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Proposed Committee Substitute by the Committee on Appropriations
(Appropriations Subcommittee on General Government)

A bill to be entitled

An act relating to drugs, devices, and cosmetics;
amending s. 499.003, F.S.; providing, revising, and
deleting definitions for purposes of the Florida Drug
and Cosmetic Act; amending s. 499.005, F.S.; revising
prohibited acts related to the distribution of
prescription drugs; conforming a cross-reference;
amending s. 499.0051, F.S.; prohibiting the
distribution of prescription drugs without delivering
a transaction history, transaction information, and
transaction statement; providing penalties; deleting
provisions and revising terminology related to
pedigree papers, to conform to changes made by the
act; amending s. 499.006, F.S.; conforming provisions;
amending s. 499.01, F.S.; requiring nonresident
prescription drug repackagers to obtain an operating
permit; authorizing a manufacturer to engage in the
wholesale distribution of prescription drugs;
providing for the issuance of virtual prescription
drug manufacturer permits and virtual nonresident
prescription drug manufacturer permits to certain
persons; providing exceptions from certain virtual
manufacturer requirements; requiring a nonresident
prescription drug repackager permit for certain
persons; deleting surety bond requirements for
prescription drug wholesale distributors; requiring
that certain persons obtain an out-of-state



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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
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



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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.
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; increasing the quantity of unit doses of
67 a controlled substance that may be ordered in any
68 given month by a customer without triggering a
69 requirement that a wholesale distributor perform a
70 reasonableness assessment; conforming provisions;
71 amending s. 499.015, F.S.; providing for the
72 expiration, renewal, and issuance of certain drug,
73 device, and cosmetic product registrations; providing
74 for product registration fees; amending ss. 499.03,
75 499.05, and 499.051, F.S.; conforming provisions to
76 changes made by the act; amending s. 499.066, F.S.;
77 authorizing the issuance of nondisciplinary citations;
78 authorizing the department to adopt rules designating
79 violations for which a citation may be issued;
80 authorizing the department to recover investigative
81 costs pursuant to the citation; specifying a time
82 limitation for issuance of a citation; providing for
83 service of a citation; amending s. 499.82, F.S.;
84 revising the definition of "wholesale distribution"
85 for purposes of medical gas requirements; amending s.



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86 499.89, F.S.; conforming provisions; repealing s.
87 499.01212, F.S., relating to pedigree papers; amending
88 ss. 409.9201, 499.067, 794.075, and 921.0022, F.S.;
89 conforming cross-references; providing an effective
90 date.

91
92 Be It Enacted by the Legislature of the State of Florida:

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

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

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

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

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

114 (a) The business entity controls, or has the power to



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115 control, the other business entity; or

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

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

124 (4)(3) "Affiliated party" means:

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

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

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

137 (d) The five largest natural shareholders that own at least
138 5 percent of the permittee or applicant.

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

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



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

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

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

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

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

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

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

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



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

176 (11) "Contraband prescription drug" means any adulterated
177 drug, as defined in s. 499.006, any counterfeit drug, as defined
178 in this section, and also means any prescription drug for which
179 a transaction history, transaction information, or transaction
180 statement pedigree paper does not exist, or for which the
181 transaction history, transaction information, or transaction
182 statement pedigree paper in existence has been forged,
183 counterfeited, falsely created, or contains any altered, false,
184 or misrepresented matter.

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

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

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

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



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202 drug, device, or cosmetic manufacturer, processor, packer, or
203 distributor.

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

206 (15) "Device" means any instrument, apparatus, implement,
207 machine, contrivance, implant, in vitro reagent, or other
208 similar or related article, including its components, parts, or
209 accessories, which is:

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

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

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

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

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

229 ~~(17) "Drop shipment" means the sale of a prescription drug~~
230 ~~from a manufacturer to a wholesale distributor, where the~~



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231 ~~wholesale distributor takes title to, but not possession of, the~~
232 ~~prescription drug, and the manufacturer of the prescription drug~~
233 ~~ships the prescription drug directly to a chain pharmacy~~
234 ~~warehouse or a person authorized by law to purchase prescription~~
235 ~~drugs for the purpose of administering or dispensing the drug,~~
236 ~~as defined in s. 465.003.~~

237 ~~(17)~~(18) "Drug" means an article that is:

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

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

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

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



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

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

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

275 ~~(21)-(22)~~ "Health care entity" means a closed pharmacy or
276 any person, organization, or business entity that provides
277 diagnostic, medical, surgical, or dental treatment or care, or
278 chronic or rehabilitative care, but does not include any
279 wholesale distributor or retail pharmacy licensed under state
280 law to deal in prescription drugs. However, a blood
281 establishment is a health care entity that may engage in the
282 wholesale distribution of prescription drugs under s.
283 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

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

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

288 ~~(24)-(25)~~ "Hospital" means a facility as defined in s.



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289 395.002 and licensed under chapter 395.

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

292 ~~(26)-(27)~~ "Label" means a display of written, printed, or
293 graphic matter upon the immediate container of any drug, device,
294 or cosmetic. A requirement made by or under authority of this
295 part or rules adopted under this part that any word, statement,
296 or other information appear on the label is not complied with
297 unless such word, statement, or other information also appears
298 on the outside container or wrapper, if any, of the retail
299 package of such drug, device, or cosmetic or is easily legible
300 through the outside container or wrapper.

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

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

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

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

310 ~~(29)-(30)~~ "Manufacturer" means:

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



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318 ~~drug or biologics prepares, derives, manufactures, or produces a~~
319 ~~drug, device, or cosmetic;~~

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

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

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

344 ~~(e) A member of an affiliated group that includes, but is~~
345 ~~not limited to, persons described in paragraph (a), paragraph~~
346 ~~(b), paragraph (c), or paragraph (d), which member distributes~~



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347 ~~prescription drugs, whether or not obtaining title to the drugs,~~
348 ~~only for the manufacturer of the drugs who is also a member of~~
349 ~~the affiliated group. As used in this paragraph, the term~~
350 ~~"affiliated group" means an affiliated group as defined in s.~~
351 ~~1504 of the Internal Revenue Code of 1986, as amended. The~~
352 ~~manufacturer must disclose the names of all of its affiliated~~
353 ~~group members to the department; or~~

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

359

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

363 (30)~~(31)~~ "Medical convenience kit" means packages or units
364 that contain combination products as defined in 21 C.F.R. s.
365 3.2(e) (2).

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

369 (32)~~(33)~~ "New drug" means:

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



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

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

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

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

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

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



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

413 ~~(37)-(40)~~ "Pharmacist" means a person licensed under chapter
414 465.

415 ~~(38)-(41)~~ "Pharmacy" means an entity licensed under chapter
416 465.

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

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

432 ~~(41)-(44)~~ "Prescription drug label" means any display of
433 written, printed, or graphic matter upon the immediate container



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434 of any prescription drug before it is dispensed ~~prior to its~~
435 ~~dispensing~~ to an individual patient pursuant to a prescription
436 of a practitioner authorized by law to prescribe.

437 ~~(42)-(45)~~ "Prescription label" means any display of written,
438 printed, or graphic matter upon the immediate container of any
439 prescription drug dispensed pursuant to a prescription of a
440 practitioner authorized by law to prescribe.

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

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

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

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

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

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

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

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

462 ~~b.~~ The wholesale distributor discloses to the department



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

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

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

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

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

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

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



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492 veterinarian."

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

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

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

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

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

519 4. The distribution ~~sale, purchase, trade, or other~~
520 ~~transfer~~ of a prescription drug from or for any federal, state,



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521 or local government agency or any entity eligible to purchase
522 prescription drugs at public health services prices pursuant to
523 Pub. L. No. 102-585, s. 602 to a contract provider or its
524 subcontractor for eligible patients of the agency or entity
525 under the following conditions:

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

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

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

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

546 e. The contract provider or subcontractor may administer or
547 dispense the prescription drugs only to the eligible patients of
548 the agency or entity or must return the prescription drugs for
549 or to the agency or entity. The contract provider or



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550 subcontractor must require proof from each person seeking to
551 fill a prescription or obtain treatment that the person is an
552 eligible patient of the agency or entity and must, at a minimum,
553 maintain a copy of this proof as part of the records of the
554 contractor or subcontractor required under sub-subparagraph d.

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

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

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

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



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

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

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

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

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



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608 resolve any discrepancies in a timely manner.

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

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

613 (e) ~~(e)~~ The distribution of prescription drug samples by
614 manufacturers' representatives or distributors' representatives
615 conducted in accordance with s. 499.028.

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

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

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

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



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637 times.

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

691
692 if the distributor and the receiving entity receive no direct or
693 indirect financial benefit other than tax benefits related to
694 charitable contributions. Distributions under this section that



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695 involve controlled substances must comply with all state and
696 federal regulations pertaining to the handling of controlled
697 substances.

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

700 (49)(54) "Wholesale distributor" means a ~~any~~ person, other
701 than a manufacturer, a manufacturer's co-licensed partner, a
702 third-party logistics provider, or a repackager, who is engaged
703 in wholesale distribution of prescription drugs in or into this
704 state, including, but not limited to, manufacturers;
705 repackagers; own-label distributors; jobbers; private-label
706 distributors; brokers; warehouses, including manufacturers' and
707 distributors' warehouses, chain drug warehouses, and wholesale
708 drug warehouses; independent wholesale drug traders; exporters;
709 retail pharmacies; and the agents thereof that conduct wholesale
710 distributions.

711 Section 2. Subsections (21), (28), and (29) of section
712 499.005, Florida Statutes, are amended to read:

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

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

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

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

722
723 unless the wholesale distribution of the prescription drug is



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724 authorized in s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.e.~~

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

728 ~~(29) The receipt of a prescription drug pursuant to a~~
729 ~~wholesale distribution without having previously received or~~
730 ~~simultaneously receiving a pedigree paper that was attested to~~
731 ~~as accurate and complete by the wholesale distributor as~~
732 ~~required under this part.~~

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

739 499.0051 Criminal acts.—

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

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



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753 (b) A person engaged in the ~~wholesale~~ distribution of
754 prescription drugs who fails to acquire a complete and accurate
755 transaction history, transaction information, or transaction
756 statement ~~pedigree papers~~ concerning a prescription drug or
757 contraband prescription drug, as required by this chapter and
758 rules adopted under this chapter, before ~~prior to~~, or
759 simultaneous with, the receipt of the prescription drug or
760 contraband prescription drug from another person commits a
761 felony of the third degree, punishable as provided in s.
762 775.082, s. 775.083, or s. 775.084.

763 (c) Any person who knowingly destroys, alters, conceals, or
764 fails to maintain a complete and accurate transaction history,
765 transaction information, or transaction statement ~~pedigree~~
766 ~~papers~~ concerning any prescription drug or contraband
767 prescription drug, as required by this chapter and rules adopted
768 under this chapter, in his or her possession commits a felony of
769 the third degree, punishable as provided in s. 775.082, s.
770 775.083, or s. 775.084.

771 ~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS. Effective July~~
772 ~~1, 2006:~~

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

781 ~~(b) A person in possession of pedigree papers concerning~~



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782 ~~prescription drugs or contraband prescription drugs who falsely~~
783 ~~swears or certifies that he or she has authenticated the matters~~
784 ~~contained in the pedigree papers commits a felony of the third~~
785 ~~degree, punishable as provided in s. 775.082, s. 775.083, or s.~~
786 ~~775.084.~~

787 (2) ~~(3)~~ KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION
788 INFORMATION, OR TRANSACTION STATEMENT PEDIGREE PAPERS.—A person
789 who knowingly forges, counterfeits, or falsely creates any
790 transaction history, transaction information, or transaction
791 statement pedigree paper; who falsely represents any factual
792 matter contained on any transaction history, transaction
793 information, or transaction statement pedigree paper; or who
794 knowingly omits to record material information required to be
795 recorded in a transaction history, transaction information, or
796 transaction statement pedigree paper, commits a felony of the
797 second degree, punishable as provided in s. 775.082, s. 775.083,
798 or s. 775.084.

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

808 (h) The failure to maintain records related to a drug as
809 required by this part and rules adopted under this part, except
810 for transaction histories, transaction information, or



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811 transaction statements ~~pedigree papers~~, invoices, or shipping
812 documents related to prescription drugs.

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

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

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

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

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



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

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

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

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

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

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

864 (6) ~~If~~ It purports to be, or is represented as, a drug the
865 name of which is recognized in the official compendium, and its
866 strength differs from, or its quality or purity falls below, the
867 standard set forth in such compendium. The determination as to
868 strength, quality, or purity must be made in accordance with the



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869 tests or methods of assay set forth in such compendium, or, when
870 such tests or methods of assay are absent or inadequate, in
871 accordance with those tests or methods of assay prescribed under
872 authority of the federal act. A drug defined in the official
873 compendium is not adulterated under this subsection merely
874 because it differs from the standard of strength, quality, or
875 purity set forth for that drug in such compendium if its
876 difference in strength, quality, or purity from such standard is
877 plainly stated on its label.~~†~~

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

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

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

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

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

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

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



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898 limited prescription drug veterinary wholesale distributor.

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

901 499.01 Permits.—

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

904 (a) A prescription drug manufacturer;

905 (b) A prescription drug repackager;

906 (c) A nonresident prescription drug manufacturer;

907 (d) A nonresident prescription drug repackager;

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

909 (f) ~~(e)~~ An out-of-state prescription drug wholesale
910 distributor;

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

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

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

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

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

916 (l) ~~(k)~~ A veterinary prescription drug wholesale
917 distributor;

918 (m) ~~(l)~~ A limited prescription drug veterinary wholesale
919 distributor;

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

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

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

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

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

925 (2) The following permits are established:

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



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927 drug manufacturer permit is required for any person that is a
928 manufacturer of a prescription drug and that manufactures or
929 distributes such prescription drugs in this state.

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

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

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

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



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

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

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

981 1. A person that distributes prescription drugs for which
982 the person is not the manufacturer must also obtain an out-of-
983 state prescription drug wholesale distributor permit or third
984 party logistics provider permit pursuant to this section to



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985 engage in the ~~wholesale~~ distribution of such prescription drugs
986 when required by this part. This subparagraph does not apply to
987 a manufacturer that distributes prescription drugs only for the
988 manufacturer of the prescription drugs where both manufacturers
989 are affiliates as defined in s. 499.003(30)(e).

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

1000 (d) Nonresident prescription drug repackager permit.-A
1001 nonresident prescription drug repackager permit is required for
1002 any person located outside of this state, but within the United
1003 States or its territories, that repackages prescription drugs
1004 and engages in the distribution of such prescription drugs into
1005 this state.

1006 1. A nonresident prescription drug repackager must comply
1007 with all of the provisions of this section and the rules adopted
1008 under this section that apply to a prescription drug
1009 manufacturer.

1010 2. A nonresident prescription drug repackager must be
1011 permitted by the department and comply with all appropriate
1012 state and federal good manufacturing practices.

1013 3. A nonresident prescription drug repackager must be



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1014 registered as a drug establishment with the United States Food
1015 and Drug Administration.

1016 (e)~~(d)~~ *Prescription drug wholesale distributor permit.*—A
1017 prescription drug wholesale distributor permit is required for
1018 any person who is a wholesale distributor of prescription drugs
1019 and that may engage in the wholesale distributes such
1020 distribution of prescription drugs in this state. A ~~prescription~~
1021 ~~drug wholesale distributor that applies to the department for a~~
1022 ~~new permit or the renewal of a permit must submit a bond of~~
1023 ~~\$100,000, or other equivalent means of security acceptable to~~
1024 ~~the department, such as an irrevocable letter of credit or a~~
1025 ~~deposit in a trust account or financial institution, payable to~~
1026 ~~the Professional Regulation Trust Fund. The purpose of the bond~~
1027 ~~is to secure payment of any administrative penalties imposed by~~
1028 ~~the department and any fees and costs incurred by the department~~
1029 ~~regarding that permit which are authorized under state law and~~
1030 ~~which the permittee fails to pay 30 days after the fine or costs~~
1031 ~~become final. The department may make a claim against such bond~~
1032 ~~or security until 1 year after the permittee's license ceases to~~
1033 ~~be valid or until 60 days after any administrative or legal~~
1034 ~~proceeding authorized in this part which involves the permittee~~
1035 ~~is concluded, including any appeal, whichever occurs later. The~~
1036 department may adopt rules for issuing a prescription drug
1037 wholesale distributor-broker permit to a person who engages in
1038 the wholesale distribution of prescription drugs and does not
1039 take physical possession of any prescription drugs.

1040 (f)~~(e)~~ *Out-of-state prescription drug wholesale distributor*
1041 *permit.*—An out-of-state prescription drug wholesale distributor
1042 permit is required for any person that is a wholesale



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1043 distributor located outside this state, but within the United
1044 States or its territories, which engages in the wholesale
1045 distribution of prescription drugs into this state ~~and which~~
1046 ~~must be permitted by the department and comply with all the~~
1047 ~~provisions required of a wholesale distributor under this part.~~
1048 ~~An out-of-state prescription drug wholesale distributor that~~
1049 ~~applies to the department for a new permit or the renewal of a~~
1050 ~~permit must submit a bond of \$100,000, or other equivalent means~~
1051 ~~of security acceptable to the department, such as an irrevocable~~
1052 ~~letter of credit or a deposit in a trust account or financial~~
1053 ~~institution, payable to the Professional Regulation Trust Fund.~~
1054 ~~The purpose of the bond is to secure payment of any~~
1055 ~~administrative penalties imposed by the department and any fees~~
1056 ~~and costs incurred by the department regarding that permit which~~
1057 ~~are authorized under state law and which the permittee fails to~~
1058 ~~pay 30 days after the fine or costs become final. The department~~
1059 ~~may make a claim against such bond or security until 1 year~~
1060 ~~after the permittee's license ceases to be valid or until 60~~
1061 ~~days after any administrative or legal proceeding authorized in~~
1062 ~~this part which involves the permittee is concluded, including~~
1063 ~~any appeal, whichever occurs later. The out-of-state~~
1064 prescription drug wholesale distributor must maintain at all
1065 times a license or permit to engage in the wholesale
1066 distribution of prescription drugs in compliance with laws of
1067 the state in which it is a resident. If the state from which the
1068 wholesale distributor distributes prescription drugs does not
1069 require a license to engage in the wholesale distribution of
1070 prescription drugs, the distributor must be licensed as a
1071 wholesale distributor as required by the federal act.



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1072 (g)~~(f)~~ *Retail pharmacy drug wholesale distributor permit.*—A
1073 retail pharmacy drug wholesale distributor is a retail pharmacy
1074 engaged in wholesale distribution of prescription drugs within
1075 this state under the following conditions:

1076 1. The pharmacy must obtain a retail pharmacy drug
1077 wholesale distributor permit pursuant to this part and ~~the~~ rules
1078 adopted under this part.

1079 2. The wholesale distribution activity does not exceed 30
1080 percent of the total annual purchases of prescription drugs. If
1081 the wholesale distribution activity exceeds the 30-percent
1082 maximum, the pharmacy must obtain a prescription drug wholesale
1083 distributor permit.

1084 3. The transfer of prescription drugs that appear in any
1085 schedule contained in chapter 893 is subject to chapter 893 and
1086 the federal Comprehensive Drug Abuse Prevention and Control Act
1087 of 1970.

1088 4. The transfer is between a retail pharmacy and another
1089 retail pharmacy, or a Modified Class II institutional pharmacy,
1090 or a health care practitioner licensed in this state and
1091 authorized by law to dispense or prescribe prescription drugs.

1092 5. All records of sales of prescription drugs subject to
1093 this section must be maintained separate and distinct from other
1094 records and comply with the recordkeeping requirements of this
1095 part.

1096 (h)~~(g)~~ *Restricted prescription drug distributor permit.*—

1097 1. A restricted prescription drug distributor permit is
1098 required for:

1099 a. Any person located in this state who engages in the
1100 distribution of a prescription drug, which distribution is not



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1101 considered "wholesale distribution" under s. 499.003(48)(a)
1102 ~~499.003(53)(a)~~.

1103 b. Any person located in this state who engages in the
1104 receipt or distribution of a prescription drug in this state for
1105 the purpose of processing its return or its destruction if such
1106 person is not the person initiating the return, the prescription
1107 drug wholesale supplier of the person initiating the return, or
1108 the manufacturer of the drug.

1109 c. A blood establishment located in this state which
1110 collects blood and blood components only from volunteer donors
1111 as defined in s. 381.06014 or pursuant to an authorized
1112 practitioner's order for medical treatment or therapy and
1113 engages in the wholesale distribution of a prescription drug not
1114 described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care
1115 entity. A mobile blood unit operated by a blood establishment
1116 permitted under this sub-subparagraph is not required to be
1117 separately permitted. The health care entity receiving a
1118 prescription drug distributed under this sub-subparagraph must
1119 be licensed as a closed pharmacy or provide health care services
1120 at that establishment. The blood establishment must operate in
1121 accordance with s. 381.06014 and may distribute only:

1122 (I) Prescription drugs indicated for a bleeding or clotting
1123 disorder or anemia;

1124 (II) Blood-collection containers approved under s. 505 of
1125 the federal act;

1126 (III) Drugs that are blood derivatives, or a recombinant or
1127 synthetic form of a blood derivative;

1128 (IV) Prescription drugs that are identified in rules
1129 adopted by the department and that are essential to services



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1130 performed or provided by blood establishments and authorized for
1131 distribution by blood establishments under federal law; or

1132 (V) To the extent authorized by federal law, drugs
1133 necessary to collect blood or blood components from volunteer
1134 blood donors; for blood establishment personnel to perform
1135 therapeutic procedures under the direction and supervision of a
1136 licensed physician; and to diagnose, treat, manage, and prevent
1137 any reaction of a volunteer blood donor or a patient undergoing
1138 a therapeutic procedure performed under the direction and
1139 supervision of a licensed physician,

1140
1141 as long as all of the health care services provided by the blood
1142 establishment are related to its activities as a registered
1143 blood establishment or the health care services consist of
1144 collecting, processing, storing, or administering human
1145 hematopoietic stem cells or progenitor cells or performing
1146 diagnostic testing of specimens if such specimens are tested
1147 together with specimens undergoing routine donor testing. The
1148 blood establishment may purchase and possess the drugs described
1149 in this sub-subparagraph without a health care clinic
1150 establishment permit.

1151 2. Storage, handling, and recordkeeping of these
1152 distributions by a person required to be permitted as a
1153 restricted prescription drug distributor must be in accordance
1154 with the requirements for wholesale distributors under s.
1155 499.0121, ~~but not those set forth in s. 499.01212 if the~~
1156 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~
1157 ~~subparagraph 1.b.~~

1158 3. A person who applies for a permit as a restricted



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1159 prescription drug distributor, or for the renewal of such a
1160 permit, must provide to the department the information required
1161 under s. 499.012.

1162 4. The department may adopt rules regarding the
1163 distribution of prescription drugs by hospitals, health care
1164 entities, charitable organizations, other persons not involved
1165 in wholesale distribution, and blood establishments, which rules
1166 are necessary for the protection of the public health, safety,
1167 and welfare.

1168 (i)~~(h)~~ *Complimentary drug distributor permit.*—A
1169 complimentary drug distributor permit is required for any person
1170 that engages in the distribution of a complimentary drug,
1171 subject to the requirements of s. 499.028.

1172 (j)~~(i)~~ *Freight forwarder permit.*—A freight forwarder permit
1173 is required for any person that engages in the distribution of a
1174 prescription drug as a freight forwarder unless the person is a
1175 common carrier. The storage, handling, and recordkeeping of such
1176 distributions must comply with the requirements for wholesale
1177 distributors under s. 499.0121, ~~but not those set forth in s.~~
1178 ~~499.01212.~~ A freight forwarder must provide the source of the
1179 prescription drugs with a validated airway bill, bill of lading,
1180 or other appropriate documentation to evidence the exportation
1181 of the product.

1182 (k)~~(j)~~ *Veterinary prescription drug retail establishment*
1183 *permit.*—A veterinary prescription drug retail establishment
1184 permit is required for any person that sells veterinary
1185 prescription drugs to the public but does not include a pharmacy
1186 licensed under chapter 465.

1187 1. The sale to the public must be based on a valid written



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1188 order from a veterinarian licensed in this state who has a valid
1189 client-veterinarian relationship with the purchaser's animal.

1190 2. Veterinary prescription drugs may not be sold in excess
1191 of the amount clearly indicated on the order or beyond the date
1192 indicated on the order.

1193 3. An order may not be valid for more than 1 year.

1194 4. A veterinary prescription drug retail establishment may
1195 not purchase, sell, trade, or possess human prescription drugs
1196 or any controlled substance as defined in chapter 893.

1197 5. A veterinary prescription drug retail establishment must
1198 sell a veterinary prescription drug in the original, sealed
1199 manufacturer's container with all labeling intact and legible.
1200 The department may adopt by rule additional labeling
1201 requirements for the sale of a veterinary prescription drug.

1202 6. A veterinary prescription drug retail establishment must
1203 comply with all of the wholesale distribution requirements of s.
1204 499.0121.

1205 7. Prescription drugs sold by a veterinary prescription
1206 drug retail establishment pursuant to a practitioner's order may
1207 not be returned into the retail establishment's inventory.

1208 (1)~~(*)~~ *Veterinary prescription drug wholesale distributor*
1209 *permit.*—A veterinary prescription drug wholesale distributor
1210 permit is required for any person that engages in the
1211 distribution of veterinary prescription drugs in or into this
1212 state. A veterinary prescription drug wholesale distributor that
1213 also distributes prescription drugs subject to, defined by, or
1214 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1215 Act which it did not manufacture must obtain a permit as a
1216 prescription drug wholesale distributor, an out-of-state



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1217 prescription drug wholesale distributor, or a limited
1218 prescription drug veterinary wholesale distributor in lieu of
1219 the veterinary prescription drug wholesale distributor permit. A
1220 veterinary prescription drug wholesale distributor must comply
1221 with the requirements for wholesale distributors under s.
1222 499.0121, ~~but not those set forth in s. 499.01212.~~

1223 (m) ~~(l)~~ *Limited prescription drug veterinary wholesale*
1224 *distributor permit.*—Unless engaging in the activities of and
1225 permitted as a prescription drug manufacturer, nonresident
1226 prescription drug manufacturer, prescription drug wholesale
1227 distributor, or out-of-state prescription drug wholesale
1228 distributor, a limited prescription drug veterinary wholesale
1229 distributor permit is required for any person that engages in
1230 the distribution in or into this state of veterinary
1231 prescription drugs and prescription drugs subject to, defined
1232 by, or described by s. 503(b) of the Federal Food, Drug, and
1233 Cosmetic Act under the following conditions:

1234 1. The person is engaged in the business of wholesaling
1235 prescription and veterinary prescription drugs to persons:

1236 a. Licensed as veterinarians practicing on a full-time
1237 basis;

1238 b. Regularly and lawfully engaged in instruction in
1239 veterinary medicine;

1240 c. Regularly and lawfully engaged in law enforcement
1241 activities;

1242 d. For use in research not involving clinical use; or

1243 e. For use in chemical analysis or physical testing or for
1244 purposes of instruction in law enforcement activities, research,
1245 or testing.



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1246 2. No more than 30 percent of total annual prescription
1247 drug sales may be prescription drugs approved for human use
1248 which are subject to, defined by, or described by s. 503(b) of
1249 the Federal Food, Drug, and Cosmetic Act.

1250 3. The person does not distribute in any jurisdiction
1251 prescription drugs subject to, defined by, or described by s.
1252 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
1253 who is authorized to sell, distribute, purchase, trade, or use
1254 these drugs on or for humans.

1255 4. A limited prescription drug veterinary wholesale
1256 distributor that applies to the department for a new permit or
1257 the renewal of a permit must submit a bond of \$20,000, or other
1258 equivalent means of security acceptable to the department, such
1259 as an irrevocable letter of credit or a deposit in a trust
1260 account or financial institution, payable to the Professional
1261 Regulation Trust Fund. The purpose of the bond is to secure
1262 payment of any administrative penalties imposed by the
1263 department and any fees and costs incurred by the department
1264 regarding that permit which are authorized under state law and
1265 which the permittee fails to pay 30 days after the fine or costs
1266 become final. The department may make a claim against such bond
1267 or security until 1 year after the permittee's license ceases to
1268 be valid or until 60 days after any administrative or legal
1269 proceeding authorized in this part which involves the permittee
1270 is concluded, including any appeal, whichever occurs later.

1271 5. A limited prescription drug veterinary wholesale
1272 distributor must maintain at all times a license or permit to
1273 engage in the wholesale distribution of prescription drugs in
1274 compliance with laws of the state in which it is a resident.



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1275 6. A limited prescription drug veterinary wholesale
1276 distributor must comply with the requirements for wholesale
1277 distributors under s. ss. 499.0121 and ~~499.01212~~, except that a
1278 ~~limited prescription drug veterinary wholesale distributor is~~
1279 ~~not required to provide a pedigree paper as required by s.~~
1280 ~~499.01212 upon the wholesale distribution of a prescription drug~~
1281 ~~to a veterinarian.~~

1282 7. A limited prescription drug veterinary wholesale
1283 distributor may not return to inventory for subsequent wholesale
1284 distribution any prescription drug subject to, defined by, or
1285 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1286 Act which has been returned by a veterinarian.

1287 8. A limited prescription drug veterinary wholesale
1288 distributor permit is not required for an intracompany sale or
1289 transfer of a prescription drug from an out-of-state
1290 establishment that is duly licensed to engage in the wholesale
1291 distribution of prescription drugs in its state of residence to
1292 a licensed limited prescription drug veterinary wholesale
1293 distributor in this state if both wholesale distributors conduct
1294 wholesale distributions of prescription drugs under the same
1295 business name. The recordkeeping requirements of s. ss.
1296 ~~499.0121(6) and 499.01212~~ must be followed for this transaction.

1297 (n) ~~(m)~~ *Over-the-counter drug manufacturer permit.*—An over-
1298 the-counter drug manufacturer permit is required for any person
1299 that engages in the manufacture or repackaging of an over-the-
1300 counter drug.

1301 1. An over-the-counter drug manufacturer may not possess or
1302 purchase prescription drugs.

1303 2. A pharmacy is exempt from obtaining an over-the-counter



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1304 drug manufacturer permit if it is operating in compliance with
1305 pharmacy practice standards as defined in chapter 465 and ~~the~~
1306 rules adopted under that chapter.

1307 3. An over-the-counter drug manufacturer must comply with
1308 all appropriate state and federal good manufacturing practices.

1309 (o) ~~(n)~~ *Device manufacturer permit.*—

1310 1. A device manufacturer permit is required for any person
1311 that engages in the manufacture, repackaging, or assembly of
1312 medical devices for human use in this state, except that a
1313 permit is not required if:

1314 a. The person is engaged only in manufacturing,
1315 repackaging, or assembling a medical device pursuant to a
1316 practitioner's order for a specific patient; or

1317 b. The person does not manufacture, repackage, or assemble
1318 any medical devices or components for such devices, except those
1319 devices or components which are exempt from registration
1320 pursuant to s. 499.015(8).

1321 2. A manufacturer or repackager of medical devices in this
1322 state must comply with all appropriate state and federal good
1323 manufacturing practices and quality system rules.

1324 3. The department shall adopt rules related to storage,
1325 handling, and recordkeeping requirements for manufacturers of
1326 medical devices for human use.

1327 (p) ~~(e)~~ *Cosmetic manufacturer permit.*—A cosmetic
1328 manufacturer permit is required for any person that manufactures
1329 or repackages cosmetics in this state. A person that only labels
1330 or changes the labeling of a cosmetic but does not open the
1331 container sealed by the manufacturer of the product is exempt
1332 from obtaining a permit under this paragraph.



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1333 (q) ~~(p)~~ *Third party logistics provider permit.*—A third party
1334 logistics provider permit is required for any person that
1335 contracts with a prescription drug wholesale distributor or
1336 prescription drug manufacturer to provide warehousing,
1337 distribution, or other logistics services on behalf of a
1338 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who
1339 does not take title to the prescription drug or have
1340 responsibility to direct the sale or disposition of the
1341 prescription drug. A third party logistics provider located
1342 outside of this state, must be licensed in the state or
1343 territory from which the prescription drug is distributed by the
1344 third party logistics provider. If the state or territory from
1345 which the third party logistics provider originates does not
1346 require a license to operate as a third party logistics
1347 provider, the third party logistic provider must be licensed as
1348 a third party logistics provider as required by the federal act.
1349 Each third party logistics provider permittee shall comply with
1350 s. ~~the requirements for wholesale distributors under ss.~~
1351 499.0121 and 499.01212, with the exception of those wholesale
1352 distributions described in s. 499.01212(3)(a), and other rules
1353 that the department requires.

1354 (r) ~~(q)~~ *Health care clinic establishment permit.*—~~Effective~~
1355 ~~January 1, 2009,~~ A health care clinic establishment permit is
1356 required for the purchase of a prescription drug by a place of
1357 business at one general physical location that provides health
1358 care or veterinary services, which is owned and operated by a
1359 business entity that has been issued a federal employer tax
1360 identification number. For the purpose of this paragraph, the
1361 term “qualifying practitioner” means a licensed health care



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1362 practitioner defined in s. 456.001, or a veterinarian licensed
1363 under chapter 474, who is authorized under the appropriate
1364 practice act to prescribe and administer a prescription drug.

1365 1. An establishment must provide, as part of the
1366 application required under s. 499.012, designation of a
1367 qualifying practitioner who will be responsible for complying
1368 with all legal and regulatory requirements related to the
1369 purchase, recordkeeping, storage, and handling of the
1370 prescription drugs. In addition, the designated qualifying
1371 practitioner shall be the practitioner whose name, establishment
1372 address, and license number is used on all distribution
1373 documents for prescription drugs purchased or returned by the
1374 health care clinic establishment. Upon initial appointment of a
1375 qualifying practitioner, the qualifying practitioner and the
1376 health care clinic establishment shall notify the department on
1377 a form furnished by the department within 10 days after such
1378 employment. In addition, the qualifying practitioner and health
1379 care clinic establishment shall notify the department within 10
1380 days after any subsequent change.

1381 2. The health care clinic establishment must employ a
1382 qualifying practitioner at each establishment.

1383 3. In addition to the remedies and penalties provided in
1384 this part, a violation of this chapter by the health care clinic
1385 establishment or qualifying practitioner constitutes grounds for
1386 discipline of the qualifying practitioner by the appropriate
1387 regulatory board.

1388 4. The purchase of prescription drugs by the health care
1389 clinic establishment is prohibited during any period of time
1390 when the establishment does not comply with this paragraph.



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1391 5. A health care clinic establishment permit is not a
1392 pharmacy permit or otherwise subject to chapter 465. A health
1393 care clinic establishment that meets the criteria of a modified
1394 Class II institutional pharmacy under s. 465.019 is not eligible
1395 to be permitted under this paragraph.

1396 6. This paragraph does not apply to the purchase of a
1397 prescription drug by a licensed practitioner under his or her
1398 license.

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



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1420 ~~amount of prescription drugs distributed into the state for~~
1421 ~~purposes of this exemption.~~ The failure to comply with the
1422 requirements of this subsection, or rules adopted by the
1423 department to administer this subsection, for the purchase of
1424 prescription drug active pharmaceutical ingredients is a
1425 violation of s. 499.005(14), and a knowing failure is a
1426 violation of s. 499.0051(3) ~~499.0051(4)~~.

1427 (a) The immediate package or container of a prescription
1428 drug active pharmaceutical ingredient distributed into the state
1429 that is intended for research and development under this
1430 subsection shall bear a label prominently displaying the
1431 statement: "Caution: Research and Development Only-Not for
1432 Manufacturing, Compounding, or Resale."

1433 (b) A prescription drug manufacturer that obtains a
1434 prescription drug active pharmaceutical ingredient under this
1435 subsection for use in clinical trials and or biostudies
1436 authorized and regulated by federal law must create and maintain
1437 records detailing the specific clinical trials or biostudies for
1438 which the prescription drug active pharmaceutical ingredient was
1439 obtained.

1440 (4) (a) A permit issued under this part is not required to
1441 distribute a prescription drug active pharmaceutical ingredient
1442 from an establishment located in the United States to an
1443 establishment located in this state permitted as a prescription
1444 drug manufacturer under this part for use by the recipient in
1445 preparing, deriving, processing, producing, or fabricating a
1446 prescription drug finished dosage form at the establishment in
1447 this state where the product is received under an approved and
1448 otherwise valid New Drug Approval Application, Abbreviated New



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1449 Drug Application, New Animal Drug Application, or Therapeutic
1450 Biologic Application, provided that the application, active
1451 pharmaceutical ingredient, or finished dosage form has not been
1452 withdrawn or removed from the market in this country for public
1453 health reasons.

1454 1. Any distributor claiming exemption from permitting
1455 requirements pursuant to this paragraph shall maintain a
1456 license, permit, or registration to engage in the wholesale
1457 distribution of prescription drugs under the laws of the state
1458 from which the product is distributed. If the state from which
1459 the prescription drugs are distributed does not require a
1460 license to engage in the wholesale distribution of prescription
1461 drugs, the distributor must be licensed as a wholesale
1462 distributor as required by the federal act.

1463 2. Any distributor claiming exemption from permitting
1464 requirements pursuant to this paragraph and the prescription
1465 drug manufacturer purchasing and receiving the active
1466 pharmaceutical ingredient shall comply with the recordkeeping
1467 requirements of s. 499.0121(6), ~~but not the requirements of s.~~
1468 ~~499.01212.~~

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



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1478 ~~a given period of time and the amounts of prescription drugs~~
1479 ~~distributed into the state for purposes of this exemption.~~

1480 1. Any distributor claiming exemption from permitting
1481 requirements pursuant to this paragraph shall maintain a
1482 license, permit, or registration to engage in the wholesale
1483 distribution of prescription drugs under the laws of the state
1484 from which the product is distributed. If the state from which
1485 the prescription drugs are distributed does not require a
1486 license to engage in the wholesale distribution of prescription
1487 drugs, the distributor must be licensed as a wholesale
1488 distributor as required by the federal act.

1489 2. All purchasers and recipients of any prescription drugs
1490 distributed pursuant to this paragraph shall ensure that the
1491 products are not resold or used, directly or indirectly, on
1492 humans except in lawful clinical trials and biostudies
1493 authorized and regulated by federal law.

1494 3. Any distributor claiming exemption from permitting
1495 requirements pursuant to this paragraph, and the purchaser and
1496 recipient of the prescription drug, shall comply with the
1497 recordkeeping requirements of s. 499.0121(6), ~~but not the~~
1498 ~~requirements of s. 499.01212.~~

1499 4. The immediate package or container of any active
1500 pharmaceutical ingredient distributed into the state that is
1501 intended for teaching, testing, research, and development shall
1502 bear a label prominently displaying the statement: "Caution:
1503 Research, Teaching, or Testing Only - Not for Manufacturing,
1504 Compounding, or Resale."

1505 (c) An out-of-state prescription drug wholesale distributor
1506 permit is not required for an intracompany sale or transfer of a



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1507 prescription drug from an out-of-state establishment that is
1508 duly licensed as a prescription drug wholesale distributor in
1509 its state of residence to a licensed prescription drug wholesale
1510 distributor in this state, if both wholesale distributors
1511 conduct wholesale distributions of prescription drugs under the
1512 same business name. The recordkeeping requirements of s. ss.
1513 499.0121(6) ~~and 499.01212~~ must be followed for such
1514 transactions.

1515 (d) Persons receiving prescription drugs from a source
1516 claimed to be exempt from permitting requirements under this
1517 subsection shall maintain on file:

1518 1. A record of the FDA establishment registration number,
1519 if any;

1520 2. The resident state or federal license, registration, or
1521 permit that authorizes the source to distribute prescription
1522 drugs ~~drug wholesale distribution license, permit, or~~
1523 ~~registration number~~; and

1524 3. A copy of the most recent resident state or FDA
1525 inspection report, for all distributors and establishments from
1526 whom they purchase or receive prescription drugs under this
1527 subsection.

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



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1536 records are stored.

1537 (f) A person purchasing and receiving a prescription drug
1538 from a person claimed to be exempt from licensing requirements
1539 pursuant to this subsection shall report to the department in
1540 writing within 14 days after receiving any product that is
1541 misbranded or adulterated or that fails to meet minimum
1542 standards set forth in the official compendium or state or
1543 federal good manufacturing practices for identity, purity,
1544 potency, or sterility, regardless of whether the product is
1545 thereafter rehabilitated, quarantined, returned, or destroyed.

1546 (g) The department may adopt rules to administer this
1547 subsection which are necessary for the protection of the public
1548 health, safety, and welfare. Failure to comply with the
1549 requirements of this subsection, or rules adopted by the
1550 department to administer this subsection, is a violation of s.
1551 499.005(14), and a knowing failure is a violation of s.
1552 499.0051(3) ~~499.0051(4)~~.

1553 (h) This subsection does not relieve any person from any
1554 requirement prescribed by law with respect to controlled
1555 substances as defined in the applicable federal and state laws.

1556 (5) A prescription drug repackager permit issued under this
1557 part is not required for a restricted prescription drug
1558 distributor permitholder that is a health care entity to
1559 repackage prescription drugs in this state for its own use or
1560 for distribution to hospitals or other health care entities in
1561 the state for their own use, pursuant to s. 499.003(48)(a)3.
1562 ~~499.003(53)(a)3.~~, if:

1563 (a) The prescription drug distributor notifies the
1564 department, in writing, of its intention to engage in



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1565 repackaging under this exemption, 30 days before engaging in the
1566 repackaging of prescription drugs at the permitted
1567 establishment;

1568 (b) The prescription drug distributor is under common
1569 control with the hospitals or other health care entities to
1570 which the prescription drug distributor is distributing
1571 prescription drugs. As used in this paragraph, "common control"
1572 means the power to direct or cause the direction of the
1573 management and policies of a person or an organization, whether
1574 by ownership of stock, voting rights, contract, or otherwise;

1575 (c) The prescription drug distributor repackages the
1576 prescription drugs in accordance with current state and federal
1577 good manufacturing practices; and

1578 (d) The prescription drug distributor labels the
1579 prescription drug it repackages in accordance with state and
1580 federal laws and rules.

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



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1594 for the prescription drug by hard copy or by electronic means.

1595 Section 6. Section 499.012, Florida Statutes, is amended to
1596 read:

1597 499.012 Permit application requirements.—

1598 (1) (a) A permit issued pursuant to this part may be issued
1599 only to a natural person who is at least 18 years of age or to
1600 an applicant that is not a natural person if each person who,
1601 directly or indirectly, manages, controls, or oversees the
1602 operation of that applicant is at least 18 years of age.

1603 (b) An establishment that is a place of residence may not
1604 receive a permit and may not operate under this part.

1605 (c) A person that applies for or renews a permit to
1606 manufacture or distribute prescription drugs may not use a name
1607 identical to the name used by any other establishment or
1608 licensed person authorized to purchase prescription drugs in
1609 this state, except that a restricted drug distributor permit
1610 issued to a health care entity will be issued in the name in
1611 which the institutional pharmacy permit is issued and a retail
1612 pharmacy drug wholesale distributor will be issued a permit in
1613 the name of its retail pharmacy permit.

1614 (d) A permit for a prescription drug manufacturer,
1615 prescription drug repackager, prescription drug wholesale
1616 distributor, limited prescription drug veterinary wholesale
1617 distributor, or retail pharmacy drug wholesale distributor may
1618 not be issued to the address of a health care entity or to a
1619 pharmacy licensed under chapter 465, except as provided in this
1620 paragraph. The department may issue a prescription drug
1621 manufacturer permit to an applicant at the same address as a
1622 licensed nuclear pharmacy, which is a health care entity, even



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1623 if the nuclear pharmacy holds a special sterile compounding
1624 permit under chapter 465, for the purpose of manufacturing
1625 prescription drugs used in positron emission tomography or other
1626 radiopharmaceuticals, as listed in a rule adopted by the
1627 department pursuant to this paragraph. The purpose of this
1628 exemption is to assure availability of state-of-the-art
1629 pharmaceuticals that would pose a significant danger to the
1630 public health if manufactured at a separate establishment
1631 address from the nuclear pharmacy from which the prescription
1632 drugs are dispensed. The department may also issue a retail
1633 pharmacy drug wholesale distributor permit to the address of a
1634 community pharmacy licensed under chapter 465, even if the
1635 community pharmacy holds a special sterile compounding permit
1636 under chapter 465, as long as the community pharmacy ~~which~~ does
1637 not meet the definition of a closed pharmacy in s. 499.003.

1638 (e) A county or municipality may not issue an occupational
1639 license for ~~any licensing period beginning on or after October~~
1640 ~~1, 2003, for~~ any establishment that requires a permit pursuant
1641 to this part, unless the establishment exhibits a current permit
1642 issued by the department for the establishment. Upon
1643 presentation of the requisite permit issued by the department,
1644 an occupational license may be issued by the municipality or
1645 county in which application is made. The department shall
1646 furnish to local agencies responsible for issuing occupational
1647 licenses a current list of all establishments licensed pursuant
1648 to this part.

1649 (2) Notwithstanding subsection (6), a permitted person in
1650 good standing may change the type of permit issued to that
1651 person by completing a new application for the requested permit,



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1652 paying the amount of the difference in the permit fees if the
1653 fee for the new permit is more than the fee for the original
1654 permit, and meeting the applicable permitting conditions for the
1655 new permit type. The new permit expires on the expiration date
1656 of the original permit being changed; however, a new permit for
1657 a prescription drug wholesale distributor, an out-of-state
1658 prescription drug wholesale distributor, or a retail pharmacy
1659 drug wholesale distributor shall expire on the expiration date
1660 of the original permit or 1 year after the date of issuance of
1661 the new permit, whichever is earlier. A refund may not be issued
1662 if the fee for the new permit is less than the fee that was paid
1663 for the original permit.

1664 (3) (a) A written application for a permit or to renew a
1665 permit must be filed with the department on forms furnished by
1666 the department. The department shall establish, by rule, the
1667 form and content of the application to obtain or renew a permit.
1668 The applicant must submit to the department with the application
1669 a statement that swears or affirms that the information is true
1670 and correct.

1671 (b) Upon a determination that 2 years have elapsed since
1672 the department notified an applicant for permit, certification,
1673 or product registration of a deficiency in the application and
1674 that the applicant has failed to cure the deficiency, the
1675 application shall expire. The determination regarding the 2-year
1676 lapse of time shall be based on documentation that the
1677 department notified the applicant of the deficiency in
1678 accordance with s. 120.60.

1679 (c) Information submitted by an applicant on an application
1680 required pursuant to this subsection which is a trade secret, as



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1681 defined in s. 812.081, shall be maintained by the department as
1682 trade secret information pursuant to s. 499.051(7).

1683 (4) (a) Except for a permit for a prescription drug
1684 wholesale distributor or an out-of-state prescription drug
1685 wholesale distributor, an application for a permit must include:

1686 1. The name, full business address, and telephone number of
1687 the applicant;

1688 2. All trade or business names used by the applicant;

1689 3. The address, telephone numbers, and the names of contact
1690 persons for each facility used by the applicant for the storage,
1691 handling, and distribution of prescription drugs;

1692 4. The type of ownership or operation, such as a
1693 partnership, corporation, or sole proprietorship; and

1694 5. The names of the owner and the operator of the
1695 establishment, including:

1696 a. If an individual, the name of the individual;

1697 b. If a partnership, the name of each partner and the name
1698 of the partnership;

1699 c. If a corporation, the name and title of each corporate
1700 officer and director, the corporate names, and the name of the
1701 state of incorporation;

1702 d. If a sole proprietorship, the full name of the sole
1703 proprietor and the name of the business entity;

1704 e. If a limited liability company, the name of each member,
1705 the name of each manager, the name of the limited liability
1706 company, and the name of the state in which the limited
1707 liability company was organized; and

1708 f. Any other relevant information that the department
1709 requires.



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1710 (b) Upon approval of the application by the department and
1711 payment of the required fee, the department shall issue a permit
1712 to the applicant, if the applicant meets the requirements of
1713 this part and rules adopted under this part.

1714 (c) Any change in information required under paragraph (a)
1715 must be submitted to the department before the change occurs.

1716 (d) The department shall consider, at a minimum, the
1717 following factors in reviewing the qualifications of persons to
1718 be permitted under this part:

1719 1. The applicant's having been found guilty, regardless of
1720 adjudication, in a court of this state or other jurisdiction, of
1721 a violation of a law that directly relates to a drug, device, or
1722 cosmetic. A plea of nolo contendere constitutes a finding of
1723 guilt for purposes of this subparagraph.

1724 2. The applicant's having been disciplined by a regulatory
1725 agency in any state for any offense that would constitute a
1726 violation of this part.

1727 3. Any felony conviction of the applicant under a federal,
1728 state, or local law;

1729 4. The applicant's past experience in manufacturing or
1730 distributing drugs, devices, or cosmetics;

1731 5. The furnishing by the applicant of false or fraudulent
1732 material in any application made in connection with
1733 manufacturing or distributing drugs, devices, or cosmetics;

1734 6. Suspension or revocation by a federal, state, or local
1735 government of any permit currently or previously held by the
1736 applicant for the manufacture or distribution of any drugs,
1737 devices, or cosmetics;

1738 7. Compliance with permitting requirements under any



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1739 previously granted permits;

1740 8. Compliance with requirements to maintain or make
1741 available to the state permitting authority or to federal,
1742 state, or local law enforcement officials those records required
1743 under this section; and

1744 9. Any other factors or qualifications the department
1745 considers relevant to and consistent with the public health and
1746 safety.

1747 ~~(5) Except for a permit for a prescription drug wholesale~~
1748 ~~distributor or an out-of-state prescription drug wholesale~~
1749 ~~distributor:~~

1750 (a) The department shall adopt rules for the biennial
1751 renewal of permits; however, the department may issue up to a 4-
1752 year permit to selected permittees notwithstanding any other
1753 provision of law. Fees for such renewal may not exceed the fee
1754 caps set forth in s. 499.041 on an annualized basis as
1755 authorized by law.

1756 (b) The department shall renew a permit upon receipt of the
1757 renewal application and renewal fee if the applicant meets the
1758 requirements established under this part and ~~the~~ rules adopted
1759 under this part.

1760 (c) At least 90 days before the expiration date of a
1761 permit, the department shall forward a permit renewal
1762 notification to the permittee at the mailing address of the
1763 permitted establishment on file with the department. The permit
1764 renewal notification must state conspicuously the date on which
1765 the permit for the establishment will expire and that the
1766 establishment may not operate unless the permit for the
1767 establishment is renewed timely. ~~A permit, unless sooner~~



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1768 ~~suspended or revoked, automatically expires 2 years after the~~
1769 ~~last day of the anniversary month in which the permit was~~
1770 ~~originally issued.~~

1771 (d) A permit issued under this part may be renewed by
1772 making application for renewal on forms furnished by the
1773 department and paying the appropriate fees.

1774 1. If a prescription drug wholesale distributor or an out-
1775 of-state prescription drug wholesale distributor renewal
1776 application and fee are submitted and postmarked later than 45
1777 days before the expiration date of the permit, the permit may be
1778 renewed only upon payment of a late renewal fee of \$100, plus
1779 the required renewal fee.

1780 2. If any other a renewal application and fee are submitted
1781 and postmarked after the expiration date of the permit, the
1782 permit may be renewed only upon payment of a late renewal
1783 delinquent fee of \$100, plus the required renewal fee, not later
1784 than 60 days after the expiration date.

1785 3. A permittee who submits a renewal application in
1786 accordance with this paragraph may continue to operate under its
1787 permit, unless the permit is suspended or revoked, until final
1788 disposition of the renewal application.

1789 4. (d) Failure to renew a permit in accordance with this
1790 section precludes any future renewal of that permit. If a permit
1791 issued pursuant to this part has expired and cannot be renewed,
1792 before an establishment may engage in activities that require a
1793 permit under this part, the establishment must submit an
1794 application for a new permit, pay the applicable application
1795 fee, the initial permit fee, and all applicable penalties, and
1796 be issued a new permit by the department.



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1797 (6) A permit issued by the department is nontransferable.
1798 Each permit is valid only for the person or governmental unit to
1799 which it is issued and is not subject to sale, assignment, or
1800 other transfer, voluntarily or involuntarily; nor is a permit
1801 valid for any establishment other than the establishment for
1802 which it was originally issued.

1803 (a) A person permitted under this part must notify the
1804 department before making a change of address. The department
1805 shall set a change of location fee not to exceed \$100.

1806 (b)1. An application for a new permit is required when a
1807 majority of the ownership or controlling interest of a permitted
1808 establishment is transferred or assigned or when a lessee agrees
1809 to undertake or provide services to the extent that legal
1810 liability for operation of the establishment will rest with the
1811 lessee. The application for the new permit must be made before
1812 the date of the sale, transfer, assignment, or lease.

1813 2. A permittee that is authorized to distribute
1814 prescription drugs may transfer such drugs to the new owner or
1815 lessee under subparagraph 1. only after the new owner or lessee
1816 has been approved for a permit to distribute prescription drugs.

1817 (c) If an establishment permitted under this part closes,
1818 the owner must notify the department in writing before the
1819 effective date of closure and must:

1820 1. Return the permit to the department;

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



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1826 ownership of prescription drugs may be made only to persons
1827 authorized to possess prescription drugs under this part.

1828
1829 The department may revoke the permit of any person that fails to
1830 comply with the requirements of this subsection.

1831 (7) A permit must be posted in a conspicuous place on the
1832 licensed premises.

1833 (8) An application for a permit or to renew a permit for a
1834 prescription drug wholesale distributor or an out-of-state
1835 prescription drug wholesale distributor submitted to the
1836 department must include:

1837 (a) The name, full business address, and telephone number
1838 of the applicant.

1839 (b) All trade or business names used by the applicant.

1840 (c) The address, telephone numbers, and the names of
1841 contact persons for each facility used by the applicant for the
1842 storage, handling, and distribution of prescription drugs.

1843 (d) The type of ownership or operation, such as a
1844 partnership, corporation, or sole proprietorship.

1845 (e) The names of the owner and the operator of the
1846 establishment, including:

1847 1. If an individual, the name of the individual.

1848 2. If a partnership, the name of each partner and the name
1849 of the partnership.

1850 3. If a corporation:

1851 a. The name, address, and title of each corporate officer
1852 and director.

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



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1855 corporation's state of incorporation.

1856 c. The name and address of each shareholder of the
1857 corporation that owns 5 percent or more of the outstanding stock
1858 of the corporation.

1859 4. If a sole proprietorship, the full name of the sole
1860 proprietor and the name of the business entity.

1861 5. If a limited liability company:

1862 a. The name and address of each member.

1863 b. The name and address of each manager.

1864 c. The name and address of the limited liability company,
1865 the resident agent of the limited liability company, and the
1866 name of the state in which the limited liability company was
1867 organized.

1868 (f) If applicable, the name and address of each affiliate
1869 of member of the affiliated group of which the applicant is a
1870 member.

1871 (g) ~~1. The applicant's gross annual receipts attributable to~~
1872 ~~prescription drug wholesale distribution activities for the~~
1873 ~~previous tax year. For an application for a new permit, the~~
1874 ~~estimated annual dollar volume of prescription drug sales of the~~
1875 ~~applicant, the estimated annual percentage of the applicant's~~
1876 ~~total company sales that are prescription drugs, the applicant's~~
1877 ~~estimated annual total dollar volume of purchases of~~
1878 ~~prescription drugs, and the applicant's estimated annual total~~
1879 ~~dollar volume of prescription drug purchases directly from~~
1880 ~~manufacturers.~~

1881 2. ~~For an application to renew a permit, the total dollar~~
1882 ~~volume of prescription drug sales in the previous year, the~~
1883 ~~total dollar volume of prescription drug sales made in the~~



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1884 ~~previous 6 months, the percentage of total company sales that~~
1885 ~~were prescription drugs in the previous year, the total dollar~~
1886 ~~volume of purchases of prescription drugs in the previous year,~~
1887 ~~and the total dollar volume of prescription drug purchases~~
1888 ~~directly from manufacturers in the previous year.~~

1889
1890 ~~Such portions of the information required pursuant to this~~
1891 ~~paragraph which are a trade secret, as defined in s. 812.081,~~
1892 ~~shall be maintained by the department as trade secret~~
1893 ~~information is required to be maintained under s. 499.051.~~

1894 (h) The tax year of the applicant.

1895 (i) A copy of the deed for the property on which
1896 applicant's establishment is located, if the establishment is
1897 owned by the applicant, or a copy of the applicant's lease for
1898 the property on which applicant's establishment is located that
1899 has an original term of not less than 1 calendar year, if the
1900 establishment is not owned by the applicant.

1901 (j) A list of all licenses and permits issued to the
1902 applicant by any other state which authorize the applicant to
1903 purchase or possess prescription drugs.

1904 (k) The name of the manager of the establishment that is
1905 applying for the permit or to renew the permit, the next four
1906 highest ranking employees responsible for prescription drug
1907 wholesale operations for the establishment, and the name of all
1908 affiliated parties for the establishment, together with the
1909 personal information statement and fingerprints required
1910 pursuant to subsection (9) for each of such persons.

1911 (l) The name of each of the applicant's designated
1912 representatives as required by subsection (15) ~~(16)~~, together



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1913 with the personal information statement and fingerprints
1914 required pursuant to subsection (9) for each such person.

1915 (m) Evidence of a surety bond in this state or any other
1916 state in the United States in the amount of \$100,000. If the
1917 annual gross receipts of the applicant's previous tax year is
1918 \$10 million or less, evidence of a surety bond in the amount of
1919 \$25,000. The specific language of the surety bond must include
1920 the State of Florida as a beneficiary, payable to the
1921 Professional Regulation Trust Fund. In lieu of the surety bond,
1922 the applicant may provide other equivalent security such as an
1923 irrevocable letter of credit, or a deposit in a trust account or
1924 financial institution, which includes the State of Florida as a
1925 beneficiary, payable to the Professional Regulation Trust Fund.
1926 The purpose of the bond or other security is to secure payment
1927 of any administrative penalties imposed by the department and
1928 any fees and costs incurred by the department regarding that
1929 permit which are authorized under state law and which the
1930 permittee fails to pay 30 days after the fine or costs become
1931 final. The department may make a claim against such bond or
1932 security until 1 year after the permittee's license ceases to be
1933 valid or until 60 days after any administrative or legal
1934 proceeding authorized in this part which involves the permittee
1935 is concluded, including any appeal, whichever occurs later. For
1936 an applicant that is a secondary wholesale distributor, each of
1937 the following:

1938 1. A personal background information statement containing
1939 the background information and fingerprints required pursuant to
1940 subsection (9) for each person named in the applicant's response
1941 to paragraphs (k) and (l) and for each affiliated party of the



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1942 applicant.

1943 ~~2. If any of the five largest shareholders of the~~
1944 ~~corporation seeking the permit is a corporation, the name,~~
1945 ~~address, and title of each corporate officer and director of~~
1946 ~~each such corporation; the name and address of such corporation;~~
1947 ~~the name of such corporation's resident agent, such~~
1948 ~~corporation's resident agent's address, and such corporation's~~
1949 ~~state of its incorporation; and the name and address of each~~
1950 ~~shareholder of such corporation that owns 5 percent or more of~~
1951 ~~the stock of such corporation.~~

1952 ~~3. The name and address of all financial institutions in~~
1953 ~~which the applicant has an account which is used to pay for the~~
1954 ~~operation of the establishment or to pay for drugs purchased for~~
1955 ~~the establishment, together with the names of all persons that~~
1956 ~~are authorized signatories on such accounts. The portions of the~~
1957 ~~information required pursuant to this subparagraph which are a~~
1958 ~~trade secret, as defined in s. 812.081, shall be maintained by~~
1959 ~~the department as trade secret information is required to be~~
1960 ~~maintained under s. 499.051.~~

1961 ~~4. The sources of all funds and the amounts of such funds~~
1962 ~~used to purchase or finance purchases of prescription drugs or~~
1963 ~~to finance the premises on which the establishment is to be~~
1964 ~~located.~~

1965 ~~5. If any of the funds identified in subparagraph 4. were~~
1966 ~~borrowed, copies of all promissory notes or loans used to obtain~~
1967 ~~such funds.~~

1968 (n) For establishments used in wholesale distribution,
1969 proof of an inspection conducted by the department, the United
1970 States Food and Drug Administration, or another governmental



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1971 entity charged with the regulation of good manufacturing
1972 practices related to wholesale distribution of prescription
1973 drugs, within timeframes set forth by the department in
1974 departmental rules, which demonstrates substantial compliance
1975 with current good manufacturing practices applicable to
1976 wholesale distribution of prescription drugs. The department may
1977 recognize another state's inspection of a wholesale distributor
1978 located in that state if such state's laws are deemed to be
1979 substantially equivalent to the law of this state by the
1980 department. The department may accept an inspection by a third-
1981 party accreditation or inspection service which meets the
1982 criteria set forth in department rule.

1983 (o) ~~(n)~~ Any other relevant information that the department
1984 requires, including, but not limited to, any information related
1985 to whether the applicant satisfies the definition of a primary
1986 wholesale distributor or a secondary wholesale distributor.

1987 (p) ~~(e)~~ Documentation of the credentialing policies and
1988 procedures required by s. 499.0121(15).

1989 (9) (a) Each person required by subsection (8) or subsection
1990 (15) to provide a personal information statement and
1991 fingerprints shall provide the following information to the
1992 department on forms prescribed by the department:

1993 1. The person's places of residence for the past 7 years.

1994 2. The person's date and place of birth.

1995 3. The person's occupations, positions of employment, and
1996 offices held during the past 7 years.

1997 4. The principal business and address of any business,
1998 corporation, or other organization in which each such office of
1999 the person was held or in which each such occupation or position



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2000 of employment was carried on.

2001 5. Whether the person has been, during the past 7 years,
2002 the subject of any proceeding for the revocation of any license
2003 and, if so, the nature of the proceeding and the disposition of
2004 the proceeding.

2005 6. Whether, during the past 7 years, the person has been
2006 enjoined, temporarily or permanently, by a court of competent
2007 jurisdiction from violating any federal or state law regulating
2008 the possession, control, or distribution of prescription drugs,
2009 together with details concerning any such event.

2010 7. A description of any involvement by the person with any
2011 business, including any investments, other than the ownership of
2012 stock in a publicly traded company or mutual fund, during the
2013 past 4 7 years, which manufactured, administered, prescribed,
2014 distributed, or stored pharmaceutical products and any lawsuits
2015 in which such businesses were named as a party.

2016 8. A description of any felony criminal offense of which
2017 the person, as an adult, was found guilty, regardless of whether
2018 adjudication of guilt was withheld or whether the person pled
2019 guilty or nolo contendere. A criminal offense committed in
2020 another jurisdiction which would have been a felony in this
2021 state must be reported. If the person indicates that a criminal
2022 conviction is under appeal and submits a copy of the notice of
2023 appeal of that criminal offense, the applicant must, within 15
2024 days after the disposition of the appeal, submit to the
2025 department a copy of the final written order of disposition.

2026 9. A photograph of the person taken in the previous 180 ~~30~~
2027 days.

2028 10. A set of fingerprints for the person on a form and



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2029 under procedures specified by the department, together with
2030 payment of an amount equal to the costs incurred by the
2031 department for the criminal record check of the person.

2032 11. The name, address, occupation, and date and place of
2033 birth for each member of the person's immediate family who is 18
2034 years of age or older. As used in this subparagraph, the term
2035 "member of the person's immediate family" includes the person's
2036 spouse, children, parents, siblings, the spouses of the person's
2037 children, and the spouses of the person's siblings.

2038 12. Any other relevant information that the department
2039 requires.

2040 (b) The information required pursuant to paragraph (a)
2041 shall be provided under oath.

2042 (c) The department shall submit the fingerprints provided
2043 by a person for initial licensure to the Department of Law
2044 Enforcement for a statewide criminal record check and for
2045 forwarding to the Federal Bureau of Investigation for a national
2046 criminal record check of the person. The department shall submit
2047 the fingerprints provided by a person as a part of a renewal
2048 application to the Department of Law Enforcement for a statewide
2049 criminal record check, and for forwarding to the Federal Bureau
2050 of Investigation for a national criminal record check, for the
2051 initial renewal of a permit after January 1, 2004; for any
2052 subsequent renewal of a permit, the department shall submit the
2053 required information for a statewide and national criminal
2054 record check of the person. Any person who as a part of an
2055 initial permit application or initial permit renewal after
2056 January 1, 2004, submits to the department a set of fingerprints
2057 required for the criminal record check required in this



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2058 paragraph are ~~shall~~ not ~~be~~ required to provide a subsequent set
2059 of fingerprints for a criminal record check to the department,
2060 if the person has undergone a criminal record check as a
2061 condition of the issuance of an initial permit or the initial
2062 renewal of a permit of an applicant after January 1, 2004. The
2063 department is authorized to contract with private vendors, or
2064 enter into interagency agreements, to collect electronic
2065 fingerprints where fingerprints are required for registration,
2066 certification, or the licensure process or where criminal
2067 history record checks are required.

2068 (d) For purposes of applying for renewal of a permit under
2069 subsection (8) or certification under subsection (16), a person
2070 may submit the following in lieu of satisfying the requirements
2071 of paragraphs (a), (b), and (c):

2072 1. A photograph of the individual taken within 180 days;
2073 and

2074 2. A copy of the personal information statement form most
2075 recently submitted to the department and a certification under
2076 oath, on a form specified by the department, that the individual
2077 has reviewed the previously submitted personal information
2078 statement form and that the information contained therein
2079 remains unchanged.

2080 (10) The department may deny an application for a permit or
2081 refuse to renew a permit for a prescription drug wholesale
2082 distributor or an out-of-state prescription drug wholesale
2083 distributor if:

2084 (a) The applicant has not met the requirements for the
2085 permit.

2086 (b) The management, officers, or directors of the applicant



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2087 or any affiliated party are found by the department to be
2088 incompetent or untrustworthy.

2089 (c) The applicant is so lacking in experience in managing a
2090 wholesale distributor as to make the issuance of the proposed
2091 permit hazardous to the public health.

2092 (d) The applicant is so lacking in experience in managing a
2093 wholesale distributor as to jeopardize the reasonable promise of
2094 successful operation of the wholesale distributor.

2095 (e) The applicant is lacking in experience in the
2096 distribution of prescription drugs.

2097 (f) The applicant's past experience in manufacturing or
2098 distributing prescription drugs indicates that the applicant
2099 poses a public health risk.

2100 (g) The applicant is affiliated directly or indirectly
2101 through ownership, control, or other business relations, with
2102 any person or persons whose business operations are or have been
2103 detrimental to the public health.

2104 (h) The applicant, or any affiliated party, has been found
2105 guilty of or has pleaded guilty or nolo contendere to any felony
2106 or crime punishable by imprisonment for 1 year or more under the
2107 laws of the United States, any state, or any other country,
2108 regardless of whether adjudication of guilt was withheld.

2109 (i) The applicant or any affiliated party has been charged
2110 with a felony in a state or federal court and the disposition of
2111 that charge is pending during the application review or renewal
2112 review period.

2113 (j) The applicant has furnished false or fraudulent
2114 information or material in any application made in this state or
2115 any other state in connection with obtaining a permit or license



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2116 to manufacture or distribute drugs, devices, or cosmetics.

2117 (k) That a federal, state, or local government permit
2118 currently or previously held by the applicant, or any affiliated
2119 party, for the manufacture or distribution of any drugs,
2120 devices, or cosmetics has been disciplined, suspended, or
2121 revoked and has not been reinstated.

2122 (l) The applicant does not possess the financial or
2123 physical resources to operate in compliance with the permit
2124 being sought, this chapter, and the rules adopted under this
2125 chapter.

2126 (m) The applicant or any affiliated party receives,
2127 directly or indirectly, financial support and assistance from a
2128 person who was an affiliated party of a permittee whose permit
2129 was subject to discipline or was suspended or revoked, other
2130 than through the ownership of stock in a publicly traded company
2131 or a mutual fund.

2132 (n) The applicant or any affiliated party receives,
2133 directly or indirectly, financial support and assistance from a
2134 person who has been found guilty of any violation of this part
2135 or chapter 465, chapter 501, or chapter 893, any rules adopted
2136 under this part or those chapters, any federal or state drug
2137 law, or any felony where the underlying facts related to drugs,
2138 regardless of whether the person has been pardoned, had her or
2139 his civil rights restored, or had adjudication withheld, other
2140 than through the ownership of stock in a publicly traded company
2141 or a mutual fund.

2142 (o) The applicant for renewal of a permit under s.
2143 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged
2144 in the wholesale distribution of prescription drugs, as



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2145 demonstrated by the regular and systematic distribution of
2146 prescription drugs throughout the year as evidenced by not fewer
2147 than 12 wholesale distributions in the previous year and not
2148 fewer than three wholesale distributions in the previous 6
2149 months.

2150 (p) Information obtained in response to s. 499.01(2)(e) or
2151 (f) 499.01(2)(d) or (e) demonstrates it would not be in the best
2152 interest of the public health, safety, and welfare to issue a
2153 permit.

2154 (q) The applicant does not possess the financial standing
2155 and business experience for the successful operation of the
2156 applicant.

2157 (r) The applicant or any affiliated party has failed to
2158 comply with the requirements for manufacturing or distributing
2159 prescription drugs under this part, similar federal laws,
2160 similar laws in other states, or the rules adopted under such
2161 laws.

2162 (11) Upon approval of the application by the department and
2163 payment of the required fee, the department shall issue or renew
2164 a prescription drug wholesale distributor or an out-of-state
2165 prescription drug wholesale distributor permit to the applicant.

2166 ~~(12) For a permit for a prescription drug wholesale~~
2167 ~~distributor or an out-of-state prescription drug wholesale~~
2168 ~~distributor:~~

2169 ~~(a) The department shall adopt rules for the annual renewal~~
2170 ~~of permits. At least 90 days before the expiration of a permit,~~
2171 ~~the department shall forward a permit renewal notification and~~
2172 ~~renewal application to the prescription drug wholesale~~
2173 ~~distributor or out-of-state prescription drug wholesale~~



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2174 ~~distributor at the mailing address of the permitted~~
2175 ~~establishment on file with the department. The permit renewal~~
2176 ~~notification must state conspicuously the date on which the~~
2177 ~~permit for the establishment will expire and that the~~
2178 ~~establishment may not operate unless the permit for the~~
2179 ~~establishment is renewed timely.~~

2180 ~~(b) A permit, unless sooner suspended or revoked,~~
2181 ~~automatically expires 1 year after the last day of the~~
2182 ~~anniversary month in which the permit was originally issued. A~~
2183 ~~permit may be renewed by making application for renewal on forms~~
2184 ~~furnished by the department and paying the appropriate fees. If~~
2185 ~~a renewal application and fee are submitted and postmarked after~~
2186 ~~45 days prior to the expiration date of the permit, the permit~~
2187 ~~may be renewed only upon payment of a late renewal fee of \$100,~~
2188 ~~plus the required renewal fee. A permittee that has submitted a~~
2189 ~~renewal application in accordance with this paragraph may~~
2190 ~~continue to operate under its permit, unless the permit is~~
2191 ~~suspended or revoked, until final disposition of the renewal~~
2192 ~~application.~~

2193 ~~(c) Failure to renew a permit in accordance with this~~
2194 ~~section precludes any future renewal of that permit. If a permit~~
2195 ~~issued pursuant to this section has expired and cannot be~~
2196 ~~renewed, before an establishment may engage in activities that~~
2197 ~~require a permit under this part, the establishment must submit~~
2198 ~~an application for a new permit; pay the applicable application~~
2199 ~~fee, initial permit fee, and all applicable penalties; and be~~
2200 ~~issued a new permit by the department.~~

2201 ~~(12)-(13)~~ A person that engages in wholesale distribution of
2202 prescription drugs in this state must have a wholesale



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2203 distributor's permit issued by the department, except as noted
2204 in this section. Each establishment must be separately permitted
2205 except as noted in this subsection.

2206 (a) A separate establishment permit is not required when a
2207 permitted prescription drug wholesale distributor consigns a
2208 prescription drug to a pharmacy that is permitted under chapter
2209 465 and located in this state, provided that:

2210 1. The consignor wholesale distributor notifies the
2211 department in writing of the contract to consign prescription
2212 drugs to a pharmacy along with the identity and location of each
2213 consignee pharmacy;

2214 2. The pharmacy maintains its permit under chapter 465;

2215 3. The consignor wholesale distributor, which has no legal
2216 authority to dispense prescription drugs, complies with all
2217 wholesale distribution requirements of s. ss. 499.0121 ~~and~~
2218 ~~499.01212~~ with respect to the consigned drugs and maintains
2219 records documenting the transfer of title or other completion of
2220 the wholesale distribution of the consigned prescription drugs;

2221 4. The distribution of the prescription drug is otherwise
2222 lawful under this chapter and other applicable law;

2223 5. Open packages containing prescription drugs within a
2224 pharmacy are the responsibility of the pharmacy, regardless of
2225 how the drugs are titled; and

2226 6. The pharmacy dispenses the consigned prescription drug
2227 in accordance with the limitations of its permit under chapter
2228 465 or returns the consigned prescription drug to the consignor
2229 wholesale distributor. In addition, a person who holds title to
2230 prescription drugs may transfer the drugs to a person permitted
2231 or licensed to handle the reverse distribution or destruction of



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2232 drugs. Any other distribution by and means of the consigned
2233 prescription drug by any person, not limited to the consignor
2234 wholesale distributor or consignee pharmacy, to any other person
2235 is prohibited.

2236 (b) A wholesale distributor's permit is not required for
2237 the one-time transfer of title of a pharmacy's lawfully acquired
2238 prescription drug inventory by a pharmacy with a valid permit
2239 issued under chapter 465 to a consignor prescription drug
2240 wholesale distributor, permitted under this chapter, in
2241 accordance with a written consignment agreement between the
2242 pharmacy and that wholesale distributor if the permitted
2243 pharmacy and the permitted prescription drug wholesale
2244 distributor comply with all of the provisions of paragraph (a)
2245 and the prescription drugs continue to be within the permitted
2246 pharmacy's inventory for dispensing in accordance with the
2247 limitations of the pharmacy permit under chapter 465. A
2248 consignor drug wholesale distributor may not use the pharmacy as
2249 a wholesale distributor through which it distributes the
2250 prescription drugs to other pharmacies. Nothing in this section
2251 is intended to prevent a wholesale distributor from obtaining
2252 this inventory in the event of nonpayment by the pharmacy.

2253 (c) A separate establishment permit is not required when a
2254 permitted prescription drug wholesale distributor operates
2255 temporary transit storage facilities for the sole purpose of
2256 storage, for up to 16 hours, of a delivery of prescription drugs
2257 when the wholesale distributor was temporarily unable to
2258 complete the delivery to the recipient.

2259 (d) The department shall require information from each
2260 wholesale distributor as part of the permit and renewal of such



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2261 permit, as required under this section.

2262 (13)~~(14)~~ Personnel employed in wholesale distribution must
2263 have appropriate education and experience to enable them to
2264 perform their duties in compliance with state permitting
2265 requirements.

2266 (14)~~(15)~~ The name of a permittee or establishment on a
2267 prescription drug wholesale distributor permit or an out-of-
2268 state prescription drug wholesale distributor permit may not
2269 include any indicia of attainment of any educational degree, any
2270 indicia that the permittee or establishment possesses a
2271 professional license, or any name or abbreviation that the
2272 department determines is likely to cause confusion or mistake or
2273 that the department determines is deceptive, including that of
2274 any other entity authorized to purchase prescription drugs.

2275 (15)~~(16)~~ (a) Each establishment that is issued an initial or
2276 renewal permit as a prescription drug wholesale distributor or
2277 an out-of-state prescription drug wholesale distributor must
2278 designate in writing to the department at least one natural
2279 person to serve as the designated representative of the
2280 wholesale distributor. Such person must have an active
2281 certification as a designated representative from the
2282 department.

2283 (b) To be certified as a designated representative, a
2284 natural person must:

2285 1. Submit an application on a form furnished by the
2286 department and pay the appropriate fees.

2287 2. Be at least 18 years of age.

2288 3. Have at least 2 years of verifiable full-time:

2289 a. Work experience in a pharmacy licensed in this state or



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2290 another state, where the person's responsibilities included, but
2291 were not limited to, recordkeeping for prescription drugs;

2292 b. Managerial experience with a prescription drug wholesale
2293 distributor licensed in this state or in another state; or

2294 c. Managerial experience with the United States Armed
2295 Forces, where the person's responsibilities included, but were
2296 not limited to, recordkeeping, warehousing, distributing, or
2297 other logistics services pertaining to prescription drugs.

2298 4. Receive a passing score of at least 75 percent on an
2299 examination given by the department regarding federal laws
2300 governing distribution of prescription drugs and this part and
2301 the rules adopted by the department governing the wholesale
2302 distribution of prescription drugs. This requirement shall be
2303 effective 1 year after the results of the initial examination
2304 are mailed to the persons that took the examination. The
2305 department shall offer such examinations at least four times
2306 each calendar year.

2307 5. Provide the department with a personal information
2308 statement and fingerprints pursuant to subsection (9).

2309 (c) The department may deny an application for
2310 certification as a designated representative or may suspend or
2311 revoke a certification of a designated representative pursuant
2312 to s. 499.067.

2313 (d) A designated representative:

2314 1. Must be actively involved in and aware of the actual
2315 daily operation of the wholesale distributor.

2316 2. Must be employed full time in a managerial position by
2317 the wholesale distributor.

2318 3. Must be physically present at the establishment during



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2319 normal business hours, except for time periods when absent due
2320 to illness, family illness or death, scheduled vacation, or
2321 other authorized absence.

2322 4. May serve as a designated representative for only one
2323 wholesale distributor at any one time.

2324 (e) A wholesale distributor must notify the department when
2325 a designated representative leaves the employ of the wholesale
2326 distributor. Such notice must be provided to the department
2327 within 10 business days after the last day of designated
2328 representative's employment with the wholesale distributor.

2329 (f) A wholesale distributor may not operate under a
2330 prescription drug wholesale distributor permit or an out-of-
2331 state prescription drug wholesale distributor permit for more
2332 than 10 business days after the designated representative leaves
2333 the employ of the wholesale distributor, unless the wholesale
2334 distributor employs another designated representative and
2335 notifies the department within 10 business days of the identity
2336 of the new designated representative.

2337 Section 7. Section 499.01201, Florida Statutes, is amended
2338 to read:

2339 499.01201 Agency for Health Care Administration review and
2340 use of statute and rule violation or compliance data.-
2341 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~
2342 ~~contrary~~, the Agency for Health Care Administration may not:

2343 (1) Review or use any violation or alleged violation of s.
2344 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that
2345 section ~~those sections~~, as a ground for denying or withholding
2346 any payment of a Medicaid reimbursement to a pharmacy licensed
2347 under chapter 465; or



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2348 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~
2349 ~~499.01212~~, or any rules adopted under that section ~~these~~
2350 ~~sections~~, as the subject of any audit of Medicaid-related
2351 records held by a pharmacy licensed under chapter 465.

2352 Section 8. Paragraph (d) of subsection (4), subsection (6),
2353 and paragraph (b) of subsection (15) of section 499.0121,
2354 Florida Statutes, are amended to read:

2355 499.0121 Storage and handling of prescription drugs;
2356 recordkeeping.—The department shall adopt rules to implement
2357 this section as necessary to protect the public health, safety,
2358 and welfare. Such rules shall include, but not be limited to,
2359 requirements for the storage and handling of prescription drugs
2360 and for the establishment and maintenance of prescription drug
2361 distribution records.

2362 (4) EXAMINATION OF MATERIALS AND RECORDS.—

2363 (d) Upon receipt, a wholesale distributor must review
2364 records required under this section for the acquisition of
2365 prescription drugs for accuracy and completeness, considering
2366 the total facts and circumstances surrounding the transactions
2367 and the wholesale distributors involved. ~~This includes~~
2368 ~~authenticating each transaction listed on a pedigree paper, as~~
2369 ~~defined in s. 499.003(37).~~

2370 (6) RECORDKEEPING.—The department shall adopt rules that
2371 require keeping such records of prescription drugs, including
2372 active pharmaceutical ingredients, as are necessary for the
2373 protection of the public health.

2374 (a) ~~Wholesale~~ Distributors of prescription drugs and active
2375 pharmaceutical ingredients must establish and maintain
2376 inventories and records of all transactions regarding the



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2377 receipt and distribution or other disposition of prescription
2378 drugs and active pharmaceutical ingredients. These records must
2379 provide a complete audit trail from receipt to sale or other
2380 disposition, be readily retrievable for inspection, and include,
2381 at a minimum, the following information:

2382 1. The source of the prescription drugs or active
2383 pharmaceutical ingredients, including the name and principal
2384 address of the seller or transferor, and the address of the
2385 location from which the prescription drugs were shipped;

2386 2. The name, principal address, and state license permit or
2387 registration number of the person authorized to purchase
2388 prescription drugs or active pharmaceutical ingredients;

2389 3. The name, strength, dosage form, and quantity of the
2390 prescription drugs received and distributed or disposed of;

2391 4. The dates of receipt and distribution or other
2392 disposition of the prescription drugs or active pharmaceutical
2393 ingredients; and

2394 5. Any financial documentation supporting the transaction.

2395 (b) Inventories and records must be made available for
2396 inspection and photocopying by authorized federal, state, or
2397 local officials for a period of 2 years following disposition of
2398 the drugs or 3 years after the creation of the records,
2399 whichever period is longer.

2400 (c) Records described in this section that are kept at the
2401 inspection site or that can be immediately retrieved by computer
2402 or other electronic means must be readily available for
2403 authorized inspection during the retention period. Records that
2404 are kept at a central location outside of this state and that
2405 are not electronically retrievable must be made available for



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2406 inspection within 2 working days after a request by an
2407 authorized official of a federal, state, or local law
2408 enforcement agency. Records that are maintained at a central
2409 location within this state must be maintained at an
2410 establishment that is permitted pursuant to this part and must
2411 be readily available.

2412 (d) Each manufacturer or repackager of medical devices,
2413 over-the-counter drugs, or cosmetics must maintain records that
2414 include the name and principal address of the seller or
2415 transferor of the product, the address of the location from
2416 which the product was shipped, the date of the transaction, the
2417 name and quantity of the product involved, and the name and
2418 principal address of the person who purchased the product.

2419 ~~(c) When pedigree papers are required by this part, a~~
2420 ~~wholesale distributor must maintain the pedigree papers separate~~
2421 ~~and distinct from other records required under this part.~~

2422 (15) DUE DILIGENCE OF PURCHASERS.-

2423 (b) A wholesale distributor must take reasonable measures
2424 to identify its customers, understand the normal and expected
2425 transactions conducted by those customers, and identify those
2426 transactions that are suspicious in nature. A wholesale
2427 distributor must establish internal policies and procedures for
2428 identifying suspicious orders and preventing suspicious
2429 transactions. A wholesale distributor must assess orders for
2430 more ~~greater~~ than 7,500 ~~5,000~~ unit doses of any one controlled
2431 substance in any one month to determine whether the purchase is
2432 reasonable. In making such assessments, a wholesale distributor
2433 may consider the purchasing entity's clinical business needs,
2434 location, and population served, in addition to other factors



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2435 established in the distributor's policies and procedures. A
2436 wholesale distributor must report to the department any
2437 regulated transaction involving an extraordinary quantity of a
2438 listed chemical, an uncommon method of payment or delivery, or
2439 any other circumstance that the regulated person believes may
2440 indicate that the listed chemical will be used in violation of
2441 the law. The wholesale distributor shall maintain records that
2442 document the report submitted to the department in compliance
2443 with this paragraph.

2444 Section 9. Subsection (4) of section 499.015, Florida
2445 Statutes, is amended to read:

2446 499.015 Registration of drugs, devices, and cosmetics;
2447 issuance of certificates of free sale.—

2448 (4) Unless a registration is renewed, it expires 2 years
2449 after the last day of the month in which it was issued. Any
2450 product registration issued or renewed on or after July 1, 2016,
2451 shall expire on the same date as the manufacturer or repackager
2452 permit of the person seeking to register the product. If the
2453 first product registration issued to a person on or after July
2454 1, 2016, expires less than 366 days after issuance, the fee for
2455 product registration shall be \$15. If the first product
2456 registration issued to a person on or after July 1, 2016,
2457 expires more than 365 days after issuance, the fee for product
2458 registration shall be \$30. The department may issue a stop-sale
2459 notice or order against a person that is subject to the
2460 requirements of this section and that fails to comply with this
2461 section within 31 days after the date the registration expires.
2462 The notice or order shall prohibit such person from selling or
2463 causing to be sold any drugs, devices, or cosmetics covered by



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2464 this part until he or she complies with the requirements of this
2465 section.

2466 Section 10. Subsection (1) of section 499.03, Florida
2467 Statutes, is amended to read:

2468 499.03 Possession of certain drugs without prescriptions
2469 unlawful; exemptions and exceptions.—

2470 (1) A person may not possess, or possess with intent to
2471 sell, dispense, or deliver, any habit-forming, toxic, harmful,
2472 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or
2473 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,
2474 unless the possession of the drug has been obtained by a valid
2475 prescription of a practitioner licensed by law to prescribe the
2476 drug. However, this section does not apply to the delivery of
2477 such drugs to persons included in any of the classes named in
2478 this subsection, or to the agents or employees of such persons,
2479 for use in the usual course of their businesses or practices or
2480 in the performance of their official duties, as the case may be;
2481 nor does this section apply to the possession of such drugs by
2482 those persons or their agents or employees for such use:

2483 (a) A licensed pharmacist or any person under the licensed
2484 pharmacist's supervision while acting within the scope of the
2485 licensed pharmacist's practice;

2486 (b) A licensed practitioner authorized by law to prescribe
2487 prescription drugs or any person under the licensed
2488 practitioner's supervision while acting within the scope of the
2489 licensed practitioner's practice;

2490 (c) A qualified person who uses prescription drugs for
2491 lawful research, teaching, or testing, and not for resale;

2492 (d) A licensed hospital or other institution that procures



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2493 such drugs for lawful administration or dispensing by
2494 practitioners;

2495 (e) An officer or employee of a federal, state, or local
2496 government; or

2497 (f) A person that holds a valid permit issued by the
2498 department pursuant to this part which authorizes that person to
2499 possess prescription drugs.

2500 Section 11. Paragraphs (i) through (p) of subsection (1) of
2501 section 499.05, Florida Statutes, are amended to read:

2502 499.05 Rules.—

2503 (1) The department shall adopt rules to implement and
2504 enforce this chapter with respect to:

2505 (i) Additional conditions that qualify as an emergency
2506 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.
2507 499.82.

2508 ~~(j) Procedures and forms relating to the pedigree paper
2509 requirement of s. 499.01212.~~

2510 ~~(j)(k)~~ The protection of the public health, safety, and
2511 welfare regarding good manufacturing practices that
2512 manufacturers and repackagers must follow to ensure the safety
2513 of the products.

2514 ~~(k)(l)~~ Information required from each retail establishment
2515 pursuant to s. 499.012(3) or s. 499.83(2)(c), including
2516 requirements for prescriptions or orders.

2517 ~~(l)(m)~~ The recordkeeping, storage, and handling with
2518 respect to each of the distributions of prescription drugs
2519 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.
2520 499.82(14).

2521 ~~(n) Alternatives to compliance with s. 499.01212 for a~~



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2522 ~~prescription drug in the inventory of a permitted prescription~~
2523 ~~drug wholesale distributor as of June 30, 2006, and the return~~
2524 ~~of a prescription drug purchased prior to July 1, 2006. The~~
2525 ~~department may specify time limits for such alternatives.~~

2526 (m) ~~(e)~~ Wholesale distributor reporting requirements of s.
2527 499.0121(14).

2528 (n) ~~(p)~~ Wholesale distributor credentialing and distribution
2529 requirements of s. 499.0121(15).

2530 Section 12. Subsection (7) of section 499.051, Florida
2531 Statutes, is amended to read:

2532 499.051 Inspections and investigations.—

2533 (7) The complaint and all information obtained pursuant to
2534 the investigation by the department are confidential and exempt
2535 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution
2536 until the investigation and the enforcement action are
2537 completed. However, trade secret information contained therein
2538 as defined by s. 812.081(1)(c) shall remain confidential and
2539 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I
2540 of the State Constitution, as long as the information is
2541 retained by the department. This subsection does not prohibit
2542 the department from using such information for regulatory or
2543 enforcement proceedings under this chapter or from providing
2544 such information to any law enforcement agency or any other
2545 regulatory agency. However, the receiving agency shall keep such
2546 records confidential and exempt as provided in this subsection.
2547 ~~In addition, this subsection is not intended to prevent~~
2548 ~~compliance with the provisions of s. 499.01212, and the pedigree~~
2549 ~~papers required in that section shall not be deemed a trade~~
2550 ~~secret.~~



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2551 Section 13. Subsection (8) is added to section 499.066,
2552 Florida Statutes, to read:

2553 499.066 Penalties; remedies.—In addition to other penalties
2554 and other enforcement provisions:

2555 (8) (a) The department shall adopt rules to permit the
2556 issuance of remedial, nondisciplinary citations. A citation
2557 shall be issued to the person alleged to have committed a
2558 violation and contain the person's name, address, and license
2559 number, if applicable, a brief factual statement, the sections
2560 of the law allegedly violated, and the monetary assessment and
2561 or other remedial measures imposed. The citation must clearly
2562 state that the person may choose, in lieu of accepting the
2563 citation, to have the department rescind the citation and
2564 conduct an investigation pursuant to s. 499.051. If the person
2565 does not dispute the matter in the citation with the department
2566 within 30 days after the citation is served, the citation
2567 becomes a final order and does not constitute discipline.

2568 (b) The department shall adopt rules designating violations
2569 for which a citation may be issued. The rules shall designate as
2570 citable those violations for which there is no substantial
2571 threat to the public health, safety, or welfare.

2572 (c) The department is entitled to recover the costs of
2573 investigation, in addition to any penalty provided according to
2574 department rule, as part of the penalty levied pursuant to the
2575 citation.

2576 (d) A citation must be issued within 12 months after the
2577 filing of the complaint that is the basis for the citation.

2578 (e) Service of a citation may be made by personal service
2579 or certified mail, restricted delivery, to the person at the



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2580 person's last known address of record with the department or to
2581 the person's Florida registered agent.

2582 (f) The department has authority to, and shall adopt rules
2583 to, designate those violations for which a person is subject to
2584 the issuance of a citation and designate the monetary
2585 assessments and or other remedial measures that must be taken
2586 for those violations. The department has continuous authority to
2587 amend its rules adopted pursuant to this section.

2588 Section 14. Subsection (14) of section 499.82, Florida
2589 Statutes, is amended to read:

2590 499.82 Definitions.—As used in this part, the term:

2591 (14) "Wholesale distribution" means the distribution of
2592 medical gas to a person other than a consumer or patient.
2593 Wholesale distribution of medical gases does not include:

2594 (a) The sale, purchase, or trade of a medical gas; an offer
2595 to sell, purchase, or trade a medical gas; or the dispensing of
2596 a medical gas pursuant to a prescription;

2597 (b) Activities exempt from the definition of wholesale
2598 distribution in s. 499.003; or

2599 (c) The sale, purchase, or trade of a medical gas or an
2600 offer to sell, purchase, or trade a medical gas for emergency
2601 medical reasons; ~~or~~

2602 ~~(d) Other transactions excluded from the definition of~~
2603 ~~wholesale distribution under the federal act or regulations~~
2604 ~~implemented under the federal act related to medical gas.~~

2605 Section 15. Subsection (4) of section 499.89, Florida
2606 Statutes, is amended to read:

2607 499.89 Recordkeeping.—

2608 ~~(4) A pedigree paper is not required for distributing or~~



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2609 ~~dispensing medical gas.~~

2610 Section 16. Section 499.01212, Florida Statutes, is
2611 repealed.

2612 Section 17. Paragraph (a) of subsection (1) of section
2613 409.9201, Florida Statutes, is amended to read:

2614 409.9201 Medicaid fraud.—

2615 (1) As used in this section, the term:

2616 (a) "Prescription drug" means any drug, including, but not
2617 limited to, finished dosage forms or active ingredients that are
2618 subject to, defined in, or described in s. 503(b) of the Federal
2619 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)
2620 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2621
2622 The value of individual items of the legend drugs or goods or
2623 services involved in distinct transactions committed during a
2624 single scheme or course of conduct, whether involving a single
2625 person or several persons, may be aggregated when determining
2626 the punishment for the offense.

2627 Section 18. Paragraph (b) of subsection (1) of section
2628 499.067, Florida Statutes, is amended to read:

2629 499.067 Denial, suspension, or revocation of permit,
2630 certification, or registration.—

2631 (1)

2632 (b) The department may deny an application for a permit or
2633 certification, or suspend or revoke a permit or certification,
2634 if the department finds that:

2635 1. The applicant is not of good moral character or that it
2636 would be a danger or not in the best interest of the public
2637 health, safety, and welfare if the applicant were issued a



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2638 permit or certification.

2639 2. The applicant has not met the requirements for the
2640 permit or certification.

2641 3. The applicant is not eligible for a permit or
2642 certification for any of the reasons enumerated in s. 499.012.

2643 4. The applicant, permittee, or person certified under s.
2644 499.012(15) ~~s. 499.012(16)~~ demonstrates any of the conditions
2645 enumerated in s. 499.012.

2646 5. The applicant, permittee, or person certified under s.
2647 499.012(15) ~~s. 499.012(16)~~ has committed any violation of this
2648 chapter.

2649 Section 19. Subsection (1) of section 794.075, Florida
2650 Statutes, is amended to read:

2651 794.075 Sexual predators; erectile dysfunction drugs.—

2652 (1) A person may not possess a prescription drug, as
2653 defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of
2654 treating erectile dysfunction if the person is designated as a
2655 sexual predator under s. 775.21.

2656 Section 20. Paragraphs (d), (f), (i), and (j) of subsection
2657 (3) of section 921.0022, Florida Statutes, are amended to read:

2658 921.0022 Criminal Punishment Code; offense severity ranking
2659 chart.—

2660 (3) OFFENSE SEVERITY RANKING CHART

2661 (d) LEVEL 4

2662

2663

Florida Statute	Felony Degree	Description
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2664



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2665	316.1935 (3) (a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
2666	499.0051 (1)	3rd	Failure to maintain or deliver <u>transaction history, transaction information, or transaction statements</u> pedigree papers.
2667	499.0051 (2)	3rd	Failure to authenticate pedigree papers.
2668	<u>499.0051 (5)</u> 499.0051 (6)	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
2669	517.07 (1)	3rd	Failure to register securities.
2670	517.12 (1)	3rd	Failure of dealer, associated person, or issuer of securities to register.
2671	784.07 (2) (b)	3rd	Battery of law enforcement officer, firefighter, etc.



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2672

784.074 (1) (c) 3rd Battery of sexually violent predators facility staff.

2673

784.075 3rd Battery on detention or commitment facility staff.

2674

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

2675

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

2676

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

2677

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

2678

784.083 (3) 3rd Battery on code inspector.

2679

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

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



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2680

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

2681

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

2682

787.07 3rd Human smuggling.

2683

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

2684

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

2685

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

2686

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

2687

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



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2688			burglary, of an unoccupied structure; unarmed; no assault or battery.
	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
2689			
	810.06	3rd	Burglary; possession of tools.
2690			
	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
2691			
	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
2692			
	812.014 (2) (c) 4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
2693			
	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
2694			
	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s.



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			893.03(5) drugs.
2695	817.568(2)(a)	3rd	Fraudulent use of personal identification information.
2696	817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
2697	828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
2698	837.02(1)	3rd	Perjury in official proceedings.
2699	837.021(1)	3rd	Make contradictory statements in official proceedings.
2700	838.022	3rd	Official misconduct.
2701	839.13(2)(a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
2702	839.13(2)(c)	3rd	Falsifying records of the Department of Children and Families.
2703			



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2704	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
2705	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
2706	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
2707	847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
2708	874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
2709	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).
2710	914.14(2)	3rd	Witnesses accepting bribes.
	914.22(1)	3rd	Force, threaten, etc., witness,



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2711

victim, or informant.

914.23(2)

3rd

Retaliation against a witness,
victim, or informant, no bodily
injury.

2712

918.12

3rd

Tampering with jurors.

2713

934.215

3rd

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

2714

2715

2716 (f) LEVEL 6

2717

2718

Florida
Statute

Felony
Degree

Description

2719

316.027(2)(b)

2nd

Leaving the scene of a crash
involving serious bodily
injury.

2720

316.193(2)(b)

3rd

Felony DUI, 4th or subsequent
conviction.

2721

400.9935(4)(c)

2nd

Operating a clinic, or offering
services requiring licensure,
without a license.



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2722

499.0051(2)

2nd

Knowing forgery of transaction

~~499.0051(3)~~

history, transaction

information, or transaction

statement pedigree papers.

2723

499.0051(3)

2nd

Knowing purchase or receipt of

~~499.0051(4)~~

prescription drug from

unauthorized person.

2724

499.0051(4)

2nd

Knowing sale or transfer of

~~499.0051(5)~~

prescription drug to

unauthorized person.

2725

775.0875(1)

3rd

Taking firearm from law

enforcement officer.

2726

784.021(1)(a)

3rd

Aggravated assault; deadly

weapon without intent to kill.

2727

784.021(1)(b)

3rd

Aggravated assault; intent to

commit felony.

2728

784.041

3rd

Felony battery; domestic

battery by strangulation.

2729

784.048(3)

3rd

Aggravated stalking; credible

threat.

2730



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2731

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

2732

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

2733

784.074 (1) (b) 2nd Aggravated assault on sexually
violent predators facility
staff.

2734

784.08 (2) (b) 2nd Aggravated assault on a person
65 years of age or older.

2735

784.081 (2) 2nd Aggravated assault on specified
official or employee.

2736

784.082 (2) 2nd Aggravated assault by detained
person on visitor or other
detainee.

2737

784.083 (2) 2nd Aggravated assault on code
inspector.

2738

787.02 (2) 3rd False imprisonment; restraining
with purpose other than those
in s. 787.01.

790.115 (2) (d) 2nd Discharging firearm or weapon
on school property.



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2746

older.

806.031(2)

2nd

Arson resulting in great bodily harm to firefighter or any other person.

2747

810.02(3)(c)

2nd

Burglary of occupied structure; unarmed; no assault or battery.

2748

810.145(8)(b)

2nd

Video voyeurism; certain minor victims; 2nd or subsequent offense.

2749

812.014(2)(b)1.

2nd

Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.

2750

812.014(6)

2nd

Theft; property stolen \$3,000 or more; coordination of others.

2751

812.015(9)(a)

2nd

Retail theft; property stolen \$300 or more; second or subsequent conviction.

2752

812.015(9)(b)

2nd

Retail theft; property stolen \$3,000 or more; coordination of others.

2753



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2754

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

2755

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

2756

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

2757

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

2758

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

2759

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

2760

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

2761

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

2762

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



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2763

836.05 2nd Threats; extortion.

2764

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

2765

843.12 3rd Aids or assists person to
escape.

2766

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

2767

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

2768

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

2769

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

944.35(3)(a)2. 3rd Committing malicious battery
upon or inflicting cruel or
inhuman treatment on an inmate
or offender on community



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2770			supervision, resulting in great bodily harm.
2771	944.40	2nd	Escapes.
2772	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
2773	944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
2774	951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
2775			
2776	(i) LEVEL 9		
2777			
2778	Florida Statute	Felony Degree	Description
	316.193 (3)(c)3.b.	1st	DUI manslaughter; failing to render aid or give information.
2779	327.35 (3)(c)3.b.	1st	BUI manslaughter; failing to render aid or give information.



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2780

409.920 1st Medicaid provider fraud;
(2) (b) 1.c. \$50,000 or more.

2781

499.0051 (8) ~~499.0051 (9)~~ 1st Knowing sale or purchase
of contraband
prescription drugs
resulting in great bodily
harm.

2782

560.123 (8) (b) 3. 1st Failure to report
currency or payment
instruments totaling or
exceeding \$100,000 by
money transmitter.

2783

560.125 (5) (c) 1st Money transmitter
business by unauthorized
person, currency, or
payment instruments
totaling or exceeding
\$100,000.

2784

655.50 (10) (b) 3. 1st Failure to report
financial transactions
totaling or exceeding
\$100,000 by financial
institution.

2785



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2786

775.0844 1st Aggravated white collar
crime.

2787

782.04(1) 1st Attempt, conspire, or
solicit to commit
premeditated murder.

2788

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.

2789

782.051(1) 1st Attempted felony murder
while perpetrating or
attempting to perpetrate
a felony enumerated in s.
782.04(3).

2790

782.07(2) 1st Aggravated manslaughter
of an elderly person or
disabled adult.

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



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2791	787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
2792	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
2793	787.02(3)(a)	1st,PBL	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
2794	787.06(3)(c)1.	1st	Human trafficking for labor and services of an unauthorized alien child.
2795	787.06(3)(d)	1st	Human trafficking using coercion for commercial sexual activity of an unauthorized adult alien.
2796			



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2797	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.
2798	790.161	1st	Attempted capital destructive device offense.
2799	790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
2800	794.011(2)	1st	Attempted sexual battery; victim less than 12 years of age.
2801	794.011(2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
	794.011(4)(a)	1st,PBL	Sexual battery, certain circumstances; victim 12 years of age or older but



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2802

794.011 (4) (b)

1st

younger than 18 years;
offender 18 years or
older.

Sexual battery, certain
circumstances; victim and
offender 18 years of age
or older.

2803

794.011 (4) (c)

1st

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

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

2804

794.011 (4) (d)

1st, PBL

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

2805

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.

2806

794.08 (2)

1st

Female genital
mutilation; victim



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2807			younger than 18 years of age.
	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
2808			
	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
2809			
	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
2810			
	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
2811			
	817.535 (3) (b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; property owner is a public officer or employee.
2812			
	817.535 (4) (a) 2.	1st	Filing false claim or other unauthorized document; defendant is incarcerated or under



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2813

817.535 (5) (b)

1st

supervision.

Filing false lien or other unauthorized document; second or subsequent offense; owner of the property incurs financial loss as a result of the false instrument.

2814

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.

2815

827.03 (2) (a)

1st

Aggravated child abuse.

2816

847.0145 (1)

1st

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

2817

847.0145 (2)

1st

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



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2818

859.01 1st Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.

2819

893.135 1st Attempted capital trafficking offense.

2820

893.135 (1) (a) 3. 1st Trafficking in cannabis, more than 10,000 lbs.

2821

893.135 (1) (b) 1.c. 1st Trafficking in cocaine, more than 400 grams, less than 150 kilograms.

2822

893.135 (1) (c) 1.c. 1st Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.

2823

893.135 (1) (c) 2.d. 1st Trafficking in hydrocodone, 200 grams or more, less than 30 kilograms.

2824



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2825	893.135 (1) (c) 3.d.	1st	Trafficking in oxycodone, 100 grams or more, less than 30 kilograms.
2826	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
2827	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
2828	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more than 200 grams.
2829	893.135 (1) (h) 1.c.	1st	Trafficking in gamma- hydroxybutyric acid (GHB), 10 kilograms or more.
2830	893.135 (1) (j) 1.c.	1st	Trafficking in 1,4- Butanediol, 10 kilograms or more.
2831	893.135 (1) (k) 2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.



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

2832

896.104 (4) (a) 3. 1st Structuring transactions
to evade reporting or
registration
requirements, financial
transactions totaling or
exceeding \$100,000.

2833

2834

2835 (j) LEVEL 10

2836

Florida Statute	Felony Degree	Description
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2837

<u>499.0051 (9)</u>	1st	Knowing sale or purchase of contraband prescription drugs resulting in death.
499.0051 (10)		

2838

782.04 (2)	1st, PBL	Unlawful killing of human; act is homicide, unpremeditated.
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2839

782.07 (3)	1st	Aggravated manslaughter of a child.
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2840

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

2841

787.01(3)(a) Life Kidnapping; child under
age 13, perpetrator also
commits aggravated child
abuse, sexual battery,
or lewd or lascivious
battery, molestation,
conduct, or exhibition.

2842

787.06(3)(g) Life Human trafficking for
commercial sexual
activity of a child
under the age of 18 or
mentally defective or
incapacitated person.

2843

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

2844

794.011(3) Life Sexual battery; victim
12 years or older,
offender uses or
threatens to use deadly
weapon or physical force



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2845

to cause serious injury.

812.135(2)(a)

1st,PBL

Home-invasion robbery
with firearm or other
deadly weapon.

2846

876.32

1st

Treason against the
state.

2847

2848

2849

2850

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