

20161604e1

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

20161604e1

30 prescription drug wholesale distributor permit;
31 providing that a restricted prescription drug
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

20161604e1

59 renewal application to continue operations; removing
60 certain application requirements for renewal of a
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

20161604e1

88 issuance of nondisciplinary citations; authorizing the
89 department to adopt rules designating violations for
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. 499.83, F.S.;
97 authorizing licensed hospices to obtain on behalf of,
98 and sell medical oxygen to, their patients without
99 obtaining a medical oxygen retail establishment permit
100 in certain circumstances; specifying recordkeeping
101 requirements; amending s. 499.89, F.S.; conforming
102 provisions; repealing s. 499.01212, F.S., relating to
103 pedigree papers; amending ss. 409.9201, 499.067,
104 794.075, and 921.0022, F.S.; conforming cross-
105 references; providing an effective date.

106
107 Be It Enacted by the Legislature of the State of Florida:

108
109 Section 1. Section 499.003, Florida Statutes, is amended to
110 read:

111 499.003 Definitions of terms used in this part.—As used in
112 this part, the term:

113 (1) "Active pharmaceutical ingredient" includes any
114 substance or mixture of substances intended, represented, or
115 labeled for use in drug manufacturing that furnishes or is
116 intended to furnish, in a finished dosage form, any

20161604e1

117 pharmacological activity or other direct effect in the
118 diagnosis, cure, mitigation, treatment, therapy, or prevention
119 of disease in humans or other animals, or to affect the
120 structure or any function of the body of humans or animals.

121 (2)~~(1)~~ "Advertisement" means any representation
122 disseminated in any manner or by any means, other than by
123 labeling, for the purpose of inducing, or which is likely to
124 induce, directly or indirectly, the purchase of drugs, devices,
125 or cosmetics.

126 (3) "Affiliate" means a business entity that has a
127 relationship with another business entity in which, directly or
128 indirectly:

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

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

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

139 (4)~~(3)~~ "Affiliated party" means:

140 (a) A director, officer, trustee, partner, or committee
141 member of a permittee or applicant or a subsidiary or service
142 corporation of the permittee or applicant;

143 (b) A person who, directly or indirectly, manages,
144 controls, or oversees the operation of a permittee or applicant,
145 regardless of whether such person is a partner, shareholder,

20161604e1

146 manager, member, officer, director, independent contractor, or
147 employee of the permittee or applicant;

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

152 (d) The five largest natural shareholders that own at least
153 5 percent of the permittee or applicant.

154 (5)~~(4)~~ "Applicant" means a person applying for a permit or
155 certification under this part.

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

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

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

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

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

20161604e1

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

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

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

183 (a) Is a dye pigment, or other substance, made by a process
184 of synthesis or similar artifice, or extracted, isolated, or
185 otherwise derived, with or without intermediate or final change
186 of identity from a vegetable, animal, mineral, or other source;
187 or

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

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

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

202 (a) Intended to be rubbed, poured, sprinkled, or sprayed
203 on; introduced into; or otherwise applied to the human body or

20161604e1

204 any part thereof for cleansing, beautifying, promoting
205 attractiveness, or altering the appearance; or

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

207 (13) "Counterfeit drug," "counterfeit device," or
208 "counterfeit cosmetic" means a drug, device, or cosmetic which,
209 or the container, seal, or labeling of which, without
210 authorization, bears the trademark, trade name, or other
211 identifying mark, imprint, or device, or any likeness thereof,
212 of a drug, device, or cosmetic manufacturer, processor, packer,
213 or distributor other than the person that in fact manufactured,
214 processed, packed, or distributed that drug, device, or cosmetic
215 and which thereby falsely purports or is represented to be the
216 product of, or to have been packed or distributed by, that other
217 drug, device, or cosmetic manufacturer, processor, packer, or
218 distributor.

219 (14) "Department" means the Department of Business and
220 Professional Regulation.

221 (15) "Device" means any instrument, apparatus, implement,
222 machine, contrivance, implant, in vitro reagent, or other
223 similar or related article, including its components, parts, or
224 accessories, which is:

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

227 (b) Intended for use in the diagnosis, cure, mitigation,
228 treatment, therapy, or prevention of disease in humans or other
229 animals, or

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

232

20161604e1

233 and that does not achieve any of its principal intended purposes
234 through chemical action within or on the body of humans or other
235 animals and which is not dependent upon being metabolized for
236 the achievement of any of its principal intended purposes.

237 (16) "Distribute" or "distribution" means to sell,
238 purchase, trade, deliver, handle, store, or receive ~~to sell;~~
239 ~~offer to sell; give away; transfer, whether by passage of title,~~
240 ~~physical movement, or both; deliver; or offer to deliver.~~ The
241 term does not mean to administer or dispense and ~~does not~~
242 ~~include the billing and invoicing activities that commonly~~
243 ~~follow a wholesale distribution transaction.~~

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

252 (17)~~(18)~~ "Drug" means an article that is:

253 (a) Recognized in the current edition of the United States
254 Pharmacopoeia and National Formulary, official Homeopathic
255 Pharmacopoeia of the United States, or any supplement to any of
256 those publications;

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

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

20161604e1

262 (d) Intended for use as a component of any article
263 specified in paragraph (a), paragraph (b), or paragraph (c), and
264 includes active pharmaceutical ingredients, but does not include
265 devices or their nondrug components, parts, or accessories. ~~For~~
266 ~~purposes of this paragraph, an "active pharmaceutical~~
267 ~~ingredient" includes any substance or mixture of substances~~
268 ~~intended, represented, or labeled for use in drug manufacturing~~
269 ~~that furnishes or is intended to furnish, in a finished dosage~~
270 ~~form, any pharmacological activity or other direct effect in the~~
271 ~~diagnosis, cure, mitigation, treatment, therapy, or prevention~~
272 ~~of disease in humans or other animals, or to affect the~~
273 ~~structure or any function of the body of humans or other~~
274 ~~animals.~~

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

284 (19)~~(20)~~ "Federal act" means the Federal Food, Drug, and
285 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

286 (20)~~(21)~~ "Freight forwarder" means a person who receives
287 prescription drugs which are owned by another person and
288 designated by that person for export, and exports those
289 prescription drugs.

290 (21)~~(22)~~ "Health care entity" means a closed pharmacy or

20161604e1

291 any person, organization, or business entity that provides
292 diagnostic, medical, surgical, or dental treatment or care, or
293 chronic or rehabilitative care, but does not include any
294 wholesale distributor or retail pharmacy licensed under state
295 law to deal in prescription drugs. However, a blood
296 establishment is a health care entity that may engage in the
297 wholesale distribution of prescription drugs under s.

298 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

299 (22)~~(23)~~ "Health care facility" means a health care
300 facility licensed under chapter 395.

301 (23)~~(24)~~ "Hospice" means a corporation licensed under part
302 IV of chapter 400.

303 (24)~~(25)~~ "Hospital" means a facility as defined in s.
304 395.002 and licensed under chapter 395.

305 (25)~~(26)~~ "Immediate container" does not include package
306 liners.

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

316 (27)~~(28)~~ "Labeling" means all labels and other written,
317 printed, or graphic matters:

318 (a) Upon a drug, device, or cosmetic, or any of its
319 containers or wrappers; or

20161604e1

320 (b) Accompanying or related to such drug, device, or
321 cosmetic.

322 (28)~~(29)~~ "Manufacture" means the preparation, deriving,
323 compounding, propagation, processing, producing, or fabrication
324 of any drug, device, or cosmetic.

325 (29)~~(30)~~ "Manufacturer" means:

326 (a) A person who holds a New Drug Application, an
327 Abbreviated New Drug Application, a Biologics License
328 Application, or a New Animal Drug Application approved under the
329 federal act or a license issued under s. 351 of the Public
330 Health Service Act, 42 U.S.C. s. 262, for such drug or
331 biologics, or if such drug or biologics are not the subject of
332 an approved application or license, the person who manufactured
333 the drug or biologics prepares, derives, manufactures, or
334 produces a drug, device, or cosmetic;

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

343 (c) An affiliate of a person described in paragraph (a),
344 paragraph (b), or this paragraph that receives the drug or
345 biologics directly from a person described in paragraph (a),
346 paragraph (b), or this paragraph ~~A private label distributor for~~
347 ~~whom the private label distributor's prescription drugs are~~
348 ~~originally manufactured and labeled for the distributor and have~~

20161604e1

349 ~~not been repackaged; or~~

350 (d) A person who manufactures a device or a cosmetic. A
351 ~~person registered under the federal act as a manufacturer of a~~
352 ~~prescription drug, who is described in paragraph (a), paragraph~~
353 ~~(b), or paragraph (c), who has entered into a written agreement~~
354 ~~with another prescription drug manufacturer that authorizes~~
355 ~~either manufacturer to distribute the prescription drug~~
356 ~~identified in the agreement as the manufacturer of that drug~~
357 ~~consistent with the federal act and its implementing~~
358 ~~regulations;~~

359 ~~(e) A member of an affiliated group that includes, but is~~
360 ~~not limited to, persons described in paragraph (a), paragraph~~
361 ~~(b), paragraph (c), or paragraph (d), which member distributes~~
362 ~~prescription drugs, whether or not obtaining title to the drugs,~~
363 ~~only for the manufacturer of the drugs who is also a member of~~
364 ~~the affiliated group. As used in this paragraph, the term~~
365 ~~"affiliated group" means an affiliated group as defined in s.~~
366 ~~1504 of the Internal Revenue Code of 1986, as amended. The~~
367 ~~manufacturer must disclose the names of all of its affiliated~~
368 ~~group members to the department; or~~

369 ~~(f) A person permitted as a third party logistics provider,~~
370 ~~only while providing warehousing, distribution, or other~~
371 ~~logistics services on behalf of a person described in paragraph~~
372 ~~(a), paragraph (b), paragraph (c), paragraph (d), or paragraph~~
373 ~~(e).~~

374
375 The term does not include a pharmacy that is operating in
376 compliance with pharmacy practice standards as defined in
377 chapter 465 and rules adopted under that chapter.

20161604e1

378 (30)~~(31)~~ "Medical convenience kit" means packages or units
379 that contain combination products as defined in 21 C.F.R. s.
380 3.2(e)(2).

381 (31)~~(32)~~ "Medical gas" means any liquefied or vaporized gas
382 that is a prescription drug, whether alone or in combination
383 with other gases, and as defined in the federal act.

384 (32)~~(33)~~ "New drug" means:

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

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

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

20161604e1

407 ~~or transfer between any parent, division, or subsidiary wholly~~
408 ~~owned by a corporate entity.~~

409 (33)~~(35)~~ "Nursing home" means a facility licensed under
410 part II of chapter 400.

411 (34)~~(36)~~ "Official compendium" means the current edition of
412 the official United States Pharmacopoeia and National Formulary,
413 or any supplement thereto.

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

418 (35)~~(38)~~ "Permittee" means any person holding a permit
419 issued under this chapter ~~pursuant to s. 499.012.~~

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

428 (37)~~(40)~~ "Pharmacist" means a person licensed under chapter
429 465.

430 (38)~~(41)~~ "Pharmacy" means an entity licensed under chapter
431 465.

432 (39)~~(42)~~ "Prepackaged drug product" means a drug that
433 originally was in finished packaged form sealed by a
434 manufacturer and that is placed in a properly labeled container
435 by a pharmacy or practitioner authorized to dispense pursuant to

20161604e1

436 chapter 465 for the purpose of dispensing in the establishment
437 in which the prepackaging occurred.

438 (40)~~(43)~~ "Prescription drug" means a prescription,
439 medicinal, or legend drug, including, but not limited to,
440 finished dosage forms or active pharmaceutical ingredients
441 subject to, defined by, or described by s. 503(b) of the federal
442 act or s. 465.003(8), s. 499.007(13), subsection (31) ~~(32)~~, or
443 subsection (47) ~~(52)~~, except that an active pharmaceutical
444 ingredient is a prescription drug only if substantially all
445 finished dosage forms in which it may be lawfully dispensed or
446 administered in this state are also prescription drugs.

447 (41)~~(44)~~ "Prescription drug label" means any display of
448 written, printed, or graphic matter upon the immediate container
449 of any prescription drug before it is dispensed ~~prior to its~~
450 ~~dispensing~~ to an individual patient pursuant to a prescription
451 of a practitioner authorized by law to prescribe.

452 (42)~~(45)~~ "Prescription label" means any display of written,
453 printed, or graphic matter upon the immediate container of any
454 prescription drug dispensed pursuant to a prescription of a
455 practitioner authorized by law to prescribe.

456 ~~(46) "Primary wholesale distributor" means any wholesale~~
457 ~~distributor that:~~

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

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

464 ~~2. Has, or the affiliated group, as defined in s. 1504 of~~

20161604e1

465 ~~the Internal Revenue Code, of which the wholesale distributor is~~
466 ~~a member has, not fewer than 250 employees.~~

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

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

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

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

477 ~~b. The wholesale distributor discloses to the department~~
478 ~~the names of all members of the affiliated group of which the~~
479 ~~wholesale distributor is a member and the affiliated group~~
480 ~~agrees in writing to provide records on prescription drug~~
481 ~~purchases by the members of the affiliated group not later than~~
482 ~~48 hours after the department requests access to such records,~~
483 ~~regardless of the location where the records are stored.~~

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

490 ~~(44)-(48)~~ "Repackage" includes repacking or otherwise
491 changing the container, wrapper, or labeling to further the
492 distribution of the drug, device, or cosmetic.

493 ~~(45)-(49)~~ "Repackager" means a person who repackages. The

20161604e1

494 term excludes pharmacies that are operating in compliance with
495 pharmacy practice standards as defined in chapter 465 and rules
496 adopted under that chapter.

497 (46)~~(50)~~ "Retail pharmacy" means a community pharmacy
498 licensed under chapter 465 that purchases prescription drugs at
499 fair market prices and provides prescription services to the
500 public.

501 ~~(51) "Secondary wholesale distributor" means a wholesale
502 distributor that is not a primary wholesale distributor.~~

503 (47)~~(52)~~ "Veterinary prescription drug" means a
504 prescription drug intended solely for veterinary use. The label
505 of the drug must bear the statement, "Caution: Federal law
506 restricts this drug to sale by or on the order of a licensed
507 veterinarian."

508 (48)~~(53)~~ "Wholesale distribution" means the distribution of
509 a prescription drug to a person ~~drugs to persons~~ other than a
510 consumer or patient, or the receipt of a prescription drug by a
511 person other than the consumer or patient, but does not include:

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

515 1. The purchase or other acquisition by a hospital or other
516 health care entity that is a member of a group purchasing
517 organization of a prescription drug for its own use from the
518 group purchasing organization or from other hospitals or health
519 care entities that are members of that organization.

520 2. The distribution ~~sale, purchase, or trade~~ of a
521 prescription drug or an offer to distribute ~~sell, purchase, or~~
522 ~~trade~~ a prescription drug by a charitable organization described

20161604e1

523 in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended
524 and revised, to a nonprofit affiliate of the organization to the
525 extent otherwise permitted by law.

526 3. The distribution ~~sale, purchase, or trade~~ of a
527 prescription drug ~~or an offer to sell, purchase, or trade a~~
528 ~~prescription drug~~ among hospitals or other health care entities
529 that are under common control. For purposes of this
530 subparagraph, "common control" means the power to direct or
531 cause the direction of the management and policies of a person
532 or an organization, whether by ownership of stock, by voting
533 rights, by contract, or otherwise.

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

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

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

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

549 d. The contract provider and subcontractor must maintain
550 and produce immediately for inspection all records of movement
551 or transfer of all the prescription drugs belonging to the

20161604e1

552 agency or entity, including, but not limited to, the records of
553 receipt and disposition of prescription drugs. Each contractor
554 and subcontractor dispensing or administering these drugs must
555 maintain and produce records documenting the dispensing or
556 administration. Records that are required to be maintained
557 include, but are not limited to, a perpetual inventory itemizing
558 drugs received and drugs dispensed by prescription number or
559 administered by patient identifier, which must be submitted to
560 the agency or entity quarterly.

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

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

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

20161604e1

581 1. The distribution ~~sale, purchase, or trade~~ of a
582 prescription drug among federal, state, or local government
583 health care entities that are under common control and are
584 authorized to purchase such prescription drug.

585 2. The distribution ~~sale, purchase, or trade~~ of a
586 prescription drug or ~~an~~ offer to distribute ~~sell, purchase, or~~
587 ~~trade~~ a prescription drug for emergency medical reasons, which
588 may include. ~~For purposes of this subparagraph, The term~~
589 ~~"emergency medical reasons"~~ includes transfers of prescription
590 drugs by a retail pharmacy to another retail pharmacy to
591 alleviate a temporary shortage. For purposes of this
592 subparagraph, a drug shortage not caused by a public health
593 emergency does not constitute an emergency medical reason.

594 3. The distribution ~~transfer~~ of a prescription drug
595 acquired by a medical director on behalf of a licensed emergency
596 medical services provider to that emergency medical services
597 provider and its transport vehicles for use in accordance with
598 the provider's license under chapter 401.

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

601 ~~4.5.~~ The donation of a prescription drug by a health care
602 entity to a charitable organization that has been granted an
603 exemption under s. 501(c)(3) of the Internal Revenue Code of
604 1986, as amended, and that is authorized to possess prescription
605 drugs.

606 ~~5.6.~~ The distribution ~~transfer~~ of a prescription drug by a
607 person authorized to purchase or receive prescription drugs to a
608 person licensed or permitted to handle reverse distributions or
609 destruction under the laws of the jurisdiction in which the

20161604e1

610 person handling the reverse distribution or destruction receives
611 the drug.

612 ~~6.7.~~ The distribution ~~transfer~~ of a prescription drug by a
613 hospital or other health care entity to a person licensed under
614 this part to repackage prescription drugs for the purpose of
615 repackaging the prescription drug for use by that hospital, or
616 other health care entity and other health care entities that are
617 under common control, if ownership of the prescription drugs
618 remains with the hospital or other health care entity at all
619 times. In addition to the recordkeeping requirements of s.
620 499.0121(6), the hospital or health care entity that distributes
621 ~~transfers~~ prescription drugs pursuant to this subparagraph must
622 reconcile all drugs distributed ~~transferred~~ and returned and
623 resolve any discrepancies in a timely manner.

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

626 (d) The distribution of a prescription drug by the
627 manufacturer of the prescription drug.

628 ~~(e)~~ (e) The distribution of prescription drug samples by
629 manufacturers' representatives or distributors' representatives
630 conducted in accordance with s. 499.028.

631 (f) The distribution of a prescription drug by a third-
632 party logistics provider permitted or licensed pursuant to and
633 operating in compliance with the laws of this state and federal
634 law if such third-party logistics provider does not take
635 ownership of the prescription drug.

636 (g) The distribution of a prescription drug, or an offer to
637 distribute a prescription drug by a repackager registered as a
638 drug establishment with the United States Food and Drug

20161604e1

639 Administration that has taken ownership or possession of the
640 prescription drug and repacks it in accordance with this part.

641 (h) The purchase or other acquisition by a dispenser,
642 hospital, or other health care entity of a prescription drug for
643 use by such dispenser, hospital, or other health care entity.

644 (i) The distribution of a prescription drug by a hospital
645 or other health care entity, or by a wholesale distributor or
646 manufacturer operating at the direction of the hospital or other
647 health care entity, to a repackager for the purpose of
648 repackaging the prescription drug for use by that hospital, or
649 other health care entity and other health care entities that are
650 under common control, if ownership of the prescription drug
651 remains with the hospital or other health care entity at all
652 times.

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

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

661 (l)~~(f)~~ The distribution ~~sale, purchase, or trade~~ of a
662 prescription drug between pharmacies as a result of a sale,
663 transfer, merger, or consolidation of all or part of the
664 business of the pharmacies from or with another pharmacy,
665 whether accomplished as a purchase and sale of stock or of
666 business assets.

667 (m) The distribution of minimal quantities of prescription

20161604e1

668 drugs by a licensed retail pharmacy to a licensed practitioner
669 for office use in compliance with chapter 465 and rules adopted
670 thereunder. The department shall adopt rules specifying the
671 quantities of prescription drugs which are considered to be
672 minimal quantities. However, until such rules are adopted,
673 minimal quantities distributed may not exceed 3 percent of the
674 retail pharmacy's total annual purchases of prescription drugs.

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

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

682 (p) The distribution of a prescription drug that is
683 intended for irrigation or sterile water, whether intended for
684 such purposes or for injection.

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

687 (r) A common carrier that transports a prescription drug,
688 if the common carrier does not take ownership of the
689 prescription drug.

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

691 (t) Facilitating the distribution of a prescription drug by
692 providing solely administrative services, including processing
693 of orders and payments.

694 (u) The distribution by a charitable organization described
695 in s. 501(c) (3) of the Internal Revenue Code of prescription
696 drugs donated to or supplied at a reduced price to the

20161604e1

697 charitable organization to:

698 1. A licensed health care practitioner, as defined in s.
699 456.001, who is authorized under the appropriate practice act to
700 prescribe and administer prescription drugs;

701 2. A health care clinic establishment permitted pursuant to
702 chapter 499; or

703 3. The Department of Health or the licensed medical
704 director of a government agency health care entity, authorized
705 to possess prescription drugs, for storage and use in the
706 treatment of persons in need of emergency medical services,
707 including controlling communicable diseases or providing
708 protection from unsafe conditions that pose an imminent threat
709 to public health,

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

717 (v) The distribution of medical gas pursuant to part III of
718 this chapter.

719 (49)-(54) "Wholesale distributor" means a ~~any~~ person, other
720 than a manufacturer, a manufacturer's co-licensed partner, a
721 third-party logistics provider, or a repackager, who is engaged
722 in wholesale distribution of prescription drugs in or into this
723 state, including, but not limited to, manufacturers;
724 repackagers; own-label distributors; jobbers; private-label
725 distributors; brokers; warehouses, including manufacturers' and

20161604e1

726 ~~distributors' warehouses, chain drug warehouses, and wholesale~~
727 ~~drug warehouses; independent wholesale drug traders; exporters;~~
728 ~~retail pharmacies; and the agents thereof that conduct wholesale~~
729 ~~distributions.~~

730 Section 2. Subsections (21), (28), and (29) of section
731 499.005, Florida Statutes, are amended to read:

732 499.005 Prohibited acts.—It is unlawful for a person to
733 perform or cause the performance of any of the following acts in
734 this state:

735 (21) The wholesale distribution of any prescription drug
736 that was:

737 (a) Purchased by a public or private hospital or other
738 health care entity; or

739 (b) Donated or supplied at a reduced price to a charitable
740 organization,

741
742 unless the wholesale distribution of the prescription drug is
743 authorized in s. 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

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

747 ~~(29) The receipt of a prescription drug pursuant to a~~
748 ~~wholesale distribution without having previously received or~~
749 ~~simultaneously receiving a pedigree paper that was attested to~~
750 ~~as accurate and complete by the wholesale distributor as~~
751 ~~required under this part.~~

752 Section 3. Subsections (4) through (17) of section
753 499.0051, Florida Statutes, are renumbered as subsections (3)
754 through (16), respectively, and subsections (1) and (2), present

20161604e1

755 subsection (3), paragraphs (h) and (i) of present subsection
756 (12), paragraph (d) of present subsection (13), and present
757 subsection (15) of that section are amended, to read:

758 499.0051 Criminal acts.—

759 (1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY,
760 TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE~~
761 ~~PAPERS.~~—

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

772 (b) A person engaged in the ~~wholesale~~ distribution of
773 prescription drugs who fails to acquire a complete and accurate
774 transaction history, transaction information, or transaction
775 statement ~~pedigree papers~~ concerning a prescription drug or
776 contraband prescription drug, as required by this chapter and
777 rules adopted under this chapter, before ~~prior to,~~ or
778 simultaneous with, the receipt of the prescription drug or
779 contraband prescription drug from another person commits a
780 felony of the third degree, punishable as provided in s.
781 775.082, s. 775.083, or s. 775.084.

782 (c) Any person who knowingly destroys, alters, conceals, or
783 fails to maintain a complete and accurate transaction history,

20161604e1

784 transaction information, or transaction statement pedigree
785 ~~papers~~ concerning any prescription drug or contraband
786 prescription drug, as required by this chapter and rules adopted
787 under this chapter, in his or her possession commits a felony of
788 the third degree, punishable as provided in s. 775.082, s.
789 775.083, or s. 775.084.

790 ~~(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July~~
791 ~~1, 2006:~~

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

800 ~~(b) A person in possession of pedigree papers concerning~~
801 ~~prescription drugs or contraband prescription drugs who falsely~~
802 ~~swears or certifies that he or she has authenticated the matters~~
803 ~~contained in the pedigree papers commits a felony of the third~~
804 ~~degree, punishable as provided in s. 775.082, s. 775.083, or s.~~
805 ~~775.084.~~

806 ~~(2)(3)~~ KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION
807 INFORMATION, OR TRANSACTION STATEMENT PEDIGREE PAPERS.—A person
808 who knowingly forges, counterfeits, or falsely creates any
809 transaction history, transaction information, or transaction
810 statement pedigree paper; who falsely represents any factual
811 matter contained on any transaction history, transaction
812 information, or transaction statement pedigree paper; or who

20161604e1

813 knowingly omits to record material information required to be
814 recorded in a transaction history, transaction information, or
815 transaction statement ~~pedigree paper~~, commits a felony of the
816 second degree, punishable as provided in s. 775.082, s. 775.083,
817 or s. 775.084.

818 ~~(11)-(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE
819 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—
820 Any person who violates any of the following provisions commits
821 a misdemeanor of the second degree, punishable as provided in s.
822 775.082 or s. 775.083; but, if the violation is committed after
823 a conviction of such person under this subsection has become
824 final, such person commits a misdemeanor of the first degree,
825 punishable as provided in s. 775.082 or s. 775.083, or as
826 otherwise provided in this part:

827 (h) The failure to maintain records related to a drug as
828 required by this part and rules adopted under this part, except
829 for transaction histories, transaction information, or
830 transaction statements ~~pedigree papers~~, invoices, or shipping
831 documents related to prescription drugs.

832 (i) The possession of any drug in violation of this part,
833 except if the violation relates to a deficiency in transaction
834 histories, transaction information, or transaction statements
835 ~~pedigree papers~~.

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

20161604e1

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

845 (15) FALSE ADVERTISEMENT.—A publisher, radio broadcast
846 licensee, or agency or medium for the dissemination of an
847 advertisement, except the manufacturer, repackager, wholesale
848 distributor, or seller of the article to which a false
849 advertisement relates, is not liable under subsection (11) ~~(12)~~,
850 subsection (12) ~~(13)~~, or subsection (13) ~~(14)~~ by reason of the
851 dissemination by him or her of such false advertisement, unless
852 he or she has refused, on the request of the department, to
853 furnish to the department the name and post office address of
854 the manufacturer, repackager, wholesale distributor, seller, or
855 advertising agency that asked him or her to disseminate such
856 advertisement.

857 Section 4. Section 499.006, Florida Statutes, is amended to
858 read:

859 499.006 Adulterated drug or device.—A drug or device is
860 adulterated, if any of the following apply:

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

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

866 (3) ~~If~~ It is a drug and the methods used in, or the
867 facilities or controls used for, its manufacture, processing,
868 packing, or holding do not conform to, or are not operated or
869 administered in conformity with, current good manufacturing
870 practices to assure that the drug meets the requirements of this

20161604e1

871 part and that the drug has the identity and strength, and meets
872 the standard of quality and purity, which it purports or is
873 represented to possess.†

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

877 (5) ~~If~~ It is a drug and it bears or contains, for the
878 purpose of coloring only, a color additive that is unsafe within
879 the meaning of the federal act; or, if it is a color additive,
880 the intended use of which in or on drugs is for the purpose of
881 coloring only, and it is unsafe within the meaning of the
882 federal act.†

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

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

20161604e1

- 900 (8) ~~If~~ It is a drug:
- 901 (a) With which any substance has been mixed or packed so as
- 902 to reduce the quality or strength of the drug; or
- 903 (b) For which any substance has been substituted wholly or
- 904 in part.~~;~~
- 905 (9) ~~If~~ It is a drug or device for which the expiration date
- 906 has passed.~~;~~
- 907 (10) ~~If~~ It is a prescription drug for which the required
- 908 transaction history, transaction information, or transaction
- 909 statement ~~pedigree paper~~ is nonexistent, fraudulent, or
- 910 incomplete under the requirements of this part or applicable
- 911 rules, or that has been purchased, held, sold, or distributed at
- 912 any time by a person not authorized under federal or state law
- 913 to do so.~~;~~~~or~~
- 914 (11) ~~If~~ It is a prescription drug subject to, defined by,
- 915 or described by s. 503(b) of the Federal Food, Drug, and
- 916 Cosmetic Act which has been returned by a veterinarian to a
- 917 limited prescription drug veterinary wholesale distributor.
- 918 Section 5. Section 499.01, Florida Statutes, is amended to
- 919 read:
- 920 499.01 Permits.—
- 921 (1) Before ~~Prior to~~ operating, a permit is required for
- 922 each person and establishment that intends to operate as:
- 923 (a) A prescription drug manufacturer;
- 924 (b) A prescription drug repackager;
- 925 (c) A nonresident prescription drug manufacturer;
- 926 (d) A nonresident prescription drug repackager;
- 927 (e)~~(d)~~ A prescription drug wholesale distributor;
- 928 (f)~~(e)~~ An out-of-state prescription drug wholesale

20161604e1

929 distributor;

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

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

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

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

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

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

936 distributor;

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

938 distributor;

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

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

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

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

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

944 (2) The following permits are established:

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

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

947 manufacturer of a prescription drug and that manufactures or

948 distributes such prescription drugs in this state.

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

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

951 distribution of prescription drugs for which the person is the

952 manufacturer manufactured at that establishment and must comply

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

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

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

956 department shall adopt rules for issuing a virtual prescription

957 drug manufacturer permit to a person who engages in the

20161604e1

958 manufacture of prescription drugs but does not make or take
959 physical possession of any prescription drugs. The rules adopted
960 by the department under this section may exempt virtual
961 manufacturers from certain establishment, security, and storage
962 requirements set forth in s. 499.0121.

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

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

972 (b) *Prescription drug repackager permit.*—A prescription
973 drug repackager permit is required for any person that
974 repackages a prescription drug in this state.

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

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

983 (c) *Nonresident prescription drug manufacturer permit.*—A
984 nonresident prescription drug manufacturer permit is required
985 for any person that is a manufacturer of prescription drugs,
986 unless permitted as a third party logistics provider, located

20161604e1

987 outside of this state or outside the United States and that
988 engages in the ~~wholesale~~ distribution in this state of such
989 prescription drugs. Each such manufacturer must be permitted by
990 the department and comply with all of the provisions required of
991 a prescription drug manufacturer ~~wholesale distributor~~ under
992 this part, ~~except s. 499.01212.~~ The department shall adopt rules
993 for issuing a virtual nonresident prescription drug manufacturer
994 permit to a person who engages in the manufacture of
995 prescription drugs but does not make or take physical possession
996 of any prescription drugs. The rules adopted by the department
997 under this section may exempt virtual nonresident manufacturers
998 from certain establishment, security, and storage requirements
999 set forth in s. 499.0121.

1000 1. A person that distributes prescription drugs for which
1001 the person is not the manufacturer must also obtain an out-of-
1002 state prescription drug wholesale distributor permit or third
1003 party logistics provider permit pursuant to this section to
1004 engage in the ~~wholesale~~ distribution of such prescription drugs
1005 when required by this part. This subparagraph does not apply to
1006 a manufacturer that distributes prescription drugs only for the
1007 manufacturer of the prescription drugs where both manufacturers
1008 are affiliates as defined in s. 499.003(30)(e).

1009 2. Any such person must comply with the licensing or
1010 permitting requirements of the jurisdiction in which the
1011 establishment is located and the federal act, and any
1012 prescription drug distributed ~~product wholesaled~~ into this state
1013 must comply with this part. If a person intends to import
1014 prescription drugs from a foreign country into this state, the
1015 nonresident prescription drug manufacturer must provide to the

20161604e1

1016 department a list identifying each prescription drug it intends
1017 to import and document approval by the United States Food and
1018 Drug Administration for such importation.

1019 (d) Nonresident prescription drug repackager permit.-A
1020 nonresident prescription drug repackager permit is required for
1021 any person located outside of this state, but within the United
1022 States or its territories, that repackages prescription drugs
1023 and engages in the distribution of such prescription drugs into
1024 this state.

1025 1. A nonresident prescription drug repackager must comply
1026 with all of the provisions of this section and the rules adopted
1027 under this section that apply to a prescription drug
1028 manufacturer.

1029 2. A nonresident prescription drug repackager must be
1030 permitted by the department and comply with all appropriate
1031 state and federal good manufacturing practices.

1032 3. A nonresident prescription drug repackager must be
1033 registered as a drug establishment with the United States Food
1034 and Drug Administration.

1035 (e)~~(d)~~ Prescription drug wholesale distributor permit.-A
1036 prescription drug wholesale distributor permit is required for
1037 any person who is a wholesale distributor of prescription drugs
1038 and that ~~may engage in the~~ wholesale distributes such
1039 ~~distribution of~~ prescription drugs in this state. A prescription
1040 ~~drug wholesale distributor that applies to the department for a~~
1041 ~~new permit or the renewal of a permit must submit a bond of~~
1042 ~~\$100,000, or other equivalent means of security acceptable to~~
1043 ~~the department, such as an irrevocable letter of credit or a~~
1044 ~~deposit in a trust account or financial institution, payable to~~

20161604e1

1045 ~~the Professional Regulation Trust Fund. The purpose of the bond~~
1046 ~~is to secure payment of any administrative penalties imposed by~~
1047 ~~the department and any fees and costs incurred by the department~~
1048 ~~regarding that permit which are authorized under state law and~~
1049 ~~which the permittee fails to pay 30 days after the fine or costs~~
1050 ~~become final. The department may make a claim against such bond~~
1051 ~~or security until 1 year after the permittee's license ceases to~~
1052 ~~be valid or until 60 days after any administrative or legal~~
1053 ~~proceeding authorized in this part which involves the permittee~~
1054 ~~is concluded, including any appeal, whichever occurs later. The~~
1055 ~~department may adopt rules for issuing a prescription drug~~
1056 ~~wholesale distributor-broker permit to a person who engages in~~
1057 ~~the wholesale distribution of prescription drugs and does not~~
1058 ~~take physical possession of any prescription drugs.~~

1059 (f) ~~(e)~~ *Out-of-state prescription drug wholesale distributor*
1060 *permit.*—An out-of-state prescription drug wholesale distributor
1061 permit is required for any person that is a wholesale
1062 distributor located outside this state, but within the United
1063 States or its territories, which engages in the wholesale
1064 distribution of prescription drugs into this state ~~and which~~
1065 ~~must be permitted by the department and comply with all the~~
1066 ~~provisions required of a wholesale distributor under this part.~~
1067 ~~An out-of-state prescription drug wholesale distributor that~~
1068 ~~applies to the department for a new permit or the renewal of a~~
1069 ~~permit must submit a bond of \$100,000, or other equivalent means~~
1070 ~~of security acceptable to the department, such as an irrevocable~~
1071 ~~letter of credit or a deposit in a trust account or financial~~
1072 ~~institution, payable to the Professional Regulation Trust Fund.~~
1073 ~~The purpose of the bond is to secure payment of any~~

20161604e1

1074 ~~administrative penalties imposed by the department and any fees~~
1075 ~~and costs incurred by the department regarding that permit which~~
1076 ~~are authorized under state law and which the permittee fails to~~
1077 ~~pay 30 days after the fine or costs become final. The department~~
1078 ~~may make a claim against such bond or security until 1 year~~
1079 ~~after the permittee's license ceases to be valid or until 60~~
1080 ~~days after any administrative or legal proceeding authorized in~~
1081 ~~this part which involves the permittee is concluded, including~~
1082 ~~any appeal, whichever occurs later. The out-of-state~~
1083 ~~prescription drug wholesale distributor must maintain at all~~
1084 ~~times a license or permit to engage in the wholesale~~
1085 ~~distribution of prescription drugs in compliance with laws of~~
1086 ~~the state in which it is a resident. If the state from which the~~
1087 ~~wholesale distributor distributes prescription drugs does not~~
1088 ~~require a license to engage in the wholesale distribution of~~
1089 ~~prescription drugs, the distributor must be licensed as a~~
1090 ~~wholesale distributor as required by the federal act.~~

1091 ~~(g)~~ ~~(f)~~ *Retail pharmacy drug wholesale distributor permit.*—A
1092 retail pharmacy drug wholesale distributor is a retail pharmacy
1093 engaged in wholesale distribution of prescription drugs within
1094 this state under the following conditions:

1095 1. The pharmacy must obtain a retail pharmacy drug
1096 wholesale distributor permit pursuant to this part and ~~the~~ rules
1097 adopted under this part.

1098 2. The wholesale distribution activity does not exceed 30
1099 percent of the total annual purchases of prescription drugs. If
1100 the wholesale distribution activity exceeds the 30-percent
1101 maximum, the pharmacy must obtain a prescription drug wholesale
1102 distributor permit.

20161604e1

1103 3. The transfer of prescription drugs that appear in any
1104 schedule contained in chapter 893 is subject to chapter 893 and
1105 the federal Comprehensive Drug Abuse Prevention and Control Act
1106 of 1970.

1107 4. The transfer is between a retail pharmacy and another
1108 retail pharmacy, or a Modified Class II institutional pharmacy,
1109 or a health care practitioner licensed in this state and
1110 authorized by law to dispense or prescribe prescription drugs.

1111 5. All records of sales of prescription drugs subject to
1112 this section must be maintained separate and distinct from other
1113 records and comply with the recordkeeping requirements of this
1114 part.

1115 (h) ~~(g)~~ *Restricted prescription drug distributor permit.*—

1116 1. A restricted prescription drug distributor permit is
1117 required for:

1118 a. Any person located in this state who engages in the
1119 distribution of a prescription drug, which distribution is not
1120 considered "wholesale distribution" under s. 499.003(48)(a)
1121 ~~499.003(53)(a)~~.

1122 b. Any person located in this state who engages in the
1123 receipt or distribution of a prescription drug in this state for
1124 the purpose of processing its return or its destruction if such
1125 person is not the person initiating the return, the prescription
1126 drug wholesale supplier of the person initiating the return, or
1127 the manufacturer of the drug.

1128 c. A blood establishment located in this state which
1129 collects blood and blood components only from volunteer donors
1130 as defined in s. 381.06014 or pursuant to an authorized
1131 practitioner's order for medical treatment or therapy and

20161604e1

1132 engages in the wholesale distribution of a prescription drug not
1133 described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care
1134 entity. A mobile blood unit operated by a blood establishment
1135 permitted under this sub-subparagraph is not required to be
1136 separately permitted. The health care entity receiving a
1137 prescription drug distributed under this sub-subparagraph must
1138 be licensed as a closed pharmacy or provide health care services
1139 at that establishment. The blood establishment must operate in
1140 accordance with s. 381.06014 and may distribute only:

1141 (I) Prescription drugs indicated for a bleeding or clotting
1142 disorder or anemia;

1143 (II) Blood-collection containers approved under s. 505 of
1144 the federal act;

1145 (III) Drugs that are blood derivatives, or a recombinant or
1146 synthetic form of a blood derivative;

1147 (IV) Prescription drugs that are identified in rules
1148 adopted by the department and that are essential to services
1149 performed or provided by blood establishments and authorized for
1150 distribution by blood establishments under federal law; or

1151 (V) To the extent authorized by federal law, drugs
1152 necessary to collect blood or blood components from volunteer
1153 blood donors; for blood establishment personnel to perform
1154 therapeutic procedures under the direction and supervision of a
1155 licensed physician; and to diagnose, treat, manage, and prevent
1156 any reaction of a volunteer blood donor or a patient undergoing
1157 a therapeutic procedure performed under the direction and
1158 supervision of a licensed physician,

1159
1160 as long as all of the health care services provided by the blood

20161604e1

1161 establishment are related to its activities as a registered
1162 blood establishment or the health care services consist of
1163 collecting, processing, storing, or administering human
1164 hematopoietic stem cells or progenitor cells or performing
1165 diagnostic testing of specimens if such specimens are tested
1166 together with specimens undergoing routine donor testing. The
1167 blood establishment may purchase and possess the drugs described
1168 in this sub-subparagraph without a health care clinic
1169 establishment permit.

1170 2. Storage, handling, and recordkeeping of these
1171 distributions by a person required to be permitted as a
1172 restricted prescription drug distributor must be in accordance
1173 with the requirements for wholesale distributors under s.
1174 499.0121, ~~but not those set forth in s. 499.01212 if the~~
1175 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~
1176 ~~subparagraph 1.b.~~

1177 3. A person who applies for a permit as a restricted
1178 prescription drug distributor, or for the renewal of such a
1179 permit, must provide to the department the information required
1180 under s. 499.012.

1181 4. The department may adopt rules regarding the
1182 distribution of prescription drugs by hospitals, health care
1183 entities, charitable organizations, other persons not involved
1184 in wholesale distribution, and blood establishments, which rules
1185 are necessary for the protection of the public health, safety,
1186 and welfare.

1187 5. A restricted prescription drug distributor permit is not
1188 required for distributions between pharmacies that each hold an
1189 active permit under chapter 465, have a common ownership, and

20161604e1

1190 are operating in a freestanding end-stage renal dialysis clinic,
1191 if such distributions are made to meet the immediate emergency
1192 medical needs of specifically identified patients and do not
1193 occur with such frequency as to amount to the regular and
1194 systematic supplying of that drug between the pharmacies. The
1195 department shall adopt rules establishing when the distribution
1196 of a prescription drug under this subparagraph amounts to the
1197 regular and systematic supplying of that drug.

1198 (i)~~(h)~~ *Complimentary drug distributor permit.*—A
1199 complimentary drug distributor permit is required for any person
1200 that engages in the distribution of a complimentary drug,
1201 subject to the requirements of s. 499.028.

1202 (j)~~(i)~~ *Freight forwarder permit.*—A freight forwarder permit
1203 is required for any person that engages in the distribution of a
1204 prescription drug as a freight forwarder unless the person is a
1205 common carrier. The storage, handling, and recordkeeping of such
1206 distributions must comply with the requirements for wholesale
1207 distributors under s. 499.0121, ~~but not those set forth in s.~~
1208 ~~499.01212.~~ A freight forwarder must provide the source of the
1209 prescription drugs with a validated airway bill, bill of lading,
1210 or other appropriate documentation to evidence the exportation
1211 of the product.

1212 (k)~~(j)~~ *Veterinary prescription drug retail establishment*
1213 *permit.*—A veterinary prescription drug retail establishment
1214 permit is required for any person that sells veterinary
1215 prescription drugs to the public but does not include a pharmacy
1216 licensed under chapter 465.

1217 1. The sale to the public must be based on a valid written
1218 order from a veterinarian licensed in this state who has a valid

20161604e1

1219 client-veterinarian relationship with the purchaser's animal.

1220 2. Veterinary prescription drugs may not be sold in excess
1221 of the amount clearly indicated on the order or beyond the date
1222 indicated on the order.

1223 3. An order may not be valid for more than 1 year.

1224 4. A veterinary prescription drug retail establishment may
1225 not purchase, sell, trade, or possess human prescription drugs
1226 or any controlled substance as defined in chapter 893.

1227 5. A veterinary prescription drug retail establishment must
1228 sell a veterinary prescription drug in the original, sealed
1229 manufacturer's container with all labeling intact and legible.
1230 The department may adopt by rule additional labeling
1231 requirements for the sale of a veterinary prescription drug.

1232 6. A veterinary prescription drug retail establishment must
1233 comply with all of the wholesale distribution requirements of s.
1234 499.0121.

1235 7. Prescription drugs sold by a veterinary prescription
1236 drug retail establishment pursuant to a practitioner's order may
1237 not be returned into the retail establishment's inventory.

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

20161604e1

1248 prescription drug veterinary wholesale distributor in lieu of
1249 the veterinary prescription drug wholesale distributor permit. A
1250 veterinary prescription drug wholesale distributor must comply
1251 with the requirements for wholesale distributors under s.
1252 499.0121, ~~but not those set forth in s. 499.01212.~~

1253 (m) ~~(l)~~ *Limited prescription drug veterinary wholesale*
1254 *distributor permit.*—Unless engaging in the activities of and
1255 permitted as a prescription drug manufacturer, nonresident
1256 prescription drug manufacturer, prescription drug wholesale
1257 distributor, or out-of-state prescription drug wholesale
1258 distributor, a limited prescription drug veterinary wholesale
1259 distributor permit is required for any person that engages in
1260 the distribution in or into this state of veterinary
1261 prescription drugs and prescription drugs subject to, defined
1262 by, or described by s. 503(b) of the Federal Food, Drug, and
1263 Cosmetic Act under the following conditions:

- 1264 1. The person is engaged in the business of wholesaling
1265 prescription and veterinary prescription drugs to persons:
- 1266 a. Licensed as veterinarians practicing on a full-time
1267 basis;
 - 1268 b. Regularly and lawfully engaged in instruction in
1269 veterinary medicine;
 - 1270 c. Regularly and lawfully engaged in law enforcement
1271 activities;
 - 1272 d. For use in research not involving clinical use; or
 - 1273 e. For use in chemical analysis or physical testing or for
1274 purposes of instruction in law enforcement activities, research,
1275 or testing.
- 1276 2. No more than 30 percent of total annual prescription

20161604e1

1277 drug sales may be prescription drugs approved for human use
1278 which are subject to, defined by, or described by s. 503(b) of
1279 the Federal Food, Drug, and Cosmetic Act.

1280 3. The person does not distribute in any jurisdiction
1281 prescription drugs subject to, defined by, or described by s.
1282 503(b) of the Federal Food, Drug, and Cosmetic Act to any person
1283 who is authorized to sell, distribute, purchase, trade, or use
1284 these drugs on or for humans.

1285 4. A limited prescription drug veterinary wholesale
1286 distributor that applies to the department for a new permit or
1287 the renewal of a permit must submit a bond of \$20,000, or other
1288 equivalent means of security acceptable to the department, such
1289 as an irrevocable letter of credit or a deposit in a trust
1290 account or financial institution, payable to the Professional
1291 Regulation Trust Fund. The purpose of the bond is to secure
1292 payment of any administrative penalties imposed by the
1293 department and any fees and costs incurred by the department
1294 regarding that permit which are authorized under state law and
1295 which the permittee fails to pay 30 days after the fine or costs
1296 become final. The department may make a claim against such bond
1297 or security until 1 year after the permittee's license ceases to
1298 be valid or until 60 days after any administrative or legal
1299 proceeding authorized in this part which involves the permittee
1300 is concluded, including any appeal, whichever occurs later.

1301 5. A limited prescription drug veterinary wholesale
1302 distributor must maintain at all times a license or permit to
1303 engage in the wholesale distribution of prescription drugs in
1304 compliance with laws of the state in which it is a resident.

1305 6. A limited prescription drug veterinary wholesale

20161604e1

1306 distributor must comply with the requirements for wholesale
1307 distributors under s. ss. 499.0121 and ~~499.01212~~, except that a
1308 limited prescription drug veterinary wholesale distributor is
1309 not required to provide a pedigree paper as required by ~~s.~~
1310 ~~499.01212~~ upon the wholesale distribution of a prescription drug
1311 to a veterinarian.

1312 7. A limited prescription drug veterinary wholesale
1313 distributor may not return to inventory for subsequent wholesale
1314 distribution any prescription drug subject to, defined by, or
1315 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1316 Act which has been returned by a veterinarian.

1317 8. A limited prescription drug veterinary wholesale
1318 distributor permit is not required for an intracompany sale or
1319 transfer of a prescription drug from an out-of-state
1320 establishment that is duly licensed to engage in the wholesale
1321 distribution of prescription drugs in its state of residence to
1322 a licensed limited prescription drug veterinary wholesale
1323 distributor in this state if both wholesale distributors conduct
1324 wholesale distributions of prescription drugs under the same
1325 business name. The recordkeeping requirements of s. ss.
1326 499.0121(6) and ~~499.01212~~ must be followed for this transaction.

1327 (n) ~~(m)~~ *Over-the-counter drug manufacturer permit.*—An over-
1328 the-counter drug manufacturer permit is required for any person
1329 that engages in the manufacture or repackaging of an over-the-
1330 counter drug.

1331 1. An over-the-counter drug manufacturer may not possess or
1332 purchase prescription drugs.

1333 2. A pharmacy is exempt from obtaining an over-the-counter
1334 drug manufacturer permit if it is operating in compliance with

20161604e1

1335 pharmacy practice standards as defined in chapter 465 and ~~the~~
1336 rules adopted under that chapter.

1337 3. An over-the-counter drug manufacturer must comply with
1338 all appropriate state and federal good manufacturing practices.

1339 (o)~~(n)~~ *Device manufacturer permit.*—

1340 1. A device manufacturer permit is required for any person
1341 that engages in the manufacture, repackaging, or assembly of
1342 medical devices for human use in this state, except that a
1343 permit is not required if:

1344 a. The person is engaged only in manufacturing,
1345 repackaging, or assembling a medical device pursuant to a
1346 practitioner's order for a specific patient; or

1347 b. The person does not manufacture, repackage, or assemble
1348 any medical devices or components for such devices, except those
1349 devices or components which are exempt from registration
1350 pursuant to s. 499.015(8).

1351 2. A manufacturer or repackager of medical devices in this
1352 state must comply with all appropriate state and federal good
1353 manufacturing practices and quality system rules.

1354 3. The department shall adopt rules related to storage,
1355 handling, and recordkeeping requirements for manufacturers of
1356 medical devices for human use.

1357 (p)~~(o)~~ *Cosmetic manufacturer permit.*—A cosmetic
1358 manufacturer permit is required for any person that manufactures
1359 or repackages cosmetics in this state. A person that only labels
1360 or changes the labeling of a cosmetic but does not open the
1361 container sealed by the manufacturer of the product is exempt
1362 from obtaining a permit under this paragraph.

1363 (q)~~(p)~~ *Third party logistics provider permit.*—A third party

20161604e1

1364 logistics provider permit is required for any person that
1365 contracts with a prescription drug wholesale distributor or
1366 prescription drug manufacturer to provide warehousing,
1367 distribution, or other logistics services on behalf of a
1368 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who
1369 does not take title to the prescription drug or have
1370 responsibility to direct the sale or disposition of the
1371 prescription drug. A third party logistics provider located
1372 outside of this state, must be licensed in the state or
1373 territory from which the prescription drug is distributed by the
1374 third party logistics provider. If the state or territory from
1375 which the third party logistics provider originates does not
1376 require a license to operate as a third party logistics
1377 provider, the third party logistics provider must be licensed as
1378 a third party logistics provider as required by the federal act.
1379 Each third party logistics provider permittee shall comply with
1380 s. the requirements for wholesale distributors under ss.
1381 499.0121 and 499.01212, with the exception of those wholesale
1382 distributions described in s. 499.01212(3)(a), and other rules
1383 that the department requires.

1384 (r)(g) Health care clinic establishment permit. ~~Effective~~
1385 ~~January 1, 2009,~~ A health care clinic establishment permit is
1386 required for the purchase of a prescription drug by a place of
1387 business at one general physical location that provides health
1388 care or veterinary services, which is owned and operated by a
1389 business entity that has been issued a federal employer tax
1390 identification number. For the purpose of this paragraph, the
1391 term "qualifying practitioner" means a licensed health care
1392 practitioner defined in s. 456.001, or a veterinarian licensed

20161604e1

1393 under chapter 474, who is authorized under the appropriate
1394 practice act to prescribe and administer a prescription drug.

1395 1. An establishment must provide, as part of the
1396 application required under s. 499.012, designation of a
1397 qualifying practitioner who will be responsible for complying
1398 with all legal and regulatory requirements related to the
1399 purchase, recordkeeping, storage, and handling of the
1400 prescription drugs. In addition, the designated qualifying
1401 practitioner shall be the practitioner whose name, establishment
1402 address, and license number is used on all distribution
1403 documents for prescription drugs purchased or returned by the
1404 health care clinic establishment. Upon initial appointment of a
1405 qualifying practitioner, the qualifying practitioner and the
1406 health care clinic establishment shall notify the department on
1407 a form furnished by the department within 10 days after such
1408 employment. In addition, the qualifying practitioner and health
1409 care clinic establishment shall notify the department within 10
1410 days after any subsequent change.

1411 2. The health care clinic establishment must employ a
1412 qualifying practitioner at each establishment.

1413 3. In addition to the remedies and penalties provided in
1414 this part, a violation of this chapter by the health care clinic
1415 establishment or qualifying practitioner constitutes grounds for
1416 discipline of the qualifying practitioner by the appropriate
1417 regulatory board.

1418 4. The purchase of prescription drugs by the health care
1419 clinic establishment is prohibited during any period of time
1420 when the establishment does not comply with this paragraph.

1421 5. A health care clinic establishment permit is not a

20161604e1

1422 pharmacy permit or otherwise subject to chapter 465. A health
1423 care clinic establishment that meets the criteria of a modified
1424 Class II institutional pharmacy under s. 465.019 is not eligible
1425 to be permitted under this paragraph.

1426 6. This paragraph does not apply to the purchase of a
1427 prescription drug by a licensed practitioner under his or her
1428 license.

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

20161604e1

1451 ~~purposes of this exemption.~~ The failure to comply with the
1452 requirements of this subsection, or rules adopted by the
1453 department to administer this subsection, for the purchase of
1454 prescription drug active pharmaceutical ingredients is a
1455 violation of s. 499.005(14), and a knowing failure is a
1456 violation of s. 499.0051(3) ~~499.0051(4)~~.

1457 (a) The immediate package or container of a prescription
1458 drug active pharmaceutical ingredient distributed into the state
1459 that is intended for research and development under this
1460 subsection shall bear a label prominently displaying the
1461 statement: "Caution: Research and Development Only—Not for
1462 Manufacturing, Compounding, or Resale."

1463 (b) A prescription drug manufacturer that obtains a
1464 prescription drug active pharmaceutical ingredient under this
1465 subsection for use in clinical trials and or biostudies
1466 authorized and regulated by federal law must create and maintain
1467 records detailing the specific clinical trials or biostudies for
1468 which the prescription drug active pharmaceutical ingredient was
1469 obtained.

1470 (4) (a) A permit issued under this part is not required to
1471 distribute a prescription drug active pharmaceutical ingredient
1472 from an establishment located in the United States to an
1473 establishment located in this state permitted as a prescription
1474 drug manufacturer under this part for use by the recipient in
1475 preparing, deriving, processing, producing, or fabricating a
1476 prescription drug finished dosage form at the establishment in
1477 this state where the product is received under an approved and
1478 otherwise valid New Drug Approval Application, Abbreviated New
1479 Drug Application, New Animal Drug Application, or Therapeutic

20161604e1

1480 Biologic Application, provided that the application, active
1481 pharmaceutical ingredient, or finished dosage form has not been
1482 withdrawn or removed from the market in this country for public
1483 health reasons.

1484 1. Any distributor claiming exemption from permitting
1485 requirements pursuant to this paragraph shall maintain a
1486 license, permit, or registration to engage in the wholesale
1487 distribution of prescription drugs under the laws of the state
1488 from which the product is distributed. If the state from which
1489 the prescription drugs are distributed does not require a
1490 license to engage in the wholesale distribution of prescription
1491 drugs, the distributor must be licensed as a wholesale
1492 distributor as required by the federal act.

1493 2. Any distributor claiming exemption from permitting
1494 requirements pursuant to this paragraph and the prescription
1495 drug manufacturer purchasing and receiving the active
1496 pharmaceutical ingredient shall comply with the recordkeeping
1497 requirements of s. 499.0121(6), ~~but not the requirements of s.~~
1498 ~~499.01212.~~

1499 (b) A permit issued under this part is not required to
1500 distribute ~~limited quantities of~~ a prescription drug that has
1501 not been repackaged from an establishment located in the United
1502 States to an establishment located in this state permitted as a
1503 prescription drug manufacturer under this part for research and
1504 development or to a holder of a letter of exemption issued by
1505 the department under s. 499.03(4) for research, teaching, or
1506 testing. ~~The department shall define "limited quantities" by~~
1507 ~~rule and may include the allowable number of transactions within~~
1508 ~~a given period of time and the amounts of prescription drugs~~

20161604e1

1509 ~~distributed into the state for purposes of this exemption.~~

1510 1. Any distributor claiming exemption from permitting
1511 requirements pursuant to this paragraph shall maintain a
1512 license, permit, or registration to engage in the wholesale
1513 distribution of prescription drugs under the laws of the state
1514 from which the product is distributed. If the state from which
1515 the prescription drugs are distributed does not require a
1516 license to engage in the wholesale distribution of prescription
1517 drugs, the distributor must be licensed as a wholesale
1518 distributor as required by the federal act.

1519 2. All purchasers and recipients of any prescription drugs
1520 distributed pursuant to this paragraph shall ensure that the
1521 products are not resold or used, directly or indirectly, on
1522 humans except in lawful clinical trials and biostudies
1523 authorized and regulated by federal law.

1524 3. Any distributor claiming exemption from permitting
1525 requirements pursuant to this paragraph, and the purchaser and
1526 recipient of the prescription drug, shall comply with the
1527 recordkeeping requirements of s. 499.0121(6), ~~but not the~~
1528 ~~requirements of s. 499.01212.~~

1529 4. The immediate package or container of any active
1530 pharmaceutical ingredient distributed into the state that is
1531 intended for teaching, testing, research, and development shall
1532 bear a label prominently displaying the statement: "Caution:
1533 Research, Teaching, or Testing Only - Not for Manufacturing,
1534 Compounding, or Resale."

1535 (c) An out-of-state prescription drug wholesale distributor
1536 permit is not required for an intracompany sale or transfer of a
1537 prescription drug from an out-of-state establishment that is

20161604e1

1538 duly licensed as a prescription drug wholesale distributor in
1539 its state of residence to a licensed prescription drug wholesale
1540 distributor in this state, if both wholesale distributors
1541 conduct wholesale distributions of prescription drugs under the
1542 same business name. The recordkeeping requirements of s. ss.
1543 499.0121(6) ~~and 499.01212~~ must be followed for such
1544 transactions.

1545 (d) Persons receiving prescription drugs from a source
1546 claimed to be exempt from permitting requirements under this
1547 subsection shall maintain on file:

1548 1. A record of the FDA establishment registration number,
1549 if any;

1550 2. The resident state or federal license, registration, or
1551 permit that authorizes the source to distribute prescription
1552 drugs ~~drug wholesale distribution license, permit, or~~
1553 ~~registration number~~; and

1554 3. A copy of the most recent resident state or FDA
1555 inspection report, for all distributors and establishments from
1556 whom they purchase or receive prescription drugs under this
1557 subsection.

1558 (e) All persons claiming exemption from permitting
1559 requirements pursuant to this subsection who engage in the
1560 distribution of prescription drugs within or into the state are
1561 subject to this part, including ss. 499.005 and 499.0051, and
1562 shall make available, within 48 hours, to the department on
1563 request all records related to any prescription drugs
1564 distributed under this subsection, including those records
1565 described in s. 499.051(4), regardless of the location where the
1566 records are stored.

20161604e1

1567 (f) A person purchasing and receiving a prescription drug
1568 from a person claimed to be exempt from licensing requirements
1569 pursuant to this subsection shall report to the department in
1570 writing within 14 days after receiving any product that is
1571 misbranded or adulterated or that fails to meet minimum
1572 standards set forth in the official compendium or state or
1573 federal good manufacturing practices for identity, purity,
1574 potency, or sterility, regardless of whether the product is
1575 thereafter rehabilitated, quarantined, returned, or destroyed.

1576 (g) The department may adopt rules to administer this
1577 subsection which are necessary for the protection of the public
1578 health, safety, and welfare. Failure to comply with the
1579 requirements of this subsection, or rules adopted by the
1580 department to administer this subsection, is a violation of s.
1581 499.005(14), and a knowing failure is a violation of s.
1582 499.0051(3) ~~499.0051(4)~~.

1583 (h) This subsection does not relieve any person from any
1584 requirement prescribed by law with respect to controlled
1585 substances as defined in the applicable federal and state laws.

1586 (5) A prescription drug repackager permit issued under this
1587 part is not required for a restricted prescription drug
1588 distributor permitholder that is a health care entity to
1589 repackage prescription drugs in this state for its own use or
1590 for distribution to hospitals or other health care entities in
1591 the state for their own use, pursuant to s. 499.003(48)(a)3.
1592 ~~499.003(53)(a)3~~, if:

1593 (a) The prescription drug distributor notifies the
1594 department, in writing, of its intention to engage in
1595 repackaging under this exemption, 30 days before engaging in the

20161604e1

1596 repackaging of prescription drugs at the permitted
1597 establishment;

1598 (b) The prescription drug distributor is under common
1599 control with the hospitals or other health care entities to
1600 which the prescription drug distributor is distributing
1601 prescription drugs. As used in this paragraph, "common control"
1602 means the power to direct or cause the direction of the
1603 management and policies of a person or an organization, whether
1604 by ownership of stock, voting rights, contract, or otherwise;

1605 (c) The prescription drug distributor repackages the
1606 prescription drugs in accordance with current state and federal
1607 good manufacturing practices; and

1608 (d) The prescription drug distributor labels the
1609 prescription drug it repackages in accordance with state and
1610 federal laws and rules.

1611
1612 The prescription drug distributor is exempt from the product
1613 registration requirements of s. 499.015 with regard to the
1614 prescription drugs that it repackages and distributes under this
1615 subsection. A prescription drug distributor that repackages and
1616 distributes prescription drugs under this subsection to a not-
1617 for-profit rural hospital, as defined in s. 395.602, is not
1618 required to comply with paragraph (c) or paragraph (d), but must
1619 provide to each health care entity for which it repackages, for
1620 each prescription drug that is repackaged and distributed, the
1621 information required by department rule for labeling
1622 prescription drugs. The department shall adopt rules to ensure
1623 the safety and integrity of prescription drugs repackaged and
1624 distributed under this subsection, including rules regarding

20161604e1

1625 prescription drug manufacturing and labeling requirements.

1626 Section 6. Section 499.012, Florida Statutes, is amended to
1627 read:

1628 499.012 Permit application requirements.—

1629 (1) (a) A permit issued pursuant to this part may be issued
1630 only to a natural person who is at least 18 years of age or to
1631 an applicant that is not a natural person if each person who,
1632 directly or indirectly, manages, controls, or oversees the
1633 operation of that applicant is at least 18 years of age.

1634 (b) An establishment that is a place of residence may not
1635 receive a permit and may not operate under this part.

1636 (c) A person that applies for or renews a permit to
1637 manufacture or distribute prescription drugs may not use a name
1638 identical to the name used by any other establishment or
1639 licensed person authorized to purchase prescription drugs in
1640 this state, except that a restricted drug distributor permit
1641 issued to a health care entity will be issued in the name in
1642 which the institutional pharmacy permit is issued and a retail
1643 pharmacy drug wholesale distributor will be issued a permit in
1644 the name of its retail pharmacy permit.

1645 (d) A permit for a prescription drug manufacturer,
1646 prescription drug repackager, prescription drug wholesale
1647 distributor, limited prescription drug veterinary wholesale
1648 distributor, or retail pharmacy drug wholesale distributor may
1649 not be issued to the address of a health care entity or to a
1650 pharmacy licensed under chapter 465, except as provided in this
1651 paragraph. The department may issue a prescription drug
1652 manufacturer permit to an applicant at the same address as a
1653 licensed nuclear pharmacy, which is a health care entity, even

20161604e1

1654 if the nuclear pharmacy holds a special sterile compounding
1655 permit under chapter 465, for the purpose of manufacturing
1656 prescription drugs used in positron emission tomography or other
1657 radiopharmaceuticals, as listed in a rule adopted by the
1658 department pursuant to this paragraph. The purpose of this
1659 exemption is to assure availability of state-of-the-art
1660 pharmaceuticals that would pose a significant danger to the
1661 public health if manufactured at a separate establishment
1662 address from the nuclear pharmacy from which the prescription
1663 drugs are dispensed. The department may also issue a retail
1664 pharmacy drug wholesale distributor permit to the address of a
1665 community pharmacy licensed under chapter 465, even if the
1666 community pharmacy holds a special sterile compounding permit
1667 under chapter 465, as long as the community pharmacy ~~which~~ does
1668 not meet the definition of a closed pharmacy in s. 499.003.

1669 (e) A county or municipality may not issue an occupational
1670 license for ~~any licensing period beginning on or after October~~
1671 ~~1, 2003, for~~ any establishment that requires a permit pursuant
1672 to this part, unless the establishment exhibits a current permit
1673 issued by the department for the establishment. Upon
1674 presentation of the requisite permit issued by the department,
1675 an occupational license may be issued by the municipality or
1676 county in which application is made. The department shall
1677 furnish to local agencies responsible for issuing occupational
1678 licenses a current list of all establishments licensed pursuant
1679 to this part.

1680 (2) Notwithstanding subsection (6), a permitted person in
1681 good standing may change the type of permit issued to that
1682 person by completing a new application for the requested permit,

20161604e1

1683 paying the amount of the difference in the permit fees if the
1684 fee for the new permit is more than the fee for the original
1685 permit, and meeting the applicable permitting conditions for the
1686 new permit type. The new permit expires on the expiration date
1687 of the original permit being changed; however, a new permit for
1688 a prescription drug wholesale distributor, an out-of-state
1689 prescription drug wholesale distributor, or a retail pharmacy
1690 drug wholesale distributor shall expire on the expiration date
1691 of the original permit or 1 year after the date of issuance of
1692 the new permit, whichever is earlier. A refund may not be issued
1693 if the fee for the new permit is less than the fee that was paid
1694 for the original permit.

1695 (3) (a) A written application for a permit or to renew a
1696 permit must be filed with the department on forms furnished by
1697 the department. The department shall establish, by rule, the
1698 form and content of the application to obtain or renew a permit.
1699 The applicant must submit to the department with the application
1700 a statement that swears or affirms that the information is true
1701 and correct.

1702 (b) Upon a determination that 2 years have elapsed since
1703 the department notified an applicant for permit, certification,
1704 or product registration of a deficiency in the application and
1705 that the applicant has failed to cure the deficiency, the
1706 application shall expire. The determination regarding the 2-year
1707 lapse of time shall be based on documentation that the
1708 department notified the applicant of the deficiency in
1709 accordance with s. 120.60.

1710 (c) Information submitted by an applicant on an application
1711 required pursuant to this subsection which is a trade secret, as

20161604e1

1712 defined in s. 812.081, shall be maintained by the department as
1713 trade secret information pursuant to s. 499.051(7).

1714 (4) (a) Except for a permit for a prescription drug
1715 wholesale distributor or an out-of-state prescription drug
1716 wholesale distributor, an application for a permit must include:

1717 1. The name, full business address, and telephone number of
1718 the applicant;

1719 2. All trade or business names used by the applicant;

1720 3. The address, telephone numbers, and the names of contact
1721 persons for each facility used by the applicant for the storage,
1722 handling, and distribution of prescription drugs;

1723 4. The type of ownership or operation, such as a
1724 partnership, corporation, or sole proprietorship; and

1725 5. The names of the owner and the operator of the
1726 establishment, including:

1727 a. If an individual, the name of the individual;

1728 b. If a partnership, the name of each partner and the name
1729 of the partnership;

1730 c. If a corporation, the name and title of each corporate
1731 officer and director, the corporate names, and the name of the
1732 state of incorporation;

1733 d. If a sole proprietorship, the full name of the sole
1734 proprietor and the name of the business entity;

1735 e. If a limited liability company, the name of each member,
1736 the name of each manager, the name of the limited liability
1737 company, and the name of the state in which the limited
1738 liability company was organized; and

1739 f. Any other relevant information that the department
1740 requires.

20161604e1

1741 (b) Upon approval of the application by the department and
1742 payment of the required fee, the department shall issue a permit
1743 to the applicant, if the applicant meets the requirements of
1744 this part and rules adopted under this part.

1745 (c) Any change in information required under paragraph (a)
1746 must be submitted to the department before the change occurs.

1747 (d) The department shall consider, at a minimum, the
1748 following factors in reviewing the qualifications of persons to
1749 be permitted under this part:

1750 1. The applicant's having been found guilty, regardless of
1751 adjudication, in a court of this state or other jurisdiction, of
1752 a violation of a law that directly relates to a drug, device, or
1753 cosmetic. A plea of nolo contendere constitutes a finding of
1754 guilt for purposes of this subparagraph.

1755 2. The applicant's having been disciplined by a regulatory
1756 agency in any state for any offense that would constitute a
1757 violation of this part.

1758 3. Any felony conviction of the applicant under a federal,
1759 state, or local law;

1760 4. The applicant's past experience in manufacturing or
1761 distributing drugs, devices, or cosmetics;

1762 5. The furnishing by the applicant of false or fraudulent
1763 material in any application made in connection with
1764 manufacturing or distributing drugs, devices, or cosmetics;

1765 6. Suspension or revocation by a federal, state, or local
1766 government of any permit currently or previously held by the
1767 applicant for the manufacture or distribution of any drugs,
1768 devices, or cosmetics;

1769 7. Compliance with permitting requirements under any

20161604e1

1770 previously granted permits;

1771 8. Compliance with requirements to maintain or make
1772 available to the state permitting authority or to federal,
1773 state, or local law enforcement officials those records required
1774 under this section; and

1775 9. Any other factors or qualifications the department
1776 considers relevant to and consistent with the public health and
1777 safety.

1778 (5) ~~Except for a permit for a prescription drug wholesale~~
1779 ~~distributor or an out-of-state prescription drug wholesale~~
1780 ~~distributor:~~

1781 (a) The department shall adopt rules for the biennial
1782 renewal of permits; however, the department may issue up to a 4-
1783 year permit to selected permittees notwithstanding any other
1784 provision of law. Fees for such renewal may not exceed the fee
1785 caps set forth in s. 499.041 on an annualized basis as
1786 authorized by law.

1787 (b) The department shall renew a permit upon receipt of the
1788 renewal application and renewal fee if the applicant meets the
1789 requirements established under this part and ~~the~~ rules adopted
1790 under this part.

1791 (c) At least 90 days before the expiration date of a
1792 permit, the department shall forward a permit renewal
1793 notification to the permittee at the mailing address of the
1794 permitted establishment on file with the department. The permit
1795 renewal notification must state conspicuously the date on which
1796 the permit for the establishment will expire and that the
1797 establishment may not operate unless the permit for the
1798 establishment is renewed timely. ~~A permit, unless sooner~~

20161604e1

1799 ~~suspended or revoked, automatically expires 2 years after the~~
1800 ~~last day of the anniversary month in which the permit was~~
1801 ~~originally issued.~~

1802 (d) A permit issued under this part may be renewed by
1803 making application for renewal on forms furnished by the
1804 department and paying the appropriate fees.

1805 1. If a prescription drug wholesale distributor or an out-
1806 of-state prescription drug wholesale distributor renewal
1807 application and fee are submitted and postmarked later than 45
1808 days before the expiration date of the permit, the permit may be
1809 renewed only upon payment of a late renewal fee of \$100, plus
1810 the required renewal fee.

1811 2. If any other a renewal application and fee are submitted
1812 and postmarked after the expiration date of the permit, the
1813 permit may be renewed only upon payment of a late renewal
1814 delinquent fee of \$100, plus the required renewal fee, not later
1815 than 60 days after the expiration date.

1816 3. A permittee who submits a renewal application in
1817 accordance with this paragraph may continue to operate under its
1818 permit, unless the permit is suspended or revoked, until final
1819 disposition of the renewal application.

1820 4.~~(d)~~ Failure to renew a permit in accordance with this
1821 section precludes any future renewal of that permit. If a permit
1822 issued pursuant to this part has expired and cannot be renewed,
1823 before an establishment may engage in activities that require a
1824 permit under this part, the establishment must submit an
1825 application for a new permit, pay the applicable application
1826 fee, the initial permit fee, and all applicable penalties, and
1827 be issued a new permit by the department.

20161604e1

1828 (6) A permit issued by the department is nontransferable.
1829 Each permit is valid only for the person or governmental unit to
1830 which it is issued and is not subject to sale, assignment, or
1831 other transfer, voluntarily or involuntarily; nor is a permit
1832 valid for any establishment other than the establishment for
1833 which it was originally issued.

1834 (a) A person permitted under this part must notify the
1835 department before making a change of address. The department
1836 shall set a change of location fee not to exceed \$100.

1837 (b)1. An application for a new permit is required when a
1838 majority of the ownership or controlling interest of a permitted
1839 establishment is transferred or assigned or when a lessee agrees
1840 to undertake or provide services to the extent that legal
1841 liability for operation of the establishment will rest with the
1842 lessee. The application for the new permit must be made before
1843 the date of the sale, transfer, assignment, or lease.

1844 2. A permittee that is authorized to distribute
1845 prescription drugs may transfer such drugs to the new owner or
1846 lessee under subparagraph 1. only after the new owner or lessee
1847 has been approved for a permit to distribute prescription drugs.

1848 (c) If an establishment permitted under this part closes,
1849 the owner must notify the department in writing before the
1850 effective date of closure and must:

1851 1. Return the permit to the department;

1852 2. If the permittee is authorized to distribute
1853 prescription drugs, indicate the disposition of such drugs,
1854 including the name, address, and inventory, and provide the name
1855 and address of a person to contact regarding access to records
1856 that are required to be maintained under this part. Transfer of

20161604e1

1857 ownership of prescription drugs may be made only to persons
1858 authorized to possess prescription drugs under this part.

1859

1860 The department may revoke the permit of any person that fails to
1861 comply with the requirements of this subsection.

1862 (7) A permit must be posted in a conspicuous place on the
1863 licensed premises.

1864 (8) An application for a permit or to renew a permit for a
1865 prescription drug wholesale distributor or an out-of-state
1866 prescription drug wholesale distributor submitted to the
1867 department must include:

1868 (a) The name, full business address, and telephone number
1869 of the applicant.

1870 (b) All trade or business names used by the applicant.

1871 (c) The address, telephone numbers, and the names of
1872 contact persons for each facility used by the applicant for the
1873 storage, handling, and distribution of prescription drugs.

1874 (d) The type of ownership or operation, such as a
1875 partnership, corporation, or sole proprietorship.

1876 (e) The names of the owner and the operator of the
1877 establishment, including:

1878 1. If an individual, the name of the individual.

1879 2. If a partnership, the name of each partner and the name
1880 of the partnership.

1881 3. If a corporation:

1882 a. The name, address, and title of each corporate officer
1883 and director.

1884 b. The name and address of the corporation, resident agent
1885 of the corporation, the resident agent's address, and the

20161604e1

1886 corporation's state of incorporation.

1887 c. The name and address of each shareholder of the
1888 corporation that owns 5 percent or more of the outstanding stock
1889 of the corporation.

1890 4. If a sole proprietorship, the full name of the sole
1891 proprietor and the name of the business entity.

1892 5. If a limited liability company:

1893 a. The name and address of each member.

1894 b. The name and address of each manager.

1895 c. The name and address of the limited liability company,
1896 the resident agent of the limited liability company, and the
1897 name of the state in which the limited liability company was
1898 organized.

1899 (f) If applicable, the name and address of each affiliate
1900 ~~of member of the affiliated group of which the applicant is a~~
1901 ~~member.~~

1902 (g) ~~1. The applicant's gross annual receipts attributable to~~
1903 ~~prescription drug wholesale distribution activities for the~~
1904 ~~previous tax year. For an application for a new permit, the~~
1905 ~~estimated annual dollar volume of prescription drug sales of the~~
1906 ~~applicant, the estimated annual percentage of the applicant's~~
1907 ~~total company sales that are prescription drugs, the applicant's~~
1908 ~~estimated annual total dollar volume of purchases of~~
1909 ~~prescription drugs, and the applicant's estimated annual total~~
1910 ~~dollar volume of prescription drug purchases directly from~~
1911 ~~manufacturers.~~

1912 2. ~~For an application to renew a permit, the total dollar~~
1913 ~~volume of prescription drug sales in the previous year, the~~
1914 ~~total dollar volume of prescription drug sales made in the~~

20161604e1

1915 ~~previous 6 months, the percentage of total company sales that~~
1916 ~~were prescription drugs in the previous year, the total dollar~~
1917 ~~volume of purchases of prescription drugs in the previous year,~~
1918 ~~and the total dollar volume of prescription drug purchases~~
1919 ~~directly from manufacturers in the previous year.~~

1920
1921 ~~Such portions of the information required pursuant to this~~
1922 ~~paragraph which are a trade secret, as defined in s. 812.081,~~
1923 ~~shall be maintained by the department as trade secret~~
1924 ~~information is required to be maintained under s. 499.051.~~

1925 (h) The tax year of the applicant.

1926 (i) A copy of the deed for the property on which
1927 applicant's establishment is located, if the establishment is
1928 owned by the applicant, or a copy of the applicant's lease for
1929 the property on which applicant's establishment is located that
1930 has an original term of not less than 1 calendar year, if the
1931 establishment is not owned by the applicant.

1932 (j) A list of all licenses and permits issued to the
1933 applicant by any other state which authorize the applicant to
1934 purchase or possess prescription drugs.

1935 (k) The name of the manager of the establishment that is
1936 applying for the permit or to renew the permit, the next four
1937 highest ranking employees responsible for prescription drug
1938 wholesale operations for the establishment, and the name of all
1939 affiliated parties for the establishment, together with the
1940 personal information statement and fingerprints required
1941 pursuant to subsection (9) for each of such persons.

1942 (l) The name of each of the applicant's designated
1943 representatives as required by subsection (15) ~~(16)~~, together

20161604e1

1944 with the personal information statement and fingerprints
1945 required pursuant to subsection (9) for each such person.

1946 (m) Evidence of a surety bond in this state or any other
1947 state in the United States in the amount of \$100,000. If the
1948 annual gross receipts of the applicant's previous tax year is
1949 \$10 million or less, evidence of a surety bond in the amount of
1950 \$25,000. The specific language of the surety bond must include
1951 the State of Florida as a beneficiary, payable to the
1952 Professional Regulation Trust Fund. In lieu of the surety bond,
1953 the applicant may provide other equivalent security such as an
1954 irrevocable letter of credit, or a deposit in a trust account or
1955 financial institution, which includes the State of Florida as a
1956 beneficiary, payable to the Professional Regulation Trust Fund.
1957 The purpose of the bond or other security is to secure payment
1958 of any administrative penalties imposed by the department and
1959 any fees and costs incurred by the department regarding that
1960 permit which are authorized under state law and which the
1961 permittee fails to pay 30 days after the fine or costs become
1962 final. The department may make a claim against such bond or
1963 security until 1 year after the permittee's license ceases to be
1964 valid or until 60 days after any administrative or legal
1965 proceeding authorized in this part which involves the permittee
1966 is concluded, including any appeal, whichever occurs later. For
1967 an applicant that is a secondary wholesale distributor, each of
1968 the following:

1969 1. ~~A personal background information statement containing~~
1970 ~~the background information and fingerprints required pursuant to~~
1971 ~~subsection (9) for each person named in the applicant's response~~
1972 ~~to paragraphs (k) and (l) and for each affiliated party of the~~

20161604e1

1973 applicant.

1974 ~~2. If any of the five largest shareholders of the~~
1975 ~~corporation seeking the permit is a corporation, the name,~~
1976 ~~address, and title of each corporate officer and director of~~
1977 ~~each such corporation; the name and address of such corporation;~~
1978 ~~the name of such corporation's resident agent, such~~
1979 ~~corporation's resident agent's address, and such corporation's~~
1980 ~~state of its incorporation; and the name and address of each~~
1981 ~~shareholder of such corporation that owns 5 percent or more of~~
1982 ~~the stock of such corporation.~~

1983 ~~3. The name and address of all financial institutions in~~
1984 ~~which the applicant has an account which is used to pay for the~~
1985 ~~operation of the establishment or to pay for drugs purchased for~~
1986 ~~the establishment, together with the names of all persons that~~
1987 ~~are authorized signatories on such accounts. The portions of the~~
1988 ~~information required pursuant to this subparagraph which are a~~
1989 ~~trade secret, as defined in s. 812.081, shall be maintained by~~
1990 ~~the department as trade secret information is required to be~~
1991 ~~maintained under s. 499.051.~~

1992 ~~4. The sources of all funds and the amounts of such funds~~
1993 ~~used to purchase or finance purchases of prescription drugs or~~
1994 ~~to finance the premises on which the establishment is to be~~
1995 ~~located.~~

1996 ~~5. If any of the funds identified in subparagraph 4. were~~
1997 ~~borrowed, copies of all promissory notes or loans used to obtain~~
1998 ~~such funds.~~

1999 (n) For establishments used in wholesale distribution,
2000 proof of an inspection conducted by the department, the United
2001 States Food and Drug Administration, or another governmental

20161604e1

2002 entity charged with the regulation of good manufacturing
2003 practices related to wholesale distribution of prescription
2004 drugs, within timeframes set forth by the department in
2005 departmental rules, which demonstrates substantial compliance
2006 with current good manufacturing practices applicable to
2007 wholesale distribution of prescription drugs. The department may
2008 recognize another state's inspection of a wholesale distributor
2009 located in that state if such state's laws are deemed to be
2010 substantially equivalent to the law of this state by the
2011 department. The department may accept an inspection by a third-
2012 party accreditation or inspection service which meets the
2013 criteria set forth in department rule.

2014 (o) ~~(n)~~ Any other relevant information that the department
2015 requires, including, but not limited to, any information related
2016 to whether the applicant satisfies the definition of a primary
2017 wholesale distributor or a secondary wholesale distributor.

2018 (p) ~~(e)~~ Documentation of the credentialing policies and
2019 procedures required by s. 499.0121(15).

2020 (9) (a) Each person required by subsection (8) or subsection
2021 (15) to provide a personal information statement and
2022 fingerprints shall provide the following information to the
2023 department on forms prescribed by the department:

- 2024 1. The person's places of residence for the past 7 years.
- 2025 2. The person's date and place of birth.
- 2026 3. The person's occupations, positions of employment, and
2027 offices held during the past 7 years.
- 2028 4. The principal business and address of any business,
2029 corporation, or other organization in which each such office of
2030 the person was held or in which each such occupation or position

20161604e1

2031 of employment was carried on.

2032 5. Whether the person has been, during the past 7 years,
2033 the subject of any proceeding for the revocation of any license
2034 and, if so, the nature of the proceeding and the disposition of
2035 the proceeding.

2036 6. Whether, during the past 7 years, the person has been
2037 enjoined, temporarily or permanently, by a court of competent
2038 jurisdiction from violating any federal or state law regulating
2039 the possession, control, or distribution of prescription drugs,
2040 together with details concerning any such event.

2041 7. A description of any involvement by the person with any
2042 business, including any investments, other than the ownership of
2043 stock in a publicly traded company or mutual fund, during the
2044 past 4 7 years, which manufactured, administered, prescribed,
2045 distributed, or stored pharmaceutical products and any lawsuits
2046 in which such businesses were named as a party.

2047 8. A description of any felony criminal offense of which
2048 the person, as an adult, was found guilty, regardless of whether
2049 adjudication of guilt was withheld or whether the person pled
2050 guilty or nolo contendere. A criminal offense committed in
2051 another jurisdiction which would have been a felony in this
2052 state must be reported. If the person indicates that a criminal
2053 conviction is under appeal and submits a copy of the notice of
2054 appeal of that criminal offense, the applicant must, within 15
2055 days after the disposition of the appeal, submit to the
2056 department a copy of the final written order of disposition.

2057 9. A photograph of the person taken in the previous 180 ~~30~~
2058 days.

2059 10. A set of fingerprints for the person on a form and

20161604e1

2060 under procedures specified by the department, together with
2061 payment of an amount equal to the costs incurred by the
2062 department for the criminal record check of the person.

2063 11. The name, address, occupation, and date and place of
2064 birth for each member of the person's immediate family who is 18
2065 years of age or older. As used in this subparagraph, the term
2066 "member of the person's immediate family" includes the person's
2067 spouse, children, parents, siblings, the spouses of the person's
2068 children, and the spouses of the person's siblings.

2069 12. Any other relevant information that the department
2070 requires.

2071 (b) The information required pursuant to paragraph (a)
2072 shall be provided under oath.

2073 (c) The department shall submit the fingerprints provided
2074 by a person for initial licensure to the Department of Law
2075 Enforcement for a statewide criminal record check and for
2076 forwarding to the Federal Bureau of Investigation for a national
2077 criminal record check of the person. The department shall submit
2078 the fingerprints provided by a person as a part of a renewal
2079 application to the Department of Law Enforcement for a statewide
2080 criminal record check, and for forwarding to the Federal Bureau
2081 of Investigation for a national criminal record check, for the
2082 initial renewal of a permit after January 1, 2004; for any
2083 subsequent renewal of a permit, the department shall submit the
2084 required information for a statewide and national criminal
2085 record check of the person. Any person who as a part of an
2086 initial permit application or initial permit renewal after
2087 January 1, 2004, submits to the department a set of fingerprints
2088 required for the criminal record check required in this

20161604e1

2089 paragraph are ~~shall~~ not ~~be~~ required to provide a subsequent set
2090 of fingerprints for a criminal record check to the department,
2091 if the person has undergone a criminal record check as a
2092 condition of the issuance of an initial permit or the initial
2093 renewal of a permit of an applicant after January 1, 2004. The
2094 department is authorized to contract with private vendors, or
2095 enter into interagency agreements, to collect electronic
2096 fingerprints where fingerprints are required for registration,
2097 certification, or the licensure process or where criminal
2098 history record checks are required.

2099 (d) For purposes of applying for renewal of a permit under
2100 subsection (8) or certification under subsection (16), a person
2101 may submit the following in lieu of satisfying the requirements
2102 of paragraphs (a), (b), and (c):

2103 1. A photograph of the individual taken within 180 days;
2104 and

2105 2. A copy of the personal information statement form most
2106 recently submitted to the department and a certification under
2107 oath, on a form specified by the department, that the individual
2108 has reviewed the previously submitted personal information
2109 statement form and that the information contained therein
2110 remains unchanged.

2111 (10) The department may deny an application for a permit or
2112 refuse to renew a permit for a prescription drug wholesale
2113 distributor or an out-of-state prescription drug wholesale
2114 distributor if:

2115 (a) The applicant has not met the requirements for the
2116 permit.

2117 (b) The management, officers, or directors of the applicant

20161604e1

2118 or any affiliated party are found by the department to be
2119 incompetent or untrustworthy.

2120 (c) The applicant is so lacking in experience in managing a
2121 wholesale distributor as to make the issuance of the proposed
2122 permit hazardous to the public health.

2123 (d) The applicant is so lacking in experience in managing a
2124 wholesale distributor as to jeopardize the reasonable promise of
2125 successful operation of the wholesale distributor.

2126 (e) The applicant is lacking in experience in the
2127 distribution of prescription drugs.

2128 (f) The applicant's past experience in manufacturing or
2129 distributing prescription drugs indicates that the applicant
2130 poses a public health risk.

2131 (g) The applicant is affiliated directly or indirectly
2132 through ownership, control, or other business relations, with
2133 any person or persons whose business operations are or have been
2134 detrimental to the public health.

2135 (h) The applicant, or any affiliated party, has been found
2136 guilty of or has pleaded guilty or nolo contendere to any felony
2137 or crime punishable by imprisonment for 1 year or more under the
2138 laws of the United States, any state, or any other country,
2139 regardless of whether adjudication of guilt was withheld.

2140 (i) The applicant or any affiliated party has been charged
2141 with a felony in a state or federal court and the disposition of
2142 that charge is pending during the application review or renewal
2143 review period.

2144 (j) The applicant has furnished false or fraudulent
2145 information or material in any application made in this state or
2146 any other state in connection with obtaining a permit or license

20161604e1

2147 to manufacture or distribute drugs, devices, or cosmetics.

2148 (k) That a federal, state, or local government permit
2149 currently or previously held by the applicant, or any affiliated
2150 party, for the manufacture or distribution of any drugs,
2151 devices, or cosmetics has been disciplined, suspended, or
2152 revoked and has not been reinstated.

2153 (l) The applicant does not possess the financial or
2154 physical resources to operate in compliance with the permit
2155 being sought, this chapter, and the rules adopted under this
2156 chapter.

2157 (m) The applicant or any affiliated party receives,
2158 directly or indirectly, financial support and assistance from a
2159 person who was an affiliated party of a permittee whose permit
2160 was subject to discipline or was suspended or revoked, other
2161 than through the ownership of stock in a publicly traded company
2162 or a mutual fund.

2163 (n) The applicant or any affiliated party receives,
2164 directly or indirectly, financial support and assistance from a
2165 person who has been found guilty of any violation of this part
2166 or chapter 465, chapter 501, or chapter 893, any rules adopted
2167 under this part or those chapters, any federal or state drug
2168 law, or any felony where the underlying facts related to drugs,
2169 regardless of whether the person has been pardoned, had her or
2170 his civil rights restored, or had adjudication withheld, other
2171 than through the ownership of stock in a publicly traded company
2172 or a mutual fund.

2173 (o) The applicant for renewal of a permit under s.
2174 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged
2175 in the wholesale distribution of prescription drugs, as

20161604e1

2176 demonstrated by the regular and systematic distribution of
2177 prescription drugs throughout the year as evidenced by not fewer
2178 than 12 wholesale distributions in the previous year and not
2179 fewer than three wholesale distributions in the previous 6
2180 months.

2181 (p) Information obtained in response to s. 499.01(2)(e) or
2182 (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best
2183 interest of the public health, safety, and welfare to issue a
2184 permit.

2185 (q) The applicant does not possess the financial standing
2186 and business experience for the successful operation of the
2187 applicant.

2188 (r) The applicant or any affiliated party has failed to
2189 comply with the requirements for manufacturing or distributing
2190 prescription drugs under this part, similar federal laws,
2191 similar laws in other states, or the rules adopted under such
2192 laws.

2193 (11) Upon approval of the application by the department and
2194 payment of the required fee, the department shall issue or renew
2195 a prescription drug wholesale distributor or an out-of-state
2196 prescription drug wholesale distributor permit to the applicant.

2197 ~~(12) For a permit for a prescription drug wholesale~~
2198 ~~distributor or an out-of-state prescription drug wholesale~~
2199 ~~distributor:~~

2200 ~~(a) The department shall adopt rules for the annual renewal~~
2201 ~~of permits. At least 90 days before the expiration of a permit,~~
2202 ~~the department shall forward a permit renewal notification and~~
2203 ~~renewal application to the prescription drug wholesale~~
2204 ~~distributor or out-of-state prescription drug wholesale~~

20161604e1

2205 ~~distributor at the mailing address of the permitted~~
2206 ~~establishment on file with the department. The permit renewal~~
2207 ~~notification must state conspicuously the date on which the~~
2208 ~~permit for the establishment will expire and that the~~
2209 ~~establishment may not operate unless the permit for the~~
2210 ~~establishment is renewed timely.~~

2211 ~~(b) A permit, unless sooner suspended or revoked,~~
2212 ~~automatically expires 1 year after the last day of the~~
2213 ~~anniversary month in which the permit was originally issued. A~~
2214 ~~permit may be renewed by making application for renewal on forms~~
2215 ~~furnished by the department and paying the appropriate fees. If~~
2216 ~~a renewal application and fee are submitted and postmarked after~~
2217 ~~45 days prior to the expiration date of the permit, the permit~~
2218 ~~may be renewed only upon payment of a late renewal fee of \$100,~~
2219 ~~plus the required renewal fee. A permittee that has submitted a~~
2220 ~~renewal application in accordance with this paragraph may~~
2221 ~~continue to operate under its permit, unless the permit is~~
2222 ~~suspended or revoked, until final disposition of the renewal~~
2223 ~~application.~~

2224 ~~(c) Failure to renew a permit in accordance with this~~
2225 ~~section precludes any future renewal of that permit. If a permit~~
2226 ~~issued pursuant to this section has expired and cannot be~~
2227 ~~renewed, before an establishment may engage in activities that~~
2228 ~~require a permit under this part, the establishment must submit~~
2229 ~~an application for a new permit; pay the applicable application~~
2230 ~~fee, initial permit fee, and all applicable penalties; and be~~
2231 ~~issued a new permit by the department.~~

2232 ~~(12)~~(13) A person that engages in wholesale distribution of
2233 prescription drugs in this state must have a wholesale

20161604e1

2234 distributor's permit issued by the department, except as noted
2235 in this section. Each establishment must be separately permitted
2236 except as noted in this subsection.

2237 (a) A separate establishment permit is not required when a
2238 permitted prescription drug wholesale distributor consigns a
2239 prescription drug to a pharmacy that is permitted under chapter
2240 465 and located in this state, provided that:

2241 1. The consignor wholesale distributor notifies the
2242 department in writing of the contract to consign prescription
2243 drugs to a pharmacy along with the identity and location of each
2244 consignee pharmacy;

2245 2. The pharmacy maintains its permit under chapter 465;

2246 3. The consignor wholesale distributor, which has no legal
2247 authority to dispense prescription drugs, complies with all
2248 wholesale distribution requirements of s. ss. 499.0121 ~~and~~
2249 ~~499.01212~~ with respect to the consigned drugs and maintains
2250 records documenting the transfer of title or other completion of
2251 the wholesale distribution of the consigned prescription drugs;

2252 4. The distribution of the prescription drug is otherwise
2253 lawful under this chapter and other applicable law;

2254 5. Open packages containing prescription drugs within a
2255 pharmacy are the responsibility of the pharmacy, regardless of
2256 how the drugs are titled; and

2257 6. The pharmacy dispenses the consigned prescription drug
2258 in accordance with the limitations of its permit under chapter
2259 465 or returns the consigned prescription drug to the consignor
2260 wholesale distributor. In addition, a person who holds title to
2261 prescription drugs may transfer the drugs to a person permitted
2262 or licensed to handle the reverse distribution or destruction of

20161604e1

2263 drugs. Any other distribution by and means of the consigned
2264 prescription drug by any person, not limited to the consignor
2265 wholesale distributor or consignee pharmacy, to any other person
2266 is prohibited.

2267 (b) A wholesale distributor's permit is not required for
2268 the one-time transfer of title of a pharmacy's lawfully acquired
2269 prescription drug inventory by a pharmacy with a valid permit
2270 issued under chapter 465 to a consignor prescription drug
2271 wholesale distributor, permitted under this chapter, in
2272 accordance with a written consignment agreement between the
2273 pharmacy and that wholesale distributor if the permitted
2274 pharmacy and the permitted prescription drug wholesale
2275 distributor comply with all of the provisions of paragraph (a)
2276 and the prescription drugs continue to be within the permitted
2277 pharmacy's inventory for dispensing in accordance with the
2278 limitations of the pharmacy permit under chapter 465. A
2279 consignor drug wholesale distributor may not use the pharmacy as
2280 a wholesale distributor through which it distributes the
2281 prescription drugs to other pharmacies. Nothing in this section
2282 is intended to prevent a wholesale distributor from obtaining
2283 this inventory in the event of nonpayment by the pharmacy.

2284 (c) A separate establishment permit is not required when a
2285 permitted prescription drug wholesale distributor operates
2286 temporary transit storage facilities for the sole purpose of
2287 storage, for up to 16 hours, of a delivery of prescription drugs
2288 when the wholesale distributor was temporarily unable to
2289 complete the delivery to the recipient.

2290 (d) The department shall require information from each
2291 wholesale distributor as part of the permit and renewal of such

20161604e1

2292 permit, as required under this section.

2293 (13)~~(14)~~ Personnel employed in wholesale distribution must
2294 have appropriate education and experience to enable them to
2295 perform their duties in compliance with state permitting
2296 requirements.

2297 (14)~~(15)~~ The name of a permittee or establishment on a
2298 prescription drug wholesale distributor permit or an out-of-
2299 state prescription drug wholesale distributor permit may not
2300 include any indicia of attainment of any educational degree, any
2301 indicia that the permittee or establishment possesses a
2302 professional license, or any name or abbreviation that the
2303 department determines is likely to cause confusion or mistake or
2304 that the department determines is deceptive, including that of
2305 any other entity authorized to purchase prescription drugs.

2306 (15)~~(16)~~(a) Each establishment that is issued an initial or
2307 renewal permit as a prescription drug wholesale distributor or
2308 an out-of-state prescription drug wholesale distributor must
2309 designate in writing to the department at least one natural
2310 person to serve as the designated representative of the
2311 wholesale distributor. Such person must have an active
2312 certification as a designated representative from the
2313 department.

2314 (b) To be certified as a designated representative, a
2315 natural person must:

2316 1. Submit an application on a form furnished by the
2317 department and pay the appropriate fees.

2318 2. Be at least 18 years of age.

2319 3. Have at least 2 years of verifiable full-time:

2320 a. Work experience in a pharmacy licensed in this state or

20161604e1

2321 another state, where the person's responsibilities included, but
2322 were not limited to, recordkeeping for prescription drugs;

2323 b. Managerial experience with a prescription drug wholesale
2324 distributor licensed in this state or in another state; or

2325 c. Managerial experience with the United States Armed
2326 Forces, where the person's responsibilities included, but were
2327 not limited to, recordkeeping, warehousing, distributing, or
2328 other logistics services pertaining to prescription drugs.

2329 4. Receive a passing score of at least 75 percent on an
2330 examination given by the department regarding federal laws
2331 governing distribution of prescription drugs and this part and
2332 the rules adopted by the department governing the wholesale
2333 distribution of prescription drugs. This requirement shall be
2334 effective 1 year after the results of the initial examination
2335 are mailed to the persons that took the examination. The
2336 department shall offer such examinations at least four times
2337 each calendar year.

2338 5. Provide the department with a personal information
2339 statement and fingerprints pursuant to subsection (9).

2340 (c) The department may deny an application for
2341 certification as a designated representative or may suspend or
2342 revoke a certification of a designated representative pursuant
2343 to s. 499.067.

2344 (d) A designated representative:

2345 1. Must be actively involved in and aware of the actual
2346 daily operation of the wholesale distributor.

2347 2. Must be employed full time in a managerial position by
2348 the wholesale distributor.

2349 3. Must be physically present at the establishment during

20161604e1

2350 normal business hours, except for time periods when absent due
2351 to illness, family illness or death, scheduled vacation, or
2352 other authorized absence.

2353 4. May serve as a designated representative for only one
2354 wholesale distributor at any one time.

2355 (e) A wholesale distributor must notify the department when
2356 a designated representative leaves the employ of the wholesale
2357 distributor. Such notice must be provided to the department
2358 within 10 business days after the last day of designated
2359 representative's employment with the wholesale distributor.

2360 (f) A wholesale distributor may not operate under a
2361 prescription drug wholesale distributor permit or an out-of-
2362 state prescription drug wholesale distributor permit for more
2363 than 10 business days after the designated representative leaves
2364 the employ of the wholesale distributor, unless the wholesale
2365 distributor employs another designated representative and
2366 notifies the department within 10 business days of the identity
2367 of the new designated representative.

2368 Section 7. Section 499.01201, Florida Statutes, is amended
2369 to read:

2370 499.01201 Agency for Health Care Administration review and
2371 use of statute and rule violation or compliance data.—

2372 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~
2373 ~~contrary~~, the Agency for Health Care Administration may not:

2374 (1) Review or use any violation or alleged violation of s.
2375 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that
2376 section ~~these sections~~, as a ground for denying or withholding
2377 any payment of a Medicaid reimbursement to a pharmacy licensed
2378 under chapter 465; or

20161604e1

2379 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~
2380 ~~499.01212~~, or any rules adopted under that section ~~those~~
2381 ~~sections~~, as the subject of any audit of Medicaid-related
2382 records held by a pharmacy licensed under chapter 465.

2383 Section 8. Paragraph (d) of subsection (4), subsection (6),
2384 and paragraph (b) of subsection (15) of section 499.0121,
2385 Florida Statutes, are amended to read:

2386 499.0121 Storage and handling of prescription drugs;
2387 recordkeeping.—The department shall adopt rules to implement
2388 this section as necessary to protect the public health, safety,
2389 and welfare. Such rules shall include, but not be limited to,
2390 requirements for the storage and handling of prescription drugs
2391 and for the establishment and maintenance of prescription drug
2392 distribution records.

2393 (4) EXAMINATION OF MATERIALS AND RECORDS.—

2394 (d) Upon receipt, a wholesale distributor must review
2395 records required under this section for the acquisition of
2396 prescription drugs for accuracy and completeness, considering
2397 the total facts and circumstances surrounding the transactions
2398 and the wholesale distributors involved. ~~This includes~~
2399 ~~authenticating each transaction listed on a pedigree paper, as~~
2400 ~~defined in s. 499.003(37).~~

2401 (6) RECORDKEEPING.—The department shall adopt rules that
2402 require keeping such records of prescription drugs, including
2403 active pharmaceutical ingredients, as are necessary for the
2404 protection of the public health.

2405 (a) The following persons must maintain business records
2406 that include the information specified in paragraph (b)
2407 ~~Wholesale distributors must establish and maintain inventories~~

20161604e1

2408 ~~and records of all transactions regarding the receipt and~~
2409 ~~distribution or other disposition of prescription drugs. These~~
2410 ~~records must provide a complete audit trail from receipt to sale~~
2411 ~~or other disposition, be readily retrievable for inspection, and~~
2412 ~~include, at a minimum, the following information:~~

2413 1. Persons permitted or required to be permitted under
2414 chapter 499 to engage in the manufacture, repackaging, or
2415 distribution of active pharmaceutical ingredients or
2416 prescription drugs. ~~The source of the drugs, including the name~~
2417 ~~and principal address of the seller or transferor, and the~~
2418 ~~address of the location from which the drugs were shipped;~~

2419 2. Persons other than those set forth in subparagraph 1.
2420 that engage in the receipt of active pharmaceutical ingredients
2421 or prescription drugs. ~~The name, principal address, and state~~
2422 ~~license permit or registration number of the person authorized~~
2423 ~~to purchase prescription drugs;~~

2424 3. The name, strength, dosage form, and quantity of the
2425 drugs received and distributed or disposed of;

2426 4. The dates of receipt and distribution or other
2427 disposition of the drugs; and

2428 5. Any financial documentation supporting the transaction.

2429 (b) Business records for persons specified in paragraph (a)
2430 must include:

2431 1. The name and address of the seller, and the Florida
2432 permit number of the seller if such seller is not exempt from
2433 Florida permitting requirements, of the active pharmaceutical
2434 ingredient or prescription drug.

2435 2. The address of the location the active pharmaceutical
2436 ingredient or prescription drug was shipped from.

20161604e1

2437 3. The distribution date of the active pharmaceutical
2438 ingredient or prescription drug.

2439 4. The name, strength, and quantity, and the National Drug
2440 Code if such code has been assigned, of the distributed active
2441 pharmaceutical ingredient or prescription drug.

2442 5. The name and Florida permit number of the person that
2443 purchased the active pharmaceutical ingredient or prescription
2444 drug.

2445 6. The financial data, including the unit type and unit
2446 price, for the distributions involving active pharmaceutical
2447 ingredients or prescription drugs.

2448 7. The date and method of disposition of the active
2449 pharmaceutical ingredient or prescription drug. Inventories and
2450 records must be made available for inspection and photocopying
2451 by authorized federal, state, or local officials for a period of
2452 2 years following disposition of the drugs or 3 years after the
2453 creation of the records, whichever period is longer.

2454 (c) Each manufacturer or repackager of medical devices,
2455 over-the-counter drugs, or cosmetics must maintain business
2456 records that include:

2457 1. The name and address of the seller or transferor of the
2458 product.

2459 2. The address of the location the product was shipped
2460 from.

2461 3. The date of the sale or distribution of the product.

2462 4. The name and quantity of the product involved.

2463 5. The name and address of the person who purchased the
2464 product ~~Records described in this section that are kept at the~~
2465 ~~inspection site or that can be immediately retrieved by computer~~

20161604e1

2466 ~~or other electronic means must be readily available for~~
2467 ~~authorized inspection during the retention period. Records that~~
2468 ~~are kept at a central location outside of this state and that~~
2469 ~~are not electronically retrievable must be made available for~~
2470 ~~inspection within 2 working days after a request by an~~
2471 ~~authorized official of a federal, state, or local law~~
2472 ~~enforcement agency. Records that are maintained at a central~~
2473 ~~location within this state must be maintained at an~~
2474 ~~establishment that is permitted pursuant to this part and must~~
2475 ~~be readily available.~~

2476 (d) Persons permitted, or required to be permitted, under
2477 this chapter to engage in the manufacture, repackaging, or
2478 distribution of active pharmaceutical ingredients or
2479 prescription drugs; or the manufacture or repackaging of medical
2480 devices, over-the-counter drugs, and cosmetics; must establish,
2481 maintain, or have the capability to create a current inventory
2482 of the active pharmaceutical ingredients, prescription drugs,
2483 over-the-counter drugs, cosmetics, and devices at an
2484 establishment where activities specified in this paragraph are
2485 undertaken and must be able to produce such inventory for
2486 inspection by the department within 2 business days ~~Each~~
2487 ~~manufacturer or repackager of medical devices, over-the-counter~~
2488 ~~drugs, or cosmetics must maintain records that include the name~~
2489 ~~and principal address of the seller or transferor of the~~
2490 ~~product, the address of the location from which the product was~~
2491 ~~shipped, the date of the transaction, the name and quantity of~~
2492 ~~the product involved, and the name and principal address of the~~
2493 ~~person who purchased the product.~~

2494 (e) Business records required to be kept pursuant to this

20161604e1

2495 section, and that are kept at the inspection site or can be
2496 immediately retrieved by computer or other electronic means,
2497 must be readily available for authorized inspection during the
2498 retention period. Records kept at a central location outside of
2499 this state which are not electronically retrievable must be made
2500 available for inspection within 2 working days after a request
2501 by an authorized official of a federal, state, or local law
2502 enforcement agency. Records maintained at a central location
2503 within this state must be maintained at an establishment that is
2504 permitted pursuant to this part and such records must be readily
2505 available for inspection ~~When pedigree papers are required by~~
2506 ~~this part, a wholesale distributor must maintain the pedigree~~
2507 ~~papers separate and distinct from other records required under~~
2508 ~~this part.~~

2509 (f) Records required to be kept pursuant to this subsection
2510 must be maintained as specified for a period of not less than 6
2511 years from the date of disposition of the active pharmaceutical
2512 ingredients, prescription drugs, over-the-counter drugs, medical
2513 devices, or cosmetics.

2514 (g) To the extent that prescription drugs are also products
2515 as defined in the federal act, as amended, and the information
2516 required by the business records requirements of this section
2517 are also included in the tracking and tracing requirements of
2518 the federal act, as amended, and departmental rules, the
2519 manufacturer, wholesale distributor, repackager, or dispenser
2520 must follow both the requirements of the federal act, as
2521 amended, and departmental rules.

2522 (15) DUE DILIGENCE OF PURCHASERS.—

2523 (b) A wholesale distributor must take reasonable measures

20161604e1

2524 to identify its customers, understand the normal and expected
2525 transactions conducted by those customers, and identify those
2526 transactions that are suspicious in nature. A wholesale
2527 distributor must establish internal policies and procedures for
2528 identifying suspicious orders and preventing suspicious
2529 transactions. A wholesale distributor must assess orders for
2530 more ~~greater~~ than 7,500 ~~5,000~~ unit doses of any one controlled
2531 substance in any one month to determine whether the purchase is
2532 reasonable. In making such assessments, a wholesale distributor
2533 may consider the purchasing entity's clinical business needs,
2534 location, and population served, in addition to other factors
2535 established in the distributor's policies and procedures. A
2536 wholesale distributor must report to the department any
2537 regulated transaction involving an extraordinary quantity of a
2538 listed chemical, an uncommon method of payment or delivery, or
2539 any other circumstance that the regulated person believes may
2540 indicate that the listed chemical will be used in violation of
2541 the law. The wholesale distributor shall maintain records that
2542 document the report submitted to the department in compliance
2543 with this paragraph.

2544 Section 9. Subsection (4) of section 499.015, Florida
2545 Statutes, is amended to read:

2546 499.015 Registration of drugs, devices, and cosmetics;
2547 issuance of certificates of free sale.—

2548 (4) Unless a registration is renewed, it expires 2 years
2549 after the last day of the month in which it was issued. Any
2550 product registration issued or renewed on or after July 1, 2016,
2551 shall expire on the same date as the manufacturer or repackager
2552 permit of the person seeking to register the product. If the

20161604e1

2553 first product registration issued to a person on or after July
2554 1, 2016, expires less than 366 days after issuance, the fee for
2555 product registration shall be \$15. If the first product
2556 registration issued to a person on or after July 1, 2016,
2557 expires more than 365 days after issuance, the fee for product
2558 registration shall be \$30. The department may issue a stop-sale
2559 notice or order against a person that is subject to the
2560 requirements of this section and that fails to comply with this
2561 section within 31 days after the date the registration expires.
2562 The notice or order shall prohibit such person from selling or
2563 causing to be sold any drugs, devices, or cosmetics covered by
2564 this part until he or she complies with the requirements of this
2565 section.

2566 Section 10. Subsection (1) of section 499.03, Florida
2567 Statutes, is amended to read:

2568 499.03 Possession of certain drugs without prescriptions
2569 unlawful; exemptions and exceptions.-

2570 (1) A person may not possess, or possess with intent to
2571 sell, dispense, or deliver, any habit-forming, toxic, harmful,
2572 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or
2573 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,
2574 unless the possession of the drug has been obtained by a valid
2575 prescription of a practitioner licensed by law to prescribe the
2576 drug. However, this section does not apply to the delivery of
2577 such drugs to persons included in any of the classes named in
2578 this subsection, or to the agents or employees of such persons,
2579 for use in the usual course of their businesses or practices or
2580 in the performance of their official duties, as the case may be;
2581 nor does this section apply to the possession of such drugs by

20161604e1

2582 those persons or their agents or employees for such use:

2583 (a) A licensed pharmacist or any person under the licensed
2584 pharmacist's supervision while acting within the scope of the
2585 licensed pharmacist's practice;

2586 (b) A licensed practitioner authorized by law to prescribe
2587 prescription drugs or any person under the licensed
2588 practitioner's supervision while acting within the scope of the
2589 licensed practitioner's practice;

2590 (c) A qualified person who uses prescription drugs for
2591 lawful research, teaching, or testing, and not for resale;

2592 (d) A licensed hospital or other institution that procures
2593 such drugs for lawful administration or dispensing by
2594 practitioners;

2595 (e) An officer or employee of a federal, state, or local
2596 government; or

2597 (f) A person that holds a valid permit issued by the
2598 department pursuant to this part which authorizes that person to
2599 possess prescription drugs.

2600 Section 11. Paragraphs (i) through (p) of subsection (1) of
2601 section 499.05, Florida Statutes, are amended to read:

2602 499.05 Rules.—

2603 (1) The department shall adopt rules to implement and
2604 enforce this chapter with respect to:

2605 (i) Additional conditions that qualify as an emergency
2606 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.
2607 499.82.

2608 ~~(j) Procedures and forms relating to the pedigree paper~~
2609 ~~requirement of s. 499.01212.~~

2610 (j) ~~(k)~~ The protection of the public health, safety, and

20161604e1

2611 welfare regarding good manufacturing practices that
2612 manufacturers and repackagers must follow to ensure the safety
2613 of the products.

2614 (k)~~(l)~~ Information required from each retail establishment
2615 pursuant to s. 499.012(3) or s. 499.83(2)(c), including
2616 requirements for prescriptions or orders.

2617 (l)~~(m)~~ The recordkeeping, storage, and handling with
2618 respect to each of the distributions of prescription drugs
2619 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.
2620 499.82(14).

2621 ~~(n) Alternatives to compliance with s. 499.01212 for a~~
2622 ~~prescription drug in the inventory of a permitted prescription~~
2623 ~~drug wholesale distributor as of June 30, 2006, and the return~~
2624 ~~of a prescription drug purchased prior to July 1, 2006. The~~
2625 ~~department may specify time limits for such alternatives.~~

2626 (m)~~(o)~~ Wholesale distributor reporting requirements of s.
2627 499.0121(14).

2628 (n)~~(p)~~ Wholesale distributor credentialing and distribution
2629 requirements of s. 499.0121(15).

2630 Section 12. Subsection (7) of section 499.051, Florida
2631 Statutes, is amended to read:

2632 499.051 Inspections and investigations.—

2633 (7) The complaint and all information obtained pursuant to
2634 the investigation by the department are confidential and exempt
2635 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution
2636 until the investigation and the enforcement action are
2637 completed. However, trade secret information contained therein
2638 as defined by s. 812.081(1)(c) shall remain confidential and
2639 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I

20161604e1

2640 of the State Constitution, as long as the information is
2641 retained by the department. This subsection does not prohibit
2642 the department from using such information for regulatory or
2643 enforcement proceedings under this chapter or from providing
2644 such information to any law enforcement agency or any other
2645 regulatory agency. However, the receiving agency shall keep such
2646 records confidential and exempt as provided in this subsection.
2647 ~~In addition, this subsection is not intended to prevent~~
2648 ~~compliance with the provisions of s. 499.01212, and the pedigree~~
2649 ~~papers required in that section shall not be deemed a trade~~
2650 ~~secret.~~

2651 Section 13. Subsection (8) is added to section 499.066,
2652 Florida Statutes, to read:

2653 499.066 Penalties; remedies.—In addition to other penalties
2654 and other enforcement provisions:

2655 (8) (a) The department shall adopt rules to permit the
2656 issuance of remedial, nondisciplinary citations. A citation
2657 shall be issued to the person alleged to have committed a
2658 violation and contain the person's name, address, and license
2659 number, if applicable, a brief factual statement, the sections
2660 of the law allegedly violated, and the monetary assessment and
2661 or other remedial measures imposed. The citation must clearly
2662 state that the person may choose, in lieu of accepting the
2663 citation, to have the department rescind the citation and
2664 conduct an investigation pursuant to s. 499.051. If the person
2665 does not dispute the matter in the citation with the department
2666 within 30 days after the citation is served, the citation
2667 becomes a final order and does not constitute discipline.

2668 (b) The department shall adopt rules designating violations

20161604e1

2669 for which a citation may be issued. The rules shall designate as
2670 citable those violations for which there is no substantial
2671 threat to the public health, safety, or welfare.

2672 (c) The department is entitled to recover the costs of
2673 investigation, in addition to any penalty provided according to
2674 department rule, as part of the penalty levied pursuant to the
2675 citation.

2676 (d) A citation must be issued within 12 months after the
2677 filing of the complaint that is the basis for the citation.

2678 (e) Service of a citation may be made by personal service
2679 or certified mail, restricted delivery, to the person at the
2680 person's last known address of record with the department or to
2681 the person's Florida registered agent.

2682 (f) The department has authority to, and shall adopt rules
2683 to, designate those violations for which a person is subject to
2684 the issuance of a citation and designate the monetary
2685 assessments and or other remedial measures that must be taken
2686 for those violations. The department has continuous authority to
2687 amend its rules adopted pursuant to this section.

2688 Section 14. Subsection (14) of section 499.82, Florida
2689 Statutes, is amended to read:

2690 499.82 Definitions.—As used in this part, the term:

2691 (14) "Wholesale distribution" means the distribution of
2692 medical gas to a person other than a consumer or patient.

2693 Wholesale distribution of medical gases does not include:

2694 (a) The sale, purchase, or trade of a medical gas; an offer
2695 to sell, purchase, or trade a medical gas; or the dispensing of
2696 a medical gas pursuant to a prescription;

2697 (b) Activities exempt from the definition of wholesale

20161604e1

2698 distribution in s. 499.003; or

2699 (c) The sale, purchase, or trade of a medical gas or an
2700 offer to sell, purchase, or trade a medical gas for emergency
2701 medical reasons; ~~or~~

2702 ~~(d) Other transactions excluded from the definition of~~
2703 ~~wholesale distribution under the federal act or regulations~~
2704 ~~implemented under the federal act related to medical gas.~~

2705 Section 15. Subsection (6) of section 499.83, Florida
2706 Statutes, is created to read:

2707 499.83 Permits.—

2708 (6) A hospice licensed by the Agency for Health Care
2709 Administration pursuant to part IV of chapter 400 is not
2710 required to obtain medical oxygen retail establishment permit to
2711 purchase on behalf of and sell medical oxygen to its hospice
2712 patients, if the hospice contracts for the purchase and delivery
2713 of medical oxygen from an establishment permitted pursuant to
2714 this part. Sale and delivery to patients by hospices pursuant to
2715 this subsection must be based upon on a prescription or an order
2716 from a practitioner authorized by law to prescribe medical
2717 oxygen. For sales to hospices pursuant to this subsection, the
2718 medical gas wholesale distributor or the medical gas
2719 manufacturer selling medical oxygen to a hospice shall reflect
2720 on its invoice the hospice license number provided by the Agency
2721 for Health Care Administration and shall maintain such record
2722 pursuant to s. 499.89. Both the hospice and the medical oxygen
2723 retailer delivering medical oxygen to the patient must maintain
2724 a copy of a valid order or prescription for medical oxygen in
2725 accordance with s. 499.89 and department rule, which copy must
2726 be readily available for inspection.

20161604e1

2727 Section 16. Subsection (4) of section 499.89, Florida
2728 Statutes, is amended to read:

2729 499.89 Recordkeeping.—

2730 ~~(4) A pedigree paper is not required for distributing or~~
2731 ~~dispensing medical gas.~~

2732 Section 17. Section 499.01212, Florida Statutes, is
2733 repealed.

2734 Section 18. Paragraph (a) of subsection (1) of section
2735 409.9201, Florida Statutes, is amended to read:

2736 409.9201 Medicaid fraud.—

2737 (1) As used in this section, the term:

2738 (a) "Prescription drug" means any drug, including, but not
2739 limited to, finished dosage forms or active ingredients that are
2740 subject to, defined in, or described in s. 503(b) of the Federal
2741 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)
2742 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2743
2744 The value of individual items of the legend drugs or goods or
2745 services involved in distinct transactions committed during a
2746 single scheme or course of conduct, whether involving a single
2747 person or several persons, may be aggregated when determining
2748 the punishment for the offense.

2749 Section 19. Paragraph (b) of subsection (1) of section
2750 499.067, Florida Statutes, is amended to read:

2751 499.067 Denial, suspension, or revocation of permit,
2752 certification, or registration.—

2753 (1)

2754 (b) The department may deny an application for a permit or
2755 certification, or suspend or revoke a permit or certification,

20161604e1

2756 if the department finds that:

2757 1. The applicant is not of good moral character or that it
2758 would be a danger or not in the best interest of the public
2759 health, safety, and welfare if the applicant were issued a
2760 permit or certification.

2761 2. The applicant has not met the requirements for the
2762 permit or certification.

2763 3. The applicant is not eligible for a permit or
2764 certification for any of the reasons enumerated in s. 499.012.

2765 4. The applicant, permittee, or person certified under s.
2766 499.012(15) ~~s. 499.012(16)~~ demonstrates any of the conditions
2767 enumerated in s. 499.012.

2768 5. The applicant, permittee, or person certified under s.
2769 499.012(15) ~~s. 499.012(16)~~ has committed any violation of this
2770 chapter.

2771 Section 20. Subsection (1) of section 794.075, Florida
2772 Statutes, is amended to read:

2773 794.075 Sexual predators; erectile dysfunction drugs.—

2774 (1) A person may not possess a prescription drug, as
2775 defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of
2776 treating erectile dysfunction if the person is designated as a
2777 sexual predator under s. 775.21.

2778 Section 21. Paragraphs (d), (f), (i), and (j) of subsection
2779 (3) of section 921.0022, Florida Statutes, are amended to read:

2780 921.0022 Criminal Punishment Code; offense severity ranking
2781 chart.—

2782 (3) OFFENSE SEVERITY RANKING CHART

2783 (d) LEVEL 4

2784

20161604e1

2785	Florida Statute	Felony Degree	Description
2786	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.
2787	499.0051 (1)	3rd	Failure to maintain or deliver <u>transaction history,</u> <u>transaction information, or</u> <u>transaction statements</u> pedigree papers.
2788	499.0051 (2)	3rd	Failure to authenticate pedigree papers.
2789	<u>499.0051 (5)</u> 499.0051 (6)	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
2790	517.07 (1)	3rd	Failure to register securities.
2791	517.12 (1)	3rd	Failure of dealer, associated person, or issuer of securities to register.

20161604e1

2792	784.07 (2) (b)	3rd	Battery of law enforcement officer, firefighter, etc.
2793	784.074 (1) (c)	3rd	Battery of sexually violent predators facility staff.
2794	784.075	3rd	Battery on detention or commitment facility staff.
2795	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
2796	784.08 (2) (c)	3rd	Battery on a person 65 years of age or older.
2797	784.081 (3)	3rd	Battery on specified official or employee.
2798	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
2799	784.083 (3)	3rd	Battery on code inspector.
2800	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.

20161604e1

2801	787.03(1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
2802	787.04(2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
2803	787.04(3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
2804	787.07	3rd	Human smuggling.
2805	790.115(1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
2806	790.115(2)(b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
2807	790.115(2)(c)	3rd	Possessing firearm on school property.
2808			

20161604e1

2809	800.04 (7) (c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
2810	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
2811	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
2812	810.06	3rd	Burglary; possession of tools.
2813	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
2814	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
2815	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.

20161604e1

2816	817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
2817	817.568(2)(a)	3rd	Fraudulent use of personal identification information.
2818	817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
2819	828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
2820	837.02(1)	3rd	Perjury in official proceedings.
2821	837.021(1)	3rd	Make contradictory statements in official proceedings.
2822	838.022	3rd	Official misconduct.
2823	839.13(2)(a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
2824			

20161604e1

2825	839.13(2)(c)	3rd	Falsifying records of the Department of Children and Families.
2826	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
2827	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
2828	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
2829	847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
2830	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).

20161604e1

2831	914.14(2)	3rd	Witnesses accepting bribes.
2832	914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
2833	914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
2834	918.12	3rd	Tampering with jurors.
2835	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.

2836
 2837
 2838 (f) LEVEL 6
 2839
 2840

Florida Statute	Felony Degree	Description
2841 316.027(2)(b)	2nd	Leaving the scene of a crash involving serious bodily injury.
2842 316.193(2)(b)	3rd	Felony DUI, 4th or subsequent conviction.

20161604e1

2843	400.9935 (4) (c)	2nd	Operating a clinic, or offering services requiring licensure, without a license.
2844	<u>499.0051 (2)</u> 499.0051 (3)	2nd	Knowing forgery of <u>transaction history, transaction information, or transaction statement</u> pedigree papers .
2845	<u>499.0051 (3)</u> 499.0051 (4)	2nd	Knowing purchase or receipt of prescription drug from unauthorized person.
2846	<u>499.0051 (4)</u> 499.0051 (5)	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
2847	775.0875 (1)	3rd	Taking firearm from law enforcement officer.
2848	784.021 (1) (a)	3rd	Aggravated assault; deadly weapon without intent to kill.
2849	784.021 (1) (b)	3rd	Aggravated assault; intent to commit felony.
2850	784.041	3rd	Felony battery; domestic battery by strangulation.

20161604e1

2851	784.048 (3)	3rd	Aggravated stalking; credible threat.
2852	784.048 (5)	3rd	Aggravated stalking of person under 16.
2853	784.07 (2) (c)	2nd	Aggravated assault on law enforcement officer.
2854	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
2855	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
2856	784.081 (2)	2nd	Aggravated assault on specified official or employee.
2857	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
2858	784.083 (2)	2nd	Aggravated assault on code inspector.
2859	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those

20161604e1

2860			in s. 787.01.
2861	790.115(2)(d)	2nd	Discharging firearm or weapon on school property.
2862	790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
2863	790.164(1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
2864	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
2865	794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
2866	794.05(1)	2nd	Unlawful sexual activity with specified minor.
	800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age;

20161604e1

2867			offender less than 18 years.
	800.04 (6) (b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
2868			
	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
2869			
	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
2870			
	810.145 (8) (b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
2871			
	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
2872			
	812.014 (6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.
2873			
	812.015 (9) (a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
2874			

20161604e1

2875	812.015 (9) (b)	2nd	Retail theft; property stolen \$3,000 or more; coordination of others.
2876	812.13 (2) (c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
2877	817.4821 (5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
2878	825.102 (1)	3rd	Abuse of an elderly person or disabled adult.
2879	825.102 (3) (c)	3rd	Neglect of an elderly person or disabled adult.
2880	825.1025 (3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
2881	825.103 (3) (c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$10,000.
2882	827.03 (2) (c)	3rd	Abuse of a child.
2883	827.03 (2) (d)	3rd	Neglect of a child.

20161604e1

2884	827.071(2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
2885	836.05	2nd	Threats; extortion.
2886	836.10	2nd	Written threats to kill or do bodily injury.
2887	843.12	3rd	Aids or assists person to escape.
2888	847.011	3rd	Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.
2889	847.012	3rd	Knowingly using a minor in the production of materials harmful to minors.
2890	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
2891	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.

20161604e1

2892	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.
2893	944.40	2nd	Escapes.
2894	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
2895	944.47 (1) (a) 5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
2896	951.22 (1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
2897			
2898	(i) LEVEL 9		
2899			
2900	Florida Statute	Felony Degree	Description
	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.

20161604e1

2901	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
2902	409.920 (2) (b) 1.c.	1st	Medicaid provider fraud; \$50,000 or more.
2903	<u>499.0051 (8)</u> 499.0051 (9)	1st	Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.
2904	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
2905	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
2906	655.50 (10) (b) 3.	1st	Failure to report financial transactions

20161604e1

			totaling or exceeding \$100,000 by financial institution.
2907	775.0844	1st	Aggravated white collar crime.
2908	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
2909	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.
2910	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3).
2911	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.

20161604e1

2912	787.01 (1) (a) 1.	1st, PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
2913	787.01 (1) (a) 2.	1st, PBL	Kidnapping with intent to commit or facilitate commission of any felony.
2914	787.01 (1) (a) 4.	1st, PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
2915	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.
2916	787.06 (3) (c) 1.	1st	Human trafficking for labor and services of an unauthorized alien child.
2917	787.06 (3) (d)	1st	Human trafficking using

20161604e1

2918	787.06(3)(f)1.	1st,PBL	coercion for commercial sexual activity of an unauthorized adult alien.
2919	790.161	1st	Human trafficking for commercial sexual activity by the transfer or transport of any child from outside Florida to within the state.
2920	790.166(2)	1st,PBL	Attempted capital destructive device offense.
2921	794.011(2)	1st	Possessing, selling, using, or attempting to use a weapon of mass destruction.
2922	794.011(2)	Life	Attempted sexual battery; victim less than 12 years of age.
			Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.

20161604e1

2923	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.
2924	794.011 (4) (b)	1st	Sexual battery, certain circumstances; victim and offender 18 years of age or older.
2925	794.011 (4) (c)	1st	Sexual battery, certain circumstances; victim 12 years of age or older; offender younger than 18 years.
2926	794.011 (4) (d)	1st, PBL	Sexual battery, certain circumstances; victim 12 years of age or older; prior conviction for specified sex offenses.
2927	794.011 (8) (b)	1st, PBL	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial

20161604e1

2928			authority.
	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
2929			
	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
2930			
	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
2931			
	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
2932			
	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
2933			
	817.535 (3) (b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; property owner is a public officer or employee.
2934			

20161604e1

2935	817.535 (4) (a) 2.	1st	Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.
2936	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.
2937	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.
2938	827.03 (2) (a)	1st	Aggravated child abuse.
	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.

20161604e1

2939	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
2940	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.
2941	893.135	1st	Attempted capital trafficking offense.
2942	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
2943	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
2944	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
2945	893.135	1st	Trafficking in

20161604e1

2946	(1) (c) 2.d.		hydrocodone, 200 grams or more, less than 30 kilograms.
	893.135	1st	Trafficking in oxycodone,
	(1) (c) 3.d.		100 grams or more, less than 30 kilograms.
2947			
	893.135	1st	Trafficking in
	(1) (d) 1.c.		phencyclidine, more than 400 grams.
2948			
	893.135	1st	Trafficking in
	(1) (e) 1.c.		methaqualone, more than 25 kilograms.
2949			
	893.135	1st	Trafficking in
	(1) (f) 1.c.		amphetamine, more than 200 grams.
2950			
	893.135	1st	Trafficking in gamma-
	(1) (h) 1.c.		hydroxybutyric acid (GHB), 10 kilograms or more.
2951			
	893.135	1st	Trafficking in 1,4-
	(1) (j) 1.c.		Butanediol, 10 kilograms or more.
2952			

20161604e1

2953	893.135 (1) (k) 2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
2954	896.101 (5) (c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
2955	896.104 (4) (a) 3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
2956	(j) LEVEL 10		
2957	Florida	Felony	
2958	Statute	Degree	Description
2959	<u>499.0051 (9)</u> 499.0051 (10)	1st	Knowing sale or purchase of contraband prescription drugs resulting in death.
2960	782.04 (2)	1st, PBL	Unlawful killing of human; act is homicide,

20161604e1

2961			unpremeditated.
2961	782.07(3)	1st	Aggravated manslaughter of a child.
2962	787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
2963	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.
2964	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.
2965	787.06(4)(a)	Life	Selling or buying of minors into human trafficking.
2966	794.011(3)	Life	Sexual battery; victim

20161604e1

2967	812.135 (2) (a)	1st, PBL	12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.
2968	876.32	1st	Home-invasion robbery with firearm or other deadly weapon.
2969			Treason against the state.
2970			
2971			
2972	Section 22. This act shall take effect July 1, 2016.		