

By the Committees on Appropriations; and Health Policy; and
Senator Grimsley

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

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32 distributor permit is not required for distributions
33 between certain pharmacies; requiring the Department
34 of Business and Professional Regulation to establish
35 by rule when such distribution constitutes regular and
36 systematic supplying of a prescription drug; requiring
37 certain third party logistic providers to be licensed;
38 requiring research and development labeling on certain
39 prescription drug active pharmaceutical ingredient
40 packaging; requiring certain manufacturers to create
41 and maintain certain records; requiring certain
42 prescription drug distributors to provide certain
43 information to health care entities for which they
44 repackage prescription drugs; requiring the department
45 to adopt rules concerning repackaged prescription drug
46 safety and integrity; amending s. 499.012, F.S.;

47 providing for issuance of a prescription drug
48 manufacturer permit or retail pharmacy drug wholesale
49 distributor permit when an applicant at the same
50 address is a licensed nuclear pharmacy or community
51 pharmacy; providing for the expiration of deficient
52 permit applications; requiring trade secret
53 information submitted by an applicant to be maintained
54 as a trade secret; authorizing the quadrennial renewal
55 of permits; providing for calculation of fees for such
56 permit renewals; revising procedures and application
57 requirements for permit renewals; providing for late
58 renewal fees; allowing a permittee who submits a
59 renewal application to continue operations; removing
60 certain application requirements for renewal of a

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61 permit; requiring bonds or other surety of a specified
62 amount; requiring proof of inspection of
63 establishments used in wholesale distribution;
64 authorizing the Department of Business and
65 Professional Regulation to contract for the collection
66 of electronic fingerprints under certain
67 circumstances; providing information that may be
68 submitted in lieu of certain application requirements
69 for specified permits and certifications; removing
70 provisions relating to annual renewal and expiration
71 of permits; conforming cross-references; amending s.
72 499.01201, F.S.; conforming provisions; amending s.
73 499.0121, F.S.; revising prescription drug
74 recordkeeping requirements; specifying recordkeeping
75 requirements for manufacturers and repackagers of
76 medical devices, over-the-counter drugs, and
77 cosmetics; increasing the quantity of unit doses of a
78 controlled substance that may be ordered in any given
79 month by a customer without triggering a requirement
80 that a wholesale distributor perform a reasonableness
81 assessment; conforming provisions; amending s.
82 499.015, F.S.; providing for the expiration, renewal,
83 and issuance of certain drug, device, and cosmetic
84 product registrations; providing for product
85 registration fees; amending ss. 499.03, 499.05, and
86 499.051, F.S.; conforming provisions to changes made
87 by the act; amending s. 499.066, F.S.; authorizing the
88 issuance of nondisciplinary citations; authorizing the
89 department to adopt rules designating violations for

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90 which a citation may be issued; authorizing the
91 department to recover investigative costs pursuant to
92 the citation; specifying a time limitation for
93 issuance of a citation; providing for service of a
94 citation; amending s. 499.82, F.S.; revising the
95 definition of "wholesale distribution" for purposes of
96 medical gas requirements; amending s. 499.89, F.S.;
97 conforming provisions; repealing s. 499.01212, F.S.,
98 relating to pedigree papers; amending ss. 409.9201,
99 499.067, 794.075, and 921.0022, F.S.; conforming
100 cross-references; providing an effective date.

101
102 Be It Enacted by the Legislature of the State of Florida:

103
104 Section 1. Section 499.003, Florida Statutes, is amended to
105 read:

106 499.003 Definitions of terms used in this part.—As used in
107 this part, the term:

108 (1) "Active pharmaceutical ingredient" includes any
109 substance or mixture of substances intended, represented, or
110 labeled for use in drug manufacturing that furnishes or is
111 intended to furnish, in a finished dosage form, any
112 pharmacological activity or other direct effect in the
113 diagnosis, cure, mitigation, treatment, therapy, or prevention
114 of disease in humans or other animals, or to affect the
115 structure or any function of the body of humans or animals.

116 (2)~~(1)~~ "Advertisement" means any representation
117 disseminated in any manner or by any means, other than by
118 labeling, for the purpose of inducing, or which is likely to

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119 induce, directly or indirectly, the purchase of drugs, devices,
120 or cosmetics.

121 (3) "Affiliate" means a business entity that has a
122 relationship with another business entity in which, directly or
123 indirectly:

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

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

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

134 (4)~~(3)~~ "Affiliated party" means:

135 (a) A director, officer, trustee, partner, or committee
136 member of a permittee or applicant or a subsidiary or service
137 corporation of the permittee or applicant;

138 (b) A person who, directly or indirectly, manages,
139 controls, or oversees the operation of a permittee or applicant,
140 regardless of whether such person is a partner, shareholder,
141 manager, member, officer, director, independent contractor, or
142 employee of the permittee or applicant;

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

147 (d) The five largest natural shareholders that own at least

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148 5 percent of the permittee or applicant.

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

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

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

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

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

164 (7) "Chain pharmacy warehouse" means a ~~wholesale~~
165 distributor permitted pursuant to s. 499.01 that maintains a
166 physical location for prescription drugs that functions solely
167 as a central warehouse to perform intracompany transfers of such
168 drugs between members of an affiliate ~~to a member of its~~
169 ~~affiliated group.~~

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

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

175 (10) "Color additive" means, with the exception of any
176 material that has been or hereafter is exempt under the federal

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177 act, a material that:

178 (a) Is a dye pigment, or other substance, made by a process
179 of synthesis or similar artifice, or extracted, isolated, or
180 otherwise derived, with or without intermediate or final change
181 of identity from a vegetable, animal, mineral, or other source;
182 or

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

186 (11) "Contraband prescription drug" means any adulterated
187 drug, as defined in s. 499.006, any counterfeit drug, as defined
188 in this section, and also means any prescription drug for which
189 a transaction history, transaction information, or transaction
190 statement ~~pedigree paper~~ does not exist, or for which the
191 transaction history, transaction information, or transaction
192 statement ~~pedigree paper~~ in existence has been forged,
193 counterfeited, falsely created, or contains any altered, false,
194 or misrepresented matter.

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

197 (a) Intended to be rubbed, poured, sprinkled, or sprayed
198 on; introduced into; or otherwise applied to the human body or
199 any part thereof for cleansing, beautifying, promoting
200 attractiveness, or altering the appearance; or

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

202 (13) "Counterfeit drug," "counterfeit device," or
203 "counterfeit cosmetic" means a drug, device, or cosmetic which,
204 or the container, seal, or labeling of which, without
205 authorization, bears the trademark, trade name, or other

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206 identifying mark, imprint, or device, or any likeness thereof,
207 of a drug, device, or cosmetic manufacturer, processor, packer,
208 or distributor other than the person that in fact manufactured,
209 processed, packed, or distributed that drug, device, or cosmetic
210 and which thereby falsely purports or is represented to be the
211 product of, or to have been packed or distributed by, that other
212 drug, device, or cosmetic manufacturer, processor, packer, or
213 distributor.

214 (14) "Department" means the Department of Business and
215 Professional Regulation.

216 (15) "Device" means any instrument, apparatus, implement,
217 machine, contrivance, implant, in vitro reagent, or other
218 similar or related article, including its components, parts, or
219 accessories, which is:

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

222 (b) Intended for use in the diagnosis, cure, mitigation,
223 treatment, therapy, or prevention of disease in humans or other
224 animals, or

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

227

228 and that does not achieve any of its principal intended purposes
229 through chemical action within or on the body of humans or other
230 animals and which is not dependent upon being metabolized for
231 the achievement of any of its principal intended purposes.

232 (16) "Distribute" or "distribution" means to sell,
233 purchase, trade, deliver, handle, store, or receive ~~to sell;~~
234 ~~offer to sell; give away; transfer, whether by passage of title,~~

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235 ~~physical movement, or both; deliver; or offer to deliver. The~~
236 ~~term does not mean to administer or dispense and does not~~
237 ~~include the billing and invoicing activities that commonly~~
238 ~~follow a wholesale distribution transaction.~~

239 ~~(17) "Drop shipment" means the sale of a prescription drug~~
240 ~~from a manufacturer to a wholesale distributor, where the~~
241 ~~wholesale distributor takes title to, but not possession of, the~~
242 ~~prescription drug, and the manufacturer of the prescription drug~~
243 ~~ships the prescription drug directly to a chain pharmacy~~
244 ~~warehouse or a person authorized by law to purchase prescription~~
245 ~~drugs for the purpose of administering or dispensing the drug,~~
246 ~~as defined in s. 465.003.~~

247 ~~(17)~~(18) "Drug" means an article that is:

248 (a) Recognized in the current edition of the United States
249 Pharmacopoeia and National Formulary, official Homeopathic
250 Pharmacopoeia of the United States, or any supplement to any of
251 those publications;

252 (b) Intended for use in the diagnosis, cure, mitigation,
253 treatment, therapy, or prevention of disease in humans or other
254 animals;

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

257 (d) Intended for use as a component of any article
258 specified in paragraph (a), paragraph (b), or paragraph (c), and
259 includes active pharmaceutical ingredients, but does not include
260 devices or their nondrug components, parts, or accessories. ~~For~~
261 ~~purposes of this paragraph, an "active pharmaceutical~~
262 ~~ingredient" includes any substance or mixture of substances~~
263 ~~intended, represented, or labeled for use in drug manufacturing~~

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264 ~~that furnishes or is intended to furnish, in a finished dosage~~
265 ~~form, any pharmacological activity or other direct effect in the~~
266 ~~diagnosis, cure, mitigation, treatment, therapy, or prevention~~
267 ~~of disease in humans or other animals, or to affect the~~
268 ~~structure or any function of the body of humans or other~~
269 ~~animals.~~

270 (18)~~(19)~~ "Establishment" means a place of business which is
271 at one general physical location and may extend to one or more
272 contiguous suites, units, floors, or buildings operated and
273 controlled exclusively by entities under common operation and
274 control. Where multiple buildings are under common exclusive
275 ownership, operation, and control, an intervening thoroughfare
276 does not affect the contiguous nature of the buildings. For
277 purposes of permitting, each suite, unit, floor, or building
278 must be identified in the most recent permit application.

279 (19)~~(20)~~ "Federal act" means the Federal Food, Drug, and
280 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

281 (20)~~(21)~~ "Freight forwarder" means a person who receives
282 prescription drugs which are owned by another person and
283 designated by that person for export, and exports those
284 prescription drugs.

285 (21)~~(22)~~ "Health care entity" means a closed pharmacy or
286 any person, organization, or business entity that provides
287 diagnostic, medical, surgical, or dental treatment or care, or
288 chronic or rehabilitative care, but does not include any
289 wholesale distributor or retail pharmacy licensed under state
290 law to deal in prescription drugs. However, a blood
291 establishment is a health care entity that may engage in the
292 wholesale distribution of prescription drugs under s.

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293 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

294 (22)~~(23)~~ "Health care facility" means a health care
295 facility licensed under chapter 395.

296 (23)~~(24)~~ "Hospice" means a corporation licensed under part
297 IV of chapter 400.

298 (24)~~(25)~~ "Hospital" means a facility as defined in s.
299 395.002 and licensed under chapter 395.

300 (25)~~(26)~~ "Immediate container" does not include package
301 liners.

302 (26)~~(27)~~ "Label" means a display of written, printed, or
303 graphic matter upon the immediate container of any drug, device,
304 or cosmetic. A requirement made by or under authority of this
305 part or rules adopted under this part that any word, statement,
306 or other information appear on the label is not complied with
307 unless such word, statement, or other information also appears
308 on the outside container or wrapper, if any, of the retail
309 package of such drug, device, or cosmetic or is easily legible
310 through the outside container or wrapper.

311 (27)~~(28)~~ "Labeling" means all labels and other written,
312 printed, or graphic matters:

313 (a) Upon a drug, device, or cosmetic, or any of its
314 containers or wrappers; or

315 (b) Accompanying or related to such drug, device, or
316 cosmetic.

317 (28)~~(29)~~ "Manufacture" means the preparation, deriving,
318 compounding, propagation, processing, producing, or fabrication
319 of any drug, device, or cosmetic.

320 (29)~~(30)~~ "Manufacturer" means:

321 (a) A person who holds a New Drug Application, an

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322 Abbreviated New Drug Application, a Biologics License
323 Application, or a New Animal Drug Application approved under the
324 federal act or a license issued under s. 351 of the Public
325 Health Service Act, 42 U.S.C. s. 262, for such drug or
326 biologics, or if such drug or biologics are not the subject of
327 an approved application or license, the person who manufactured
328 the drug or biologics ~~prepares, derives, manufactures, or~~
329 ~~produces a drug, device, or cosmetic;~~

330 (b) A co-licensed partner of the person described in
331 paragraph (a) who obtains the drug or biologics directly from a
332 person described in paragraph (a), paragraph (c), or this
333 paragraph ~~The holder or holders of a New Drug Application (NDA),~~
334 ~~an Abbreviated New Drug Application (ANDA), a Biologics License~~
335 ~~Application (BLA), or a New Animal Drug Application (NADA),~~
336 ~~provided such application has become effective or is otherwise~~
337 ~~approved consistent with s. 499.023;~~

338 (c) An affiliate of a person described in paragraph (a),
339 paragraph (b), or this paragraph that receives the drug or
340 biologics directly from a person described in paragraph (a),
341 paragraph (b), or this paragraph ~~A private label distributor for~~
342 ~~whom the private label distributor's prescription drugs are~~
343 ~~originally manufactured and labeled for the distributor and have~~
344 ~~not been repackaged; or~~

345 (d) A person who manufactures a device or a cosmetic. A
346 person registered under the federal act as a manufacturer of a
347 prescription drug, who is described in paragraph (a), paragraph
348 (b), or paragraph (c), who has entered into a written agreement
349 with another prescription drug manufacturer that authorizes
350 either manufacturer to distribute the prescription drug

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351 ~~identified in the agreement as the manufacturer of that drug~~
352 ~~consistent with the federal act and its implementing~~
353 ~~regulations;~~

354 ~~(e) A member of an affiliated group that includes, but is~~
355 ~~not limited to, persons described in paragraph (a), paragraph~~
356 ~~(b), paragraph (c), or paragraph (d), which member distributes~~
357 ~~prescription drugs, whether or not obtaining title to the drugs,~~
358 ~~only for the manufacturer of the drugs who is also a member of~~
359 ~~the affiliated group. As used in this paragraph, the term~~
360 ~~"affiliated group" means an affiliated group as defined in s.~~
361 ~~1504 of the Internal Revenue Code of 1986, as amended. The~~
362 ~~manufacturer must disclose the names of all of its affiliated~~
363 ~~group members to the department; or~~

364 ~~(f) A person permitted as a third party logistics provider,~~
365 ~~only while providing warehousing, distribution, or other~~
366 ~~logistics services on behalf of a person described in paragraph~~
367 ~~(a), paragraph (b), paragraph (c), paragraph (d), or paragraph~~
368 ~~(e).~~

369
370 The term does not include a pharmacy that is operating in
371 compliance with pharmacy practice standards as defined in
372 chapter 465 and rules adopted under that chapter.

373 (30)~~(31)~~ "Medical convenience kit" means packages or units
374 that contain combination products as defined in 21 C.F.R. s.
375 3.2(e)(2).

376 (31)~~(32)~~ "Medical gas" means any liquefied or vaporized gas
377 that is a prescription drug, whether alone or in combination
378 with other gases, and as defined in the federal act.

379 (32)~~(33)~~ "New drug" means:

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380 (a) Any drug the composition of which is such that the drug
381 is not generally recognized, among experts qualified by
382 scientific training and experience to evaluate the safety and
383 effectiveness of drugs, as safe and effective for use under the
384 conditions prescribed, recommended, or suggested in the labeling
385 of that drug; or

386 (b) Any drug the composition of which is such that the
387 drug, as a result of investigations to determine its safety and
388 effectiveness for use under certain conditions, has been
389 recognized for use under such conditions, but which drug has
390 not, other than in those investigations, been used to a material
391 extent or for a material time under such conditions.

392 ~~(34) "Normal distribution chain" means a wholesale~~
393 ~~distribution of a prescription drug in which the wholesale~~
394 ~~distributor or its wholly owned subsidiary purchases and~~
395 ~~receives the specific unit of the prescription drug directly~~
396 ~~from the manufacturer and distributes the prescription drug~~
397 ~~directly, or through up to two intracompany transfers, to a~~
398 ~~chain pharmacy warehouse or a person authorized by law to~~
399 ~~purchase prescription drugs for the purpose of administering or~~
400 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~
401 ~~this subsection, the term "intracompany" means any transaction~~
402 ~~or transfer between any parent, division, or subsidiary wholly~~
403 ~~owned by a corporate entity.~~

404 (33)~~(35)~~ "Nursing home" means a facility licensed under
405 part II of chapter 400.

406 (34)~~(36)~~ "Official compendium" means the current edition of
407 the official United States Pharmacopoeia and National Formulary,
408 or any supplement thereto.

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

413 (35)~~(38)~~ "Permittee" means any person holding a permit
414 issued under this chapter ~~pursuant to s. 499.012.~~

415 (36)~~(39)~~ "Person" means any individual, child, joint
416 venture, syndicate, fiduciary, partnership, corporation,
417 division of a corporation, firm, trust, business trust, company,
418 estate, public or private institution, association,
419 organization, group, city, county, city and county, political
420 subdivision of this state, other governmental agency within this
421 state, and any representative, agent, or agency of any of the
422 foregoing, or any other group or combination of the foregoing.

423 (37)~~(40)~~ "Pharmacist" means a person licensed under chapter
424 465.

425 (38)~~(41)~~ "Pharmacy" means an entity licensed under chapter
426 465.

427 (39)~~(42)~~ "Prepackaged drug product" means a drug that
428 originally was in finished packaged form sealed by a
429 manufacturer and that is placed in a properly labeled container
430 by a pharmacy or practitioner authorized to dispense pursuant to
431 chapter 465 for the purpose of dispensing in the establishment
432 in which the prepackaging occurred.

433 (40)~~(43)~~ "Prescription drug" means a prescription,
434 medicinal, or legend drug, including, but not limited to,
435 finished dosage forms or active pharmaceutical ingredients
436 subject to, defined by, or described by s. 503(b) of the federal
437 act or s. 465.003(8), s. 499.007(13), subsection (31) ~~(32)~~, or

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438 subsection (47) ~~(52)~~, except that an active pharmaceutical
439 ingredient is a prescription drug only if substantially all
440 finished dosage forms in which it may be lawfully dispensed or
441 administered in this state are also prescription drugs.

442 (41) ~~(44)~~ "Prescription drug label" means any display of
443 written, printed, or graphic matter upon the immediate container
444 of any prescription drug before it is dispensed ~~prior to its~~
445 ~~dispensing~~ to an individual patient pursuant to a prescription
446 of a practitioner authorized by law to prescribe.

447 (42) ~~(45)~~ "Prescription label" means any display of written,
448 printed, or graphic matter upon the immediate container of any
449 prescription drug dispensed pursuant to a prescription of a
450 practitioner authorized by law to prescribe.

451 ~~(46) "Primary wholesale distributor" means any wholesale~~
452 ~~distributor that:~~

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

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

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

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

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

466 ~~2. Transfers from a member of an affiliated group, as~~

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467 ~~defined in s. 1504 of the Internal Revenue Code, of which the~~
468 ~~wholesale distributor is a member, if:~~

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

472 ~~b. The wholesale distributor discloses to the department~~
473 ~~the names of all members of the affiliated group of which the~~
474 ~~wholesale distributor is a member and the affiliated group~~
475 ~~agrees in writing to provide records on prescription drug~~
476 ~~purchases by the members of the affiliated group not later than~~
477 ~~48 hours after the department requests access to such records,~~
478 ~~regardless of the location where the records are stored.~~

479 ~~(43)-(47)~~ "Proprietary drug," or "OTC drug," means a patent
480 or over-the-counter drug in its unbroken, original package,
481 which drug is sold to the public by, or under the authority of,
482 the manufacturer or primary distributor thereof, is not
483 misbranded under the provisions of this part, and can be
484 purchased without a prescription.

485 ~~(44)-(48)~~ "Repackage" includes repacking or otherwise
486 changing the container, wrapper, or labeling to further the
487 distribution of the drug, device, or cosmetic.

488 ~~(45)-(49)~~ "Repackager" means a person who repackages. The
489 term excludes pharmacies that are operating in compliance with
490 pharmacy practice standards as defined in chapter 465 and rules
491 adopted under that chapter.

492 ~~(46)-(50)~~ "Retail pharmacy" means a community pharmacy
493 licensed under chapter 465 that purchases prescription drugs at
494 fair market prices and provides prescription services to the
495 public.

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496 ~~(51) "Secondary wholesale distributor" means a wholesale~~
497 ~~distributor that is not a primary wholesale distributor.~~

498 (47)~~(52)~~ "Veterinary prescription drug" means a
499 prescription drug intended solely for veterinary use. The label
500 of the drug must bear the statement, "Caution: Federal law
501 restricts this drug to sale by or on the order of a licensed
502 veterinarian."

503 (48)~~(53)~~ "Wholesale distribution" means the distribution of
504 a prescription drug to a person ~~drugs to persons~~ other than a
505 consumer or patient, or the receipt of a prescription drug by a
506 person other than the consumer or patient, but does not include:

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

510 1. The purchase or other acquisition by a hospital or other
511 health care entity that is a member of a group purchasing
512 organization of a prescription drug for its own use from the
513 group purchasing organization or from other hospitals or health
514 care entities that are members of that organization.

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

521 3. The distribution ~~sale, purchase, or trade~~ of a
522 prescription drug ~~or an offer to sell, purchase, or trade a~~
523 ~~prescription drug~~ among hospitals or other health care entities
524 that are under common control. For purposes of this

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525 subparagraph, "common control" means the power to direct or
526 cause the direction of the management and policies of a person
527 or an organization, whether by ownership of stock, by voting
528 rights, by contract, or otherwise.

529 4. The distribution ~~sale, purchase, trade, or other~~
530 ~~transfer~~ of a prescription drug from or for any federal, state,
531 or local government agency or any entity eligible to purchase
532 prescription drugs at public health services prices pursuant to
533 Pub. L. No. 102-585, s. 602 to a contract provider or its
534 subcontractor for eligible patients of the agency or entity
535 under the following conditions:

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

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

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

544 d. The contract provider and subcontractor must maintain
545 and produce immediately for inspection all records of movement
546 or transfer of all the prescription drugs belonging to the
547 agency or entity, including, but not limited to, the records of
548 receipt and disposition of prescription drugs. Each contractor
549 and subcontractor dispensing or administering these drugs must
550 maintain and produce records documenting the dispensing or
551 administration. Records that are required to be maintained
552 include, but are not limited to, a perpetual inventory itemizing
553 drugs received and drugs dispensed by prescription number or

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554 administered by patient identifier, which must be submitted to
555 the agency or entity quarterly.

556 e. The contract provider or subcontractor may administer or
557 dispense the prescription drugs only to the eligible patients of
558 the agency or entity or must return the prescription drugs for
559 or to the agency or entity. The contract provider or
560 subcontractor must require proof from each person seeking to
561 fill a prescription or obtain treatment that the person is an
562 eligible patient of the agency or entity and must, at a minimum,
563 maintain a copy of this proof as part of the records of the
564 contractor or subcontractor required under sub-subparagraph d.

565 f. In addition to the departmental inspection authority set
566 forth in s. 499.051, the establishment of the contract provider
567 and subcontractor and all records pertaining to prescription
568 drugs subject to this subparagraph shall be subject to
569 inspection by the agency or entity. All records relating to
570 prescription drugs of a manufacturer under this subparagraph
571 shall be subject to audit by the manufacturer of those drugs,
572 without identifying individual patient information.

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

576 1. The distribution ~~sale, purchase, or trade~~ of a
577 prescription drug among federal, state, or local government
578 health care entities that are under common control and are
579 authorized to purchase such prescription drug.

580 2. The distribution ~~sale, purchase, or trade~~ of a
581 prescription drug or ~~an~~ offer to distribute ~~sell, purchase, or~~
582 ~~trade~~ a prescription drug for emergency medical reasons, which

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583 ~~may include. For purposes of this subparagraph, The term~~
584 ~~"emergency medical reasons" includes~~ transfers of prescription
585 drugs by a retail pharmacy to another retail pharmacy to
586 alleviate a temporary shortage. For purposes of this
587 subparagraph, a drug shortage not caused by a public health
588 emergency does not constitute an emergency medical reason.

589 3. The distribution ~~transfer~~ of a prescription drug
590 acquired by a medical director on behalf of a licensed emergency
591 medical services provider to that emergency medical services
592 provider and its transport vehicles for use in accordance with
593 the provider's license under chapter 401.

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

596 ~~4.5.~~ The donation of a prescription drug by a health care
597 entity to a charitable organization that has been granted an
598 exemption under s. 501(c)(3) of the Internal Revenue Code of
599 1986, as amended, and that is authorized to possess prescription
600 drugs.

601 ~~5.6.~~ The distribution ~~transfer~~ of a prescription drug by a
602 person authorized to purchase or receive prescription drugs to a
603 person licensed or permitted to handle reverse distributions or
604 destruction under the laws of the jurisdiction in which the
605 person handling the reverse distribution or destruction receives
606 the drug.

607 ~~6.7.~~ The distribution ~~transfer~~ of a prescription drug by a
608 hospital or other health care entity to a person licensed under
609 this part to repackage prescription drugs for the purpose of
610 repackaging the prescription drug for use by that hospital, or
611 other health care entity and other health care entities that are

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612 under common control, if ownership of the prescription drugs
613 remains with the hospital or other health care entity at all
614 times. In addition to the recordkeeping requirements of s.
615 499.0121(6), the hospital or health care entity that distributes
616 ~~transfers~~ prescription drugs pursuant to this subparagraph must
617 reconcile all drugs distributed ~~transferred~~ and returned and
618 resolve any discrepancies in a timely manner.

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

621 (d) The distribution of a prescription drug by the
622 manufacturer of the prescription drug.

623 (e) ~~(e)~~ The distribution of prescription drug samples by
624 manufacturers' representatives or distributors' representatives
625 conducted in accordance with s. 499.028.

626 (f) The distribution of a prescription drug by a third-
627 party logistics provider permitted or licensed pursuant to and
628 operating in compliance with the laws of this state and federal
629 law if such third-party logistics provider does not take
630 ownership of the prescription drug.

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

636 (h) The purchase or other acquisition by a dispenser,
637 hospital, or other health care entity of a prescription drug for
638 use by such dispenser, hospital, or other health care entity.

639 (i) The distribution of a prescription drug by a hospital
640 or other health care entity, or by a wholesale distributor or

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641 manufacturer operating at the direction of the hospital or other
642 health care entity, to a repackager for the purpose of
643 repackaging the prescription drug for use by that hospital, or
644 other health care entity and other health care entities that are
645 under common control, if ownership of the prescription drug
646 remains with the hospital or other health care entity at all
647 times.

648 ~~(j)~~~~(d)~~ The distribution ~~sale, purchase, or trade~~ of blood
649 and blood components intended for transfusion. As used in this
650 paragraph, the term "blood" means whole blood collected from a
651 single donor and processed for transfusion or further
652 manufacturing, and the term "blood components" means that part
653 of the blood separated by physical or mechanical means.

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

656 ~~(l)~~~~(f)~~ The distribution ~~sale, purchase, or trade~~ of a
657 prescription drug between pharmacies as a result of a sale,
658 transfer, merger, or consolidation of all or part of the
659 business of the pharmacies from or with another pharmacy,
660 whether accomplished as a purchase and sale of stock or of
661 business assets.

662 ~~(m)~~ The distribution of minimal quantities of prescription
663 drugs by a licensed retail pharmacy to a licensed practitioner
664 for office use in compliance with chapter 465 and rules adopted
665 thereunder. The department shall adopt rules specifying the
666 quantities of prescription drugs which are considered to be
667 minimal quantities. However, until such rules are adopted,
668 minimal quantities distributed may not exceed 3 percent of the
669 retail pharmacy's total annual purchases of prescription drugs.

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

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

677 (p) The distribution of a prescription drug that is
678 intended for irrigation or sterile water, whether intended for
679 such purposes or for injection.

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

682 (r) A common carrier that transports a prescription drug,
683 if the common carrier does not take ownership of the
684 prescription drug.

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

686 (t) Facilitating the distribution of a prescription drug by
687 providing solely administrative services, including processing
688 of orders and payments.

689 (u) The distribution by a charitable organization described
690 in s. 501(c) (3) of the Internal Revenue Code of prescription
691 drugs donated to or supplied at a reduced price to the
692 charitable organization to:

693 1. A licensed health care practitioner, as defined in s.
694 456.001, who is authorized under the appropriate practice act to
695 prescribe and administer prescription drugs;

696 2. A health care clinic establishment permitted pursuant to
697 chapter 499; or

698 3. The Department of Health or the licensed medical

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699 director of a government agency health care entity, authorized
700 to possess prescription drugs, for storage and use in the
701 treatment of persons in need of emergency medical services,
702 including controlling communicable diseases or providing
703 protection from unsafe conditions that pose an imminent threat
704 to public health,

705
706 if the distributor and the receiving entity receive no direct or
707 indirect financial benefit other than tax benefits related to
708 charitable contributions. Distributions under this section that
709 involve controlled substances must comply with all state and
710 federal regulations pertaining to the handling of controlled
711 substances.

712 (v) The distribution of medical gas pursuant to part III of
713 this chapter.

714 (49)-(54) "Wholesale distributor" means a ~~any~~ person, other
715 than a manufacturer, a manufacturer's co-licensed partner, a
716 third-party logistics provider, or a repackager, who is engaged
717 in wholesale distribution of prescription drugs in or into this
718 state, including, but not limited to, manufacturers;
719 repackagers; own-label distributors; jobbers; private-label
720 distributors; brokers; warehouses, including manufacturers' and
721 distributors' warehouses, chain drug warehouses, and wholesale
722 drug warehouses; independent wholesale drug traders; exporters;
723 retail pharmacies; and the agents thereof that conduct wholesale
724 distributions.

725 Section 2. Subsections (21), (28), and (29) of section
726 499.005, Florida Statutes, are amended to read:

727 499.005 Prohibited acts.—It is unlawful for a person to

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728 perform or cause the performance of any of the following acts in
729 this state:

730 (21) The wholesale distribution of any prescription drug
731 that was:

732 (a) Purchased by a public or private hospital or other
733 health care entity; or

734 (b) Donated or supplied at a reduced price to a charitable
735 organization,

736

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

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

742 ~~(29) The receipt of a prescription drug pursuant to a~~
743 ~~wholesale distribution without having previously received or~~
744 ~~simultaneously receiving a pedigree paper that was attested to~~
745 ~~as accurate and complete by the wholesale distributor as~~
746 ~~required under this part.~~

747 Section 3. Subsections (4) through (17) of section
748 499.0051, Florida Statutes, are renumbered as subsections (3)
749 through (16), respectively, and subsections (1) and (2), present
750 subsection (3), paragraphs (h) and (i) of present subsection
751 (12), paragraph (d) of present subsection (13), and present
752 subsection (15) of that section are amended, to read:

753 499.0051 Criminal acts.—

754 (1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY,
755 TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE~~
756 ~~PAPERS.~~—

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757 (a) A person, ~~other than a manufacturer,~~ engaged in the
758 ~~wholesale~~ distribution of prescription drugs who fails to
759 deliver to another person a complete and accurate ~~transaction~~
760 history, transaction information, or transaction statement
761 ~~pedigree papers~~ concerning a prescription drug or contraband
762 prescription drug, as required by this chapter and rules adopted
763 under this chapter, before ~~prior to,~~ or simultaneous with, the
764 transfer of the prescription drug or contraband prescription
765 drug to another person commits a felony of the third degree,
766 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

767 (b) A person engaged in the ~~wholesale~~ distribution of
768 prescription drugs who fails to acquire a complete and accurate
769 transaction history, transaction information, or transaction
770 statement ~~pedigree papers~~ concerning a prescription drug or
771 contraband prescription drug, as required by this chapter and
772 rules adopted under this chapter, before ~~prior to,~~ or
773 simultaneous with, the receipt of the prescription drug or
774 contraband prescription drug from another person commits a
775 felony of the third degree, punishable as provided in s.
776 775.082, s. 775.083, or s. 775.084.

777 (c) Any person who knowingly destroys, alters, conceals, or
778 fails to maintain a complete and accurate ~~transaction history,~~
779 transaction information, or transaction statement ~~pedigree~~
780 ~~papers~~ concerning any prescription drug or contraband
781 prescription drug, as required by this chapter and rules adopted
782 under this chapter, in his or her possession commits a felony of
783 the third degree, punishable as provided in s. 775.082, s.
784 775.083, or s. 775.084.

785 ~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS. Effective July~~

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786 ~~1, 2006:~~

787 ~~(a) A person engaged in the wholesale distribution of~~
 788 ~~prescription drugs who is in possession of pedigree papers~~
 789 ~~concerning prescription drugs or contraband prescription drugs~~
 790 ~~and who fails to authenticate the matters contained in the~~
 791 ~~pedigree papers and who nevertheless attempts to further~~
 792 ~~distribute prescription drugs or contraband prescription drugs~~
 793 ~~commits a felony of the third degree, punishable as provided in~~
 794 ~~s. 775.082, s. 775.083, or s. 775.084.~~

795 ~~(b) A person in possession of pedigree papers concerning~~
 796 ~~prescription drugs or contraband prescription drugs who falsely~~
 797 ~~swears or certifies that he or she has authenticated the matters~~
 798 ~~contained in the pedigree papers commits a felony of the third~~
 799 ~~degree, punishable as provided in s. 775.082, s. 775.083, or s.~~
 800 ~~775.084.~~

801 ~~(2)-(3)~~ KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION
 802 INFORMATION, OR TRANSACTION STATEMENT PEDIGREE PAPERS.-A person
 803 who knowingly forges, counterfeits, or falsely creates any
 804 transaction history, transaction information, or transaction
 805 statement pedigree paper; who falsely represents any factual
 806 matter contained on any transaction history, transaction
 807 information, or transaction statement pedigree paper; or who
 808 knowingly omits to record material information required to be
 809 recorded in a transaction history, transaction information, or
 810 transaction statement pedigree paper, commits a felony of the
 811 second degree, punishable as provided in s. 775.082, s. 775.083,
 812 or s. 775.084.

813 ~~(11)-(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE
 814 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.-

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815 Any person who violates any of the following provisions commits
816 a misdemeanor of the second degree, punishable as provided in s.
817 775.082 or s. 775.083; but, if the violation is committed after
818 a conviction of such person under this subsection has become
819 final, such person commits a misdemeanor of the first degree,
820 punishable as provided in s. 775.082 or s. 775.083, or as
821 otherwise provided in this part:

822 (h) The failure to maintain records related to a drug as
823 required by this part and rules adopted under this part, except
824 for transaction histories, transaction information, or
825 transaction statements ~~pedigree papers~~, invoices, or shipping
826 documents related to prescription drugs.

827 (i) The possession of any drug in violation of this part,
828 except if the violation relates to a deficiency in transaction
829 histories, transaction information, or transaction statements
830 ~~pedigree papers~~.

831 (12) ~~(13)~~ REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING,
832 OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO
833 PRESCRIPTION DRUGS.—Any person who violates any of the following
834 provisions commits a felony of the third degree, punishable as
835 provided in s. 775.082, s. 775.083, or s. 775.084, or as
836 otherwise provided in this part:

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

840 (15) FALSE ADVERTISEMENT.—A publisher, radio broadcast
841 licensee, or agency or medium for the dissemination of an
842 advertisement, except the manufacturer, repackager, wholesale
843 distributor, or seller of the article to which a false

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844 advertisement relates, is not liable under subsection (11) ~~(12)~~,
845 subsection (12) ~~(13)~~, or subsection (13) ~~(14)~~ by reason of the
846 dissemination by him or her of such false advertisement, unless
847 he or she has refused, on the request of the department, to
848 furnish to the department the name and post office address of
849 the manufacturer, repackager, wholesale distributor, seller, or
850 advertising agency that asked him or her to disseminate such
851 advertisement.

852 Section 4. Section 499.006, Florida Statutes, is amended to
853 read:

854 499.006 Adulterated drug or device.—A drug or device is
855 adulterated, if any of the following apply:

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

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

861 (3) ~~If~~ It is a drug and the methods used in, or the
862 facilities or controls used for, its manufacture, processing,
863 packing, or holding do not conform to, or are not operated or
864 administered in conformity with, current good manufacturing
865 practices to assure that the drug meets the requirements of this
866 part and that the drug has the identity and strength, and meets
867 the standard of quality and purity, which it purports or is
868 represented to possess.†

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

872 (5) ~~If~~ It is a drug and it bears or contains, for the

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873 purpose of coloring only, a color additive that is unsafe within
874 the meaning of the federal act; or, if it is a color additive,
875 the intended use of which in or on drugs is for the purpose of
876 coloring only, and it is unsafe within the meaning of the
877 federal act.†

878 (6) ~~If~~ It purports to be, or is represented as, a drug the
879 name of which is recognized in the official compendium, and its
880 strength differs from, or its quality or purity falls below, the
881 standard set forth in such compendium. The determination as to
882 strength, quality, or purity must be made in accordance with the
883 tests or methods of assay set forth in such compendium, or, when
884 such tests or methods of assay are absent or inadequate, in
885 accordance with those tests or methods of assay prescribed under
886 authority of the federal act. A drug defined in the official
887 compendium is not adulterated under this subsection merely
888 because it differs from the standard of strength, quality, or
889 purity set forth for that drug in such compendium if its
890 difference in strength, quality, or purity from such standard is
891 plainly stated on its label.†

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

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

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

898 (b) For which any substance has been substituted wholly or
899 in part.†

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

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902 (10) ~~If~~ It is a prescription drug for which the required
 903 transaction history, transaction information, or transaction
 904 statement pedigree paper is nonexistent, fraudulent, or
 905 incomplete under the requirements of this part or applicable
 906 rules, or that has been purchased, held, sold, or distributed at
 907 any time by a person not authorized under federal or state law
 908 to do so.; ~~or~~

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

913 Section 5. Section 499.01, Florida Statutes, is amended to
 914 read:

915 499.01 Permits.—

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

918 (a) A prescription drug manufacturer;

919 (b) A prescription drug repackager;

920 (c) A nonresident prescription drug manufacturer;

921 (d) A nonresident prescription drug repackager;

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

923 (f) ~~(e)~~ An out-of-state prescription drug wholesale
 924 distributor;

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

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

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

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

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

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

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931 distributor;

932 (m)~~(l)~~ A limited prescription drug veterinary wholesale
933 distributor;

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

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

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

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

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

939 (2) The following permits are established:

940 (a) *Prescription drug manufacturer permit.*—A prescription
941 drug manufacturer permit is required for any person that is a
942 manufacturer of a prescription drug and that manufactures or
943 distributes such prescription drugs in this state.

944 1. A person that operates an establishment permitted as a
945 prescription drug manufacturer may engage in ~~wholesale~~
946 distribution of prescription drugs for which the person is the
947 manufacturer manufactured at that establishment and must comply
948 with s. 499.0121 and all other ~~of the~~ provisions of this part,
949 ~~except s. 499.01212,~~ and the rules adopted under this part,
950 ~~except s. 499.01212,~~ which apply to a wholesale distributor. The
951 department shall adopt rules for issuing a virtual prescription
952 drug manufacturer permit to a person who engages in the
953 manufacture of prescription drugs but does not make or take
954 physical possession of any prescription drugs. The rules adopted
955 by the department under this section may exempt virtual
956 manufacturers from certain establishment, security, and storage
957 requirements set forth in s. 499.0121.

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

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

967 (b) *Prescription drug repackager permit.*—A prescription
968 drug repackager permit is required for any person that
969 repackages a prescription drug in this state.

970 1. A person that operates an establishment permitted as a
971 prescription drug repackager may engage in ~~wholesale~~
972 distribution of prescription drugs repackaged at that
973 establishment and must comply with all of the provisions of this
974 part and the rules adopted under this part that apply to a
975 prescription drug manufacturer ~~wholesale distributor~~.

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

978 (c) *Nonresident prescription drug manufacturer permit.*—A
979 nonresident prescription drug manufacturer permit is required
980 for any person that is a manufacturer of prescription drugs,
981 unless permitted as a third party logistics provider, located
982 outside of this state or outside the United States and that
983 engages in the ~~wholesale~~ distribution in this state of such
984 prescription drugs. Each such manufacturer must be permitted by
985 the department and comply with all of the provisions required of
986 a prescription drug manufacturer ~~wholesale distributor~~ under
987 this part, ~~except s. 499.01212.~~ The department shall adopt rules
988 for issuing a virtual nonresident prescription drug manufacturer

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989 permit to a person who engages in the manufacture of
990 prescription drugs but does not make or take physical possession
991 of any prescription drugs. The rules adopted by the department
992 under this section may exempt virtual nonresident manufacturers
993 from certain establishment, security, and storage requirements
994 set forth in s. 499.0121.

995 1. A person that distributes prescription drugs for which
996 the person is not the manufacturer must also obtain an out-of-
997 state prescription drug wholesale distributor permit or third
998 party logistics provider permit pursuant to this section to
999 engage in the ~~wholesale~~ distribution of such prescription drugs
1000 when required by this part. This subparagraph does not apply to
1001 a manufacturer that distributes prescription drugs only for the
1002 manufacturer of the prescription drugs where both manufacturers
1003 are affiliates as defined in s. 499.003(30)(e).

1004 2. Any such person must comply with the licensing or
1005 permitting requirements of the jurisdiction in which the
1006 establishment is located and the federal act, and any
1007 prescription drug distributed ~~product wholesaled~~ into this state
1008 must comply with this part. If a person intends to import
1009 prescription drugs from a foreign country into this state, the
1010 nonresident prescription drug manufacturer must provide to the
1011 department a list identifying each prescription drug it intends
1012 to import and document approval by the United States Food and
1013 Drug Administration for such importation.

1014 (d) Nonresident prescription drug repackager permit.-A
1015 nonresident prescription drug repackager permit is required for
1016 any person located outside of this state, but within the United
1017 States or its territories, that repackages prescription drugs

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1018 and engages in the distribution of such prescription drugs into
1019 this state.

1020 1. A nonresident prescription drug repackager must comply
1021 with all of the provisions of this section and the rules adopted
1022 under this section that apply to a prescription drug
1023 manufacturer.

1024 2. A nonresident prescription drug repackager must be
1025 permitted by the department and comply with all appropriate
1026 state and federal good manufacturing practices.

1027 3. A nonresident prescription drug repackager must be
1028 registered as a drug establishment with the United States Food
1029 and Drug Administration.

1030 (e) ~~(d)~~ Prescription drug wholesale distributor permit.—A
1031 prescription drug wholesale distributor permit is required for
1032 any person who is a wholesale distributor of prescription drugs
1033 and that ~~may engage in the~~ wholesale distributes such
1034 ~~distribution of~~ prescription drugs in this state. A ~~prescription~~
1035 ~~drug wholesale distributor that applies to the department for a~~
1036 ~~new permit or the renewal of a permit must submit a bond of~~
1037 ~~\$100,000, or other equivalent means of security acceptable to~~
1038 ~~the department, such as an irrevocable letter of credit or a~~
1039 ~~deposit in a trust account or financial institution, payable to~~
1040 ~~the Professional Regulation Trust Fund. The purpose of the bond~~
1041 ~~is to secure payment of any administrative penalties imposed by~~
1042 ~~the department and any fees and costs incurred by the department~~
1043 ~~regarding that permit which are authorized under state law and~~
1044 ~~which the permittee fails to pay 30 days after the fine or costs~~
1045 ~~become final. The department may make a claim against such bond~~
1046 ~~or security until 1 year after the permittee's license ceases to~~

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1047 ~~be valid or until 60 days after any administrative or legal~~
1048 ~~proceeding authorized in this part which involves the permittee~~
1049 ~~is concluded, including any appeal, whichever occurs later.~~ The
1050 department may adopt rules for issuing a prescription drug
1051 wholesale distributor-broker permit to a person who engages in
1052 the wholesale distribution of prescription drugs and does not
1053 take physical possession of any prescription drugs.

1054 (f) ~~(e)~~ *Out-of-state prescription drug wholesale distributor*
1055 *permit.*—An out-of-state prescription drug wholesale distributor
1056 permit is required for any person that is a wholesale
1057 distributor located outside this state, but within the United
1058 States or its territories, which engages in the wholesale
1059 distribution of prescription drugs into this state ~~and which~~
1060 ~~must be permitted by the department and comply with all the~~
1061 ~~provisions required of a wholesale distributor under this part.~~
1062 ~~An out-of-state prescription drug wholesale distributor that~~
1063 ~~applies to the department for a new permit or the renewal of a~~
1064 ~~permit must submit a bond of \$100,000, or other equivalent means~~
1065 ~~of security acceptable to the department, such as an irrevocable~~
1066 ~~letter of credit or a deposit in a trust account or financial~~
1067 ~~institution, payable to the Professional Regulation Trust Fund.~~
1068 ~~The purpose of the bond is to secure payment of any~~
1069 ~~administrative penalties imposed by the department and any fees~~
1070 ~~and costs incurred by the department regarding that permit which~~
1071 ~~are authorized under state law and which the permittee fails to~~
1072 ~~pay 30 days after the fine or costs become final. The department~~
1073 ~~may make a claim against such bond or security until 1 year~~
1074 ~~after the permittee's license ceases to be valid or until 60~~
1075 ~~days after any administrative or legal proceeding authorized in~~

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1076 ~~this part which involves the permittee is concluded, including~~
1077 ~~any appeal, whichever occurs later.~~ The out-of-state
1078 prescription drug wholesale distributor must maintain at all
1079 times a license or permit to engage in the wholesale
1080 distribution of prescription drugs in compliance with laws of
1081 the state in which it is a resident. If the state from which the
1082 wholesale distributor distributes prescription drugs does not
1083 require a license to engage in the wholesale distribution of
1084 prescription drugs, the distributor must be licensed as a
1085 wholesale distributor as required by the federal act.

1086 (g) ~~(f)~~ *Retail pharmacy drug wholesale distributor permit.*—A
1087 retail pharmacy drug wholesale distributor is a retail pharmacy
1088 engaged in wholesale distribution of prescription drugs within
1089 this state under the following conditions:

1090 1. The pharmacy must obtain a retail pharmacy drug
1091 wholesale distributor permit pursuant to this part and ~~the~~ rules
1092 adopted under this part.

1093 2. The wholesale distribution activity does not exceed 30
1094 percent of the total annual purchases of prescription drugs. If
1095 the wholesale distribution activity exceeds the 30-percent
1096 maximum, the pharmacy must obtain a prescription drug wholesale
1097 distributor permit.

1098 3. The transfer of prescription drugs that appear in any
1099 schedule contained in chapter 893 is subject to chapter 893 and
1100 the federal Comprehensive Drug Abuse Prevention and Control Act
1101 of 1970.

1102 4. The transfer is between a retail pharmacy and another
1103 retail pharmacy, or a Modified Class II institutional pharmacy,
1104 or a health care practitioner licensed in this state and

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1105 authorized by law to dispense or prescribe prescription drugs.

1106 5. All records of sales of prescription drugs subject to
1107 this section must be maintained separate and distinct from other
1108 records and comply with the recordkeeping requirements of this
1109 part.

1110 (h)~~(g)~~ *Restricted prescription drug distributor permit.*—

1111 1. A restricted prescription drug distributor permit is
1112 required for:

1113 a. Any person located in this state who engages in the
1114 distribution of a prescription drug, which distribution is not
1115 considered “wholesale distribution” under s. 499.003(48)(a)
1116 ~~499.003(53)(a)~~.

1117 b. Any person located in this state who engages in the
1118 receipt or distribution of a prescription drug in this state for
1119 the purpose of processing its return or its destruction if such
1120 person is not the person initiating the return, the prescription
1121 drug wholesale supplier of the person initiating the return, or
1122 the manufacturer of the drug.

1123 c. A blood establishment located in this state which
1124 collects blood and blood components only from volunteer donors
1125 as defined in s. 381.06014 or pursuant to an authorized
1126 practitioner’s order for medical treatment or therapy and
1127 engages in the wholesale distribution of a prescription drug not
1128 described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care
1129 entity. A mobile blood unit operated by a blood establishment
1130 permitted under this sub-subparagraph is not required to be
1131 separately permitted. The health care entity receiving a
1132 prescription drug distributed under this sub-subparagraph must
1133 be licensed as a closed pharmacy or provide health care services

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1134 at that establishment. The blood establishment must operate in
1135 accordance with s. 381.06014 and may distribute only:

1136 (I) Prescription drugs indicated for a bleeding or clotting
1137 disorder or anemia;

1138 (II) Blood-collection containers approved under s. 505 of
1139 the federal act;

1140 (III) Drugs that are blood derivatives, or a recombinant or
1141 synthetic form of a blood derivative;

1142 (IV) Prescription drugs that are identified in rules
1143 adopted by the department and that are essential to services
1144 performed or provided by blood establishments and authorized for
1145 distribution by blood establishments under federal law; or

1146 (V) To the extent authorized by federal law, drugs
1147 necessary to collect blood or blood components from volunteer
1148 blood donors; for blood establishment personnel to perform
1149 therapeutic procedures under the direction and supervision of a
1150 licensed physician; and to diagnose, treat, manage, and prevent
1151 any reaction of a volunteer blood donor or a patient undergoing
1152 a therapeutic procedure performed under the direction and
1153 supervision of a licensed physician,

1154
1155 as long as all of the health care services provided by the blood
1156 establishment are related to its activities as a registered
1157 blood establishment or the health care services consist of
1158 collecting, processing, storing, or administering human
1159 hematopoietic stem cells or progenitor cells or performing
1160 diagnostic testing of specimens if such specimens are tested
1161 together with specimens undergoing routine donor testing. The
1162 blood establishment may purchase and possess the drugs described

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1163 in this sub-subparagraph without a health care clinic
1164 establishment permit.

1165 2. Storage, handling, and recordkeeping of these
1166 distributions by a person required to be permitted as a
1167 restricted prescription drug distributor must be in accordance
1168 with the requirements for wholesale distributors under s.
1169 499.0121, ~~but not those set forth in s. 499.01212 if the~~
1170 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~
1171 ~~subparagraph 1.b.~~

1172 3. A person who applies for a permit as a restricted
1173 prescription drug distributor, or for the renewal of such a
1174 permit, must provide to the department the information required
1175 under s. 499.012.

1176 4. The department may adopt rules regarding the
1177 distribution of prescription drugs by hospitals, health care
1178 entities, charitable organizations, other persons not involved
1179 in wholesale distribution, and blood establishments, which rules
1180 are necessary for the protection of the public health, safety,
1181 and welfare.

1182 5. A restricted prescription drug distributor permit is not
1183 required for distributions between pharmacies that each hold an
1184 active permit under chapter 465, have a common ownership, and
1185 are operating in a freestanding end-stage renal dialysis clinic,
1186 if such distributions are made to meet the immediate emergency
1187 medical needs of specifically identified patients and do not
1188 occur with such frequency as to amount to the regular and
1189 systematic supplying of that drug between the pharmacies. The
1190 department shall adopt rules establishing when the distribution
1191 of a prescription drug under this subparagraph amounts to the

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1192 regular and systematic supplying of that drug.

1193 (i)~~(h)~~ *Complimentary drug distributor permit.*—A
1194 complimentary drug distributor permit is required for any person
1195 that engages in the distribution of a complimentary drug,
1196 subject to the requirements of s. 499.028.

1197 (j)~~(i)~~ *Freight forwarder permit.*—A freight forwarder permit
1198 is required for any person that engages in the distribution of a
1199 prescription drug as a freight forwarder unless the person is a
1200 common carrier. The storage, handling, and recordkeeping of such
1201 distributions must comply with the requirements for wholesale
1202 distributors under s. 499.0121, ~~but not those set forth in s.~~
1203 ~~499.01212.~~ A freight forwarder must provide the source of the
1204 prescription drugs with a validated airway bill, bill of lading,
1205 or other appropriate documentation to evidence the exportation
1206 of the product.

1207 (k)~~(j)~~ *Veterinary prescription drug retail establishment*
1208 *permit.*—A veterinary prescription drug retail establishment
1209 permit is required for any person that sells veterinary
1210 prescription drugs to the public but does not include a pharmacy
1211 licensed under chapter 465.

1212 1. The sale to the public must be based on a valid written
1213 order from a veterinarian licensed in this state who has a valid
1214 client-veterinarian relationship with the purchaser's animal.

1215 2. Veterinary prescription drugs may not be sold in excess
1216 of the amount clearly indicated on the order or beyond the date
1217 indicated on the order.

1218 3. An order may not be valid for more than 1 year.

1219 4. A veterinary prescription drug retail establishment may
1220 not purchase, sell, trade, or possess human prescription drugs

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1221 or any controlled substance as defined in chapter 893.

1222 5. A veterinary prescription drug retail establishment must
1223 sell a veterinary prescription drug in the original, sealed
1224 manufacturer's container with all labeling intact and legible.
1225 The department may adopt by rule additional labeling
1226 requirements for the sale of a veterinary prescription drug.

1227 6. A veterinary prescription drug retail establishment must
1228 comply with all of the wholesale distribution requirements of s.
1229 499.0121.

1230 7. Prescription drugs sold by a veterinary prescription
1231 drug retail establishment pursuant to a practitioner's order may
1232 not be returned into the retail establishment's inventory.

1233 (1)~~(*)~~ *Veterinary prescription drug wholesale distributor*
1234 *permit.*—A veterinary prescription drug wholesale distributor
1235 permit is required for any person that engages in the
1236 distribution of veterinary prescription drugs in or into this
1237 state. A veterinary prescription drug wholesale distributor that
1238 also distributes prescription drugs subject to, defined by, or
1239 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1240 Act which it did not manufacture must obtain a permit as a
1241 prescription drug wholesale distributor, an out-of-state
1242 prescription drug wholesale distributor, or a limited
1243 prescription drug veterinary wholesale distributor in lieu of
1244 the veterinary prescription drug wholesale distributor permit. A
1245 veterinary prescription drug wholesale distributor must comply
1246 with the requirements for wholesale distributors under s.
1247 499.0121, ~~but not those set forth in s. 499.01212.~~

1248 (m)~~(1)~~ *Limited prescription drug veterinary wholesale*
1249 *distributor permit.*—Unless engaging in the activities of and

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1250 permitted as a prescription drug manufacturer, nonresident
1251 prescription drug manufacturer, prescription drug wholesale
1252 distributor, or out-of-state prescription drug wholesale
1253 distributor, a limited prescription drug veterinary wholesale
1254 distributor permit is required for any person that engages in
1255 the distribution in or into this state of veterinary
1256 prescription drugs and prescription drugs subject to, defined
1257 by, or described by s. 503(b) of the Federal Food, Drug, and
1258 Cosmetic Act under the following conditions:

1259 1. The person is engaged in the business of wholesaling
1260 prescription and veterinary prescription drugs to persons:

1261 a. Licensed as veterinarians practicing on a full-time
1262 basis;

1263 b. Regularly and lawfully engaged in instruction in
1264 veterinary medicine;

1265 c. Regularly and lawfully engaged in law enforcement
1266 activities;

1267 d. For use in research not involving clinical use; or

1268 e. For use in chemical analysis or physical testing or for
1269 purposes of instruction in law enforcement activities, research,
1270 or testing.

1271 2. No more than 30 percent of total annual prescription
1272 drug sales may be prescription drugs approved for human use
1273 which are subject to, defined by, or described by s. 503(b) of
1274 the Federal Food, Drug, and Cosmetic Act.

1275 3. The person does not distribute in any jurisdiction
1276 prescription drugs subject to, defined by, or described by s.
1277 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
1278 who is authorized to sell, distribute, purchase, trade, or use

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1279 these drugs on or for humans.

1280 4. A limited prescription drug veterinary wholesale
1281 distributor that applies to the department for a new permit or
1282 the renewal of a permit must submit a bond of \$20,000, or other
1283 equivalent means of security acceptable to the department, such
1284 as an irrevocable letter of credit or a deposit in a trust
1285 account or financial institution, payable to the Professional
1286 Regulation Trust Fund. The purpose of the bond is to secure
1287 payment of any administrative penalties imposed by the
1288 department and any fees and costs incurred by the department
1289 regarding that permit which are authorized under state law and
1290 which the permittee fails to pay 30 days after the fine or costs
1291 become final. The department may make a claim against such bond
1292 or security until 1 year after the permittee's license ceases to
1293 be valid or until 60 days after any administrative or legal
1294 proceeding authorized in this part which involves the permittee
1295 is concluded, including any appeal, whichever occurs later.

1296 5. A limited prescription drug veterinary wholesale
1297 distributor must maintain at all times a license or permit to
1298 engage in the wholesale distribution of prescription drugs in
1299 compliance with laws of the state in which it is a resident.

1300 6. A limited prescription drug veterinary wholesale
1301 distributor must comply with the requirements for wholesale
1302 distributors under s. ss. 499.0121 and 499.01212, ~~except that a~~
1303 ~~limited prescription drug veterinary wholesale distributor is~~
1304 ~~not required to provide a pedigree paper as required by s.~~
1305 ~~499.01212 upon the wholesale distribution of a prescription drug~~
1306 ~~to a veterinarian.~~

1307 7. A limited prescription drug veterinary wholesale

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1308 distributor may not return to inventory for subsequent wholesale
1309 distribution any prescription drug subject to, defined by, or
1310 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1311 Act which has been returned by a veterinarian.

1312 8. A limited prescription drug veterinary wholesale
1313 distributor permit is not required for an intracompany sale or
1314 transfer of a prescription drug from an out-of-state
1315 establishment that is duly licensed to engage in the wholesale
1316 distribution of prescription drugs in its state of residence to
1317 a licensed limited prescription drug veterinary wholesale
1318 distributor in this state if both wholesale distributors conduct
1319 wholesale distributions of prescription drugs under the same
1320 business name. The recordkeeping requirements of s. ss.
1321 ~~499.0121(6) and 499.01212~~ must be followed for this transaction.

1322 (n) ~~(m)~~ *Over-the-counter drug manufacturer permit.*—An over-
1323 the-counter drug manufacturer permit is required for any person
1324 that engages in the manufacture or repackaging of an over-the-
1325 counter drug.

1326 1. An over-the-counter drug manufacturer may not possess or
1327 purchase prescription drugs.

1328 2. A pharmacy is exempt from obtaining an over-the-counter
1329 drug manufacturer permit if it is operating in compliance with
1330 pharmacy practice standards as defined in chapter 465 and ~~the~~
1331 rules adopted under that chapter.

1332 3. An over-the-counter drug manufacturer must comply with
1333 all appropriate state and federal good manufacturing practices.

1334 (o) ~~(n)~~ *Device manufacturer permit.*—

1335 1. A device manufacturer permit is required for any person
1336 that engages in the manufacture, repackaging, or assembly of

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1337 medical devices for human use in this state, except that a
1338 permit is not required if:

1339 a. The person is engaged only in manufacturing,
1340 repackaging, or assembling a medical device pursuant to a
1341 practitioner's order for a specific patient; or

1342 b. The person does not manufacture, repackage, or assemble
1343 any medical devices or components for such devices, except those
1344 devices or components which are exempt from registration
1345 pursuant to s. 499.015(8).

1346 2. A manufacturer or repackager of medical devices in this
1347 state must comply with all appropriate state and federal good
1348 manufacturing practices and quality system rules.

1349 3. The department shall adopt rules related to storage,
1350 handling, and recordkeeping requirements for manufacturers of
1351 medical devices for human use.

1352 (p)~~(e)~~ *Cosmetic manufacturer permit.*—A cosmetic
1353 manufacturer permit is required for any person that manufactures
1354 or repackages cosmetics in this state. A person that only labels
1355 or changes the labeling of a cosmetic but does not open the
1356 container sealed by the manufacturer of the product is exempt
1357 from obtaining a permit under this paragraph.

1358 (q)~~(e)~~ *Third party logistics provider permit.*—A third party
1359 logistics provider permit is required for any person that
1360 contracts with a prescription drug wholesale distributor or
1361 prescription drug manufacturer to provide warehousing,
1362 distribution, or other logistics services on behalf of a
1363 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who
1364 does not take title to the prescription drug or have
1365 responsibility to direct the sale or disposition of the

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1366 prescription drug. A third party logistics provider located
1367 outside of this state, must be licensed in the state or
1368 territory from which the prescription drug is distributed by the
1369 third party logistics provider. If the state or territory from
1370 which the third party logistics provider originates does not
1371 require a license to operate as a third party logistics
1372 provider, the third party logistics provider must be licensed as
1373 a third party logistics provider as required by the federal act.
1374 Each third party logistics provider permittee shall comply with
1375 s. the requirements for wholesale distributors under ss.
1376 499.0121 and 499.01212, with the exception of those wholesale
1377 distributions described in s. 499.01212(3)(a), and other rules
1378 that the department requires.

1379 (r)(q) Health care clinic establishment permit. ~~Effective~~
1380 ~~January 1, 2009,~~ A health care clinic establishment permit is
1381 required for the purchase of a prescription drug by a place of
1382 business at one general physical location that provides health
1383 care or veterinary services, which is owned and operated by a
1384 business entity that has been issued a federal employer tax
1385 identification number. For the purpose of this paragraph, the
1386 term "qualifying practitioner" means a licensed health care
1387 practitioner defined in s. 456.001, or a veterinarian licensed
1388 under chapter 474, who is authorized under the appropriate
1389 practice act to prescribe and administer a prescription drug.

1390 1. An establishment must provide, as part of the
1391 application required under s. 499.012, designation of a
1392 qualifying practitioner who will be responsible for complying
1393 with all legal and regulatory requirements related to the
1394 purchase, recordkeeping, storage, and handling of the

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1395 prescription drugs. In addition, the designated qualifying
1396 practitioner shall be the practitioner whose name, establishment
1397 address, and license number is used on all distribution
1398 documents for prescription drugs purchased or returned by the
1399 health care clinic establishment. Upon initial appointment of a
1400 qualifying practitioner, the qualifying practitioner and the
1401 health care clinic establishment shall notify the department on
1402 a form furnished by the department within 10 days after such
1403 employment. In addition, the qualifying practitioner and health
1404 care clinic establishment shall notify the department within 10
1405 days after any subsequent change.

1406 2. The health care clinic establishment must employ a
1407 qualifying practitioner at each establishment.

1408 3. In addition to the remedies and penalties provided in
1409 this part, a violation of this chapter by the health care clinic
1410 establishment or qualifying practitioner constitutes grounds for
1411 discipline of the qualifying practitioner by the appropriate
1412 regulatory board.

1413 4. The purchase of prescription drugs by the health care
1414 clinic establishment is prohibited during any period of time
1415 when the establishment does not comply with this paragraph.

1416 5. A health care clinic establishment permit is not a
1417 pharmacy permit or otherwise subject to chapter 465. A health
1418 care clinic establishment that meets the criteria of a modified
1419 Class II institutional pharmacy under s. 465.019 is not eligible
1420 to be permitted under this paragraph.

1421 6. This paragraph does not apply to the purchase of a
1422 prescription drug by a licensed practitioner under his or her
1423 license.

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1424 (3) A nonresident prescription drug manufacturer permit is
1425 not required for a manufacturer to distribute a prescription
1426 drug active pharmaceutical ingredient that it manufactures to a
1427 prescription drug manufacturer permitted in this state ~~in~~
1428 ~~limited quantities~~ intended for research and development and not
1429 for resale or human use other than lawful clinical trials and
1430 biostudies authorized and regulated by federal law. A
1431 manufacturer claiming to be exempt from the permit requirements
1432 of this subsection and the prescription drug manufacturer
1433 purchasing and receiving the active pharmaceutical ingredient
1434 shall comply with the recordkeeping requirements of s.
1435 499.0121(6), ~~but not the requirements of s. 499.01212.~~ The
1436 prescription drug manufacturer purchasing and receiving the
1437 active pharmaceutical ingredient shall maintain on file a record
1438 of the FDA registration number; if available, the out-of-state
1439 license, permit, or registration number; and, if available, a
1440 copy of the most current FDA inspection report, for all
1441 manufacturers from whom they purchase active pharmaceutical
1442 ingredients under this section. ~~The department shall define the~~
1443 ~~term "limited quantities" by rule, and may include the allowable~~
1444 ~~number of transactions within a given period of time and the~~
1445 ~~amount of prescription drugs distributed into the state for~~
1446 ~~purposes of this exemption.~~ The failure to comply with the
1447 requirements of this subsection, or rules adopted by the
1448 department to administer this subsection, for the purchase of
1449 prescription drug active pharmaceutical ingredients is a
1450 violation of s. 499.005(14), and a knowing failure is a
1451 violation of s. 499.0051(3) ~~499.0051(4)~~.

1452 (a) The immediate package or container of a prescription

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1453 drug active pharmaceutical ingredient distributed into the state
1454 that is intended for research and development under this
1455 subsection shall bear a label prominently displaying the
1456 statement: "Caution: Research and Development Only—Not for
1457 Manufacturing, Compounding, or Resale."

1458 (b) A prescription drug manufacturer that obtains a
1459 prescription drug active pharmaceutical ingredient under this
1460 subsection for use in clinical trials and or biostudies
1461 authorized and regulated by federal law must create and maintain
1462 records detailing the specific clinical trials or biostudies for
1463 which the prescription drug active pharmaceutical ingredient was
1464 obtained.

1465 (4) (a) A permit issued under this part is not required to
1466 distribute a prescription drug active pharmaceutical ingredient
1467 from an establishment located in the United States to an
1468 establishment located in this state permitted as a prescription
1469 drug manufacturer under this part for use by the recipient in
1470 preparing, deriving, processing, producing, or fabricating a
1471 prescription drug finished dosage form at the establishment in
1472 this state where the product is received under an approved and
1473 otherwise valid New Drug Approval Application, Abbreviated New
1474 Drug Application, New Animal Drug Application, or Therapeutic
1475 Biologic Application, provided that the application, active
1476 pharmaceutical ingredient, or finished dosage form has not been
1477 withdrawn or removed from the market in this country for public
1478 health reasons.

1479 1. Any distributor claiming exemption from permitting
1480 requirements pursuant to this paragraph shall maintain a
1481 license, permit, or registration to engage in the wholesale

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1482 distribution of prescription drugs under the laws of the state
1483 from which the product is distributed. If the state from which
1484 the prescription drugs are distributed does not require a
1485 license to engage in the wholesale distribution of prescription
1486 drugs, the distributor must be licensed as a wholesale
1487 distributor as required by the federal act.

1488 2. Any distributor claiming exemption from permitting
1489 requirements pursuant to this paragraph and the prescription
1490 drug manufacturer purchasing and receiving the active
1491 pharmaceutical ingredient shall comply with the recordkeeping
1492 requirements of s. 499.0121(6), ~~but not the requirements of s.~~
1493 ~~499.01212.~~

1494 (b) A permit issued under this part is not required to
1495 distribute ~~limited quantities of~~ a prescription drug that has
1496 not been repackaged from an establishment located in the United
1497 States to an establishment located in this state permitted as a
1498 prescription drug manufacturer under this part for research and
1499 development or to a holder of a letter of exemption issued by
1500 the department under s. 499.03(4) for research, teaching, or
1501 testing. ~~The department shall define "limited quantities" by~~
1502 ~~rule and may include the allowable number of transactions within~~
1503 ~~a given period of time and the amounts of prescription drugs~~
1504 ~~distributed into the state for purposes of this exemption.~~

1505 1. Any distributor claiming exemption from permitting
1506 requirements pursuant to this paragraph shall maintain a
1507 license, permit, or registration to engage in the wholesale
1508 distribution of prescription drugs under the laws of the state
1509 from which the product is distributed. If the state from which
1510 the prescription drugs are distributed does not require a

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1511 license to engage in the wholesale distribution of prescription
1512 drugs, the distributor must be licensed as a wholesale
1513 distributor as required by the federal act.

1514 2. All purchasers and recipients of any prescription drugs
1515 distributed pursuant to this paragraph shall ensure that the
1516 products are not resold or used, directly or indirectly, on
1517 humans except in lawful clinical trials and biostudies
1518 authorized and regulated by federal law.

1519 3. Any distributor claiming exemption from permitting
1520 requirements pursuant to this paragraph, and the purchaser and
1521 recipient of the prescription drug, shall comply with the
1522 recordkeeping requirements of s. 499.0121(6), ~~but not the~~
1523 ~~requirements of s. 499.01212.~~

1524 4. The immediate package or container of any active
1525 pharmaceutical ingredient distributed into the state that is
1526 intended for teaching, testing, research, and development shall
1527 bear a label prominently displaying the statement: "Caution:
1528 Research, Teaching, or Testing Only - Not for Manufacturing,
1529 Compounding, or Resale."

1530 (c) An out-of-state prescription drug wholesale distributor
1531 permit is not required for an intracompany sale or transfer of a
1532 prescription drug from an out-of-state establishment that is
1533 duly licensed as a prescription drug wholesale distributor in
1534 its state of residence to a licensed prescription drug wholesale
1535 distributor in this state, if both wholesale distributors
1536 conduct wholesale distributions of prescription drugs under the
1537 same business name. The recordkeeping requirements of s. ss.
1538 ~~499.0121(6) and 499.01212~~ must be followed for such
1539 transactions.

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1540 (d) Persons receiving prescription drugs from a source
1541 claimed to be exempt from permitting requirements under this
1542 subsection shall maintain on file:

1543 1. A record of the FDA establishment registration number,
1544 if any;

1545 2. The resident state or federal license, registration, or
1546 permit that authorizes the source to distribute prescription
1547 drugs ~~drug wholesale distribution license, permit, or~~
1548 ~~registration number~~; and

1549 3. A copy of the most recent resident state or FDA
1550 inspection report, for all distributors and establishments from
1551 whom they purchase or receive prescription drugs under this
1552 subsection.

1553 (e) All persons claiming exemption from permitting
1554 requirements pursuant to this subsection who engage in the
1555 distribution of prescription drugs within or into the state are
1556 subject to this part, including ss. 499.005 and 499.0051, and
1557 shall make available, within 48 hours, to the department on
1558 request all records related to any prescription drugs
1559 distributed under this subsection, including those records
1560 described in s. 499.051(4), regardless of the location where the
1561 records are stored.

1562 (f) A person purchasing and receiving a prescription drug
1563 from a person claimed to be exempt from licensing requirements
1564 pursuant to this subsection shall report to the department in
1565 writing within 14 days after receiving any product that is
1566 misbranded or adulterated or that fails to meet minimum
1567 standards set forth in the official compendium or state or
1568 federal good manufacturing practices for identity, purity,

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1569 potency, or sterility, regardless of whether the product is
1570 thereafter rehabilitated, quarantined, returned, or destroyed.

1571 (g) The department may adopt rules to administer this
1572 subsection which are necessary for the protection of the public
1573 health, safety, and welfare. Failure to comply with the
1574 requirements of this subsection, or rules adopted by the
1575 department to administer this subsection, is a violation of s.
1576 499.005(14), and a knowing failure is a violation of s.
1577 499.0051(3) ~~499.0051(4)~~.

1578 (h) This subsection does not relieve any person from any
1579 requirement prescribed by law with respect to controlled
1580 substances as defined in the applicable federal and state laws.

1581 (5) A prescription drug repackager permit issued under this
1582 part is not required for a restricted prescription drug
1583 distributor permitholder that is a health care entity to
1584 repackage prescription drugs in this state for its own use or
1585 for distribution to hospitals or other health care entities in
1586 the state for their own use, pursuant to s. 499.003(48)(a)3.
1587 ~~499.003(53)(a)3.~~, if:

1588 (a) The prescription drug distributor notifies the
1589 department, in writing, of its intention to engage in
1590 repackaging under this exemption, 30 days before engaging in the
1591 repackaging of prescription drugs at the permitted
1592 establishment;

1593 (b) The prescription drug distributor is under common
1594 control with the hospitals or other health care entities to
1595 which the prescription drug distributor is distributing
1596 prescription drugs. As used in this paragraph, "common control"
1597 means the power to direct or cause the direction of the

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1598 management and policies of a person or an organization, whether
1599 by ownership of stock, voting rights, contract, or otherwise;

1600 (c) The prescription drug distributor repackages the
1601 prescription drugs in accordance with current state and federal
1602 good manufacturing practices; and

1603 (d) The prescription drug distributor labels the
1604 prescription drug it repackages in accordance with state and
1605 federal laws and rules.

1606

1607 The prescription drug distributor is exempt from the product
1608 registration requirements of s. 499.015 with regard to the
1609 prescription drugs that it repackages and distributes under this
1610 subsection. A prescription drug distributor that repackages and
1611 distributes prescription drugs under this subsection to a not-
1612 for-profit rural hospital, as defined in s. 395.602, is not
1613 required to comply with paragraph (c) or paragraph (d), but must
1614 provide to each health care entity for which it repackages, for
1615 each prescription drug that is repackaged and distributed, the
1616 information required by department rule for labeling
1617 prescription drugs. The department shall adopt rules to ensure
1618 the safety and integrity of prescription drugs repackaged and
1619 distributed under this subsection, including rules regarding
1620 prescription drug manufacturing and labeling requirements.

1621 Section 6. Section 499.012, Florida Statutes, is amended to
1622 read:

1623 499.012 Permit application requirements.—

1624 (1) (a) A permit issued pursuant to this part may be issued
1625 only to a natural person who is at least 18 years of age or to
1626 an applicant that is not a natural person if each person who,

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1627 directly or indirectly, manages, controls, or oversees the
1628 operation of that applicant is at least 18 years of age.

1629 (b) An establishment that is a place of residence may not
1630 receive a permit and may not operate under this part.

1631 (c) A person that applies for or renews a permit to
1632 manufacture or distribute prescription drugs may not use a name
1633 identical to the name used by any other establishment or
1634 licensed person authorized to purchase prescription drugs in
1635 this state, except that a restricted drug distributor permit
1636 issued to a health care entity will be issued in the name in
1637 which the institutional pharmacy permit is issued and a retail
1638 pharmacy drug wholesale distributor will be issued a permit in
1639 the name of its retail pharmacy permit.

1640 (d) A permit for a prescription drug manufacturer,
1641 prescription drug repackager, prescription drug wholesale
1642 distributor, limited prescription drug veterinary wholesale
1643 distributor, or retail pharmacy drug wholesale distributor may
1644 not be issued to the address of a health care entity or to a
1645 pharmacy licensed under chapter 465, except as provided in this
1646 paragraph. The department may issue a prescription drug
1647 manufacturer permit to an applicant at the same address as a
1648 licensed nuclear pharmacy, which is a health care entity, even
1649 if the nuclear pharmacy holds a special sterile compounding
1650 permit under chapter 465, for the purpose of manufacturing
1651 prescription drugs used in positron emission tomography or other
1652 radiopharmaceuticals, as listed in a rule adopted by the
1653 department pursuant to this paragraph. The purpose of this
1654 exemption is to assure availability of state-of-the-art
1655 pharmaceuticals that would pose a significant danger to the

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1656 public health if manufactured at a separate establishment
1657 address from the nuclear pharmacy from which the prescription
1658 drugs are dispensed. The department may also issue a retail
1659 pharmacy drug wholesale distributor permit to the address of a
1660 community pharmacy licensed under chapter 465, even if the
1661 community pharmacy holds a special sterile compounding permit
1662 under chapter 465, as long as the community pharmacy ~~which~~ does
1663 not meet the definition of a closed pharmacy in s. 499.003.

1664 (e) A county or municipality may not issue an occupational
1665 license for ~~any licensing period beginning on or after October~~
1666 ~~1, 2003, for~~ any establishment that requires a permit pursuant
1667 to this part, unless the establishment exhibits a current permit
1668 issued by the department for the establishment. Upon
1669 presentation of the requisite permit issued by the department,
1670 an occupational license may be issued by the municipality or
1671 county in which application is made. The department shall
1672 furnish to local agencies responsible for issuing occupational
1673 licenses a current list of all establishments licensed pursuant
1674 to this part.

1675 (2) Notwithstanding subsection (6), a permitted person in
1676 good standing may change the type of permit issued to that
1677 person by completing a new application for the requested permit,
1678 paying the amount of the difference in the permit fees if the
1679 fee for the new permit is more than the fee for the original
1680 permit, and meeting the applicable permitting conditions for the
1681 new permit type. The new permit expires on the expiration date
1682 of the original permit being changed; however, a new permit for
1683 a prescription drug wholesale distributor, an out-of-state
1684 prescription drug wholesale distributor, or a retail pharmacy

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1685 drug wholesale distributor shall expire on the expiration date
1686 of the original permit or 1 year after the date of issuance of
1687 the new permit, whichever is earlier. A refund may not be issued
1688 if the fee for the new permit is less than the fee that was paid
1689 for the original permit.

1690 (3) (a) A written application for a permit or to renew a
1691 permit must be filed with the department on forms furnished by
1692 the department. The department shall establish, by rule, the
1693 form and content of the application to obtain or renew a permit.
1694 The applicant must submit to the department with the application
1695 a statement that swears or affirms that the information is true
1696 and correct.

1697 (b) Upon a determination that 2 years have elapsed since
1698 the department notified an applicant for permit, certification,
1699 or product registration of a deficiency in the application and
1700 that the applicant has failed to cure the deficiency, the
1701 application shall expire. The determination regarding the 2-year
1702 lapse of time shall be based on documentation that the
1703 department notified the applicant of the deficiency in
1704 accordance with s. 120.60.

1705 (c) Information submitted by an applicant on an application
1706 required pursuant to this subsection which is a trade secret, as
1707 defined in s. 812.081, shall be maintained by the department as
1708 trade secret information pursuant to s. 499.051(7).

1709 (4) (a) Except for a permit for a prescription drug
1710 wholesale distributor or an out-of-state prescription drug
1711 wholesale distributor, an application for a permit must include:
1712 1. The name, full business address, and telephone number of
1713 the applicant;

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- 1714 2. All trade or business names used by the applicant;
- 1715 3. The address, telephone numbers, and the names of contact
1716 persons for each facility used by the applicant for the storage,
1717 handling, and distribution of prescription drugs;
- 1718 4. The type of ownership or operation, such as a
1719 partnership, corporation, or sole proprietorship; and
- 1720 5. The names of the owner and the operator of the
1721 establishment, including:
- 1722 a. If an individual, the name of the individual;
- 1723 b. If a partnership, the name of each partner and the name
1724 of the partnership;
- 1725 c. If a corporation, the name and title of each corporate
1726 officer and director, the corporate names, and the name of the
1727 state of incorporation;
- 1728 d. If a sole proprietorship, the full name of the sole
1729 proprietor and the name of the business entity;
- 1730 e. If a limited liability company, the name of each member,
1731 the name of each manager, the name of the limited liability
1732 company, and the name of the state in which the limited
1733 liability company was organized; and
- 1734 f. Any other relevant information that the department
1735 requires.
- 1736 (b) Upon approval of the application by the department and
1737 payment of the required fee, the department shall issue a permit
1738 to the applicant, if the applicant meets the requirements of
1739 this part and rules adopted under this part.
- 1740 (c) Any change in information required under paragraph (a)
1741 must be submitted to the department before the change occurs.
- 1742 (d) The department shall consider, at a minimum, the

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1743 following factors in reviewing the qualifications of persons to
1744 be permitted under this part:

1745 1. The applicant's having been found guilty, regardless of
1746 adjudication, in a court of this state or other jurisdiction, of
1747 a violation of a law that directly relates to a drug, device, or
1748 cosmetic. A plea of nolo contendere constitutes a finding of
1749 guilt for purposes of this subparagraph.

1750 2. The applicant's having been disciplined by a regulatory
1751 agency in any state for any offense that would constitute a
1752 violation of this part.

1753 3. Any felony conviction of the applicant under a federal,
1754 state, or local law;

1755 4. The applicant's past experience in manufacturing or
1756 distributing drugs, devices, or cosmetics;

1757 5. The furnishing by the applicant of false or fraudulent
1758 material in any application made in connection with
1759 manufacturing or distributing drugs, devices, or cosmetics;

1760 6. Suspension or revocation by a federal, state, or local
1761 government of any permit currently or previously held by the
1762 applicant for the manufacture or distribution of any drugs,
1763 devices, or cosmetics;

1764 7. Compliance with permitting requirements under any
1765 previously granted permits;

1766 8. Compliance with requirements to maintain or make
1767 available to the state permitting authority or to federal,
1768 state, or local law enforcement officials those records required
1769 under this section; and

1770 9. Any other factors or qualifications the department
1771 considers relevant to and consistent with the public health and

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1772 safety.

1773 (5) ~~Except for a permit for a prescription drug wholesale~~
1774 ~~distributor or an out-of-state prescription drug wholesale~~
1775 ~~distributor:~~

1776 (a) The department shall adopt rules for the biennial
1777 renewal of permits; however, the department may issue up to a 4-
1778 year permit to selected permittees notwithstanding any other
1779 provision of law. Fees for such renewal may not exceed the fee
1780 caps set forth in s. 499.041 on an annualized basis as
1781 authorized by law.

1782 (b) The department shall renew a permit upon receipt of the
1783 renewal application and renewal fee if the applicant meets the
1784 requirements established under this part and ~~the~~ rules adopted
1785 under this part.

1786 (c) At least 90 days before the expiration date of a
1787 permit, the department shall forward a permit renewal
1788 notification to the permittee at the mailing address of the
1789 permitted establishment on file with the department. The permit
1790 renewal notification must state conspicuously the date on which
1791 the permit for the establishment will expire and that the
1792 establishment may not operate unless the permit for the
1793 establishment is renewed timely. A permit, unless sooner
1794 ~~suspended or revoked, automatically expires 2 years after the~~
1795 ~~last day of the anniversary month in which the permit was~~
1796 ~~originally issued.~~

1797 (d) A permit issued under this part may be renewed by
1798 making application for renewal on forms furnished by the
1799 department and paying the appropriate fees.

1800 1. If a prescription drug wholesale distributor or an out-

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1801 of-state prescription drug wholesale distributor renewal
1802 application and fee are submitted and postmarked later than 45
1803 days before the expiration date of the permit, the permit may be
1804 renewed only upon payment of a late renewal fee of \$100, plus
1805 the required renewal fee.

1806 2. If any other a renewal application and fee are submitted
1807 and postmarked after the expiration date of the permit, the
1808 permit may be renewed only upon payment of a late renewal
1809 delinquent fee of \$100, plus the required renewal fee, not later
1810 than 60 days after the expiration date.

1811 3. A permittee who submits a renewal application in
1812 accordance with this paragraph may continue to operate under its
1813 permit, unless the permit is suspended or revoked, until final
1814 disposition of the renewal application.

1815 4.~~(d)~~ Failure to renew a permit in accordance with this
1816 section precludes any future renewal of that permit. If a permit
1817 issued pursuant to this part has expired and cannot be renewed,
1818 before an establishment may engage in activities that require a
1819 permit under this part, the establishment must submit an
1820 application for a new permit, pay the applicable application
1821 fee, the initial permit fee, and all applicable penalties, and
1822 be issued a new permit by the department.

1823 (6) A permit issued by the department is nontransferable.
1824 Each permit is valid only for the person or governmental unit to
1825 which it is issued and is not subject to sale, assignment, or
1826 other transfer, voluntarily or involuntarily; nor is a permit
1827 valid for any establishment other than the establishment for
1828 which it was originally issued.

1829 (a) A person permitted under this part must notify the

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1830 department before making a change of address. The department
1831 shall set a change of location fee not to exceed \$100.

1832 (b)1. An application for a new permit is required when a
1833 majority of the ownership or controlling interest of a permitted
1834 establishment is transferred or assigned or when a lessee agrees
1835 to undertake or provide services to the extent that legal
1836 liability for operation of the establishment will rest with the
1837 lessee. The application for the new permit must be made before
1838 the date of the sale, transfer, assignment, or lease.

1839 2. A permittee that is authorized to distribute
1840 prescription drugs may transfer such drugs to the new owner or
1841 lessee under subparagraph 1. only after the new owner or lessee
1842 has been approved for a permit to distribute prescription drugs.

1843 (c) If an establishment permitted under this part closes,
1844 the owner must notify the department in writing before the
1845 effective date of closure and must:

1846 1. Return the permit to the department;

1847 2. If the permittee is authorized to distribute
1848 prescription drugs, indicate the disposition of such drugs,
1849 including the name, address, and inventory, and provide the name
1850 and address of a person to contact regarding access to records
1851 that are required to be maintained under this part. Transfer of
1852 ownership of prescription drugs may be made only to persons
1853 authorized to possess prescription drugs under this part.

1854
1855 The department may revoke the permit of any person that fails to
1856 comply with the requirements of this subsection.

1857 (7) A permit must be posted in a conspicuous place on the
1858 licensed premises.

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1859 (8) An application for a permit or to renew a permit for a
1860 prescription drug wholesale distributor or an out-of-state
1861 prescription drug wholesale distributor submitted to the
1862 department must include:

1863 (a) The name, full business address, and telephone number
1864 of the applicant.

1865 (b) All trade or business names used by the applicant.

1866 (c) The address, telephone numbers, and the names of
1867 contact persons for each facility used by the applicant for the
1868 storage, handling, and distribution of prescription drugs.

1869 (d) The type of ownership or operation, such as a
1870 partnership, corporation, or sole proprietorship.

1871 (e) The names of the owner and the operator of the
1872 establishment, including:

1873 1. If an individual, the name of the individual.

1874 2. If a partnership, the name of each partner and the name
1875 of the partnership.

1876 3. If a corporation:

1877 a. The name, address, and title of each corporate officer
1878 and director.

1879 b. The name and address of the corporation, resident agent
1880 of the corporation, the resident agent's address, and the
1881 corporation's state of incorporation.

1882 c. The name and address of each shareholder of the
1883 corporation that owns 5 percent or more of the outstanding stock
1884 of the corporation.

1885 4. If a sole proprietorship, the full name of the sole
1886 proprietor and the name of the business entity.

1887 5. If a limited liability company:

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- 1888 a. The name and address of each member.
- 1889 b. The name and address of each manager.
- 1890 c. The name and address of the limited liability company,
1891 the resident agent of the limited liability company, and the
1892 name of the state in which the limited liability company was
1893 organized.
- 1894 (f) If applicable, the name and address of each affiliate
1895 of member of the affiliated group of which the applicant is a
1896 member.
- 1897 (g) 1. The applicant's gross annual receipts attributable to
1898 prescription drug wholesale distribution activities for the
1899 previous tax year. For an application for a new permit, the
1900 estimated annual dollar volume of prescription drug sales of the
1901 applicant, the estimated annual percentage of the applicant's
1902 total company sales that are prescription drugs, the applicant's
1903 estimated annual total dollar volume of purchases of
1904 prescription drugs, and the applicant's estimated annual total
1905 dollar volume of prescription drug purchases directly from
1906 manufacturers.
- 1907 2. For an application to renew a permit, the total dollar
1908 volume of prescription drug sales in the previous year, the
1909 total dollar volume of prescription drug sales made in the
1910 previous 6 months, the percentage of total company sales that
1911 were prescription drugs in the previous year, the total dollar
1912 volume of purchases of prescription drugs in the previous year,
1913 and the total dollar volume of prescription drug purchases
1914 directly from manufacturers in the previous year.
- 1915
- 1916 Such portions of the information required pursuant to this

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1917 ~~paragraph which are a trade secret, as defined in s. 812.081,~~
1918 ~~shall be maintained by the department as trade secret~~
1919 ~~information is required to be maintained under s. 499.051.~~

1920 (h) The tax year of the applicant.

1921 (i) A copy of the deed for the property on which
1922 applicant's establishment is located, if the establishment is
1923 owned by the applicant, or a copy of the applicant's lease for
1924 the property on which applicant's establishment is located that
1925 has an original term of not less than 1 calendar year, if the
1926 establishment is not owned by the applicant.

1927 (j) A list of all licenses and permits issued to the
1928 applicant by any other state which authorize the applicant to
1929 purchase or possess prescription drugs.

1930 (k) The name of the manager of the establishment that is
1931 applying for the permit or to renew the permit, the next four
1932 highest ranking employees responsible for prescription drug
1933 wholesale operations for the establishment, and the name of all
1934 affiliated parties for the establishment, together with the
1935 personal information statement and fingerprints required
1936 pursuant to subsection (9) for each of such persons.

1937 (l) The name of each of the applicant's designated
1938 representatives as required by subsection (15) ~~(16)~~, together
1939 with the personal information statement and fingerprints
1940 required pursuant to subsection (9) for each such person.

1941 (m) Evidence of a surety bond in this state or any other
1942 state in the United States in the amount of \$100,000. If the
1943 annual gross receipts of the applicant's previous tax year is
1944 \$10 million or less, evidence of a surety bond in the amount of
1945 \$25,000. The specific language of the surety bond must include

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1946 the State of Florida as a beneficiary, payable to the
1947 Professional Regulation Trust Fund. In lieu of the surety bond,
1948 the applicant may provide other equivalent security such as an
1949 irrevocable letter of credit, or a deposit in a trust account or
1950 financial institution, which includes the State of Florida as a
1951 beneficiary, payable to the Professional Regulation Trust Fund.
1952 The purpose of the bond or other security is to secure payment
1953 of any administrative penalties imposed by the department and
1954 any fees and costs incurred by the department regarding that
1955 permit which are authorized under state law and which the
1956 permittee fails to pay 30 days after the fine or costs become
1957 final. The department may make a claim against such bond or
1958 security until 1 year after the permittee's license ceases to be
1959 valid or until 60 days after any administrative or legal
1960 proceeding authorized in this part which involves the permittee
1961 is concluded, including any appeal, whichever occurs later. For
1962 an applicant that is a secondary wholesale distributor, each of
1963 the following:

1964 1. A personal background information statement containing
1965 the background information and fingerprints required pursuant to
1966 subsection (9) for each person named in the applicant's response
1967 to paragraphs (k) and (l) and for each affiliated party of the
1968 applicant.

1969 2. If any of the five largest shareholders of the
1970 corporation seeking the permit is a corporation, the name,
1971 address, and title of each corporate officer and director of
1972 each such corporation; the name and address of such corporation;
1973 the name of such corporation's resident agent, such
1974 corporation's resident agent's address, and such corporation's

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1975 ~~state of its incorporation; and the name and address of each~~
1976 ~~shareholder of such corporation that owns 5 percent or more of~~
1977 ~~the stock of such corporation.~~

1978 ~~3. The name and address of all financial institutions in~~
1979 ~~which the applicant has an account which is used to pay for the~~
1980 ~~operation of the establishment or to pay for drugs purchased for~~
1981 ~~the establishment, together with the names of all persons that~~
1982 ~~are authorized signatories on such accounts. The portions of the~~
1983 ~~information required pursuant to this subparagraph which are a~~
1984 ~~trade secret, as defined in s. 812.081, shall be maintained by~~
1985 ~~the department as trade secret information is required to be~~
1986 ~~maintained under s. 499.051.~~

1987 ~~4. The sources of all funds and the amounts of such funds~~
1988 ~~used to purchase or finance purchases of prescription drugs or~~
1989 ~~to finance the premises on which the establishment is to be~~
1990 ~~located.~~

1991 ~~5. If any of the funds identified in subparagraph 4. were~~
1992 ~~borrowed, copies of all promissory notes or loans used to obtain~~
1993 ~~such funds.~~

1994 (n) For establishments used in wholesale distribution,
1995 proof of an inspection conducted by the department, the United
1996 States Food and Drug Administration, or another governmental
1997 entity charged with the regulation of good manufacturing
1998 practices related to wholesale distribution of prescription
1999 drugs, within timeframes set forth by the department in
2000 departmental rules, which demonstrates substantial compliance
2001 with current good manufacturing practices applicable to
2002 wholesale distribution of prescription drugs. The department may
2003 recognize another state's inspection of a wholesale distributor

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2004 located in that state if such state's laws are deemed to be
2005 substantially equivalent to the law of this state by the
2006 department. The department may accept an inspection by a third-
2007 party accreditation or inspection service which meets the
2008 criteria set forth in department rule.

2009 ~~(o) (n)~~ Any other relevant information that the department
2010 requires, including, but not limited to, any information related
2011 to whether the applicant satisfies the definition of a primary
2012 wholesale distributor or a secondary wholesale distributor.

2013 ~~(p) (e)~~ Documentation of the credentialing policies and
2014 procedures required by s. 499.0121(15).

2015 (9) (a) Each person required by subsection (8) or subsection
2016 (15) to provide a personal information statement and
2017 fingerprints shall provide the following information to the
2018 department on forms prescribed by the department:

- 2019 1. The person's places of residence for the past 7 years.
- 2020 2. The person's date and place of birth.
- 2021 3. The person's occupations, positions of employment, and
2022 offices held during the past 7 years.
- 2023 4. The principal business and address of any business,
2024 corporation, or other organization in which each such office of
2025 the person was held or in which each such occupation or position
2026 of employment was carried on.
- 2027 5. Whether the person has been, during the past 7 years,
2028 the subject of any proceeding for the revocation of any license
2029 and, if so, the nature of the proceeding and the disposition of
2030 the proceeding.

2031 6. Whether, during the past 7 years, the person has been
2032 enjoined, temporarily or permanently, by a court of competent

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2033 jurisdiction from violating any federal or state law regulating
2034 the possession, control, or distribution of prescription drugs,
2035 together with details concerning any such event.

2036 7. A description of any involvement by the person with any
2037 business, including any investments, other than the ownership of
2038 stock in a publicly traded company or mutual fund, during the
2039 past 4 7 years, which manufactured, administered, prescribed,
2040 distributed, or stored pharmaceutical products and any lawsuits
2041 in which such businesses were named as a party.

2042 8. A description of any felony criminal offense of which
2043 the person, as an adult, was found guilty, regardless of whether
2044 adjudication of guilt was withheld or whether the person pled
2045 guilty or nolo contendere. A criminal offense committed in
2046 another jurisdiction which would have been a felony in this
2047 state must be reported. If the person indicates that a criminal
2048 conviction is under appeal and submits a copy of the notice of
2049 appeal of that criminal offense, the applicant must, within 15
2050 days after the disposition of the appeal, submit to the
2051 department a copy of the final written order of disposition.

2052 9. A photograph of the person taken in the previous 180 ~~30~~
2053 days.

2054 10. A set of fingerprints for the person on a form and
2055 under procedures specified by the department, together with
2056 payment of an amount equal to the costs incurred by the
2057 department for the criminal record check of the person.

2058 11. The name, address, occupation, and date and place of
2059 birth for each member of the person's immediate family who is 18
2060 years of age or older. As used in this subparagraph, the term
2061 "member of the person's immediate family" includes the person's

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2062 spouse, children, parents, siblings, the spouses of the person's
2063 children, and the spouses of the person's siblings.

2064 12. Any other relevant information that the department
2065 requires.

2066 (b) The information required pursuant to paragraph (a)
2067 shall be provided under oath.

2068 (c) The department shall submit the fingerprints provided
2069 by a person for initial licensure to the Department of Law
2070 Enforcement for a statewide criminal record check and for
2071 forwarding to the Federal Bureau of Investigation for a national
2072 criminal record check of the person. The department shall submit
2073 the fingerprints provided by a person as a part of a renewal
2074 application to the Department of Law Enforcement for a statewide
2075 criminal record check, and for forwarding to the Federal Bureau
2076 of Investigation for a national criminal record check, for the
2077 initial renewal of a permit after January 1, 2004; for any
2078 subsequent renewal of a permit, the department shall submit the
2079 required information for a statewide and national criminal
2080 record check of the person. Any person who as a part of an
2081 initial permit application or initial permit renewal after
2082 January 1, 2004, submits to the department a set of fingerprints
2083 required for the criminal record check required in this
2084 paragraph are ~~shall~~ not ~~be~~ required to provide a subsequent set
2085 of fingerprints for a criminal record check to the department,
2086 if the person has undergone a criminal record check as a
2087 condition of the issuance of an initial permit or the initial
2088 renewal of a permit of an applicant after January 1, 2004. The
2089 department is authorized to contract with private vendors, or
2090 enter into interagency agreements, to collect electronic

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2091 fingerprints where fingerprints are required for registration,
2092 certification, or the licensure process or where criminal
2093 history record checks are required.

2094 (d) For purposes of applying for renewal of a permit under
2095 subsection (8) or certification under subsection (16), a person
2096 may submit the following in lieu of satisfying the requirements
2097 of paragraphs (a), (b), and (c):

2098 1. A photograph of the individual taken within 180 days;
2099 and

2100 2. A copy of the personal information statement form most
2101 recently submitted to the department and a certification under
2102 oath, on a form specified by the department, that the individual
2103 has reviewed the previously submitted personal information
2104 statement form and that the information contained therein
2105 remains unchanged.

2106 (10) The department may deny an application for a permit or
2107 refuse to renew a permit for a prescription drug wholesale
2108 distributor or an out-of-state prescription drug wholesale
2109 distributor if:

2110 (a) The applicant has not met the requirements for the
2111 permit.

2112 (b) The management, officers, or directors of the applicant
2113 or any affiliated party are found by the department to be
2114 incompetent or untrustworthy.

2115 (c) The applicant is so lacking in experience in managing a
2116 wholesale distributor as to make the issuance of the proposed
2117 permit hazardous to the public health.

2118 (d) The applicant is so lacking in experience in managing a
2119 wholesale distributor as to jeopardize the reasonable promise of

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2120 successful operation of the wholesale distributor.

2121 (e) The applicant is lacking in experience in the
2122 distribution of prescription drugs.

2123 (f) The applicant's past experience in manufacturing or
2124 distributing prescription drugs indicates that the applicant
2125 poses a public health risk.

2126 (g) The applicant is affiliated directly or indirectly
2127 through ownership, control, or other business relations, with
2128 any person or persons whose business operations are or have been
2129 detrimental to the public health.

2130 (h) The applicant, or any affiliated party, has been found
2131 guilty of or has pleaded guilty or nolo contendere to any felony
2132 or crime punishable by imprisonment for 1 year or more under the
2133 laws of the United States, any state, or any other country,
2134 regardless of whether adjudication of guilt was withheld.

2135 (i) The applicant or any affiliated party has been charged
2136 with a felony in a state or federal court and the disposition of
2137 that charge is pending during the application review or renewal
2138 review period.

2139 (j) The applicant has furnished false or fraudulent
2140 information or material in any application made in this state or
2141 any other state in connection with obtaining a permit or license
2142 to manufacture or distribute drugs, devices, or cosmetics.

2143 (k) That a federal, state, or local government permit
2144 currently or previously held by the applicant, or any affiliated
2145 party, for the manufacture or distribution of any drugs,
2146 devices, or cosmetics has been disciplined, suspended, or
2147 revoked and has not been reinstated.

2148 (l) The applicant does not possess the financial or

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2149 physical resources to operate in compliance with the permit
2150 being sought, this chapter, and the rules adopted under this
2151 chapter.

2152 (m) The applicant or any affiliated party receives,
2153 directly or indirectly, financial support and assistance from a
2154 person who was an affiliated party of a permittee whose permit
2155 was subject to discipline or was suspended or revoked, other
2156 than through the ownership of stock in a publicly traded company
2157 or a mutual fund.

2158 (n) The applicant or any affiliated party receives,
2159 directly or indirectly, financial support and assistance from a
2160 person who has been found guilty of any violation of this part
2161 or chapter 465, chapter 501, or chapter 893, any rules adopted
2162 under this part or those chapters, any federal or state drug
2163 law, or any felony where the underlying facts related to drugs,
2164 regardless of whether the person has been pardoned, had her or
2165 his civil rights restored, or had adjudication withheld, other
2166 than through the ownership of stock in a publicly traded company
2167 or a mutual fund.

2168 (o) The applicant for renewal of a permit under s.
2169 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged
2170 in the wholesale distribution of prescription drugs, as
2171 demonstrated by the regular and systematic distribution of
2172 prescription drugs throughout the year as evidenced by not fewer
2173 than 12 wholesale distributions in the previous year and not
2174 fewer than three wholesale distributions in the previous 6
2175 months.

2176 (p) Information obtained in response to s. 499.01(2)(e) or
2177 (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best

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2178 interest of the public health, safety, and welfare to issue a
2179 permit.

2180 (q) The applicant does not possess the financial standing
2181 and business experience for the successful operation of the
2182 applicant.

2183 (r) The applicant or any affiliated party has failed to
2184 comply with the requirements for manufacturing or distributing
2185 prescription drugs under this part, similar federal laws,
2186 similar laws in other states, or the rules adopted under such
2187 laws.

2188 (11) Upon approval of the application by the department and
2189 payment of the required fee, the department shall issue or renew
2190 a prescription drug wholesale distributor or an out-of-state
2191 prescription drug wholesale distributor permit to the applicant.

2192 ~~(12) For a permit for a prescription drug wholesale~~
2193 ~~distributor or an out-of-state prescription drug wholesale~~
2194 ~~distributor:~~

2195 ~~(a) The department shall adopt rules for the annual renewal~~
2196 ~~of permits. At least 90 days before the expiration of a permit,~~
2197 ~~the department shall forward a permit renewal notification and~~
2198 ~~renewal application to the prescription drug wholesale~~
2199 ~~distributor or out-of-state prescription drug wholesale~~
2200 ~~distributor at the mailing address of the permitted~~
2201 ~~establishment on file with the department. The permit renewal~~
2202 ~~notification must state conspicuously the date on which the~~
2203 ~~permit for the establishment will expire and that the~~
2204 ~~establishment may not operate unless the permit for the~~
2205 ~~establishment is renewed timely.~~

2206 ~~(b) A permit, unless sooner suspended or revoked,~~

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2207 ~~automatically expires 1 year after the last day of the~~
2208 ~~anniversary month in which the permit was originally issued. A~~
2209 ~~permit may be renewed by making application for renewal on forms~~
2210 ~~furnished by the department and paying the appropriate fees. If~~
2211 ~~a renewal application and fee are submitted and postmarked after~~
2212 ~~45 days prior to the expiration date of the permit, the permit~~
2213 ~~may be renewed only upon payment of a late renewal fee of \$100,~~
2214 ~~plus the required renewal fee. A permittee that has submitted a~~
2215 ~~renewal application in accordance with this paragraph may~~
2216 ~~continue to operate under its permit, unless the permit is~~
2217 ~~suspended or revoked, until final disposition of the renewal~~
2218 ~~application.~~

2219 ~~(c) Failure to renew a permit in accordance with this~~
2220 ~~section precludes any future renewal of that permit. If a permit~~
2221 ~~issued pursuant to this section has expired and cannot be~~
2222 ~~renewed, before an establishment may engage in activities that~~
2223 ~~require a permit under this part, the establishment must submit~~
2224 ~~an application for a new permit; pay the applicable application~~
2225 ~~fee, initial permit fee, and all applicable penalties; and be~~
2226 ~~issued a new permit by the department.~~

2227 ~~(12)~~(13) A person that engages in wholesale distribution of
2228 prescription drugs in this state must have a wholesale
2229 distributor's permit issued by the department, except as noted
2230 in this section. Each establishment must be separately permitted
2231 except as noted in this subsection.

2232 (a) A separate establishment permit is not required when a
2233 permitted prescription drug wholesale distributor consigns a
2234 prescription drug to a pharmacy that is permitted under chapter
2235 465 and located in this state, provided that:

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2236 1. The consignor wholesale distributor notifies the
2237 department in writing of the contract to consign prescription
2238 drugs to a pharmacy along with the identity and location of each
2239 consignee pharmacy;

2240 2. The pharmacy maintains its permit under chapter 465;

2241 3. The consignor wholesale distributor, which has no legal
2242 authority to dispense prescription drugs, complies with all
2243 wholesale distribution requirements of s. ss. 499.0121 ~~and~~
2244 ~~499.01212~~ with respect to the consigned drugs and maintains
2245 records documenting the transfer of title or other completion of
2246 the wholesale distribution of the consigned prescription drugs;

2247 4. The distribution of the prescription drug is otherwise
2248 lawful under this chapter and other applicable law;

2249 5. Open packages containing prescription drugs within a
2250 pharmacy are the responsibility of the pharmacy, regardless of
2251 how the drugs are titled; and

2252 6. The pharmacy dispenses the consigned prescription drug
2253 in accordance with the limitations of its permit under chapter
2254 465 or returns the consigned prescription drug to the consignor
2255 wholesale distributor. In addition, a person who holds title to
2256 prescription drugs may transfer the drugs to a person permitted
2257 or licensed to handle the reverse distribution or destruction of
2258 drugs. Any other distribution by and means of the consigned
2259 prescription drug by any person, not limited to the consignor
2260 wholesale distributor or consignee pharmacy, to any other person
2261 is prohibited.

2262 (b) A wholesale distributor's permit is not required for
2263 the one-time transfer of title of a pharmacy's lawfully acquired
2264 prescription drug inventory by a pharmacy with a valid permit

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2265 issued under chapter 465 to a consignor prescription drug
2266 wholesale distributor, permitted under this chapter, in
2267 accordance with a written consignment agreement between the
2268 pharmacy and that wholesale distributor if the permitted
2269 pharmacy and the permitted prescription drug wholesale
2270 distributor comply with all of the provisions of paragraph (a)
2271 and the prescription drugs continue to be within the permitted
2272 pharmacy's inventory for dispensing in accordance with the
2273 limitations of the pharmacy permit under chapter 465. A
2274 consignor drug wholesale distributor may not use the pharmacy as
2275 a wholesale distributor through which it distributes the
2276 prescription drugs to other pharmacies. Nothing in this section
2277 is intended to prevent a wholesale distributor from obtaining
2278 this inventory in the event of nonpayment by the pharmacy.

2279 (c) A separate establishment permit is not required when a
2280 permitted prescription drug wholesale distributor operates
2281 temporary transit storage facilities for the sole purpose of
2282 storage, for up to 16 hours, of a delivery of prescription drugs
2283 when the wholesale distributor was temporarily unable to
2284 complete the delivery to the recipient.

2285 (d) The department shall require information from each
2286 wholesale distributor as part of the permit and renewal of such
2287 permit, as required under this section.

2288 (13)~~(14)~~ Personnel employed in wholesale distribution must
2289 have appropriate education and experience to enable them to
2290 perform their duties in compliance with state permitting
2291 requirements.

2292 (14)~~(15)~~ The name of a permittee or establishment on a
2293 prescription drug wholesale distributor permit or an out-of-

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2294 state prescription drug wholesale distributor permit may not
2295 include any indicia of attainment of any educational degree, any
2296 indicia that the permittee or establishment possesses a
2297 professional license, or any name or abbreviation that the
2298 department determines is likely to cause confusion or mistake or
2299 that the department determines is deceptive, including that of
2300 any other entity authorized to purchase prescription drugs.

2301 (15)~~(16)~~(a) Each establishment that is issued an initial or
2302 renewal permit as a prescription drug wholesale distributor or
2303 an out-of-state prescription drug wholesale distributor must
2304 designate in writing to the department at least one natural
2305 person to serve as the designated representative of the
2306 wholesale distributor. Such person must have an active
2307 certification as a designated representative from the
2308 department.

2309 (b) To be certified as a designated representative, a
2310 natural person must:

2311 1. Submit an application on a form furnished by the
2312 department and pay the appropriate fees.

2313 2. Be at least 18 years of age.

2314 3. Have at least 2 years of verifiable full-time:

2315 a. Work experience in a pharmacy licensed in this state or
2316 another state, where the person's responsibilities included, but
2317 were not limited to, recordkeeping for prescription drugs;

2318 b. Managerial experience with a prescription drug wholesale
2319 distributor licensed in this state or in another state; or

2320 c. Managerial experience with the United States Armed
2321 Forces, where the person's responsibilities included, but were
2322 not limited to, recordkeeping, warehousing, distributing, or

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2323 other logistics services pertaining to prescription drugs.

2324 4. Receive a passing score of at least 75 percent on an
2325 examination given by the department regarding federal laws
2326 governing distribution of prescription drugs and this part and
2327 the rules adopted by the department governing the wholesale
2328 distribution of prescription drugs. This requirement shall be
2329 effective 1 year after the results of the initial examination
2330 are mailed to the persons that took the examination. The
2331 department shall offer such examinations at least four times
2332 each calendar year.

2333 5. Provide the department with a personal information
2334 statement and fingerprints pursuant to subsection (9).

2335 (c) The department may deny an application for
2336 certification as a designated representative or may suspend or
2337 revoke a certification of a designated representative pursuant
2338 to s. 499.067.

2339 (d) A designated representative:

2340 1. Must be actively involved in and aware of the actual
2341 daily operation of the wholesale distributor.

2342 2. Must be employed full time in a managerial position by
2343 the wholesale distributor.

2344 3. Must be physically present at the establishment during
2345 normal business hours, except for time periods when absent due
2346 to illness, family illness or death, scheduled vacation, or
2347 other authorized absence.

2348 4. May serve as a designated representative for only one
2349 wholesale distributor at any one time.

2350 (e) A wholesale distributor must notify the department when
2351 a designated representative leaves the employ of the wholesale

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2352 distributor. Such notice must be provided to the department
2353 within 10 business days after the last day of designated
2354 representative's employment with the wholesale distributor.

2355 (f) A wholesale distributor may not operate under a
2356 prescription drug wholesale distributor permit or an out-of-
2357 state prescription drug wholesale distributor permit for more
2358 than 10 business days after the designated representative leaves
2359 the employ of the wholesale distributor, unless the wholesale
2360 distributor employs another designated representative and
2361 notifies the department within 10 business days of the identity
2362 of the new designated representative.

2363 Section 7. Section 499.01201, Florida Statutes, is amended
2364 to read:

2365 499.01201 Agency for Health Care Administration review and
2366 use of statute and rule violation or compliance data.-
2367 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~
2368 ~~contrary~~, the Agency for Health Care Administration may not:

2369 (1) Review or use any violation or alleged violation of s.
2370 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that
2371 section ~~those sections~~, as a ground for denying or withholding
2372 any payment of a Medicaid reimbursement to a pharmacy licensed
2373 under chapter 465; or

2374 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~
2375 ~~499.01212~~, or any rules adopted under that section ~~these~~
2376 ~~sections~~, as the subject of any audit of Medicaid-related
2377 records held by a pharmacy licensed under chapter 465.

2378 Section 8. Paragraph (d) of subsection (4), subsection (6),
2379 and paragraph (b) of subsection (15) of section 499.0121,
2380 Florida Statutes, are amended to read:

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2381 499.0121 Storage and handling of prescription drugs;
2382 recordkeeping.—The department shall adopt rules to implement
2383 this section as necessary to protect the public health, safety,
2384 and welfare. Such rules shall include, but not be limited to,
2385 requirements for the storage and handling of prescription drugs
2386 and for the establishment and maintenance of prescription drug
2387 distribution records.

2388 (4) EXAMINATION OF MATERIALS AND RECORDS.—

2389 (d) Upon receipt, a wholesale distributor must review
2390 records required under this section for the acquisition of
2391 prescription drugs for accuracy and completeness, considering
2392 the total facts and circumstances surrounding the transactions
2393 and the wholesale distributors involved. ~~This includes~~
2394 ~~authenticating each transaction listed on a pedigree paper, as~~
2395 ~~defined in s. 499.003(37).~~

2396 (6) RECORDKEEPING.—The department shall adopt rules that
2397 require keeping such records of prescription drugs, including
2398 active pharmaceutical ingredients, as are necessary for the
2399 protection of the public health.

2400 (a) The following persons must maintain business records
2401 that include the information specified in paragraph (b)
2402 ~~Wholesale distributors must establish and maintain inventories~~
2403 ~~and records of all transactions regarding the receipt and~~
2404 ~~distribution or other disposition of prescription drugs. These~~
2405 ~~records must provide a complete audit trail from receipt to sale~~
2406 ~~or other disposition, be readily retrievable for inspection, and~~
2407 ~~include, at a minimum, the following information:~~

2408 1. Persons permitted or required to be permitted under
2409 chapter 499 to engage in the manufacture, repackaging, or

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2410 distribution of active pharmaceutical ingredients or
2411 prescription drugs. ~~The source of the drugs, including the name~~
2412 ~~and principal address of the seller or transferor, and the~~
2413 ~~address of the location from which the drugs were shipped;~~

2414 2. Persons other than those set forth in subparagraph 1.
2415 that engage in the receipt of active pharmaceutical ingredients
2416 or prescription drugs. ~~The name, principal address, and state~~
2417 ~~license permit or registration number of the person authorized~~
2418 ~~to purchase prescription drugs;~~

2419 ~~3. The name, strength, dosage form, and quantity of the~~
2420 ~~drugs received and distributed or disposed of;~~

2421 ~~4. The dates of receipt and distribution or other~~
2422 ~~disposition of the drugs; and~~

2423 ~~5. Any financial documentation supporting the transaction.~~

2424 (b) Business records for persons specified in paragraph (a)
2425 must include:

2426 1. The name and address of the seller, and the Florida
2427 permit number of the seller if such seller is not exempt from
2428 Florida permitting requirements, of the active pharmaceutical
2429 ingredient or prescription drug.

2430 2. The address of the location the active pharmaceutical
2431 ingredient or prescription drug was shipped from.

2432 3. The distribution date of the active pharmaceutical
2433 ingredient or prescription drug.

2434 4. The name, strength, and quantity, and the National Drug
2435 Code if such code has been assigned, of the distributed active
2436 pharmaceutical ingredient or prescription drug.

2437 5. The name and Florida permit number of the person that
2438 purchased the active pharmaceutical ingredient or prescription

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2439 drug.

2440 6. The financial data, including the unit type and unit
2441 price, for the distributions involving active pharmaceutical
2442 ingredients or prescription drugs.

2443 7. The date and method of disposition of the active
2444 pharmaceutical ingredient or prescription drug. ~~Inventories and~~
2445 ~~records must be made available for inspection and photocopying~~
2446 ~~by authorized federal, state, or local officials for a period of~~
2447 ~~2 years following disposition of the drugs or 3 years after the~~
2448 ~~creation of the records, whichever period is longer.~~

2449 (c) Each manufacturer or repackager of medical devices,
2450 over-the-counter drugs, or cosmetics must maintain business
2451 records that include:

2452 1. The name and address of the seller or transferor of the
2453 product.

2454 2. The address of the location the product was shipped
2455 from.

2456 3. The date of the sale or distribution of the product.

2457 4. The name and quantity of the product involved.

2458 5. The name and address of the person who purchased the
2459 product ~~Records described in this section that are kept at the~~
2460 ~~inspection site or that can be immediately retrieved by computer~~
2461 ~~or other electronic means must be readily available for~~
2462 ~~authorized inspection during the retention period. Records that~~
2463 ~~are kept at a central location outside of this state and that~~
2464 ~~are not electronically retrievable must be made available for~~
2465 ~~inspection within 2 working days after a request by an~~
2466 ~~authorized official of a federal, state, or local law~~
2467 ~~enforcement agency. Records that are maintained at a central~~

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2468 ~~location within this state must be maintained at an~~
2469 ~~establishment that is permitted pursuant to this part and must~~
2470 ~~be readily available.~~

2471 (d) Persons permitted, or required to be permitted, under
2472 this chapter to engage in the manufacture, repackaging, or
2473 distribution of active pharmaceutical ingredients or
2474 prescription drugs; or the manufacture or repackaging of medical
2475 devices, over-the-counter drugs, and cosmetics; must establish,
2476 maintain, or have the capability to create a current inventory
2477 of the active pharmaceutical ingredients, prescription drugs,
2478 over-the-counter drugs, cosmetics, and devices at an
2479 establishment where activities specified in this paragraph are
2480 undertaken and must be able to produce such inventory for
2481 inspection by the department within 2 business days ~~Each~~
2482 ~~manufacturer or repackager of medical devices, over the counter~~
2483 ~~drugs, or cosmetics must maintain records that include the name~~
2484 ~~and principal address of the seller or transferor of the~~
2485 ~~product, the address of the location from which the product was~~
2486 ~~shipped, the date of the transaction, the name and quantity of~~
2487 ~~the product involved, and the name and principal address of the~~
2488 ~~person who purchased the product.~~

2489 (e) Business records required to be kept pursuant to this
2490 section, and that are kept at the inspection site or can be
2491 immediately retrieved by computer or other electronic means,
2492 must be readily available for authorized inspection during the
2493 retention period. Records kept at a central location outside of
2494 this state which are not electronically retrievable must be made
2495 available for inspection within 2 working days after a request
2496 by an authorized official of a federal, state, or local law

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2497 enforcement agency. Records maintained at a central location
2498 within this state must be maintained at an establishment that is
2499 permitted pursuant to this part and such records must be readily
2500 available for inspection ~~When pedigree papers are required by~~
2501 ~~this part, a wholesale distributor must maintain the pedigree~~
2502 ~~papers separate and distinct from other records required under~~
2503 ~~this part.~~

2504 (f) Records required to be kept pursuant to this subsection
2505 must be maintained as specified for a period of not less than 6
2506 years from the date of disposition of the active pharmaceutical
2507 ingredients, prescription drugs, over-the-counter drugs, medical
2508 devices, or cosmetics.

2509 (g) To the extent that prescription drugs are also products
2510 as defined in the federal act, as amended, and the information
2511 required by the business records requirements of this section
2512 are also included in the tracking and tracing requirements of
2513 the federal act, as amended, and departmental rules, the
2514 manufacturer, wholesale distributor, repackager, or dispenser
2515 must follow both the requirements of the federal act, as
2516 amended, and departmental rules.

2517 (15) DUE DILIGENCE OF PURCHASERS.—

2518 (b) A wholesale distributor must take reasonable measures
2519 to identify its customers, understand the normal and expected
2520 transactions conducted by those customers, and identify those
2521 transactions that are suspicious in nature. A wholesale
2522 distributor must establish internal policies and procedures for
2523 identifying suspicious orders and preventing suspicious
2524 transactions. A wholesale distributor must assess orders for
2525 more ~~greater~~ than 7,500 ~~5,000~~ unit doses of any one controlled

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2526 substance in any one month to determine whether the purchase is
2527 reasonable. In making such assessments, a wholesale distributor
2528 may consider the purchasing entity's clinical business needs,
2529 location, and population served, in addition to other factors
2530 established in the distributor's policies and procedures. A
2531 wholesale distributor must report to the department any
2532 regulated transaction involving an extraordinary quantity of a
2533 listed chemical, an uncommon method of payment or delivery, or
2534 any other circumstance that the regulated person believes may
2535 indicate that the listed chemical will be used in violation of
2536 the law. The wholesale distributor shall maintain records that
2537 document the report submitted to the department in compliance
2538 with this paragraph.

2539 Section 9. Subsection (4) of section 499.015, Florida
2540 Statutes, is amended to read:

2541 499.015 Registration of drugs, devices, and cosmetics;
2542 issuance of certificates of free sale.-

2543 (4) Unless a registration is renewed, it expires 2 years
2544 after the last day of the month in which it was issued. Any
2545 product registration issued or renewed on or after July 1, 2016,
2546 shall expire on the same date as the manufacturer or repackager
2547 permit of the person seeking to register the product. If the
2548 first product registration issued to a person on or after July
2549 1, 2016, expires less than 366 days after issuance, the fee for
2550 product registration shall be \$15. If the first product
2551 registration issued to a person on or after July 1, 2016,
2552 expires more than 365 days after issuance, the fee for product
2553 registration shall be \$30. The department may issue a stop-sale
2554 notice or order against a person that is subject to the

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2555 requirements of this section and that fails to comply with this
2556 section within 31 days after the date the registration expires.
2557 The notice or order shall prohibit such person from selling or
2558 causing to be sold any drugs, devices, or cosmetics covered by
2559 this part until he or she complies with the requirements of this
2560 section.

2561 Section 10. Subsection (1) of section 499.03, Florida
2562 Statutes, is amended to read:

2563 499.03 Possession of certain drugs without prescriptions
2564 unlawful; exemptions and exceptions.—

2565 (1) A person may not possess, or possess with intent to
2566 sell, dispense, or deliver, any habit-forming, toxic, harmful,
2567 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or
2568 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,
2569 unless the possession of the drug has been obtained by a valid
2570 prescription of a practitioner licensed by law to prescribe the
2571 drug. However, this section does not apply to the delivery of
2572 such drugs to persons included in any of the classes named in
2573 this subsection, or to the agents or employees of such persons,
2574 for use in the usual course of their businesses or practices or
2575 in the performance of their official duties, as the case may be;
2576 nor does this section apply to the possession of such drugs by
2577 those persons or their agents or employees for such use:

2578 (a) A licensed pharmacist or any person under the licensed
2579 pharmacist's supervision while acting within the scope of the
2580 licensed pharmacist's practice;

2581 (b) A licensed practitioner authorized by law to prescribe
2582 prescription drugs or any person under the licensed
2583 practitioner's supervision while acting within the scope of the

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2584 licensed practitioner's practice;

2585 (c) A qualified person who uses prescription drugs for
2586 lawful research, teaching, or testing, and not for resale;

2587 (d) A licensed hospital or other institution that procures
2588 such drugs for lawful administration or dispensing by
2589 practitioners;

2590 (e) An officer or employee of a federal, state, or local
2591 government; or

2592 (f) A person that holds a valid permit issued by the
2593 department pursuant to this part which authorizes that person to
2594 possess prescription drugs.

2595 Section 11. Paragraphs (i) through (p) of subsection (1) of
2596 section 499.05, Florida Statutes, are amended to read:

2597 499.05 Rules.—

2598 (1) The department shall adopt rules to implement and
2599 enforce this chapter with respect to:

2600 (i) Additional conditions that qualify as an emergency
2601 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.
2602 499.82.

2603 ~~(j) Procedures and forms relating to the pedigree paper
2604 requirement of s. 499.01212.~~

2605 (j) ~~(k)~~ The protection of the public health, safety, and
2606 welfare regarding good manufacturing practices that
2607 manufacturers and repackagers must follow to ensure the safety
2608 of the products.

2609 (k) ~~(l)~~ Information required from each retail establishment
2610 pursuant to s. 499.012(3) or s. 499.83(2)(c), including
2611 requirements for prescriptions or orders.

2612 (l) ~~(m)~~ The recordkeeping, storage, and handling with

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2613 respect to each of the distributions of prescription drugs
2614 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.
2615 499.82(14).

2616 ~~(n) Alternatives to compliance with s. 499.01212 for a~~
2617 ~~prescription drug in the inventory of a permitted prescription~~
2618 ~~drug wholesale distributor as of June 30, 2006, and the return~~
2619 ~~of a prescription drug purchased prior to July 1, 2006. The~~
2620 ~~department may specify time limits for such alternatives.~~

2621 (m) ~~(e)~~ Wholesale distributor reporting requirements of s.
2622 499.0121(14).

2623 (n) ~~(p)~~ Wholesale distributor credentialing and distribution
2624 requirements of s. 499.0121(15).

2625 Section 12. Subsection (7) of section 499.051, Florida
2626 Statutes, is amended to read:

2627 499.051 Inspections and investigations.—

2628 (7) The complaint and all information obtained pursuant to
2629 the investigation by the department are confidential and exempt
2630 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution
2631 until the investigation and the enforcement action are
2632 completed. However, trade secret information contained therein
2633 as defined by s. 812.081(1)(c) shall remain confidential and
2634 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I
2635 of the State Constitution, as long as the information is
2636 retained by the department. This subsection does not prohibit
2637 the department from using such information for regulatory or
2638 enforcement proceedings under this chapter or from providing
2639 such information to any law enforcement agency or any other
2640 regulatory agency. However, the receiving agency shall keep such
2641 records confidential and exempt as provided in this subsection.

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2642 ~~In addition, this subsection is not intended to prevent~~
2643 ~~compliance with the provisions of s. 499.01212, and the pedigree~~
2644 ~~papers required in that section shall not be deemed a trade~~
2645 ~~secret.~~

2646 Section 13. Subsection (8) is added to section 499.066,
2647 Florida Statutes, to read:

2648 499.066 Penalties; remedies.—In addition to other penalties
2649 and other enforcement provisions:

2650 (8) (a) The department shall adopt rules to permit the
2651 issuance of remedial, nondisciplinary citations. A citation
2652 shall be issued to the person alleged to have committed a
2653 violation and contain the person's name, address, and license
2654 number, if applicable, a brief factual statement, the sections
2655 of the law allegedly violated, and the monetary assessment and
2656 or other remedial measures imposed. The citation must clearly
2657 state that the person may choose, in lieu of accepting the
2658 citation, to have the department rescind the citation and
2659 conduct an investigation pursuant to s. 499.051. If the person
2660 does not dispute the matter in the citation with the department
2661 within 30 days after the citation is served, the citation
2662 becomes a final order and does not constitute discipline.

2663 (b) The department shall adopt rules designating violations
2664 for which a citation may be issued. The rules shall designate as
2665 citable those violations for which there is no substantial
2666 threat to the public health, safety, or welfare.

2667 (c) The department is entitled to recover the costs of
2668 investigation, in addition to any penalty provided according to
2669 department rule, as part of the penalty levied pursuant to the
2670 citation.

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2671 (d) A citation must be issued within 12 months after the
2672 filing of the complaint that is the basis for the citation.

2673 (e) Service of a citation may be made by personal service
2674 or certified mail, restricted delivery, to the person at the
2675 person's last known address of record with the department or to
2676 the person's Florida registered agent.

2677 (f) The department has authority to, and shall adopt rules
2678 to, designate those violations for which a person is subject to
2679 the issuance of a citation and designate the monetary
2680 assessments and or other remedial measures that must be taken
2681 for those violations. The department has continuous authority to
2682 amend its rules adopted pursuant to this section.

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

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

2686 (14) "Wholesale distribution" means the distribution of
2687 medical gas to a person other than a consumer or patient.
2688 Wholesale distribution of medical gases does not include:

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

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

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

2697 ~~(d) Other transactions excluded from the definition of~~
2698 ~~wholesale distribution under the federal act or regulations~~
2699 ~~implemented under the federal act related to medical gas.~~

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2700 Section 15. Subsection (4) of section 499.89, Florida
2701 Statutes, is amended to read:

2702 499.89 Recordkeeping.—

2703 ~~(4) A pedigree paper is not required for distributing or~~
2704 ~~dispensing medical gas.~~

2705 Section 16. Section 499.01212, Florida Statutes, is
2706 repealed.

2707 Section 17. Paragraph (a) of subsection (1) of section
2708 409.9201, Florida Statutes, is amended to read:

2709 409.9201 Medicaid fraud.—

2710 (1) As used in this section, the term:

2711 (a) "Prescription drug" means any drug, including, but not
2712 limited to, finished dosage forms or active ingredients that are
2713 subject to, defined in, or described in s. 503(b) of the Federal
2714 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)
2715 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2716
2717 The value of individual items of the legend drugs or goods or
2718 services involved in distinct transactions committed during a
2719 single scheme or course of conduct, whether involving a single
2720 person or several persons, may be aggregated when determining
2721 the punishment for the offense.

2722 Section 18. Paragraph (b) of subsection (1) of section
2723 499.067, Florida Statutes, is amended to read:

2724 499.067 Denial, suspension, or revocation of permit,
2725 certification, or registration.—

2726 (1)

2727 (b) The department may deny an application for a permit or
2728 certification, or suspend or revoke a permit or certification,

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2729 if the department finds that:

2730 1. The applicant is not of good moral character or that it
2731 would be a danger or not in the best interest of the public
2732 health, safety, and welfare if the applicant were issued a
2733 permit or certification.

2734 2. The applicant has not met the requirements for the
2735 permit or certification.

2736 3. The applicant is not eligible for a permit or
2737 certification for any of the reasons enumerated in s. 499.012.

2738 4. The applicant, permittee, or person certified under s.
2739 499.012(15) ~~s. 499.012(16)~~ demonstrates any of the conditions
2740 enumerated in s. 499.012.

2741 5. The applicant, permittee, or person certified under s.
2742 499.012(15) ~~s. 499.012(16)~~ has committed any violation of this
2743 chapter.

2744 Section 19. Subsection (1) of section 794.075, Florida
2745 Statutes, is amended to read:

2746 794.075 Sexual predators; erectile dysfunction drugs.—

2747 (1) A person may not possess a prescription drug, as
2748 defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of
2749 treating erectile dysfunction if the person is designated as a
2750 sexual predator under s. 775.21.

2751 Section 20. Paragraphs (d), (f), (i), and (j) of subsection
2752 (3) of section 921.0022, Florida Statutes, are amended to read:

2753 921.0022 Criminal Punishment Code; offense severity ranking
2754 chart.—

2755 (3) OFFENSE SEVERITY RANKING CHART

2756 (d) LEVEL 4

2757

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2758

| | | |
|---------|--------|-------------|
| Florida | Felony | Description |
| Statute | Degree | |

2759

| | | |
|------------------|-----|--|
| 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. |
|------------------|-----|--|

2760

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

2761

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

2762

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

2763

| | | |
|------------|-----|---------------------------------|
| 517.07 (1) | 3rd | Failure to register securities. |
|------------|-----|---------------------------------|

2764

| | | |
|------------|-----|--|
| 517.12 (1) | 3rd | Failure of dealer, associated person, or issuer of securities to register. |
|------------|-----|--|

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2765

784.07 (2) (b) 3rd Battery of law enforcement officer, firefighter, etc.

2766

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

2767

784.075 3rd Battery on detention or commitment facility staff.

2768

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

2769

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

2770

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

2771

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

2772

784.083 (3) 3rd Battery on code inspector.

2773

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

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2774

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

2775

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

2776

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

2777

787.07 3rd Human smuggling.

2778

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

2779

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

2780

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

2781

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2782

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

2783

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

2784

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

2785

810.06 3rd Burglary; possession of tools.

2786

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

2787

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

2788

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

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

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|---------------|-----|--|
| 817.563(1) | 3rd | Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs. |
| 817.568(2)(a) | 3rd | Fraudulent use of personal identification information. |
| 817.625(2)(a) | 3rd | Fraudulent use of scanning device or reencoder. |
| 828.125(1) | 2nd | Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle. |
| 837.02(1) | 3rd | Perjury in official proceedings. |
| 837.021(1) | 3rd | Make contradictory statements in official proceedings. |
| 838.022 | 3rd | Official misconduct. |
| 839.13(2)(a) | 3rd | Falsifying records of an individual in the care and custody of a state agency. |

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2798

839.13(2)(c)

3rd

Falsifying records of the Department of Children and Families.

2799

843.021

3rd

Possession of a concealed handcuff key by a person in custody.

2800

843.025

3rd

Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.

2801

843.15(1)(a)

3rd

Failure to appear while on bail for felony (bond estreatment or bond jumping).

2802

847.0135(5)(c)

3rd

Lewd or lascivious exhibition using computer; offender less than 18 years.

2803

874.05(1)(a)

3rd

Encouraging or recruiting another to join a criminal gang.

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).

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2804

914.14(2) 3rd Witnesses accepting bribes.

2805

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

2806

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

2807

918.12 3rd Tampering with jurors.

2808

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

2809

2810

2811 (f) LEVEL 6

2812

2813

| Florida Statute | Felony Degree | Description |
|-----------------|---------------|-------------|
|-----------------|---------------|-------------|

2814

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

2815

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

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2816

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

2817

499.0051 (2) 2nd Knowing forgery of transaction history, transaction information, or transaction statement ~~pedigree papers.~~

2818

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

2819

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

2820

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

2821

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

2822

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

2823

784.041 3rd Felony battery; domestic battery by strangulation.

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2824

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

2825

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

2826

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

2827

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

2828

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

2829

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

2830

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

2831

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

2832

787.02 (2) 3rd False imprisonment; restraining with purpose other than those

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| | | | |
|------|-----------------|-----|--|
| | | | in s. 787.01. |
| 2833 | 790.115 (2) (d) | 2nd | Discharging firearm or weapon on school property. |
| 2834 | 790.161 (2) | 2nd | Make, possess, or throw destructive device with intent to do bodily harm or damage property. |
| 2835 | 790.164 (1) | 2nd | False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property. |
| 2836 | 790.19 | 2nd | Shooting or throwing deadly missiles into dwellings, vessels, or vehicles. |
| 2837 | 794.011 (8) (a) | 3rd | Solicitation of minor to participate in sexual activity by custodial adult. |
| 2838 | 794.05 (1) | 2nd | Unlawful sexual activity with specified minor. |
| 2839 | 800.04 (5) (d) | 3rd | Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; |

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2840

offender less than 18 years.

800.04 (6) (b)

2nd

Lewd or lascivious conduct;
offender 18 years of age or
older.

2841

806.031 (2)

2nd

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

2842

810.02 (3) (c)

2nd

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

2843

810.145 (8) (b)

2nd

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

2844

812.014 (2) (b) 1.

2nd

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

2845

812.014 (6)

2nd

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

2846

812.015 (9) (a)

2nd

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

2847

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2848 812.015 (9) (b) 2nd Retail theft; property stolen
\$3,000 or more; coordination of
others.

2849 812.13 (2) (c) 2nd Robbery, no firearm or other
weapon (strong-arm robbery).

2850 817.4821 (5) 2nd Possess cloning paraphernalia
with intent to create cloned
cellular telephones.

2851 825.102 (1) 3rd Abuse of an elderly person or
disabled adult.

2852 825.102 (3) (c) 3rd Neglect of an elderly person or
disabled adult.

2853 825.1025 (3) 3rd Lewd or lascivious molestation
of an elderly person or
disabled adult.

2854 825.103 (3) (c) 3rd Exploiting an elderly person or
disabled adult and property is
valued at less than \$10,000.

2855 827.03 (2) (c) 3rd Abuse of a child.

2856 827.03 (2) (d) 3rd Neglect of a child.

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2864

| | | |
|------------------|-----|---|
| 827.071(2) & (3) | 2nd | Use or induce a child in a sexual performance, or promote or direct such performance. |
| 836.05 | 2nd | Threats; extortion. |
| 836.10 | 2nd | Written threats to kill or do bodily injury. |
| 843.12 | 3rd | Aids or assists person to escape. |
| 847.011 | 3rd | Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors. |
| 847.012 | 3rd | Knowingly using a minor in the production of materials harmful to minors. |
| 847.0135(2) | 3rd | Facilitates sexual conduct of or with a minor or the visual depiction of such conduct. |
| 914.23 | 2nd | Retaliation against a witness, victim, or informant, with bodily injury. |

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2865 944.35 (3) (a) 2. 3rd Committing malicious battery
upon or inflicting cruel or
inhuman treatment on an inmate
or offender on community
supervision, resulting in great
bodily harm.

2866 944.40 2nd Escapes.

2867 944.46 3rd Harboring, concealing, aiding
escaped prisoners.

2868 944.47 (1) (a) 5. 2nd Introduction of contraband
(firearm, weapon, or explosive)
into correctional facility.

2869 951.22 (1) 3rd Intoxicating drug, firearm, or
2870 weapon introduced into county
2871 facility.

2872 (i) LEVEL 9

2873 Florida Felony
Statute Degree Description

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

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2874

327.35 1st BUI manslaughter; failing
(3) (c) 3.b. to render aid or give
information.

2875

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

2876

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

2877

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

2878

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

2879

655.50 (10) (b) 3. 1st Failure to report
financial transactions

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| | | | |
|------|-------------|----------|--|
| 2880 | 775.0844 | 1st | totaling or exceeding \$100,000 by financial institution. |
| 2881 | 782.04 (1) | 1st | Attempt, conspire, or solicit to commit premeditated murder. |
| 2882 | 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. |
| 2883 | 782.051 (1) | 1st | Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3). |
| 2884 | 782.07 (2) | 1st | Aggravated manslaughter of an elderly person or disabled adult. |

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2885

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

2886

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

2887

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

2888

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.

2889

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

2890

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

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2891

787.06(3)(f)1.

1st,PBL

coercion for commercial sexual activity of an unauthorized adult alien.

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

2892

790.161

1st

Attempted capital destructive device offense.

2893

790.166(2)

1st,PBL

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

2894

794.011(2)

1st

Attempted sexual battery; victim less than 12 years of age.

2895

794.011(2)

Life

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

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2896

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

2897

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

2898

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

2899

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

2900

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

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2901

authority.

794.08 (2)

1st

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

2902

800.04 (5) (b)

Life

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

2903

812.13 (2) (a)

1st, PBL

Robbery with firearm or
other deadly weapon.

2904

812.133 (2) (a)

1st, PBL

Carjacking; firearm or
other deadly weapon.

2905

812.135 (2) (b)

1st

Home-invasion robbery
with weapon.

2906

817.535 (3) (b)

1st

Filing false lien or
other unauthorized
document; second or
subsequent offense;
property owner is a
public officer or
employee.

2907

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2908

817.535 (4) (a) 2.

1st

Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.

2909

817.535 (5) (b)

1st

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

2910

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.

2911

827.03 (2) (a)

1st

Aggravated child abuse.

847.0145 (1)

1st

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

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2912

847.0145 (2) 1st Purchasing, or otherwise obtaining custody or control, of a minor.

2913

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.

2914

893.135 1st Attempted capital trafficking offense.

2915

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

2916

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

2917

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

2918

893.135 1st Trafficking in

| | | | |
|------|--------------|-----|---|
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| | (1) (c) 2.d. | | hydrocodone, 200 grams or more, less than 30 kilograms. |
| 2919 | 893.135 | 1st | Trafficking in oxycodone, 100 grams or more, less than 30 kilograms. |
| | (1) (c) 3.d. | | |
| 2920 | 893.135 | 1st | Trafficking in phencyclidine, more than 400 grams. |
| | (1) (d) 1.c. | | |
| 2921 | 893.135 | 1st | Trafficking in methaqualone, more than 25 kilograms. |
| | (1) (e) 1.c. | | |
| 2922 | 893.135 | 1st | Trafficking in amphetamine, more than 200 grams. |
| | (1) (f) 1.c. | | |
| 2923 | 893.135 | 1st | Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more. |
| | (1) (h) 1.c. | | |
| 2924 | 893.135 | 1st | Trafficking in 1,4-Butanediol, 10 kilograms or more. |
| | (1) (j) 1.c. | | |
| 2925 | | | |

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2926 893.135 1st Trafficking in
 (1) (k) 2.c. Phenethylamines, 400
 grams or more.

2927 896.101 (5) (c) 1st Money laundering,
 financial instruments
 totaling or exceeding
 \$100,000.

2928 896.104 (4) (a) 3. 1st Structuring transactions
 to evade reporting or
 registration
 requirements, financial
 transactions totaling or
 exceeding \$100,000.

2929
 2930 (j) LEVEL 10

2931 Florida Felony
 Statute Degree Description

2932 499.0051 (9) 1st Knowing sale or purchase
~~499.0051 (10)~~ of contraband
 prescription drugs
 resulting in death.

2933 782.04 (2) 1st,PBL Unlawful killing of
 human; act is homicide,

| | | | |
|------|----------------|---------|--|
| | 576-04227-16 | | 20161604c2 |
| 2934 | | | unpremeditated. |
| | 782.07(3) | 1st | Aggravated manslaughter of a child. |
| 2935 | | | |
| | 787.01(1)(a)3. | 1st,PBL | Kidnapping; inflict bodily harm upon or terrorize victim. |
| 2936 | | | |
| | 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. |
| 2937 | | | |
| | 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. |
| 2938 | | | |
| | 787.06(4)(a) | Life | Selling or buying of minors into human trafficking. |
| 2939 | | | |
| | 794.011(3) | Life | Sexual battery; victim |

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12 years or older,
offender uses or
threatens to use deadly
weapon or physical force
to cause serious injury.

2940

812.135 (2) (a)

1st,PBL

Home-invasion robbery
with firearm or other
deadly weapon.

2941

876.32

1st

Treason against the
state.

2942

2943

2944

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