated.

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2847

782.07 (3) 1st Aggravated manslaughter of a child.

2848

787.01 (1) (a) 3. 1st, PBL Kidnapping; inflict bodily harm upon or terrorize victim.

2849

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.

2850

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.

2851

787.06 (4) (a) Life Selling or buying of minors into human trafficking.

2852

794.011 (3) Life Sexual battery; victim 12 years or older,

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offender uses or
threatens to use deadly
weapon or physical force
to cause serious injury.

2853

812.135 (2) (a)

1st, PBL

Home-invasion robbery
with firearm or other
deadly weapon.

2854

876.32

1st

Treason against the
state.

2855

2856

2857

Section 21. This act shall take effect July 1, 2016.