

By the Committee on Health Policy; and 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.; providing for the expiration, renewal,
68 and issuance of certain drug, device, and cosmetic
69 product registrations; providing for product
70 registration fees; amending ss. 499.03, 499.05, and
71 499.051, F.S.; conforming provisions to changes made
72 by the act; amending s. 499.066, F.S.; authorizing the
73 issuance of nondisciplinary citations; authorizing the
74 department to adopt rules designating violations for
75 which a citation may be issued; authorizing the
76 department to recover investigative costs pursuant to
77 the citation; specifying a time limitation for
78 issuance of a citation; providing for service of a
79 citation; amending s. 499.82, F.S.; revising the
80 definition of "wholesale distribution" for purposes of
81 medical gas requirements; amending s. 499.89, F.S.;
82 conforming provisions; repealing s. 499.01212, F.S.,
83 relating to pedigree papers; amending ss. 409.9201,
84 499.067, 794.075, and 921.0022, F.S.; conforming
85 cross-references; providing an effective date.

86

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

88

89 Section 1. Section 499.003, Florida Statutes, is amended to
90 read:

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91 499.003 Definitions of terms used in this part.—As used in
92 this part, the term:

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

101 (2)~~(1)~~ "Advertisement" means any representation
102 disseminated in any manner or by any means, other than by
103 labeling, for the purpose of inducing, or which is likely to
104 induce, directly or indirectly, the purchase of drugs, devices,
105 or cosmetics.

106 (3) "Affiliate" means a business entity that has a
107 relationship with another business entity in which, directly or
108 indirectly:

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

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

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

119 (4)~~(3)~~ "Affiliated party" means:

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120 (a) A director, officer, trustee, partner, or committee
121 member of a permittee or applicant or a subsidiary or service
122 corporation of the permittee or applicant;

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

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

132 (d) The five largest natural shareholders that own at least
133 5 percent of the permittee or applicant.

134 (5)~~(4)~~ "Applicant" means a person applying for a permit or
135 certification under this part.

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

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

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

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

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

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

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

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

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

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

171 (11) "Contraband prescription drug" means any adulterated
172 drug, as defined in s. 499.006, any counterfeit drug, as defined
173 in this section, and also means any prescription drug for which
174 a transaction history, transaction information, or transaction
175 statement ~~pedigree paper~~ does not exist, or for which the
176 transaction history, transaction information, or transaction
177 statement ~~pedigree paper~~ in existence has been forged,

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178 counterfeited, falsely created, or contains any altered, false,
179 or misrepresented matter.

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

182 (a) Intended to be rubbed, poured, sprinkled, or sprayed
183 on; introduced into; or otherwise applied to the human body or
184 any part thereof for cleansing, beautifying, promoting
185 attractiveness, or altering the appearance; or

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

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

199 (14) "Department" means the Department of Business and
200 Professional Regulation.

201 (15) "Device" means any instrument, apparatus, implement,
202 machine, contrivance, implant, in vitro reagent, or other
203 similar or related article, including its components, parts, or
204 accessories, which is:

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

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207 (b) Intended for use in the diagnosis, cure, mitigation,
208 treatment, therapy, or prevention of disease in humans or other
209 animals, or

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

212

213 and that does not achieve any of its principal intended purposes
214 through chemical action within or on the body of humans or other
215 animals and which is not dependent upon being metabolized for
216 the achievement of any of its principal intended purposes.

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

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

232 (17)~~(18)~~ "Drug" means an article that is:

233 (a) Recognized in the current edition of the United States
234 Pharmacopoeia and National Formulary, official Homeopathic
235 Pharmacopoeia of the United States, or any supplement to any of

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236 those publications;

237 (b) Intended for use in the diagnosis, cure, mitigation,
238 treatment, therapy, or prevention of disease in humans or other
239 animals;

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

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

255 (18)~~(19)~~ "Establishment" means a place of business which is
256 at one general physical location and may extend to one or more
257 contiguous suites, units, floors, or buildings operated and
258 controlled exclusively by entities under common operation and
259 control. Where multiple buildings are under common exclusive
260 ownership, operation, and control, an intervening thoroughfare
261 does not affect the contiguous nature of the buildings. For
262 purposes of permitting, each suite, unit, floor, or building
263 must be identified in the most recent permit application.

264 (19)~~(20)~~ "Federal act" means the Federal Food, Drug, and

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265 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

266 ~~(20)(21)~~ "Freight forwarder" means a person who receives
267 prescription drugs which are owned by another person and
268 designated by that person for export, and exports those
269 prescription drugs.

270 ~~(21)(22)~~ "Health care entity" means a closed pharmacy or
271 any person, organization, or business entity that provides
272 diagnostic, medical, surgical, or dental treatment or care, or
273 chronic or rehabilitative care, but does not include any
274 wholesale distributor or retail pharmacy licensed under state
275 law to deal in prescription drugs. However, a blood
276 establishment is a health care entity that may engage in the
277 wholesale distribution of prescription drugs under s.
278 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

279 ~~(22)(23)~~ "Health care facility" means a health care
280 facility licensed under chapter 395.

281 ~~(23)(24)~~ "Hospice" means a corporation licensed under part
282 IV of chapter 400.

283 ~~(24)(25)~~ "Hospital" means a facility as defined in s.
284 395.002 and licensed under chapter 395.

285 ~~(25)(26)~~ "Immediate container" does not include package
286 liners.

287 ~~(26)(27)~~ "Label" means a display of written, printed, or
288 graphic matter upon the immediate container of any drug, device,
289 or cosmetic. A requirement made by or under authority of this
290 part or rules adopted under this part that any word, statement,
291 or other information appear on the label is not complied with
292 unless such word, statement, or other information also appears
293 on the outside container or wrapper, if any, of the retail

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294 package of such drug, device, or cosmetic or is easily legible
295 through the outside container or wrapper.

296 ~~(27)~~~~(28)~~ "Labeling" means all labels and other written,
297 printed, or graphic matters:

298 (a) Upon a drug, device, or cosmetic, or any of its
299 containers or wrappers; or

300 (b) Accompanying or related to such drug, device, or
301 cosmetic.

302 ~~(28)~~~~(29)~~ "Manufacture" means the preparation, deriving,
303 compounding, propagation, processing, producing, or fabrication
304 of any drug, device, or cosmetic.

305 ~~(29)~~~~(30)~~ "Manufacturer" means:

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

315 (b) A co-licensed partner of the person described in
316 paragraph (a) who obtains the drug or biologics directly from a
317 person described in paragraph (a), paragraph (c), or this
318 paragraph ~~The holder or holders of a New Drug Application (NDA),~~
319 ~~an Abbreviated New Drug Application (ANDA), a Biologics License~~
320 ~~Application (BLA), or a New Animal Drug Application (NADA),~~
321 ~~provided such application has become effective or is otherwise~~
322 ~~approved consistent with s. 499.023;~~

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

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

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

349 ~~(f) A person permitted as a third party logistics provider,~~
350 ~~only while providing warehousing, distribution, or other~~
351 ~~logistics services on behalf of a person described in paragraph~~

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352 ~~(a), paragraph (b), paragraph (c), paragraph (d), or paragraph~~
353 ~~(e).~~

354

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

358 (30)~~(31)~~ "Medical convenience kit" means packages or units
359 that contain combination products as defined in 21 C.F.R. s.
360 3.2(e)(2).

361 (31)~~(32)~~ "Medical gas" means any liquefied or vaporized gas
362 that is a prescription drug, whether alone or in combination
363 with other gases, and as defined in the federal act.

364 (32)~~(33)~~ "New drug" means:

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

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

377 ~~(34) "Normal distribution chain" means a wholesale~~
378 ~~distribution of a prescription drug in which the wholesale~~
379 ~~distributor or its wholly owned subsidiary purchases and~~
380 ~~receives the specific unit of the prescription drug directly~~

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381 ~~from the manufacturer and distributes the prescription drug~~
382 ~~directly, or through up to two intracompany transfers, to a~~
383 ~~chain pharmacy warehouse or a person authorized by law to~~
384 ~~purchase prescription drugs for the purpose of administering or~~
385 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~
386 ~~this subsection, the term "intracompany" means any transaction~~
387 ~~or transfer between any parent, division, or subsidiary wholly~~
388 ~~owned by a corporate entity.~~

389 (33)~~(35)~~ "Nursing home" means a facility licensed under
390 part II of chapter 400.

391 (34)~~(36)~~ "Official compendium" means the current edition of
392 the official United States Pharmacopoeia and National Formulary,
393 or any supplement thereto.

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

398 (35)~~(38)~~ "Permittee" means any person holding a permit
399 issued under this chapter pursuant to s. 499.012.

400 (36)~~(39)~~ "Person" means any individual, child, joint
401 venture, syndicate, fiduciary, partnership, corporation,
402 division of a corporation, firm, trust, business trust, company,
403 estate, public or private institution, association,
404 organization, group, city, county, city and county, political
405 subdivision of this state, other governmental agency within this
406 state, and any representative, agent, or agency of any of the
407 foregoing, or any other group or combination of the foregoing.

408 (37)~~(40)~~ "Pharmacist" means a person licensed under chapter
409 465.

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410 (38)~~(41)~~ "Pharmacy" means an entity licensed under chapter
411 465.

412 (39)~~(42)~~ "Prepackaged drug product" means a drug that
413 originally was in finished packaged form sealed by a
414 manufacturer and that is placed in a properly labeled container
415 by a pharmacy or practitioner authorized to dispense pursuant to
416 chapter 465 for the purpose of dispensing in the establishment
417 in which the prepackaging occurred.

418 (40)~~(43)~~ "Prescription drug" means a prescription,
419 medicinal, or legend drug, including, but not limited to,
420 finished dosage forms or active pharmaceutical ingredients
421 subject to, defined by, or described by s. 503(b) of the federal
422 act or s. 465.003(8), s. 499.007(13), subsection (31) ~~(32)~~, or
423 subsection (47) ~~(52)~~, except that an active pharmaceutical
424 ingredient is a prescription drug only if substantially all
425 finished dosage forms in which it may be lawfully dispensed or
426 administered in this state are also prescription drugs.

427 (41)~~(44)~~ "Prescription drug label" means any display of
428 written, printed, or graphic matter upon the immediate container
429 of any prescription drug before it is dispensed ~~prior to its~~
430 ~~dispensing~~ to an individual patient pursuant to a prescription
431 of a practitioner authorized by law to prescribe.

432 (42)~~(45)~~ "Prescription label" means any display of written,
433 printed, or graphic matter upon the immediate container of any
434 prescription drug dispensed pursuant to a prescription of a
435 practitioner authorized by law to prescribe.

436 ~~(46) "Primary wholesale distributor" means any wholesale~~
437 ~~distributor that:~~

438 ~~(a) Purchased 90 percent or more of the total dollar volume~~

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439 ~~of its purchases of prescription drugs directly from~~
440 ~~manufacturers in the previous year; and~~

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

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

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

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

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

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

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

464 ~~(43)-(47)~~ "Proprietary drug," or "OTC drug," means a patent
465 or over-the-counter drug in its unbroken, original package,
466 which drug is sold to the public by, or under the authority of,
467 the manufacturer or primary distributor thereof, is not

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468 misbranded under the provisions of this part, and can be
469 purchased without a prescription.

470 (44)~~(48)~~ "Repackage" includes repacking or otherwise
471 changing the container, wrapper, or labeling to further the
472 distribution of the drug, device, or cosmetic.

473 (45)~~(49)~~ "Repackager" means a person who repackages. The
474 term excludes pharmacies that are operating in compliance with
475 pharmacy practice standards as defined in chapter 465 and rules
476 adopted under that chapter.

477 (46)~~(50)~~ "Retail pharmacy" means a community pharmacy
478 licensed under chapter 465 that purchases prescription drugs at
479 fair market prices and provides prescription services to the
480 public.

481 ~~(51) "Secondary wholesale distributor" means a wholesale
482 distributor that is not a primary wholesale distributor.~~

483 (47)~~(52)~~ "Veterinary prescription drug" means a
484 prescription drug intended solely for veterinary use. The label
485 of the drug must bear the statement, "Caution: Federal law
486 restricts this drug to sale by or on the order of a licensed
487 veterinarian."

488 (48)~~(53)~~ "Wholesale distribution" means the distribution of
489 a prescription drug to a person ~~drugs to persons~~ other than a
490 consumer or patient, or the receipt of a prescription drug by a
491 person other than the consumer or patient, but does not include:

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

495 1. The purchase or other acquisition by a hospital or other
496 health care entity that is a member of a group purchasing

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497 organization of a prescription drug for its own use from the
498 group purchasing organization or from other hospitals or health
499 care entities that are members of that organization.

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

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

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

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

525 b. The contract provider or subcontractor must be

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526 authorized by law to administer or dispense prescription drugs.

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

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

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

550 f. In addition to the departmental inspection authority set
551 forth in s. 499.051, the establishment of the contract provider
552 and subcontractor and all records pertaining to prescription
553 drugs subject to this subparagraph shall be subject to
554 inspection by the agency or entity. All records relating to

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555 prescription drugs of a manufacturer under this subparagraph
556 shall be subject to audit by the manufacturer of those drugs,
557 without identifying individual patient information.

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

561 1. The distribution ~~sale, purchase, or trade~~ of a
562 prescription drug among federal, state, or local government
563 health care entities that are under common control and are
564 authorized to purchase such prescription drug.

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

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

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

581 ~~4.5-~~ The donation of a prescription drug by a health care
582 entity to a charitable organization that has been granted an
583 exemption under s. 501(c) (3) of the Internal Revenue Code of

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584 1986, as amended, and that is authorized to possess prescription
585 drugs.

586 ~~5.6.~~ The distribution ~~transfer~~ of a prescription drug by a
587 person authorized to purchase or receive prescription drugs to a
588 person licensed or permitted to handle reverse distributions or
589 destruction under the laws of the jurisdiction in which the
590 person handling the reverse distribution or destruction receives
591 the drug.

592 ~~6.7.~~ The distribution ~~transfer~~ of a prescription drug by a
593 hospital or other health care entity to a person licensed under
594 this part to repackage prescription drugs for the purpose of
595 repackaging the prescription drug for use by that hospital, or
596 other health care entity and other health care entities that are
597 under common control, if ownership of the prescription drugs
598 remains with the hospital or other health care entity at all
599 times. In addition to the recordkeeping requirements of s.
600 499.0121(6), the hospital or health care entity that distributes
601 ~~transfers~~ prescription drugs pursuant to this subparagraph must
602 reconcile all drugs distributed ~~transferred~~ and returned and
603 resolve any discrepancies in a timely manner.

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

606 (d) The distribution of a prescription drug by the
607 manufacturer of the prescription drug.

608 ~~(e)-(e)~~ The distribution of prescription drug samples by
609 manufacturers' representatives or distributors' representatives
610 conducted in accordance with s. 499.028.

611 (f) The distribution of a prescription drug by a third-
612 party logistics provider permitted or licensed pursuant to and

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613 operating in compliance with the laws of this state and federal
614 law if such third-party logistics provider does not take
615 ownership of the prescription drug.

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

621 (h) The purchase or other acquisition by a dispenser,
622 hospital, or other health care entity of a prescription drug for
623 use by such dispenser, hospital, or other health care entity.

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

633 (j)~~(d)~~ The distribution sale, purchase, or trade of blood
634 and blood components intended for transfusion. As used in this
635 paragraph, the term "blood" means whole blood collected from a
636 single donor and processed for transfusion or further
637 manufacturing, and the term "blood components" means that part
638 of the blood separated by physical or mechanical means.

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

641 (l)~~(f)~~ The distribution sale, purchase, or trade of a

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642 prescription drug between pharmacies as a result of a sale,
643 transfer, merger, or consolidation of all or part of the
644 business of the pharmacies from or with another pharmacy,
645 whether accomplished as a purchase and sale of stock or of
646 business assets.

647 (m) The distribution of minimal quantities of prescription
648 drugs by a licensed retail pharmacy to a licensed practitioner
649 for office use in compliance with chapter 465 and rules adopted
650 thereunder.

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

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

658 (p) The distribution of a prescription drug that is
659 intended for irrigation or sterile water, whether intended for
660 such purposes or for injection.

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

663 (r) A common carrier that transports a prescription drug,
664 if the common carrier does not take ownership of the
665 prescription drug.

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

667 (t) Facilitating the distribution of a prescription drug by
668 providing solely administrative services, including processing
669 of orders and payments.

670 (u) The distribution by a charitable organization described

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671 in s. 501(c)(3) of the Internal Revenue Code of prescription
 672 drugs donated to or supplied at a reduced price to the
 673 charitable organization to:

674 1. A licensed health care practitioner, as defined in s.
 675 456.001, who is authorized under the appropriate practice act to
 676 prescribe and administer prescription drugs;

677 2. A health care clinic establishment permitted pursuant to
 678 chapter 499; or

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

686
 687 if the distributor and the receiving entity receive no direct or
 688 indirect financial benefit other than tax benefits related to
 689 charitable contributions. Distributions under this section that
 690 involve controlled substances must comply with all state and
 691 federal regulations pertaining to the handling of controlled
 692 substances.

693 (v) The distribution of medical gas pursuant to part III of
 694 this chapter.

695 (49) ~~(54)~~ "Wholesale distributor" means a any person, other
 696 than a manufacturer, a manufacturer's co-licensed partner, a
 697 third-party logistics provider, or a repackager, who is engaged
 698 in wholesale distribution ~~of prescription drugs in or into this~~
 699 state, including, but not limited to, manufacturers;

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700 ~~repackagers; own-label distributors; jobbers; private-label~~
701 ~~distributors; brokers; warehouses, including manufacturers' and~~
702 ~~distributors' warehouses, chain drug warehouses, and wholesale~~
703 ~~drug warehouses; independent wholesale drug traders; exporters;~~
704 ~~retail pharmacies; and the agents thereof that conduct wholesale~~
705 ~~distributions.~~

706 Section 2. Subsections (21), (28), and (29) of section
707 499.005, Florida Statutes, are amended to read:

708 499.005 Prohibited acts.—It is unlawful for a person to
709 perform or cause the performance of any of the following acts in
710 this state:

711 (21) The wholesale distribution of any prescription drug
712 that was:

713 (a) Purchased by a public or private hospital or other
714 health care entity; or

715 (b) Donated or supplied at a reduced price to a charitable
716 organization,

717
718 unless the wholesale distribution of the prescription drug is
719 authorized in s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

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

723 ~~(29) The receipt of a prescription drug pursuant to a~~
724 ~~wholesale distribution without having previously received or~~
725 ~~simultaneously receiving a pedigree paper that was attested to~~
726 ~~as accurate and complete by the wholesale distributor as~~
727 ~~required under this part.~~

728 Section 3. Subsections (4) through (17) of section

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729 499.0051, Florida Statutes, are renumbered as subsections (3)
730 through (16), respectively, and subsections (1) and (2), present
731 subsection (3), paragraphs (h) and (i) of present subsection
732 (12), paragraph (d) of present subsection (13), and present
733 subsection (15) of that section are amended, to read:

734 499.0051 Criminal acts.—

735 (1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY,
736 TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE~~
737 ~~PAPERS.~~—

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

748 (b) A person engaged in the ~~wholesale~~ distribution of
749 prescription drugs who fails to acquire a complete and accurate
750 transaction history, transaction information, or transaction
751 statement ~~pedigree papers~~ concerning a prescription drug or
752 contraband prescription drug, as required by this chapter and
753 rules adopted under this chapter, before ~~prior to,~~ or
754 simultaneous with, the receipt of the prescription drug or
755 contraband prescription drug from another person commits a
756 felony of the third degree, punishable as provided in s.
757 775.082, s. 775.083, or s. 775.084.

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

766 ~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS. Effective July~~
767 ~~1, 2006:~~

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

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

782 ~~(2)(3) KNOWING FORGERY OF~~ TRANSACTION HISTORY, TRANSACTION
783 INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS.~~—A person
784 who knowingly forges, counterfeits, or falsely creates any
785 transaction history, transaction information, or transaction
786 statement ~~pedigree paper~~; who falsely represents any factual

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787 matter contained on any transaction history, transaction
788 information, or transaction statement ~~pedigree paper~~; or who
789 knowingly omits to record material information required to be
790 recorded in a transaction history, transaction information, or
791 transaction statement ~~pedigree paper~~, commits a felony of the
792 second degree, punishable as provided in s. 775.082, s. 775.083,
793 or s. 775.084.

794 (11)~~(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE
795 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—
796 Any person who violates any of the following provisions commits
797 a misdemeanor of the second degree, punishable as provided in s.
798 775.082 or s. 775.083; but, if the violation is committed after
799 a conviction of such person under this subsection has become
800 final, such person commits a misdemeanor of the first degree,
801 punishable as provided in s. 775.082 or s. 775.083, or as
802 otherwise provided in this part:

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

808 (i) The possession of any drug in violation of this part,
809 except if the violation relates to a deficiency in transaction
810 histories, transaction information, or transaction statements
811 ~~pedigree papers~~.

812 (12)~~(13)~~ REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING,
813 OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
814 PRESCRIPTION DRUGS.—Any person who violates any of the following
815 provisions commits a felony of the third degree, punishable as

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816 provided in s. 775.082, s. 775.083, or s. 775.084, or as
817 otherwise provided in this part:

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

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

833 Section 4. Section 499.006, Florida Statutes, is amended to
834 read:

835 499.006 Adulterated drug or device.—A drug or device is
836 adulterated, if any of the following apply:

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

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

842 (3) ~~If~~ It is a drug and the methods used in, or the
843 facilities or controls used for, its manufacture, processing,
844 packing, or holding do not conform to, or are not operated or

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845 administered in conformity with, current good manufacturing
846 practices to assure that the drug meets the requirements of this
847 part and that the drug has the identity and strength, and meets
848 the standard of quality and purity, which it purports or is
849 represented to possess.†

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

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

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

873 (7) ~~If~~ It is not subject to subsection (6) and its strength

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874 differs from, or its purity or quality falls below the standard
875 of, that which it purports or is represented to possess.~~†~~

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

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

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

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

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

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

894 Section 5. Section 499.01, Florida Statutes, is amended to
895 read:

896 499.01 Permits.—

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

899 (a) A prescription drug manufacturer;

900 (b) A prescription drug repackager;

901 (c) A nonresident prescription drug manufacturer;

902 (d) A nonresident prescription drug repackager;

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903 (e)~~(d)~~ A prescription drug wholesale distributor;

904 (f)~~(e)~~ An out-of-state prescription drug wholesale

905 distributor;

906 (g)~~(f)~~ A retail pharmacy drug wholesale distributor;

907 (h)~~(g)~~ A restricted prescription drug distributor;

908 (i)~~(h)~~ A complimentary drug distributor;

909 (j)~~(i)~~ A freight forwarder;

910 (k)~~(j)~~ A veterinary prescription drug retail establishment;

911 (l)~~(k)~~ A veterinary prescription drug wholesale

912 distributor;

913 (m)~~(l)~~ A limited prescription drug veterinary wholesale

914 distributor;

915 (n)~~(m)~~ An over-the-counter drug manufacturer;

916 (o)~~(n)~~ A device manufacturer;

917 (p)~~(o)~~ A cosmetic manufacturer;

918 (q)~~(p)~~ A third party logistics provider; or

919 (r)~~(q)~~ A health care clinic establishment.

920 (2) The following permits are established:

921 (a) *Prescription drug manufacturer permit.*—A prescription

922 drug manufacturer permit is required for any person that is a

923 manufacturer of a prescription drug and that manufactures or

924 distributes such prescription drugs in this state.

925 1. A person that operates an establishment permitted as a

926 prescription drug manufacturer may engage in ~~wholesale~~

927 distribution of prescription drugs for which the person is the

928 manufacturer ~~manufactured at that establishment~~ and must comply

929 with s. 499.0121 and all other ~~of the~~ provisions of this part,⁷

930 ~~except s. 499.01212,~~ and the rules adopted under this part,⁷

931 ~~except s. 499.01212, which apply to a wholesale distributor. The~~

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932 department shall adopt rules for issuing a virtual prescription
933 drug manufacturer permit to a person who engages in the
934 manufacture of prescription drugs but does not make or take
935 physical possession of any prescription drugs. The rules adopted
936 by the department under this section may exempt virtual
937 manufacturers from certain establishment, security, and storage
938 requirements set forth in s. 499.0121.

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

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

948 (b) *Prescription drug repackager permit.*—A prescription
949 drug repackager permit is required for any person that
950 repackages a prescription drug in this state.

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

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

959 (c) *Nonresident prescription drug manufacturer permit.*—A
960 nonresident prescription drug manufacturer permit is required

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

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

985 2. Any such person must comply with the licensing or
986 permitting requirements of the jurisdiction in which the
987 establishment is located and the federal act, and any
988 prescription drug distributed ~~product wholesaled~~ into this state
989 must comply with this part. If a person intends to import

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990 prescription drugs from a foreign country into this state, the
991 nonresident prescription drug manufacturer must provide to the
992 department a list identifying each prescription drug it intends
993 to import and document approval by the United States Food and
994 Drug Administration for such importation.

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

1001 1. A nonresident prescription drug repackager must comply
1002 with all of the provisions of this section and the rules adopted
1003 under this section that apply to a prescription drug
1004 manufacturer.

1005 2. A nonresident prescription drug repackager must be
1006 permitted by the department and comply with all appropriate
1007 state and federal good manufacturing practices.

1008 3. A nonresident prescription drug repackager must be
1009 registered as a drug establishment with the United States Food
1010 and Drug Administration.

1011 (e)-~~(d)~~ Prescription drug wholesale distributor permit.-A
1012 prescription drug wholesale distributor permit is required for
1013 any person who is a wholesale distributor of prescription drugs
1014 and that may engage in the wholesale distributes such
1015 distribution of prescription drugs in this state. A prescription
1016 drug wholesale distributor that applies to the department for a
1017 new permit or the renewal of a permit must submit a bond of
1018 \$100,000, or other equivalent means of security acceptable to

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

1035 ~~(f)(e)~~ Out-of-state prescription drug wholesale distributor
1036 permit.-An out-of-state prescription drug wholesale distributor
1037 permit is required for any person that is a wholesale
1038 distributor located outside this state, but within the United
1039 States or its territories, which engages in the wholesale
1040 distribution of prescription drugs into this state ~~and which~~
1041 ~~must be permitted by the department and comply with all the~~
1042 ~~provisions required of a wholesale distributor under this part.~~
1043 ~~An out-of-state prescription drug wholesale distributor that~~
1044 ~~applies to the department for a new permit or the renewal of a~~
1045 ~~permit must submit a bond of \$100,000, or other equivalent means~~
1046 ~~of security acceptable to the department, such as an irrevocable~~
1047 ~~letter of credit or a deposit in a trust account or financial~~

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

1067 ~~(g)(f)~~ *Retail pharmacy drug wholesale distributor permit.*—A
1068 retail pharmacy drug wholesale distributor is a retail pharmacy
1069 engaged in wholesale distribution of prescription drugs within
1070 this state under the following conditions:

1071 1. The pharmacy must obtain a retail pharmacy drug
1072 wholesale distributor permit pursuant to this part and ~~the~~ rules
1073 adopted under this part.

1074 2. The wholesale distribution activity does not exceed 30
1075 percent of the total annual purchases of prescription drugs. If
1076 the wholesale distribution activity exceeds the 30-percent

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1077 maximum, the pharmacy must obtain a prescription drug wholesale
1078 distributor permit.

1079 3. The transfer of prescription drugs that appear in any
1080 schedule contained in chapter 893 is subject to chapter 893 and
1081 the federal Comprehensive Drug Abuse Prevention and Control Act
1082 of 1970.

1083 4. The transfer is between a retail pharmacy and another
1084 retail pharmacy, or a Modified Class II institutional pharmacy,
1085 or a health care practitioner licensed in this state and
1086 authorized by law to dispense or prescribe prescription drugs.

1087 5. All records of sales of prescription drugs subject to
1088 this section must be maintained separate and distinct from other
1089 records and comply with the recordkeeping requirements of this
1090 part.

1091 (h) ~~(g)~~ *Restricted prescription drug distributor permit.*—

1092 1. A restricted prescription drug distributor permit is
1093 required for:

1094 a. Any person located in this state who engages in the
1095 distribution of a prescription drug, which distribution is not
1096 considered "wholesale distribution" under s. 499.003(48)(a)
1097 ~~499.003(53)(a)~~.

1098 b. Any person located in this state who engages in the
1099 receipt or distribution of a prescription drug in this state for
1100 the purpose of processing its return or its destruction if such
1101 person is not the person initiating the return, the prescription
1102 drug wholesale supplier of the person initiating the return, or
1103 the manufacturer of the drug.

1104 c. A blood establishment located in this state which
1105 collects blood and blood components only from volunteer donors

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1106 as defined in s. 381.06014 or pursuant to an authorized
1107 practitioner's order for medical treatment or therapy and
1108 engages in the wholesale distribution of a prescription drug not
1109 described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care
1110 entity. A mobile blood unit operated by a blood establishment
1111 permitted under this sub-subparagraph is not required to be
1112 separately permitted. The health care entity receiving a
1113 prescription drug distributed under this sub-subparagraph must
1114 be licensed as a closed pharmacy or provide health care services
1115 at that establishment. The blood establishment must operate in
1116 accordance with s. 381.06014 and may distribute only:

1117 (I) Prescription drugs indicated for a bleeding or clotting
1118 disorder or anemia;

1119 (II) Blood-collection containers approved under s. 505 of
1120 the federal act;

1121 (III) Drugs that are blood derivatives, or a recombinant or
1122 synthetic form of a blood derivative;

1123 (IV) Prescription drugs that are identified in rules
1124 adopted by the department and that are essential to services
1125 performed or provided by blood establishments and authorized for
1126 distribution by blood establishments under federal law; or

1127 (V) To the extent authorized by federal law, drugs
1128 necessary to collect blood or blood components from volunteer
1129 blood donors; for blood establishment personnel to perform
1130 therapeutic procedures under the direction and supervision of a
1131 licensed physician; and to diagnose, treat, manage, and prevent
1132 any reaction of a volunteer blood donor or a patient undergoing
1133 a therapeutic procedure performed under the direction and
1134 supervision of a licensed physician,

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1135
1136 as long as all of the health care services provided by the blood
1137 establishment are related to its activities as a registered
1138 blood establishment or the health care services consist of
1139 collecting, processing, storing, or administering human
1140 hematopoietic stem cells or progenitor cells or performing
1141 diagnostic testing of specimens if such specimens are tested
1142 together with specimens undergoing routine donor testing. The
1143 blood establishment may purchase and possess the drugs described
1144 in this sub-subparagraph without a health care clinic
1145 establishment permit.

1146 2. Storage, handling, and recordkeeping of these
1147 distributions by a person required to be permitted as a
1148 restricted prescription drug distributor must be in accordance
1149 with the requirements for wholesale distributors under s.
1150 499.0121, ~~but not those set forth in s. 499.01212 if the~~
1151 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~
1152 ~~subparagraph 1.b.~~

1153 3. A person who applies for a permit as a restricted
1154 prescription drug distributor, or for the renewal of such a
1155 permit, must provide to the department the information required
1156 under s. 499.012.

1157 4. The department may adopt rules regarding the
1158 distribution of prescription drugs by hospitals, health care
1159 entities, charitable organizations, other persons not involved
1160 in wholesale distribution, and blood establishments, which rules
1161 are necessary for the protection of the public health, safety,
1162 and welfare.

1163 (i) ~~(h)~~ *Complimentary drug distributor permit.*-A

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1164 complimentary drug distributor permit is required for any person
1165 that engages in the distribution of a complimentary drug,
1166 subject to the requirements of s. 499.028.

1167 (j)~~(i)~~ *Freight forwarder permit.*—A freight forwarder permit
1168 is required for any person that engages in the distribution of a
1169 prescription drug as a freight forwarder unless the person is a
1170 common carrier. The storage, handling, and recordkeeping of such
1171 distributions must comply with the requirements for wholesale
1172 distributors under s. 499.0121, ~~but not those set forth in s.~~
1173 ~~499.01212.~~ A freight forwarder must provide the source of the
1174 prescription drugs with a validated airway bill, bill of lading,
1175 or other appropriate documentation to evidence the exportation
1176 of the product.

1177 (k)~~(j)~~ *Veterinary prescription drug retail establishment*
1178 *permit.*—A veterinary prescription drug retail establishment
1179 permit is required for any person that sells veterinary
1180 prescription drugs to the public but does not include a pharmacy
1181 licensed under chapter 465.

1182 1. The sale to the public must be based on a valid written
1183 order from a veterinarian licensed in this state who has a valid
1184 client-veterinarian relationship with the purchaser's animal.

1185 2. Veterinary prescription drugs may not be sold in excess
1186 of the amount clearly indicated on the order or beyond the date
1187 indicated on the order.

1188 3. An order may not be valid for more than 1 year.

1189 4. A veterinary prescription drug retail establishment may
1190 not purchase, sell, trade, or possess human prescription drugs
1191 or any controlled substance as defined in chapter 893.

1192 5. A veterinary prescription drug retail establishment must

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1193 sell a veterinary prescription drug in the original, sealed
1194 manufacturer's container with all labeling intact and legible.
1195 The department may adopt by rule additional labeling
1196 requirements for the sale of a veterinary prescription drug.

1197 6. A veterinary prescription drug retail establishment must
1198 comply with all of the wholesale distribution requirements of s.
1199 499.0121.

1200 7. Prescription drugs sold by a veterinary prescription
1201 drug retail establishment pursuant to a practitioner's order may
1202 not be returned into the retail establishment's inventory.

1203 (1)~~(*)~~ *Veterinary prescription drug wholesale distributor*
1204 *permit.*—A veterinary prescription drug wholesale distributor
1205 permit is required for any person that engages in the
1206 distribution of veterinary prescription drugs in or into this
1207 state. A veterinary prescription drug wholesale distributor that
1208 also distributes prescription drugs subject to, defined by, or
1209 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1210 Act which it did not manufacture must obtain a permit as a
1211 prescription drug wholesale distributor, an out-of-state
1212 prescription drug wholesale distributor, or a limited
1213 prescription drug veterinary wholesale distributor in lieu of
1214 the veterinary prescription drug wholesale distributor permit. A
1215 veterinary prescription drug wholesale distributor must comply
1216 with the requirements for wholesale distributors under s.
1217 499.0121, ~~but not those set forth in s. 499.01212.~~

1218 (m)~~(l)~~ *Limited prescription drug veterinary wholesale*
1219 *distributor permit.*—Unless engaging in the activities of and
1220 permitted as a prescription drug manufacturer, nonresident
1221 prescription drug manufacturer, prescription drug wholesale

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1222 distributor, or out-of-state prescription drug wholesale
1223 distributor, a limited prescription drug veterinary wholesale
1224 distributor permit is required for any person that engages in
1225 the distribution in or into this state of veterinary
1226 prescription drugs and prescription drugs subject to, defined
1227 by, or described by s. 503(b) of the Federal Food, Drug, and
1228 Cosmetic Act under the following conditions:

1229 1. The person is engaged in the business of wholesaling
1230 prescription and veterinary prescription drugs to persons:

1231 a. Licensed as veterinarians practicing on a full-time
1232 basis;

1233 b. Regularly and lawfully engaged in instruction in
1234 veterinary medicine;

1235 c. Regularly and lawfully engaged in law enforcement
1236 activities;

1237 d. For use in research not involving clinical use; or

1238 e. For use in chemical analysis or physical testing or for
1239 purposes of instruction in law enforcement activities, research,
1240 or testing.

1241 2. No more than 30 percent of total annual prescription
1242 drug sales may be prescription drugs approved for human use
1243 which are subject to, defined by, or described by s. 503(b) of
1244 the Federal Food, Drug, and Cosmetic Act.

1245 3. The person does not distribute in any jurisdiction
1246 prescription drugs subject to, defined by, or described by s.
1247 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
1248 who is authorized to sell, distribute, purchase, trade, or use
1249 these drugs on or for humans.

1250 4. A limited prescription drug veterinary wholesale

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1251 distributor that applies to the department for a new permit or
1252 the renewal of a permit must submit a bond of \$20,000, or other
1253 equivalent means of security acceptable to the department, such
1254 as an irrevocable letter of credit or a deposit in a trust
1255 account or financial institution, payable to the Professional
1256 Regulation Trust Fund. The purpose of the bond is to secure
1257 payment of any administrative penalties imposed by the
1258 department and any fees and costs incurred by the department
1259 regarding that permit which are authorized under state law and
1260 which the permittee fails to pay 30 days after the fine or costs
1261 become final. The department may make a claim against such bond
1262 or security until 1 year after the permittee's license ceases to
1263 be valid or until 60 days after any administrative or legal
1264 proceeding authorized in this part which involves the permittee
1265 is concluded, including any appeal, whichever occurs later.

1266 5. A limited prescription drug veterinary wholesale
1267 distributor must maintain at all times a license or permit to
1268 engage in the wholesale distribution of prescription drugs in
1269 compliance with laws of the state in which it is a resident.

1270 6. A limited prescription drug veterinary wholesale
1271 distributor must comply with the requirements for wholesale
1272 distributors under s. ss. 499.0121 and 499.01212, ~~except that a~~
1273 ~~limited prescription drug veterinary wholesale distributor is~~
1274 ~~not required to provide a pedigree paper as required by s.~~
1275 ~~499.01212 upon the wholesale distribution of a prescription drug~~
1276 ~~to a veterinarian.~~

1277 7. A limited prescription drug veterinary wholesale
1278 distributor may not return to inventory for subsequent wholesale
1279 distribution any prescription drug subject to, defined by, or

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1280 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1281 Act which has been returned by a veterinarian.

1282 8. A limited prescription drug veterinary wholesale
1283 distributor permit is not required for an intracompany sale or
1284 transfer of a prescription drug from an out-of-state
1285 establishment that is duly licensed to engage in the wholesale
1286 distribution of prescription drugs in its state of residence to
1287 a licensed limited prescription drug veterinary wholesale
1288 distributor in this state if both wholesale distributors conduct
1289 wholesale distributions of prescription drugs under the same
1290 business name. The recordkeeping requirements of s. ~~ss.~~
1291 499.0121(6) and ~~499.01212~~ must be followed for this transaction.

1292 (n) ~~(m)~~ *Over-the-counter drug manufacturer permit.*—An over-
1293 the-counter drug manufacturer permit is required for any person
1294 that engages in the manufacture or repackaging of an over-the-
1295 counter drug.

1296 1. An over-the-counter drug manufacturer may not possess or
1297 purchase prescription drugs.

1298 2. A pharmacy is exempt from obtaining an over-the-counter
1299 drug manufacturer permit if it is operating in compliance with
1300 pharmacy practice standards as defined in chapter 465 and ~~the~~
1301 rules adopted under that chapter.

1302 3. An over-the-counter drug manufacturer must comply with
1303 all appropriate state and federal good manufacturing practices.

1304 (o) ~~(n)~~ *Device manufacturer permit.*—

1305 1. A device manufacturer permit is required for any person
1306 that engages in the manufacture, repackaging, or assembly of
1307 medical devices for human use in this state, except that a
1308 permit is not required if:

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1309 a. The person is engaged only in manufacturing,
1310 repackaging, or assembling a medical device pursuant to a
1311 practitioner's order for a specific patient; or

1312 b. The person does not manufacture, repackage, or assemble
1313 any medical devices or components for such devices, except those
1314 devices or components which are exempt from registration
1315 pursuant to s. 499.015(8).

1316 2. A manufacturer or repackager of medical devices in this
1317 state must comply with all appropriate state and federal good
1318 manufacturing practices and quality system rules.

1319 3. The department shall adopt rules related to storage,
1320 handling, and recordkeeping requirements for manufacturers of
1321 medical devices for human use.

1322 (p) ~~(o)~~ *Cosmetic manufacturer permit.*—A cosmetic
1323 manufacturer permit is required for any person that manufactures
1324 or repackages cosmetics in this state. A person that only labels
1325 or changes the labeling of a cosmetic but does not open the
1326 container sealed by the manufacturer of the product is exempt
1327 from obtaining a permit under this paragraph.

1328 (q) ~~(p)~~ *Third party logistics provider permit.*—A third party
1329 logistics provider permit is required for any person that
1330 contracts with a prescription drug wholesale distributor or
1331 prescription drug manufacturer to provide warehousing,
1332 distribution, or other logistics services on behalf of a
1333 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who
1334 does not take title to the prescription drug or have
1335 responsibility to direct the sale or disposition of the
1336 prescription drug. A third party logistics provider located
1337 outside of this state, must be licensed in the state or

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

1349 (r)(q) Health care clinic establishment permit. ~~Effective~~
1350 ~~January 1, 2009,~~ A health care clinic establishment permit is
1351 required for the purchase of a prescription drug by a place of
1352 business at one general physical location that provides health
1353 care or veterinary services, which is owned and operated by a
1354 business entity that has been issued a federal employer tax
1355 identification number. For the purpose of this paragraph, the
1356 term "qualifying practitioner" means a licensed health care
1357 practitioner defined in s. 456.001, or a veterinarian licensed
1358 under chapter 474, who is authorized under the appropriate
1359 practice act to prescribe and administer a prescription drug.

1360 1. An establishment must provide, as part of the
1361 application required under s. 499.012, designation of a
1362 qualifying practitioner who will be responsible for complying
1363 with all legal and regulatory requirements related to the
1364 purchase, recordkeeping, storage, and handling of the
1365 prescription drugs. In addition, the designated qualifying
1366 practitioner shall be the practitioner whose name, establishment

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1367 address, and license number is used on all distribution
1368 documents for prescription drugs purchased or returned by the
1369 health care clinic establishment. Upon initial appointment of a
1370 qualifying practitioner, the qualifying practitioner and the
1371 health care clinic establishment shall notify the department on
1372 a form furnished by the department within 10 days after such
1373 employment. In addition, the qualifying practitioner and health
1374 care clinic establishment shall notify the department within 10
1375 days after any subsequent change.

1376 2. The health care clinic establishment must employ a
1377 qualifying practitioner at each establishment.

1378 3. In addition to the remedies and penalties provided in
1379 this part, a violation of this chapter by the health care clinic
1380 establishment or qualifying practitioner constitutes grounds for
1381 discipline of the qualifying practitioner by the appropriate
1382 regulatory board.

1383 4. The purchase of prescription drugs by the health care
1384 clinic establishment is prohibited during any period of time
1385 when the establishment does not comply with this paragraph.

1386 5. A health care clinic establishment permit is not a
1387 pharmacy permit or otherwise subject to chapter 465. A health
1388 care clinic establishment that meets the criteria of a modified
1389 Class II institutional pharmacy under s. 465.019 is not eligible
1390 to be permitted under this paragraph.

1391 6. This paragraph does not apply to the purchase of a
1392 prescription drug by a licensed practitioner under his or her
1393 license.

1394 (3) A nonresident prescription drug manufacturer permit is
1395 not required for a manufacturer to distribute a prescription

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1396 drug active pharmaceutical ingredient that it manufactures to a
1397 prescription drug manufacturer permitted in this state ~~in~~
1398 ~~limited quantities~~ intended for research and development and not
1399 for resale or human use other than lawful clinical trials and
1400 biostudies authorized and regulated by federal law. A
1401 manufacturer claiming to be exempt from the permit requirements
1402 of this subsection and the prescription drug manufacturer
1403 purchasing and receiving the active pharmaceutical ingredient
1404 shall comply with the recordkeeping requirements of s.
1405 499.0121(6), ~~but not the requirements of s. 499.01212.~~ The
1406 prescription drug manufacturer purchasing and receiving the
1407 active pharmaceutical ingredient shall maintain on file a record
1408 of the FDA registration number; if available, the out-of-state
1409 license, permit, or registration number; and, if available, a
1410 copy of the most current FDA inspection report, for all
1411 manufacturers from whom they purchase active pharmaceutical
1412 ingredients under this section. ~~The department shall define the~~
1413 ~~term "limited quantities" by rule, and may include the allowable~~
1414 ~~number of transactions within a given period of time and the~~
1415 ~~amount of prescription drugs distributed into the state for~~
1416 ~~purposes of this exemption.~~ The failure to comply with the
1417 requirements of this subsection, or rules adopted by the
1418 department to administer this subsection, for the purchase of
1419 prescription drug active pharmaceutical ingredients is a
1420 violation of s. 499.005(14), and a knowing failure is a
1421 violation of s. 499.0051(3) ~~499.0051(4)~~.

1422 (a) The immediate package or container of a prescription
1423 drug active pharmaceutical ingredient distributed into the state
1424 that is intended for research and development under this

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1425 subsection shall bear a label prominently displaying the
1426 statement: "Caution: Research and Development Only—Not for
1427 Manufacturing, Compounding, or Resale."

1428 (b) A prescription drug manufacturer that obtains a
1429 prescription drug active pharmaceutical ingredient under this
1430 subsection for use in clinical trials and or biostudies
1431 authorized and regulated by federal law must create and maintain
1432 records detailing the specific clinical trials or biostudies for
1433 which the prescription drug active pharmaceutical ingredient was
1434 obtained.

1435 (4) (a) A permit issued under this part is not required to
1436 distribute a prescription drug active pharmaceutical ingredient
1437 from an establishment located in the United States to an
1438 establishment located in this state permitted as a prescription
1439 drug manufacturer under this part for use by the recipient in
1440 preparing, deriving, processing, producing, or fabricating a
1441 prescription drug finished dosage form at the establishment in
1442 this state where the product is received under an approved and
1443 otherwise valid New Drug Approval Application, Abbreviated New
1444 Drug Application, New Animal Drug Application, or Therapeutic
1445 Biologic Application, provided that the application, active
1446 pharmaceutical ingredient, or finished dosage form has not been
1447 withdrawn or removed from the market in this country for public
1448 health reasons.

1449 1. Any distributor claiming exemption from permitting
1450 requirements pursuant to this paragraph shall maintain a
1451 license, permit, or registration to engage in the wholesale
1452 distribution of prescription drugs under the laws of the state
1453 from which the product is distributed. If the state from which

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1454 the prescription drugs are distributed does not require a
1455 license to engage in the wholesale distribution of prescription
1456 drugs, the distributor must be licensed as a wholesale
1457 distributor as required by the federal act.

1458 2. Any distributor claiming exemption from permitting
1459 requirements pursuant to this paragraph and the prescription
1460 drug manufacturer purchasing and receiving the active
1461 pharmaceutical ingredient shall comply with the recordkeeping
1462 requirements of s. 499.0121(6), ~~but not the requirements of s.~~
1463 ~~499.01212.~~

1464 (b) A permit issued under this part is not required to
1465 distribute ~~limited quantities of~~ a prescription drug that has
1466 not been repackaged from an establishment located in the United
1467 States to an establishment located in this state permitted as a
1468 prescription drug manufacturer under this part for research and
1469 development or to a holder of a letter of exemption issued by
1470 the department under s. 499.03(4) for research, teaching, or
1471 testing. ~~The department shall define "limited quantities" by~~
1472 ~~rule and may include the allowable number of transactions within~~
1473 ~~a given period of time and the amounts of prescription drugs~~
1474 ~~distributed into the state for purposes of this exemption.~~

1475 1. Any distributor claiming exemption from permitting
1476 requirements pursuant to this paragraph shall maintain a
1477 license, permit, or registration to engage in the wholesale
1478 distribution of prescription drugs under the laws of the state
1479 from which the product is distributed. If the state from which
1480 the prescription drugs are distributed does not require a
1481 license to engage in the wholesale distribution of prescription
1482 drugs, the distributor must be licensed as a wholesale

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1483 distributor as required by the federal act.

1484 2. All purchasers and recipients of any prescription drugs
1485 distributed pursuant to this paragraph shall ensure that the
1486 products are not resold or used, directly or indirectly, on
1487 humans except in lawful clinical trials and biostudies
1488 authorized and regulated by federal law.

1489 3. Any distributor claiming exemption from permitting
1490 requirements pursuant to this paragraph, and the purchaser and
1491 recipient of the prescription drug, shall comply with the
1492 recordkeeping requirements of s. 499.0121(6), ~~but not the~~
1493 ~~requirements of s. 499.01212.~~

1494 4. The immediate package or container of any active
1495 pharmaceutical ingredient distributed into the state that is
1496 intended for teaching, testing, research, and development shall
1497 bear a label prominently displaying the statement: "Caution:
1498 Research, Teaching, or Testing Only - Not for Manufacturing,
1499 Compounding, or Resale."

1500 (c) An out-of-state prescription drug wholesale distributor
1501 permit is not required for an intracompany sale or transfer of a
1502 prescription drug from an out-of-state establishment that is
1503 duly licensed as a prescription drug wholesale distributor in
1504 its state of residence to a licensed prescription drug wholesale
1505 distributor in this state, if both wholesale distributors
1506 conduct wholesale distributions of prescription drugs under the
1507 same business name. The recordkeeping requirements of s. ~~ss.~~
1508 ~~499.0121(6) and 499.01212~~ must be followed for such
1509 transactions.

1510 (d) Persons receiving prescription drugs from a source
1511 claimed to be exempt from permitting requirements under this

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1512 subsection shall maintain on file:

1513 1. A record of the FDA establishment registration number,
1514 if any;

1515 2. The resident state or federal license, registration, or
1516 permit that authorizes the source to distribute prescription
1517 drugs ~~drug wholesale distribution license, permit, or~~
1518 ~~registration number~~; and

1519 3. A copy of the most recent resident state or FDA
1520 inspection report, for all distributors and establishments from
1521 whom they purchase or receive prescription drugs under this
1522 subsection.

1523 (e) All persons claiming exemption from permitting
1524 requirements pursuant to this subsection who engage in the
1525 distribution of prescription drugs within or into the state are
1526 subject to this part, including ss. 499.005 and 499.0051, and
1527 shall make available, within 48 hours, to the department on
1528 request all records related to any prescription drugs
1529 distributed under this subsection, including those records
1530 described in s. 499.051(4), regardless of the location where the
1531 records are stored.

1532 (f) A person purchasing and receiving a prescription drug
1533 from a person claimed to be exempt from licensing requirements
1534 pursuant to this subsection shall report to the department in
1535 writing within 14 days after receiving any product that is
1536 misbranded or adulterated or that fails to meet minimum
1537 standards set forth in the official compendium or state or
1538 federal good manufacturing practices for identity, purity,
1539 potency, or sterility, regardless of whether the product is
1540 thereafter rehabilitated, quarantined, returned, or destroyed.

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1541 (g) The department may adopt rules to administer this
1542 subsection which are necessary for the protection of the public
1543 health, safety, and welfare. Failure to comply with the
1544 requirements of this subsection, or rules adopted by the
1545 department to administer this subsection, is a violation of s.
1546 499.005(14), and a knowing failure is a violation of s.
1547 499.0051(3) ~~499.0051(4)~~.

1548 (h) This subsection does not relieve any person from any
1549 requirement prescribed by law with respect to controlled
1550 substances as defined in the applicable federal and state laws.

1551 (5) A prescription drug repackager permit issued under this
1552 part is not required for a restricted prescription drug
1553 distributor permitholder that is a health care entity to
1554 repackaging prescription drugs in this state for its own use or
1555 for distribution to hospitals or other health care entities in
1556 the state for their own use, pursuant to s. 499.003(48)(a)3.
1557 ~~499.003(53)(a)3.~~, if:

1558 (a) The prescription drug distributor notifies the
1559 department, in writing, of its intention to engage in
1560 repackaging under this exemption, 30 days before engaging in the
1561 repackaging of prescription drugs at the permitted
1562 establishment;

1563 (b) The prescription drug distributor is under common
1564 control with the hospitals or other health care entities to
1565 which the prescription drug distributor is distributing
1566 prescription drugs. As used in this paragraph, "common control"
1567 means the power to direct or cause the direction of the
1568 management and policies of a person or an organization, whether
1569 by ownership of stock, voting rights, contract, or otherwise;

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1570 (c) The prescription drug distributor repackages the
1571 prescription drugs in accordance with current state and federal
1572 good manufacturing practices; and

1573 (d) The prescription drug distributor labels the
1574 prescription drug it repackages in accordance with state and
1575 federal laws and rules.

1576
1577 The prescription drug distributor is exempt from the product
1578 registration requirements of s. 499.015 with regard to the
1579 prescription drugs that it repackages and distributes under this
1580 subsection. A prescription drug distributor that repackages and
1581 distributes prescription drugs under this subsection to a not-
1582 for-profit rural hospital, as defined in s. 395.602, is not
1583 required to comply with paragraph (c) or paragraph (d), but must
1584 provide to each health care entity for which it repackages, for
1585 each prescription drug that is repackaged and distributed, the
1586 information required by department rule for labeling
1587 prescription drugs. The prescription drug distributor shall also
1588 provide the additional current packaging and label information
1589 for the prescription drug by hard copy or by electronic means.

1590 Section 6. Section 499.012, Florida Statutes, is amended to
1591 read:

1592 499.012 Permit application requirements.—

1593 (1) (a) A permit issued pursuant to this part may be issued
1594 only to a natural person who is at least 18 years of age or to
1595 an applicant that is not a natural person if each person who,
1596 directly or indirectly, manages, controls, or oversees the
1597 operation of that applicant is at least 18 years of age.

1598 (b) An establishment that is a place of residence may not

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1599 receive a permit and may not operate under this part.

1600 (c) A person that applies for or renews a permit to
1601 manufacture or distribute prescription drugs may not use a name
1602 identical to the name used by any other establishment or
1603 licensed person authorized to purchase prescription drugs in
1604 this state, except that a restricted drug distributor permit
1605 issued to a health care entity will be issued in the name in
1606 which the institutional pharmacy permit is issued and a retail
1607 pharmacy drug wholesale distributor will be issued a permit in
1608 the name of its retail pharmacy permit.

1609 (d) A permit for a prescription drug manufacturer,
1610 prescription drug repackager, prescription drug wholesale
1611 distributor, limited prescription drug veterinary wholesale
1612 distributor, or retail pharmacy drug wholesale distributor may
1613 not be issued to the address of a health care entity or to a
1614 pharmacy licensed under chapter 465, except as provided in this
1615 paragraph. The department may issue a prescription drug
1616 manufacturer permit to an applicant at the same address as a
1617 licensed nuclear pharmacy, which is a health care entity, even
1618 if the nuclear pharmacy holds a special sterile compounding
1619 permit under chapter 465, for the purpose of manufacturing
1620 prescription drugs used in positron emission tomography or other
1621 radiopharmaceuticals, as listed in a rule adopted by the
1622 department pursuant to this paragraph. The purpose of this
1623 exemption is to assure availability of state-of-the-art
1624 pharmaceuticals that would pose a significant danger to the
1625 public health if manufactured at a separate establishment
1626 address from the nuclear pharmacy from which the prescription
1627 drugs are dispensed. The department may also issue a retail

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1628 pharmacy drug wholesale distributor permit to the address of a
1629 community pharmacy licensed under chapter 465, even if the
1630 community pharmacy holds a special sterile compounding permit
1631 under chapter 465, as long as the community pharmacy ~~which~~ does
1632 not meet the definition of a closed pharmacy in s. 499.003.

1633 (e) A county or municipality may not issue an occupational
1634 license for ~~any licensing period beginning on or after October~~
1635 ~~1, 2003, for~~ any establishment that requires a permit pursuant
1636 to this part, unless the establishment exhibits a current permit
1637 issued by the department for the establishment. Upon
1638 presentation of the requisite permit issued by the department,
1639 an occupational license may be issued by the municipality or
1640 county in which application is made. The department shall
1641 furnish to local agencies responsible for issuing occupational
1642 licenses a current list of all establishments licensed pursuant
1643 to this part.

1644 (2) Notwithstanding subsection (6), a permitted person in
1645 good standing may change the type of permit issued to that
1646 person by completing a new application for the requested permit,
1647 paying the amount of the difference in the permit fees if the
1648 fee for the new permit is more than the fee for the original
1649 permit, and meeting the applicable permitting conditions for the
1650 new permit type. The new permit expires on the expiration date
1651 of the original permit being changed; however, a new permit for
1652 a prescription drug wholesale distributor, an out-of-state
1653 prescription drug wholesale distributor, or a retail pharmacy
1654 drug wholesale distributor shall expire on the expiration date
1655 of the original permit or 1 year after the date of issuance of
1656 the new permit, whichever is earlier. A refund may not be issued

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1657 if the fee for the new permit is less than the fee that was paid
1658 for the original permit.

1659 (3) (a) A written application for a permit or to renew a
1660 permit must be filed with the department on forms furnished by
1661 the department. The department shall establish, by rule, the
1662 form and content of the application to obtain or renew a permit.
1663 The applicant must submit to the department with the application
1664 a statement that swears or affirms that the information is true
1665 and correct.

1666 (b) Upon a determination that 2 years have elapsed since
1667 the department notified an applicant for permit, certification,
1668 or product registration of a deficiency in the application and
1669 that the applicant has failed to cure the deficiency, the
1670 application shall expire. The determination regarding the 2-year
1671 lapse of time shall be based on documentation that the
1672 department notified the applicant of the deficiency in
1673 accordance with s. 120.60.

1674 (c) Information submitted by an applicant on an application
1675 required pursuant to this subsection which is a trade secret, as
1676 defined in s. 812.081, shall be maintained by the department as
1677 trade secret information pursuant to s. 499.051(7).

1678 (4) (a) Except for a permit for a prescription drug
1679 wholesale distributor or an out-of-state prescription drug
1680 wholesale distributor, an application for a permit must include:
1681 1. The name, full business address, and telephone number of
1682 the applicant;
1683 2. All trade or business names used by the applicant;
1684 3. The address, telephone numbers, and the names of contact
1685 persons for each facility used by the applicant for the storage,

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1686 handling, and distribution of prescription drugs;

1687 4. The type of ownership or operation, such as a
1688 partnership, corporation, or sole proprietorship; and

1689 5. The names of the owner and the operator of the
1690 establishment, including:

1691 a. If an individual, the name of the individual;

1692 b. If a partnership, the name of each partner and the name
1693 of the partnership;

1694 c. If a corporation, the name and title of each corporate
1695 officer and director, the corporate names, and the name of the
1696 state of incorporation;

1697 d. If a sole proprietorship, the full name of the sole
1698 proprietor and the name of the business entity;

1699 e. If a limited liability company, the name of each member,
1700 the name of each manager, the name of the limited liability
1701 company, and the name of the state in which the limited
1702 liability company was organized; and

1703 f. Any other relevant information that the department
1704 requires.

1705 (b) Upon approval of the application by the department and
1706 payment of the required fee, the department shall issue a permit
1707 to the applicant, if the applicant meets the requirements of
1708 this part and rules adopted under this part.

1709 (c) Any change in information required under paragraph (a)
1710 must be submitted to the department before the change occurs.

1711 (d) The department shall consider, at a minimum, the
1712 following factors in reviewing the qualifications of persons to
1713 be permitted under this part:

1714 1. The applicant's having been found guilty, regardless of

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1715 adjudication, in a court of this state or other jurisdiction, of
1716 a violation of a law that directly relates to a drug, device, or
1717 cosmetic. A plea of nolo contendere constitutes a finding of
1718 guilt for purposes of this subparagraph.

1719 2. The applicant's having been disciplined by a regulatory
1720 agency in any state for any offense that would constitute a
1721 violation of this part.

1722 3. Any felony conviction of the applicant under a federal,
1723 state, or local law;

1724 4. The applicant's past experience in manufacturing or
1725 distributing drugs, devices, or cosmetics;

1726 5. The furnishing by the applicant of false or fraudulent
1727 material in any application made in connection with
1728 manufacturing or distributing drugs, devices, or cosmetics;

1729 6. Suspension or revocation by a federal, state, or local
1730 government of any permit currently or previously held by the
1731 applicant for the manufacture or distribution of any drugs,
1732 devices, or cosmetics;

1733 7. Compliance with permitting requirements under any
1734 previously granted permits;

1735 8. Compliance with requirements to maintain or make
1736 available to the state permitting authority or to federal,
1737 state, or local law enforcement officials those records required
1738 under this section; and

1739 9. Any other factors or qualifications the department
1740 considers relevant to and consistent with the public health and
1741 safety.

1742 (5) ~~Except for a permit for a prescription drug wholesale~~
1743 ~~distributor or an out-of-state prescription drug wholesale~~

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1744 ~~distributor:~~

1745 (a) The department shall adopt rules for the biennial
1746 renewal of permits; however, the department may issue up to a 4-
1747 year permit to selected permittees notwithstanding any other
1748 provision of law. Fees for such renewal may not exceed the fee
1749 caps set forth in s. 499.041 on an annualized basis as
1750 authorized by law.

1751 (b) The department shall renew a permit upon receipt of the
1752 renewal application and renewal fee if the applicant meets the
1753 requirements established under this part and ~~the~~ rules adopted
1754 under this part.

1755 (c) At least 90 days before the expiration date of a
1756 permit, the department shall forward a permit renewal
1757 notification to the permittee at the mailing address of the
1758 permitted establishment on file with the department. The permit
1759 renewal notification must state conspicuously the date on which
1760 the permit for the establishment will expire and that the
1761 establishment may not operate unless the permit for the
1762 establishment is renewed timely. A permit, unless sooner
1763 suspended or revoked, automatically expires 2 years after the
1764 last day of the anniversary month in which the permit was
1765 originally issued.

1766 (d) A permit issued under this part may be renewed by
1767 making application for renewal on forms furnished by the
1768 department and paying the appropriate fees.

1769 1. If a prescription drug wholesale distributor or an out-
1770 of-state prescription drug wholesale distributor renewal
1771 application and fee are submitted and postmarked later than 45
1772 days before the expiration date of the permit, the permit may be

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1773 renewed only upon payment of a late renewal fee of \$100, plus
1774 the required renewal fee.

1775 2. If any other a renewal application and fee are submitted
1776 and postmarked after the expiration date of the permit, the
1777 permit may be renewed only upon payment of a late renewal
1778 delinquent fee of \$100, plus the required renewal fee, not later
1779 than 60 days after the expiration date.

1780 3. A permittee who submits a renewal application in
1781 accordance with this paragraph may continue to operate under its
1782 permit, unless the permit is suspended or revoked, until final
1783 disposition of the renewal application.

1784 4.~~(d)~~ Failure to renew a permit in accordance with this
1785 section precludes any future renewal of that permit. If a permit
1786 issued pursuant to this part has expired and cannot be renewed,
1787 before an establishment may engage in activities that require a
1788 permit under this part, the establishment must submit an
1789 application for a new permit, pay the applicable application
1790 fee, the initial permit fee, and all applicable penalties, and
1791 be issued a new permit by the department.

1792 (6) A permit issued by the department is nontransferable.
1793 Each permit is valid only for the person or governmental unit to
1794 which it is issued and is not subject to sale, assignment, or
1795 other transfer, voluntarily or involuntarily; nor is a permit
1796 valid for any establishment other than the establishment for
1797 which it was originally issued.

1798 (a) A person permitted under this part must notify the
1799 department before making a change of address. The department
1800 shall set a change of location fee not to exceed \$100.

1801 (b)1. An application for a new permit is required when a

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1802 majority of the ownership or controlling interest of a permitted
1803 establishment is transferred or assigned or when a lessee agrees
1804 to undertake or provide services to the extent that legal
1805 liability for operation of the establishment will rest with the
1806 lessee. The application for the new permit must be made before
1807 the date of the sale, transfer, assignment, or lease.

1808 2. A permittee that is authorized to distribute
1809 prescription drugs may transfer such drugs to the new owner or
1810 lessee under subparagraph 1. only after the new owner or lessee
1811 has been approved for a permit to distribute prescription drugs.

1812 (c) If an establishment permitted under this part closes,
1813 the owner must notify the department in writing before the
1814 effective date of closure and must:

1815 1. Return the permit to the department;

1816 2. If the permittee is authorized to distribute
1817 prescription drugs, indicate the disposition of such drugs,
1818 including the name, address, and inventory, and provide the name
1819 and address of a person to contact regarding access to records
1820 that are required to be maintained under this part. Transfer of
1821 ownership of prescription drugs may be made only to persons
1822 authorized to possess prescription drugs under this part.

1823
1824 The department may revoke the permit of any person that fails to
1825 comply with the requirements of this subsection.

1826 (7) A permit must be posted in a conspicuous place on the
1827 licensed premises.

1828 (8) An application for a permit or to renew a permit for a
1829 prescription drug wholesale distributor or an out-of-state
1830 prescription drug wholesale distributor submitted to the

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1831 department must include:

1832 (a) The name, full business address, and telephone number
1833 of the applicant.

1834 (b) All trade or business names used by the applicant.

1835 (c) The address, telephone numbers, and the names of
1836 contact persons for each facility used by the applicant for the
1837 storage, handling, and distribution of prescription drugs.

1838 (d) The type of ownership or operation, such as a
1839 partnership, corporation, or sole proprietorship.

1840 (e) The names of the owner and the operator of the
1841 establishment, including:

1842 1. If an individual, the name of the individual.

1843 2. If a partnership, the name of each partner and the name
1844 of the partnership.

1845 3. If a corporation:

1846 a. The name, address, and title of each corporate officer
1847 and director.

1848 b. The name and address of the corporation, resident agent
1849 of the corporation, the resident agent's address, and the
1850 corporation's state of incorporation.

1851 c. The name and address of each shareholder of the
1852 corporation that owns 5 percent or more of the outstanding stock
1853 of the corporation.

1854 4. If a sole proprietorship, the full name of the sole
1855 proprietor and the name of the business entity.

1856 5. If a limited liability company:

1857 a. The name and address of each member.

1858 b. The name and address of each manager.

1859 c. The name and address of the limited liability company,

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1860 the resident agent of the limited liability company, and the
1861 name of the state in which the limited liability company was
1862 organized.

1863 (f) If applicable, the name and address of each affiliate
1864 ~~of member of the affiliated group of which the applicant is a~~
1865 ~~member.~~

1866 (g)~~1.~~ The applicant's gross annual receipts attributable to
1867 prescription drug wholesale distribution activities for the
1868 previous tax year. ~~For an application for a new permit, the~~
1869 ~~estimated annual dollar volume of prescription drug sales of the~~
1870 ~~applicant, the estimated annual percentage of the applicant's~~
1871 ~~total company sales that are prescription drugs, the applicant's~~
1872 ~~estimated annual total dollar volume of purchases of~~
1873 ~~prescription drugs, and the applicant's estimated annual total~~
1874 ~~dollar volume of prescription drug purchases directly from~~
1875 ~~manufacturers.~~

1876 ~~2. For an application to renew a permit, the total dollar~~
1877 ~~volume of prescription drug sales in the previous year, the~~
1878 ~~total dollar volume of prescription drug sales made in the~~
1879 ~~previous 6 months, the percentage of total company sales that~~
1880 ~~were prescription drugs in the previous year, the total dollar~~
1881 ~~volume of purchases of prescription drugs in the previous year,~~
1882 ~~and the total dollar volume of prescription drug purchases~~
1883 ~~directly from manufacturers in the previous year.~~

1884
1885 ~~Such portions of the information required pursuant to this~~
1886 ~~paragraph which are a trade secret, as defined in s. 812.081,~~
1887 ~~shall be maintained by the department as trade secret~~
1888 ~~information is required to be maintained under s. 499.051.~~

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1889 (h) The tax year of the applicant.

1890 (i) A copy of the deed for the property on which
1891 applicant's establishment is located, if the establishment is
1892 owned by the applicant, or a copy of the applicant's lease for
1893 the property on which applicant's establishment is located that
1894 has an original term of not less than 1 calendar year, if the
1895 establishment is not owned by the applicant.

1896 (j) A list of all licenses and permits issued to the
1897 applicant by any other state which authorize the applicant to
1898 purchase or possess prescription drugs.

1899 (k) The name of the manager of the establishment that is
1900 applying for the permit or to renew the permit, the next four
1901 highest ranking employees responsible for prescription drug
1902 wholesale operations for the establishment, and the name of all
1903 affiliated parties for the establishment, together with the
1904 personal information statement and fingerprints required
1905 pursuant to subsection (9) for each of such persons.

1906 (l) The name of each of the applicant's designated
1907 representatives as required by subsection (15) ~~(16)~~, together
1908 with the personal information statement and fingerprints
1909 required pursuant to subsection (9) for each such person.

1910 (m) Evidence of a surety bond in this state or any other
1911 state in the United States in the amount of \$100,000. If the
1912 annual gross receipts of the applicant's previous tax year is
1913 \$10 million or less, evidence of a surety bond in the amount of
1914 \$25,000. The specific language of the surety bond must include
1915 the State of Florida as a beneficiary, payable to the
1916 Professional Regulation Trust Fund. In lieu of the surety bond,
1917 the applicant may provide other equivalent security such as an

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

1932 1. ~~A personal background information statement containing~~
1933 ~~the background information and fingerprints required pursuant to~~
1934 ~~subsection (9) for each person named in the applicant's response~~
1935 ~~to paragraphs (k) and (l) and for each affiliated party of the~~
1936 ~~applicant.~~

1937 2. ~~If any of the five largest shareholders of the~~
1938 ~~corporation seeking the permit is a corporation, the name,~~
1939 ~~address, and title of each corporate officer and director of~~
1940 ~~each such corporation; the name and address of such corporation;~~
1941 ~~the name of such corporation's resident agent, such~~
1942 ~~corporation's resident agent's address, and such corporation's~~
1943 ~~state of its incorporation; and the name and address of each~~
1944 ~~shareholder of such corporation that owns 5 percent or more of~~
1945 ~~the stock of such corporation.~~

1946 3. ~~The name and address of all financial institutions in~~

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1947 ~~which the applicant has an account which is used to pay for the~~
1948 ~~operation of the establishment or to pay for drugs purchased for~~
1949 ~~the establishment, together with the names of all persons that~~
1950 ~~are authorized signatories on such accounts. The portions of the~~
1951 ~~information required pursuant to this subparagraph which are a~~
1952 ~~trade secret, as defined in s. 812.081, shall be maintained by~~
1953 ~~the department as trade secret information is required to be~~
1954 ~~maintained under s. 499.051.~~

1955 ~~4. The sources of all funds and the amounts of such funds~~
1956 ~~used to purchase or finance purchases of prescription drugs or~~
1957 ~~to finance the premises on which the establishment is to be~~
1958 ~~located.~~

1959 ~~5. If any of the funds identified in subparagraph 4. were~~
1960 ~~borrowed, copies of all promissory notes or loans used to obtain~~
1961 ~~such funds.~~

1962 (n) For establishments used in wholesale distribution,
1963 proof of an inspection conducted by the department, the United
1964 States Food and Drug Administration, or another governmental
1965 entity charged with the regulation of good manufacturing
1966 practices related to wholesale distribution of prescription
1967 drugs, within timeframes set forth by the department in
1968 departmental rules, which demonstrates substantial compliance
1969 with current good manufacturing practices applicable to
1970 wholesale distribution of prescription drugs. The department may
1971 recognize another state's inspection of a wholesale distributor
1972 located in that state if such state's laws are deemed to be
1973 substantially equivalent to the law of this state by the
1974 department. The department may accept an inspection by a third-
1975 party accreditation or inspection service which meets the

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1976 criteria set forth in department rule.

1977 (o) ~~(n)~~ Any other relevant information that the department
1978 requires, ~~including, but not limited to, any information related~~
1979 ~~to whether the applicant satisfies the definition of a primary~~
1980 ~~wholesale distributor or a secondary wholesale distributor.~~

1981 (p) ~~(e)~~ Documentation of the credentialing policies and
1982 procedures required by s. 499.0121(15).

1983 (9) (a) Each person required by subsection (8) or subsection
1984 (15) to provide a personal information statement and
1985 fingerprints shall provide the following information to the
1986 department on forms prescribed by the department:

- 1987 1. The person's places of residence for the past 7 years.
- 1988 2. The person's date and place of birth.
- 1989 3. The person's occupations, positions of employment, and
1990 offices held during the past 7 years.
- 1991 4. The principal business and address of any business,
1992 corporation, or other organization in which each such office of
1993 the person was held or in which each such occupation or position
1994 of employment was carried on.
- 1995 5. Whether the person has been, during the past 7 years,
1996 the subject of any proceeding for the revocation of any license
1997 and, if so, the nature of the proceeding and the disposition of
1998 the proceeding.
- 1999 6. Whether, during the past 7 years, the person has been
2000 enjoined, temporarily or permanently, by a court of competent
2001 jurisdiction from violating any federal or state law regulating
2002 the possession, control, or distribution of prescription drugs,
2003 together with details concerning any such event.
- 2004 7. A description of any involvement by the person with any

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2005 business, including any investments, other than the ownership of
2006 stock in a publicly traded company or mutual fund, during the
2007 past 4 ~~7~~ years, which manufactured, administered, prescribed,
2008 distributed, or stored pharmaceutical products and any lawsuits
2009 in which such businesses were named as a party.

2010 8. A description of any felony criminal offense of which
2011 the person, as an adult, was found guilty, regardless of whether
2012 adjudication of guilt was withheld or whether the person pled
2013 guilty or nolo contendere. A criminal offense committed in
2014 another jurisdiction which would have been a felony in this
2015 state must be reported. If the person indicates that a criminal
2016 conviction is under appeal and submits a copy of the notice of
2017 appeal of that criminal offense, the applicant must, within 15
2018 days after the disposition of the appeal, submit to the
2019 department a copy of the final written order of disposition.

2020 9. A photograph of the person taken in the previous 180 ~~30~~
2021 days.

2022 10. A set of fingerprints for the person on a form and
2023 under procedures specified by the department, together with
2024 payment of an amount equal to the costs incurred by the
2025 department for the criminal record check of the person.

2026 11. The name, address, occupation, and date and place of
2027 birth for each member of the person's immediate family who is 18
2028 years of age or older. As used in this subparagraph, the term
2029 "member of the person's immediate family" includes the person's
2030 spouse, children, parents, siblings, the spouses of the person's
2031 children, and the spouses of the person's siblings.

2032 12. Any other relevant information that the department
2033 requires.

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2034 (b) The information required pursuant to paragraph (a)
2035 shall be provided under oath.

2036 (c) The department shall submit the fingerprints provided
2037 by a person for initial licensure to the Department of Law
2038 Enforcement for a statewide criminal record check and for
2039 forwarding to the Federal Bureau of Investigation for a national
2040 criminal record check of the person. The department shall submit
2041 the fingerprints provided by a person as a part of a renewal
2042 application to the Department of Law Enforcement for a statewide
2043 criminal record check, and for forwarding to the Federal Bureau
2044 of Investigation for a national criminal record check, for the
2045 initial renewal of a permit after January 1, 2004; for any
2046 subsequent renewal of a permit, the department shall submit the
2047 required information for a statewide and national criminal
2048 record check of the person. Any person who as a part of an
2049 initial permit application or initial permit renewal after
2050 January 1, 2004, submits to the department a set of fingerprints
2051 required for the criminal record check required in this
2052 paragraph are ~~shall~~ not be required to provide a subsequent set
2053 of fingerprints for a criminal record check to the department,
2054 if the person has undergone a criminal record check as a
2055 condition of the issuance of an initial permit or the initial
2056 renewal of a permit of an applicant after January 1, 2004. The
2057 department is authorized to contract with private vendors, or
2058 enter into interagency agreements, to collect electronic
2059 fingerprints where fingerprints are required for registration,
2060 certification, or the licensure process or where criminal
2061 history record checks are required.

2062 (d) For purposes of applying for renewal of a permit under

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2063 subsection (8) or certification under subsection (16), a person
2064 may submit the following in lieu of satisfying the requirements
2065 of paragraphs (a), (b), and (c):

2066 1. A photograph of the individual taken within 180 days;
2067 and

2068 2. A copy of the personal information statement form most
2069 recently submitted to the department and a certification under
2070 oath, on a form specified by the department, that the individual
2071 has reviewed the previously submitted personal information
2072 statement form and that the information contained therein
2073 remains unchanged.

2074 (10) The department may deny an application for a permit or
2075 refuse to renew a permit for a prescription drug wholesale
2076 distributor or an out-of-state prescription drug wholesale
2077 distributor if:

2078 (a) The applicant has not met the requirements for the
2079 permit.

2080 (b) The management, officers, or directors of the applicant
2081 or any affiliated party are found by the department to be
2082 incompetent or untrustworthy.

2083 (c) The applicant is so lacking in experience in managing a
2084 wholesale distributor as to make the issuance of the proposed
2085 permit hazardous to the public health.

2086 (d) The applicant is so lacking in experience in managing a
2087 wholesale distributor as to jeopardize the reasonable promise of
2088 successful operation of the wholesale distributor.

2089 (e) The applicant is lacking in experience in the
2090 distribution of prescription drugs.

2091 (f) The applicant's past experience in manufacturing or

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2092 distributing prescription drugs indicates that the applicant
2093 poses a public health risk.

2094 (g) The applicant is affiliated directly or indirectly
2095 through ownership, control, or other business relations, with
2096 any person or persons whose business operations are or have been
2097 detrimental to the public health.

2098 (h) The applicant, or any affiliated party, has been found
2099 guilty of or has pleaded guilty or nolo contendere to any felony
2100 or crime punishable by imprisonment for 1 year or more under the
2101 laws of the United States, any state, or any other country,
2102 regardless of whether adjudication of guilt was withheld.

2103 (i) The applicant or any affiliated party has been charged
2104 with a felony in a state or federal court and the disposition of
2105 that charge is pending during the application review or renewal
2106 review period.

2107 (j) The applicant has furnished false or fraudulent
2108 information or material in any application made in this state or
2109 any other state in connection with obtaining a permit or license
2110 to manufacture or distribute drugs, devices, or cosmetics.

2111 (k) That a federal, state, or local government permit
2112 currently or previously held by the applicant, or any affiliated
2113 party, for the manufacture or distribution of any drugs,
2114 devices, or cosmetics has been disciplined, suspended, or
2115 revoked and has not been reinstated.

2116 (l) The applicant does not possess the financial or
2117 physical resources to operate in compliance with the permit
2118 being sought, this chapter, and the rules adopted under this
2119 chapter.

2120 (m) The applicant or any affiliated party receives,

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2121 directly or indirectly, financial support and assistance from a
2122 person who was an affiliated party of a permittee whose permit
2123 was subject to discipline or was suspended or revoked, other
2124 than through the ownership of stock in a publicly traded company
2125 or a mutual fund.

2126 (n) The applicant or any affiliated party receives,
2127 directly or indirectly, financial support and assistance from a
2128 person who has been found guilty of any violation of this part
2129 or chapter 465, chapter 501, or chapter 893, any rules adopted
2130 under this part or those chapters, any federal or state drug
2131 law, or any felony where the underlying facts related to drugs,
2132 regardless of whether the person has been pardoned, had her or
2133 his civil rights restored, or had adjudication withheld, other
2134 than through the ownership of stock in a publicly traded company
2135 or a mutual fund.

2136 (o) The applicant for renewal of a permit under s.
2137 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged
2138 in the wholesale distribution of prescription drugs, as
2139 demonstrated by the regular and systematic distribution of
2140 prescription drugs throughout the year as evidenced by not fewer
2141 than 12 wholesale distributions in the previous year and not
2142 fewer than three wholesale distributions in the previous 6
2143 months.

2144 (p) Information obtained in response to s. 499.01(2)(e) or
2145 (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best
2146 interest of the public health, safety, and welfare to issue a
2147 permit.

2148 (q) The applicant does not possess the financial standing
2149 and business experience for the successful operation of the

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2150 applicant.

2151 (r) The applicant or any affiliated party has failed to
2152 comply with the requirements for manufacturing or distributing
2153 prescription drugs under this part, similar federal laws,
2154 similar laws in other states, or the rules adopted under such
2155 laws.

2156 (11) Upon approval of the application by the department and
2157 payment of the required fee, the department shall issue or renew
2158 a prescription drug wholesale distributor or an out-of-state
2159 prescription drug wholesale distributor permit to the applicant.

2160 ~~(12) For a permit for a prescription drug wholesale~~
2161 ~~distributor or an out-of-state prescription drug wholesale~~
2162 ~~distributor:~~

2163 ~~(a) The department shall adopt rules for the annual renewal~~
2164 ~~of permits. At least 90 days before the expiration of a permit,~~
2165 ~~the department shall forward a permit renewal notification and~~
2166 ~~renewal application to the prescription drug wholesale~~
2167 ~~distributor or out-of-state prescription drug wholesale~~
2168 ~~distributor at the mailing address of the permitted~~
2169 ~~establishment on file with the department. The permit renewal~~
2170 ~~notification must state conspicuously the date on which the~~
2171 ~~permit for the establishment will expire and that the~~
2172 ~~establishment may not operate unless the permit for the~~
2173 ~~establishment is renewed timely.~~

2174 ~~(b) A permit, unless sooner suspended or revoked,~~
2175 ~~automatically expires 1 year after the last day of the~~
2176 ~~anniversary month in which the permit was originally issued. A~~
2177 ~~permit may be renewed by making application for renewal on forms~~
2178 ~~furnished by the department and paying the appropriate fees. If~~

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2179 ~~a renewal application and fee are submitted and postmarked after~~
2180 ~~45 days prior to the expiration date of the permit, the permit~~
2181 ~~may be renewed only upon payment of a late renewal fee of \$100,~~
2182 ~~plus the required renewal fee. A permittee that has submitted a~~
2183 ~~renewal application in accordance with this paragraph may~~
2184 ~~continue to operate under its permit, unless the permit is~~
2185 ~~suspended or revoked, until final disposition of the renewal~~
2186 ~~application.~~

2187 ~~(c) Failure to renew a permit in accordance with this~~
2188 ~~section precludes any future renewal of that permit. If a permit~~
2189 ~~issued pursuant to this section has expired and cannot be~~
2190 ~~renewed, before an establishment may engage in activities that~~
2191 ~~require a permit under this part, the establishment must submit~~
2192 ~~an application for a new permit; pay the applicable application~~
2193 ~~fee, initial permit fee, and all applicable penalties; and be~~
2194 ~~issued a new permit by the department.~~

2195 ~~(12)~~ (13) A person that engages in wholesale distribution of
2196 prescription drugs in this state must have a wholesale
2197 distributor's permit issued by the department, except as noted
2198 in this section. Each establishment must be separately permitted
2199 except as noted in this subsection.

2200 (a) A separate establishment permit is not required when a
2201 permitted prescription drug wholesale distributor consigns a
2202 prescription drug to a pharmacy that is permitted under chapter
2203 465 and located in this state, provided that:

2204 1. The consignor wholesale distributor notifies the
2205 department in writing of the contract to consign prescription
2206 drugs to a pharmacy along with the identity and location of each
2207 consignee pharmacy;

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- 2208 2. The pharmacy maintains its permit under chapter 465;
- 2209 3. The consignor wholesale distributor, which has no legal
2210 authority to dispense prescription drugs, complies with all
2211 wholesale distribution requirements of s. ss. 499.0121 ~~and~~
2212 ~~499.01212~~ with respect to the consigned drugs and maintains
2213 records documenting the transfer of title or other completion of
2214 the wholesale distribution of the consigned prescription drugs;
- 2215 4. The distribution of the prescription drug is otherwise
2216 lawful under this chapter and other applicable law;
- 2217 5. Open packages containing prescription drugs within a
2218 pharmacy are the responsibility of the pharmacy, regardless of
2219 how the drugs are titled; and
- 2220 6. The pharmacy dispenses the consigned prescription drug
2221 in accordance with the limitations of its permit under chapter
2222 465 or returns the consigned prescription drug to the consignor
2223 wholesale distributor. In addition, a person who holds title to
2224 prescription drugs may transfer the drugs to a person permitted
2225 or licensed to handle the reverse distribution or destruction of
2226 drugs. Any other distribution by and means of the consigned
2227 prescription drug by any person, not limited to the consignor
2228 wholesale distributor or consignee pharmacy, to any other person
2229 is prohibited.
- 2230 (b) A wholesale distributor's permit is not required for
2231 the one-time transfer of title of a pharmacy's lawfully acquired
2232 prescription drug inventory by a pharmacy with a valid permit
2233 issued under chapter 465 to a consignor prescription drug
2234 wholesale distributor, permitted under this chapter, in
2235 accordance with a written consignment agreement between the
2236 pharmacy and that wholesale distributor if the permitted

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

2247 (c) A separate establishment permit is not required when a
2248 permitted prescription drug wholesale distributor operates
2249 temporary transit storage facilities for the sole purpose of
2250 storage, for up to 16 hours, of a delivery of prescription drugs
2251 when the wholesale distributor was temporarily unable to
2252 complete the delivery to the recipient.

2253 (d) The department shall require information from each
2254 wholesale distributor as part of the permit and renewal of such
2255 permit, as required under this section.

2256 (13)~~(14)~~ Personnel employed in wholesale distribution must
2257 have appropriate education and experience to enable them to
2258 perform their duties in compliance with state permitting
2259 requirements.

2260 (14)~~(15)~~ The name of a permittee or establishment on a
2261 prescription drug wholesale distributor permit or an out-of-
2262 state prescription drug wholesale distributor permit may not
2263 include any indicia of attainment of any educational degree, any
2264 indicia that the permittee or establishment possesses a
2265 professional license, or any name or abbreviation that the

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2266 department determines is likely to cause confusion or mistake or
2267 that the department determines is deceptive, including that of
2268 any other entity authorized to purchase prescription drugs.

2269 (15)~~(16)~~(a) Each establishment that is issued an initial or
2270 renewal permit as a prescription drug wholesale distributor or
2271 an out-of-state prescription drug wholesale distributor must
2272 designate in writing to the department at least one natural
2273 person to serve as the designated representative of the
2274 wholesale distributor. Such person must have an active
2275 certification as a designated representative from the
2276 department.

2277 (b) To be certified as a designated representative, a
2278 natural person must:

2279 1. Submit an application on a form furnished by the
2280 department and pay the appropriate fees.

2281 2. Be at least 18 years of age.

2282 3. Have at least 2 years of verifiable full-time:

2283 a. Work experience in a pharmacy licensed in this state or
2284 another state, where the person's responsibilities included, but
2285 were not limited to, recordkeeping for prescription drugs;

2286 b. Managerial experience with a prescription drug wholesale
2287 distributor licensed in this state or in another state; or

2288 c. Managerial experience with the United States Armed
2289 Forces, where the person's responsibilities included, but were
2290 not limited to, recordkeeping, warehousing, distributing, or
2291 other logistics services pertaining to prescription drugs.

2292 4. Receive a passing score of at least 75 percent on an
2293 examination given by the department regarding federal laws
2294 governing distribution of prescription drugs and this part and

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2295 the rules adopted by the department governing the wholesale
2296 distribution of prescription drugs. This requirement shall be
2297 effective 1 year after the results of the initial examination
2298 are mailed to the persons that took the examination. The
2299 department shall offer such examinations at least four times
2300 each calendar year.

2301 5. Provide the department with a personal information
2302 statement and fingerprints pursuant to subsection (9).

2303 (c) The department may deny an application for
2304 certification as a designated representative or may suspend or
2305 revoke a certification of a designated representative pursuant
2306 to s. 499.067.

2307 (d) A designated representative:

2308 1. Must be actively involved in and aware of the actual
2309 daily operation of the wholesale distributor.

2310 2. Must be employed full time in a managerial position by
2311 the wholesale distributor.

2312 3. Must be physically present at the establishment during
2313 normal business hours, except for time periods when absent due
2314 to illness, family illness or death, scheduled vacation, or
2315 other authorized absence.

2316 4. May serve as a designated representative for only one
2317 wholesale distributor at any one time.

2318 (e) A wholesale distributor must notify the department when
2319 a designated representative leaves the employ of the wholesale
2320 distributor. Such notice must be provided to the department
2321 within 10 business days after the last day of designated
2322 representative's employment with the wholesale distributor.

2323 (f) A wholesale distributor may not operate under a

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2324 prescription drug wholesale distributor permit or an out-of-
2325 state prescription drug wholesale distributor permit for more
2326 than 10 business days after the designated representative leaves
2327 the employ of the wholesale distributor, unless the wholesale
2328 distributor employs another designated representative and
2329 notifies the department within 10 business days of the identity
2330 of the new designated representative.

2331 Section 7. Section 499.01201, Florida Statutes, is amended
2332 to read:

2333 499.01201 Agency for Health Care Administration review and
2334 use of statute and rule violation or compliance data.—

2335 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~
2336 ~~contrary~~, the Agency for Health Care Administration may not:

2337 (1) Review or use any violation or alleged violation of s.
2338 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that
2339 section ~~those sections~~, as a ground for denying or withholding
2340 any payment of a Medicaid reimbursement to a pharmacy licensed
2341 under chapter 465; or

2342 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~
2343 ~~499.01212~~, or any rules adopted under that section ~~those~~
2344 ~~sections~~, as the subject of any audit of Medicaid-related
2345 records held by a pharmacy licensed under chapter 465.

2346 Section 8. Paragraph (d) of subsection (4) and subsection
2347 (6) of section 499.0121, Florida Statutes, are amended to read:

2348 499.0121 Storage and handling of prescription drugs;
2349 recordkeeping.—The department shall adopt rules to implement
2350 this section as necessary to protect the public health, safety,
2351 and welfare. Such rules shall include, but not be limited to,
2352 requirements for the storage and handling of prescription drugs

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2353 and for the establishment and maintenance of prescription drug
2354 distribution records.

2355 (4) EXAMINATION OF MATERIALS AND RECORDS.—

2356 (d) Upon receipt, a wholesale distributor must review
2357 records required under this section for the acquisition of
2358 prescription drugs for accuracy and completeness, considering
2359 the total facts and circumstances surrounding the transactions
2360 and the wholesale distributors involved. ~~This includes~~
2361 ~~authenticating each transaction listed on a pedigree paper, as~~
2362 ~~defined in s. 499.003(37).~~

2363 (6) RECORDKEEPING.—The department shall adopt rules that
2364 require keeping such records of prescription drugs, including
2365 active pharmaceutical ingredients, as are necessary for the
2366 protection of the public health.

2367 (a) ~~Wholesale Distributors~~ of prescription drugs and active
2368 pharmaceutical ingredients must establish and maintain
2369 inventories and records of all transactions regarding the
2370 receipt and distribution or other disposition of prescription
2371 drugs and active pharmaceutical ingredients. These records must
2372 provide a complete audit trail from receipt to sale or other
2373 disposition, be readily retrievable for inspection, and include,
2374 at a minimum, the following information:

2375 1. The source of the prescription drugs or active
2376 pharmaceutical ingredients, including the name and principal
2377 address of the seller or transferor, and the address of the
2378 location from which the prescription drugs were shipped;

2379 2. The name, principal address, and state license permit or
2380 registration number of the person authorized to purchase
2381 prescription drugs or active pharmaceutical ingredients;

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2382 3. The name, strength, dosage form, and quantity of the
2383 prescription drugs received and distributed or disposed of;

2384 4. The dates of receipt and distribution or other
2385 disposition of the prescription drugs or active pharmaceutical
2386 ingredients; and

2387 5. Any financial documentation supporting the transaction.

2388 (b) Inventories and records must be made available for
2389 inspection and photocopying by authorized federal, state, or
2390 local officials for a period of 2 years following disposition of
2391 the drugs or 3 years after the creation of the records,
2392 whichever period is longer.

2393 (c) Records described in this section that are kept at the
2394 inspection site or that can be immediately retrieved by computer
2395 or other electronic means must be readily available for
2396 authorized inspection during the retention period. Records that
2397 are kept at a central location outside of this state and that
2398 are not electronically retrievable must be made available for
2399 inspection within 2 working days after a request by an
2400 authorized official of a federal, state, or local law
2401 enforcement agency. Records that are maintained at a central
2402 location within this state must be maintained at an
2403 establishment that is permitted pursuant to this part and must
2404 be readily available.

2405 (d) Each manufacturer or repackager of medical devices,
2406 over-the-counter drugs, or cosmetics must maintain records that
2407 include the name and principal address of the seller or
2408 transferor of the product, the address of the location from
2409 which the product was shipped, the date of the transaction, the
2410 name and quantity of the product involved, and the name and

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2411 principal address of the person who purchased the product.

2412 ~~(c) When pedigree papers are required by this part, a~~
2413 ~~wholesale distributor must maintain the pedigree papers separate~~
2414 ~~and distinct from other records required under this part.~~

2415 Section 9. Subsection (4) of section 499.015, Florida
2416 Statutes, is amended to read:

2417 499.015 Registration of drugs, devices, and cosmetics;
2418 issuance of certificates of free sale.-

2419 (4) Unless a registration is renewed, it expires 2 years
2420 after the last day of the month in which it was issued. Any
2421 product registration issued or renewed on or after July 1, 2016,
2422 shall expire on the same date as the manufacturer or repackager
2423 permit of the person seeking to register the product. If the
2424 first product registration issued to a person on or after July
2425 1, 2016, expires less than 366 days after issuance, the fee for
2426 product registration shall be \$15. If the first product
2427 registration issued to a person on or after July 1, 2016,
2428 expires more than 365 days after issuance, the fee for product
2429 registration shall be \$30. The department may issue a stop-sale
2430 notice or order against a person that is subject to the
2431 requirements of this section and that fails to comply with this
2432 section within 31 days after the date the registration expires.
2433 The notice or order shall prohibit such person from selling or
2434 causing to be sold any drugs, devices, or cosmetics covered by
2435 this part until he or she complies with the requirements of this
2436 section.

2437 Section 10. Subsection (1) of section 499.03, Florida
2438 Statutes, is amended to read:

2439 499.03 Possession of certain drugs without prescriptions

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2440 unlawful; exemptions and exceptions.—

2441 (1) A person may not possess, or possess with intent to
2442 sell, dispense, or deliver, any habit-forming, toxic, harmful,
2443 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or
2444 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,
2445 unless the possession of the drug has been obtained by a valid
2446 prescription of a practitioner licensed by law to prescribe the
2447 drug. However, this section does not apply to the delivery of
2448 such drugs to persons included in any of the classes named in
2449 this subsection, or to the agents or employees of such persons,
2450 for use in the usual course of their businesses or practices or
2451 in the performance of their official duties, as the case may be;
2452 nor does this section apply to the possession of such drugs by
2453 those persons or their agents or employees for such use:

2454 (a) A licensed pharmacist or any person under the licensed
2455 pharmacist's supervision while acting within the scope of the
2456 licensed pharmacist's practice;

2457 (b) A licensed practitioner authorized by law to prescribe
2458 prescription drugs or any person under the licensed
2459 practitioner's supervision while acting within the scope of the
2460 licensed practitioner's practice;

2461 (c) A qualified person who uses prescription drugs for
2462 lawful research, teaching, or testing, and not for resale;

2463 (d) A licensed hospital or other institution that procures
2464 such drugs for lawful administration or dispensing by
2465 practitioners;

2466 (e) An officer or employee of a federal, state, or local
2467 government; or

2468 (f) A person that holds a valid permit issued by the

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2469 department pursuant to this part which authorizes that person to
2470 possess prescription drugs.

2471 Section 11. Paragraphs (i) through (p) of subsection (1) of
2472 section 499.05, Florida Statutes, are amended to read:

2473 499.05 Rules.—

2474 (1) The department shall adopt rules to implement and
2475 enforce this chapter with respect to:

2476 (i) Additional conditions that qualify as an emergency
2477 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.
2478 499.82.

2479 ~~(j) Procedures and forms relating to the pedigree paper
2480 requirement of s. 499.01212.~~

2481 (j) ~~(k)~~ The protection of the public health, safety, and
2482 welfare regarding good manufacturing practices that
2483 manufacturers and repackagers must follow to ensure the safety
2484 of the products.

2485 (k) ~~(l)~~ Information required from each retail establishment
2486 pursuant to s. 499.012(3) or s. 499.83(2)(c), including
2487 requirements for prescriptions or orders.

2488 (l) ~~(m)~~ The recordkeeping, storage, and handling with
2489 respect to each of the distributions of prescription drugs
2490 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.
2491 499.82(14).

2492 ~~(n) Alternatives to compliance with s. 499.01212 for a
2493 prescription drug in the inventory of a permitted prescription
2494 drug wholesale distributor as of June 30, 2006, and the return
2495 of a prescription drug purchased prior to July 1, 2006. The
2496 department may specify time limits for such alternatives.~~

2497 (m) ~~(o)~~ Wholesale distributor reporting requirements of s.

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2498 499.0121(14).

2499 (n)~~(p)~~ Wholesale distributor credentialing and distribution
2500 requirements of s. 499.0121(15).2501 Section 12. Subsection (7) of section 499.051, Florida
2502 Statutes, is amended to read:

2503 499.051 Inspections and investigations.—

2504 (7) The complaint and all information obtained pursuant to
2505 the investigation by the department are confidential and exempt
2506 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution
2507 until the investigation and the enforcement action are
2508 completed. However, trade secret information contained therein
2509 as defined by s. 812.081(1)(c) shall remain confidential and
2510 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I
2511 of the State Constitution, as long as the information is
2512 retained by the department. This subsection does not prohibit
2513 the department from using such information for regulatory or
2514 enforcement proceedings under this chapter or from providing
2515 such information to any law enforcement agency or any other
2516 regulatory agency. However, the receiving agency shall keep such
2517 records confidential and exempt as provided in this subsection.
2518 ~~In addition, this subsection is not intended to prevent~~
2519 ~~compliance with the provisions of s. 499.01212, and the pedigree~~
2520 ~~papers required in that section shall not be deemed a trade~~
2521 ~~secret.~~2522 Section 13. Subsection (8) is added to section 499.066,
2523 Florida Statutes, to read:2524 499.066 Penalties; remedies.—In addition to other penalties
2525 and other enforcement provisions:2526 (8) (a) The department shall adopt rules to permit the

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2527 issuance of remedial, nondisciplinary citations. A citation
2528 shall be issued to the person alleged to have committed a
2529 violation and contain the person's name, address, and license
2530 number, if applicable, a brief factual statement, the sections
2531 of the law allegedly violated, and the monetary assessment and
2532 or other remedial measures imposed. The citation must clearly
2533 state that the person may choose, in lieu of accepting the
2534 citation, to have the department rescind the citation and
2535 conduct an investigation pursuant to s. 499.051. If the person
2536 does not dispute the matter in the citation with the department
2537 within 30 days after the citation is served, the citation
2538 becomes a final order and does not constitute discipline.

2539 (b) The department shall adopt rules designating violations
2540 for which a citation may be issued. The rules shall designate as
2541 citable those violations for which there is no substantial
2542 threat to the public health, safety, or welfare.

2543 (c) The department is entitled to recover the costs of
2544 investigation, in addition to any penalty provided according to
2545 department rule, as part of the penalty levied pursuant to the
2546 citation.

2547 (d) A citation must be issued within 12 months after the
2548 filing of the complaint that is the basis for the citation.

2549 (e) Service of a citation may be made by personal service
2550 or certified mail, restricted delivery, to the person at the
2551 person's last known address of record with the department or to
2552 the person's Florida registered agent.

2553 (f) The department has authority to, and shall adopt rules
2554 to, designate those violations for which a person is subject to
2555 the issuance of a citation and designate the monetary

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2556 assessments and or other remedial measures that must be taken
2557 for those violations. The department has continuous authority to
2558 amend its rules adopted pursuant to this section.

2559 Section 14. Subsection (14) of section 499.82, Florida
2560 Statutes, is amended to read:

2561 499.82 Definitions.—As used in this part, the term:

2562 (14) "Wholesale distribution" means the distribution of
2563 medical gas to a person other than a consumer or patient.

2564 Wholesale distribution of medical gases does not include:

2565 (a) The sale, purchase, or trade of a medical gas; an offer
2566 to sell, purchase, or trade a medical gas; or the dispensing of
2567 a medical gas pursuant to a prescription;

2568 (b) Activities exempt from the definition of wholesale
2569 distribution in s. 499.003; or

2570 (c) The sale, purchase, or trade of a medical gas or an
2571 offer to sell, purchase, or trade a medical gas for emergency
2572 medical reasons; ~~or~~

2573 ~~(d) Other transactions excluded from the definition of~~
2574 ~~wholesale distribution under the federal act or regulations~~
2575 ~~implemented under the federal act related to medical gas.~~

2576 Section 15. Subsection (4) of section 499.89, Florida
2577 Statutes, is amended to read:

2578 499.89 Recordkeeping.—

2579 ~~(4) A pedigree paper is not required for distributing or~~
2580 ~~dispensing medical gas.~~

2581 Section 16. Section 499.01212, Florida Statutes, is
2582 repealed.

2583 Section 17. Paragraph (a) of subsection (1) of section
2584 409.9201, Florida Statutes, is amended to read:

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2585 409.9201 Medicaid fraud.—

2586 (1) As used in this section, the term:

2587 (a) "Prescription drug" means any drug, including, but not
2588 limited to, finished dosage forms or active ingredients that are
2589 subject to, defined in, or described in s. 503(b) of the Federal
2590 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)
2591 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2592

2593 The value of individual items of the legend drugs or goods or
2594 services involved in distinct transactions committed during a
2595 single scheme or course of conduct, whether involving a single
2596 person or several persons, may be aggregated when determining
2597 the punishment for the offense.

2598 Section 18. Paragraph (b) of subsection (1) of section
2599 499.067, Florida Statutes, is amended to read:

2600 499.067 Denial, suspension, or revocation of permit,
2601 certification, or registration.—

2602 (1)

2603 (b) The department may deny an application for a permit or
2604 certification, or suspend or revoke a permit or certification,
2605 if the department finds that:

2606 1. The applicant is not of good moral character or that it
2607 would be a danger or not in the best interest of the public
2608 health, safety, and welfare if the applicant were issued a
2609 permit or certification.

2610 2. The applicant has not met the requirements for the
2611 permit or certification.

2612 3. The applicant is not eligible for a permit or
2613 certification for any of the reasons enumerated in s. 499.012.

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2614 4. The applicant, permittee, or person certified under s.
 2615 499.012(15) ~~s. 499.012(16)~~ demonstrates any of the conditions
 2616 enumerated in s. 499.012.

2617 5. The applicant, permittee, or person certified under s.
 2618 499.012(15) ~~s. 499.012(16)~~ has committed any violation of this
 2619 chapter.

2620 Section 19. Subsection (1) of section 794.075, Florida
 2621 Statutes, is amended to read:

2622 794.075 Sexual predators; erectile dysfunction drugs.-

2623 (1) A person may not possess a prescription drug, as
 2624 defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of
 2625 treating erectile dysfunction if the person is designated as a
 2626 sexual predator under s. 775.21.

2627 Section 20. Paragraphs (d), (f), (i), and (j) of subsection
 2628 (3) of section 921.0022, Florida Statutes, are amended to read:

2629 921.0022 Criminal Punishment Code; offense severity ranking
 2630 chart.-

2631 (3) OFFENSE SEVERITY RANKING CHART

2632 (d) LEVEL 4

2633

2634

Florida Statute	Felony Degree	Description
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

2635

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2636

siren and lights activated.

499.0051(1)

3rd

Failure to maintain or deliver transaction history,
transaction information, or
transaction statements ~~pedigree~~
~~papers.~~

2637

~~499.0051(2)~~

~~3rd~~

~~Failure to authenticate~~
~~pedigree papers.~~

2638

499.0051(5)

2nd

~~499.0051(6)~~

Knowing sale or delivery, or
possession with intent to sell,
contraband prescription drugs.

2639

517.07(1)

3rd

Failure to register securities.

2640

517.12(1)

3rd

Failure of dealer, associated
person, or issuer of securities
to register.

2641

784.07(2)(b)

3rd

Battery of law enforcement
officer, firefighter, etc.

2642

784.074(1)(c)

3rd

Battery of sexually violent
predators facility staff.

2643

784.075

3rd

Battery on detention or
commitment facility staff.

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2644

784.078 3rd Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.

2645

784.08 (2) (c) 3rd Battery on a person 65 years of age or older.

2646

784.081 (3) 3rd Battery on specified official or employee.

2647

784.082 (3) 3rd Battery by detained person on visitor or other detainee.

2648

784.083 (3) 3rd Battery on code inspector.

2649

784.085 3rd Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.

2650

787.03 (1) 3rd Interference with custody; wrongly takes minor from appointed guardian.

2651

787.04 (2) 3rd Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.

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2652

787.04 (3) 3rd Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.

2653

787.07 3rd Human smuggling.

2654

790.115 (1) 3rd Exhibiting firearm or weapon within 1,000 feet of a school.

2655

790.115 (2) (b) 3rd Possessing electric weapon or device, destructive device, or other weapon on school property.

2656

790.115 (2) (c) 3rd Possessing firearm on school property.

2657

800.04 (7) (c) 3rd Lewd or lascivious exhibition; offender less than 18 years.

2658

810.02 (4) (a) 3rd Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.

2659

810.02 (4) (b) 3rd Burglary, or attempted

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2660 burglary, of an unoccupied
conveyance; unarmed; no assault
or battery.

2661 810.06 3rd Burglary; possession of tools.

2662 810.08 (2) (c) 3rd Trespass on property, armed
with firearm or dangerous
weapon.

2663 812.014 (2) (c) 3. 3rd Grand theft, 3rd degree \$10,000
or more but less than \$20,000.

2664 812.014 3rd Grand theft, 3rd degree, a
(2) (c) 4.-10. will, firearm, motor vehicle,
livestock, etc.

2665 812.0195 (2) 3rd Dealing in stolen property by
use of the Internet; property
stolen \$300 or more.

2666 817.563 (1) 3rd Sell or deliver substance other
than controlled substance
agreed upon, excluding s.
893.03 (5) drugs.

2667 817.568 (2) (a) 3rd Fraudulent use of personal
identification information.

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2668	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
2669	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
2670	837.02 (1)	3rd	Perjury in official proceedings.
2671	837.021 (1)	3rd	Make contradictory statements in official proceedings.
2672	838.022	3rd	Official misconduct.
2673	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
2674	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Families.
2675	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
	843.025	3rd	Deprive law enforcement,

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2676	correctional, or correctional probation officer of means of protection or communication.
2677	843.15(1)(a) 3rd Failure to appear while on bail for felony (bond estreature or bond jumping).
2678	847.0135(5)(c) 3rd Lewd or lascivious exhibition using computer; offender less than 18 years.
2679	874.05(1)(a) 3rd Encouraging or recruiting another to join a criminal gang.
2680	893.13(2)(a)1. 2nd Purchase of cocaine (or other s. 893.03(1)(a), (b), or (d), (2)(a), (2)(b), or (2)(c)4. drugs).
2681	914.14(2) 3rd Witnesses accepting bribes.
2682	914.22(1) 3rd Force, threaten, etc., witness, victim, or informant.
	914.23(2) 3rd Retaliation against a witness, victim, or informant, no bodily injury.

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918.12	3rd	Tampering with jurors.
934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
(f) LEVEL 6		
Florida Statute	Felony Degree	Description
316.027(2)(b)	2nd	Leaving the scene of a crash involving serious bodily injury.
316.193(2)(b)	3rd	Felony DUI, 4th or subsequent conviction.
400.9935(4)(c)	2nd	Operating a clinic, or offering services requiring licensure, without a license.
<u>499.0051(2)</u> 499.0051(3)	2nd	Knowing forgery of <u>transaction history, transaction information, or transaction statement</u> pedigree papers .

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2694 499.0051(3) 2nd Knowing purchase or receipt of
~~499.0051(4)~~ prescription drug from
 unauthorized person.

2695 499.0051(4) 2nd Knowing sale or transfer of
~~499.0051(5)~~ prescription drug to
 unauthorized person.

2696 775.0875(1) 3rd Taking firearm from law
 enforcement officer.

2697 784.021(1)(a) 3rd Aggravated assault; deadly
 weapon without intent to kill.

2698 784.021(1)(b) 3rd Aggravated assault; intent to
 commit felony.

2699 784.041 3rd Felony battery; domestic
 battery by strangulation.

2700 784.048(3) 3rd Aggravated stalking; credible
 threat.

2701 784.048(5) 3rd Aggravated stalking of person
 under 16.

2702 784.07(2)(c) 2nd Aggravated assault on law
 enforcement officer.

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2703	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
2704	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
2705	784.081 (2)	2nd	Aggravated assault on specified official or employee.
2706	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
2707	784.083 (2)	2nd	Aggravated assault on code inspector.
2708	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
2709	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
2710	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.

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2711

790.164 (1) 2nd False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.

2712

790.19 2nd Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.

2713

794.011 (8) (a) 3rd Solicitation of minor to participate in sexual activity by custodial adult.

2714

794.05 (1) 2nd Unlawful sexual activity with specified minor.

2715

800.04 (5) (d) 3rd Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; offender less than 18 years.

2716

800.04 (6) (b) 2nd Lewd or lascivious conduct; offender 18 years of age or older.

2717

806.031 (2) 2nd Arson resulting in great bodily harm to firefighter or any other person.

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2718 810.02 (3) (c) 2nd Burglary of occupied structure;
unarmed; no assault or battery.

2719 810.145 (8) (b) 2nd Video voyeurism; certain minor
victims; 2nd or subsequent
offense.

2720 812.014 (2) (b) 1. 2nd Property stolen \$20,000 or
more, but less than \$100,000,
grand theft in 2nd degree.

2721 812.014 (6) 2nd Theft; property stolen \$3,000
or more; coordination of
others.

2722 812.015 (9) (a) 2nd Retail theft; property stolen
\$300 or more; second or
subsequent conviction.

2723 812.015 (9) (b) 2nd Retail theft; property stolen
\$3,000 or more; coordination of
others.

2724 812.13 (2) (c) 2nd Robbery, no firearm or other
weapon (strong-arm robbery).

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

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2725

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

2726

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

2727

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

2728

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

2729

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

2730

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

2731

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

2732

836.05 2nd Threats; extortion.

2733

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

2734

843.12 3rd Aids or assists person to

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2735			escape.
	847.011	3rd	Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.
2736			
	847.012	3rd	Knowingly using a minor in the production of materials harmful to minors.
2737			
	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
2738			
	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
2739			
	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.
2740			
	944.40	2nd	Escapes.
2741			
	944.46	3rd	Harboring, concealing, aiding

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2742

escaped prisoners.

944.47(1)(a)5.

2nd

Introduction of contraband
(firearm, weapon, or explosive)
into correctional facility.

2743

951.22(1)

3rd

Intoxicating drug, firearm, or
weapon introduced into county
facility.

2744

(i) LEVEL 9

2745

2746

Florida
Statute

Felony
Degree

Description

2747

316.193
(3)(c)3.b.

1st

DUI manslaughter; failing
to render aid or give
information.

2748

327.35
(3)(c)3.b.

1st

BUI manslaughter; failing
to render aid or give
information.

2749

409.920
(2)(b)1.c.

1st

Medicaid provider fraud;
\$50,000 or more.

2750

499.0051(8) ~~499.0051(9)~~

1st

Knowing sale or purchase
of contraband
prescription drugs

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2751
2752
2753
2754
2755
2756

560.123 (8) (b) 3.

1st

resulting in great bodily harm.

Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.

560.125 (5) (c)

1st

Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.

655.50 (10) (b) 3.

1st

Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.

775.0844

1st

Aggravated white collar crime.

782.04 (1)

1st

Attempt, conspire, or solicit to commit premeditated murder.

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	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.
2757	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
2758	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
2759	787.01 (1) (a) 1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
2760	787.01 (1) (a) 2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
2761	787.01 (1) (a) 4.	1st,PBL	Kidnapping with intent to interfere with

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2762

787.02 (3) (a)

1st, PBL

performance of any governmental or political function.

False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.

2763

787.06 (3) (c) 1.

1st

Human trafficking for labor and services of an unauthorized alien child.

2764

787.06 (3) (d)

1st

Human trafficking using coercion for commercial sexual activity of an unauthorized adult alien.

2765

787.06 (3) (f) 1.

1st, PBL

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

2766

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	790.161	1st	Attempted capital destructive device offense.
2767	790.166 (2)	1st, PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
2768	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
2769	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
2770	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.
2771	794.011 (4) (b)	1st	Sexual battery, certain circumstances; victim and offender 18 years of age

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2772

794.011 (4) (c)

1st

or older.

Sexual battery, certain circumstances; victim 12 years of age or older; offender younger than 18 years.

2773

794.011 (4) (d)

1st, PBL

Sexual battery, certain circumstances; victim 12 years of age or older; prior conviction for specified sex offenses.

2774

794.011 (8) (b)

1st, PBL

Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.

2775

794.08 (2)

1st

Female genital mutilation; victim younger than 18 years of age.

2776

800.04 (5) (b)

Life

Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.

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2777

812.13 (2) (a) 1st, PBL Robbery with firearm or other deadly weapon.

2778

812.133 (2) (a) 1st, PBL Carjacking; firearm or other deadly weapon.

2779

812.135 (2) (b) 1st Home-invasion robbery with weapon.

2780

817.535 (3) (b) 1st Filing false lien or other unauthorized document; second or subsequent offense; property owner is a public officer or employee.

2781

817.535 (4) (a) 2. 1st Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.

2782

817.535 (5) (b) 1st Filing false lien or other unauthorized document; second or subsequent offense; owner of the property incurs

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2783

financial loss as a
result of the false
instrument.

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.

2784

827.03 (2) (a)

1st

Aggravated child abuse.

2785

847.0145 (1)

1st

Selling, or otherwise
transferring custody or
control, of a minor.

2786

847.0145 (2)

1st

Purchasing, or otherwise
obtaining custody or
control, of a minor.

2787

859.01

1st

Poisoning or introducing
bacteria, radioactive
materials, viruses, or
chemical compounds into
food, drink, medicine, or
water with intent to kill

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2788

or injure another person.

893.135

1st

Attempted capital
trafficking offense.

2789

893.135 (1) (a) 3.

1st

Trafficking in cannabis,
more than 10,000 lbs.

2790

893.135
(1) (b) 1.c.

1st

Trafficking in cocaine,
more than 400 grams, less
than 150 kilograms.

2791

893.135
(1) (c) 1.c.

1st

Trafficking in illegal
drugs, more than 28
grams, less than 30
kilograms.

2792

893.135
(1) (c) 2.d.

1st

Trafficking in
hydrocodone, 200 grams or
more, less than 30
kilograms.

2793

893.135
(1) (c) 3.d.

1st

Trafficking in oxycodone,
100 grams or more, less
than 30 kilograms.

2794

893.135
(1) (d) 1.c.

1st

Trafficking in
phencyclidine, more than
400 grams.

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2795

893.135 1st Trafficking in
 (1) (e) 1.c. methaqualone, more than
 25 kilograms.

2796

893.135 1st Trafficking in
 (1) (f) 1.c. amphetamine, more than
 200 grams.

2797

893.135 1st Trafficking in gamma-
 (1) (h) 1.c. hydroxybutyric acid
 (GHB), 10 kilograms or
 more.

2798

893.135 1st Trafficking in 1,4-
 (1) (j) 1.c. Butanediol, 10 kilograms
 or more.

2799

893.135 1st Trafficking in
 (1) (k) 2.c. Phenethylamines, 400
 grams or more.

2800

896.101 (5) (c) 1st Money laundering,
 financial instruments
 totaling or exceeding
 \$100,000.

2801

896.104 (4) (a) 3. 1st Structuring transactions
 to evade reporting or

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registration
 requirements, financial
 transactions totaling or
 exceeding \$100,000.

2802

2803 (j) LEVEL 10

2804

Florida
 Statute

Felony
 Degree

Description

2805

499.0051(9)

1st

Knowing sale or purchase
 of contraband
 prescription drugs
 resulting in death.

~~499.0051(10)~~

2806

782.04(2)

1st,PBL

Unlawful killing of
 human; act is homicide,
 unpremeditated.

2807

782.07(3)

1st

Aggravated manslaughter
 of a child.

2808

787.01(1)(a)3.

1st,PBL

Kidnapping; inflict
 bodily harm upon or
 terrorize victim.

2809

787.01(3)(a)

Life

Kidnapping; child under
 age 13, perpetrator also
 commits aggravated child

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2810	787.06 (3) (g)	Life	abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
2811	787.06 (4) (a)	Life	Human trafficking for commercial sexual activity of a child under the age of 18 or mentally defective or incapacitated person.
2812	794.011 (3)	Life	Selling or buying of minors into human trafficking.
2813	812.135 (2) (a)	1st, PBL	Sexual battery; victim 12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.
2814	876.32	1st	Treason against the state.

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2815

2816

2817

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