

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

27 | that certain persons obtain an out-of-state
28 | prescription drug wholesale distributor permit;
29 | requiring certain third party logistic providers to be
30 | licensed; requiring research and development labeling
31 | on certain prescription drug active pharmaceutical
32 | ingredient packaging; requiring certain manufacturers
33 | to create and maintain certain records; requiring
34 | certain prescription drug distributors to provide
35 | certain information to health care entities for which
36 | they repackage prescription drugs; amending s.
37 | 499.012, F.S.; providing for issuance of a
38 | prescription drug manufacturer permit or retail
39 | pharmacy drug wholesale distributor permit when an
40 | applicant at the same address is a licensed nuclear
41 | pharmacy or community pharmacy; providing for the
42 | expiration of deficient permit applications; requiring
43 | trade secret information submitted by an applicant to
44 | be maintained as a trade secret; authorizing the
45 | quadrennial renewal of permits; providing for
46 | calculation of fees for such permit renewals; revising
47 | procedures and application requirements for permit
48 | renewals; providing for late renewal fees; allowing a
49 | permittee who submits a renewal application to
50 | continue operations; removing certain application
51 | requirements for renewal of a permit; requiring bonds
52 | or other surety of a specified amount; requiring proof

53 of inspection of establishments used in wholesale
54 distribution; authorizing the Department of Business
55 and Professional Regulation to contract for the
56 collection of electronic fingerprints under certain
57 circumstances; providing information that may be
58 submitted in lieu of certain application requirements
59 for specified permits and certifications; removing
60 provisions relating to annual renewal and expiration
61 of permits; conforming cross-references; amending s.
62 499.01201, F.S.; conforming provisions; amending s.
63 499.0121, F.S.; revising prescription drug
64 recordkeeping requirements; requiring inventories and
65 records of transactions for active pharmaceutical
66 ingredients; revising the monthly number of unit doses
67 of a controlled substance purchased which requires a
68 wholesale distributor to perform an assessment of the
69 purchase; conforming provisions; amending s. 499.015,
70 F.S.; providing for the expiration, renewal, and
71 issuance of certain product registrations; providing
72 for product registration fees; amending ss. 499.03,
73 499.05, and 499.051, F.S.; conforming provisions to
74 changes made by the act; amending s. 499.066, F.S.;
75 authorizing the issuance of nondisciplinary citations;
76 authorizing the department to adopt rules designating
77 violations for which a citation may be issued;
78 authorizing the department to recover investigative

79 costs pursuant to the citation; specifying a time
 80 limitation for issuance of a citation; providing for
 81 service of a citation; amending s. 499.82, F.S.;
 82 revising the definition of "wholesale distribution"
 83 for purposes of medical gas requirements; amending s.
 84 499.89, F.S.; conforming provisions; repealing s.
 85 499.01212, F.S., relating to pedigree papers; amending
 86 ss. 409.9201, 499.067, 794.075, and 921.0022, F.S.;
 87 conforming provisions to changes made by the act;
 88 providing an effective date.

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

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

94 499.003 Definitions of terms used in this part.—As used in
 95 this part, the term:

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

104 (2)~~(1)~~ "Advertisement" means any representation

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

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

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

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

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

122 (4)-(3) "Affiliated party" means:

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

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

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

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

137 (5)-(4) "Applicant" means a person applying for a permit or
 138 certification under this part.

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

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

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

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

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

157 ~~affiliated group.~~

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

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

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

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

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

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

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

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

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

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

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

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

208 (a) Recognized in the current edition of the United States

209 Pharmacopoeia and National Formulary, or any supplement thereof,
 210 (b) Intended for use in the diagnosis, cure, mitigation,
 211 treatment, therapy, or prevention of disease in humans or other
 212 animals, or

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

215

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

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

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

235 (17)~~(18)~~ "Drug" means an article that is:

236 (a) Recognized in the current edition of the United States

237 Pharmacopoeia and National Formulary, official Homeopathic

238 Pharmacopoeia of the United States, or any supplement to any of

239 those publications;

240 (b) Intended for use in the diagnosis, cure, mitigation,

241 treatment, therapy, or prevention of disease in humans or other

242 animals;

243 (c) Intended to affect the structure or any function of

244 the body of humans or other animals; or

245 (d) Intended for use as a component of any article

246 specified in paragraph (a), paragraph (b), or paragraph (c), and

247 includes active pharmaceutical ingredients, but does not include

248 devices or their nondrug components, parts, or accessories. ~~For~~

249 ~~purposes of this paragraph, an "active pharmaceutical~~

250 ~~ingredient" includes any substance or mixture of substances~~

251 ~~intended, represented, or labeled for use in drug manufacturing~~

252 ~~that furnishes or is intended to furnish, in a finished dosage~~

253 ~~form, any pharmacological activity or other direct effect in the~~

254 ~~diagnosis, cure, mitigation, treatment, therapy, or prevention~~

255 ~~of disease in humans or other animals, or to affect the~~

256 ~~structure or any function of the body of humans or other~~

257 ~~animals.~~

258 (18)~~(19)~~ "Establishment" means a place of business which

259 is at one general physical location and may extend to one or

260 more contiguous suites, units, floors, or buildings operated and

261 controlled exclusively by entities under common operation and
262 control. Where multiple buildings are under common exclusive
263 ownership, operation, and control, an intervening thoroughfare
264 does not affect the contiguous nature of the buildings. For
265 purposes of permitting, each suite, unit, floor, or building
266 must be identified in the most recent permit application.

267 (19)~~(20)~~ "Federal act" means the Federal Food, Drug, and
268 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

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

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

281 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

282 (22)~~(23)~~ "Health care facility" means a health care
283 facility licensed under chapter 395.

284 (23)~~(24)~~ "Hospice" means a corporation licensed under part
285 IV of chapter 400.

286 (24)~~(25)~~ "Hospital" means a facility as defined in s.

287 395.002 and licensed under chapter 395.

288 ~~(25)-(26)~~ "Immediate container" does not include package
289 liners.

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

299 ~~(27)-(28)~~ "Labeling" means all labels and other written,
300 printed, or graphic matters:

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

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

305 ~~(28)-(29)~~ "Manufacture" means the preparation, deriving,
306 compounding, propagation, processing, producing, or fabrication
307 of any drug, device, or cosmetic.

308 ~~(29)-(30)~~ "Manufacturer" means:

309 (a) A person who holds a New Drug Application, an
310 Abbreviated New Drug Application, a Biologics License
311 Application, or a New Animal Drug Application approved under the
312 federal act or a license issued under s. 351 of the Public

313 Health Service Act, 42 U.S.C. s. 262, for such drug or
314 biologics, or if such drug or biologics is not the subject of an
315 approved application or license, the person who manufactured the
316 drug or biologics ~~prepares, derives, manufactures, or produces a~~
317 ~~drug, device, or cosmetic;~~

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

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

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

339 ~~identified in the agreement as the manufacturer of that drug~~
 340 ~~consistent with the federal act and its implementing~~
 341 ~~regulations;~~

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

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

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

361 (30)~~(31)~~ "Medical convenience kit" means packages or units
 362 that contain combination products as defined in 21 C.F.R. s.
 363 3.2(e)(2).

364 (31)~~(32)~~ "Medical gas" means any liquefied or vaporized

365 gas that is a prescription drug, whether alone or in combination
366 with other gases, and as defined in the federal act.

367 (32)~~(33)~~ "New drug" means:

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

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

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

391 ~~owned by a corporate entity.~~

392 (33)~~(35)~~ "Nursing home" means a facility licensed under
393 part II of chapter 400.

394 (34)~~(36)~~ "Official compendium" means the current edition
395 of the official United States Pharmacopoeia and National
396 Formulary, or any supplement thereto.

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

401 (35)~~(38)~~ "Permittee" means any person holding a permit
402 issued under this chapter ~~pursuant to s. 499.012.~~

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

411 (37)~~(40)~~ "Pharmacist" means a person licensed under
412 chapter 465.

413 (38)~~(41)~~ "Pharmacy" means an entity licensed under chapter
414 465.

415 (39)~~(42)~~ "Prepackaged drug product" means a drug that
416 originally was in finished packaged form sealed by a

417 manufacturer and that is placed in a properly labeled container
 418 by a pharmacy or practitioner authorized to dispense pursuant to
 419 chapter 465 for the purpose of dispensing in the establishment
 420 in which the prepackaging occurred.

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

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

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

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

441 ~~(a) Purchased 90 percent or more of the total dollar~~
 442 ~~volume of its purchases of prescription drugs directly from~~

443 ~~manufacturers in the previous year; and~~

444 ~~(b)1. Directly purchased prescription drugs from not fewer~~

445 ~~than 50 different prescription drug manufacturers in the~~

446 ~~previous year; or~~

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

448 ~~the Internal Revenue Code, of which the wholesale distributor is~~

449 ~~a member has, not fewer than 250 employees.~~

450 ~~(c) For purposes of this subsection, "directly from~~

451 ~~manufacturers" means:~~

452 ~~1. Purchases made by the wholesale distributor directly~~

453 ~~from the manufacturer of prescription drugs; and~~

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

455 ~~defined in s. 1504 of the Internal Revenue Code, of which the~~

456 ~~wholesale distributor is a member, if:~~

457 ~~a. The affiliated group purchases 90 percent or more of~~

458 ~~the total dollar volume of its purchases of prescription drugs~~

459 ~~from the manufacturer in the previous year; and~~

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

461 ~~the names of all members of the affiliated group of which the~~

462 ~~wholesale distributor is a member and the affiliated group~~

463 ~~agrees in writing to provide records on prescription drug~~

464 ~~purchases by the members of the affiliated group not later than~~

465 ~~48 hours after the department requests access to such records,~~

466 ~~regardless of the location where the records are stored.~~

467 ~~(43)(47) "Proprietary drug," or "OTC drug," means a patent~~

468 ~~or over-the-counter drug in its unbroken, original package,~~

469 | which drug is sold to the public by, or under the authority of,
 470 | the manufacturer or primary distributor thereof, is not
 471 | misbranded under the provisions of this part, and can be
 472 | purchased without a prescription.

473 | ~~(44)-(48)~~ "Repackage" includes repacking or otherwise
 474 | changing the container, wrapper, or labeling to further the
 475 | distribution of the drug, device, or cosmetic.

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

480 | ~~(46)-(50)~~ "Retail pharmacy" means a community pharmacy
 481 | licensed under chapter 465 that purchases prescription drugs at
 482 | fair market prices and provides prescription services to the
 483 | public.

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

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

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

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

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

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

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

517 4. The distribution ~~sale, purchase, trade, or other~~
 518 ~~transfer~~ of a prescription drug from or for any federal, state,
 519 or local government agency or any entity eligible to purchase
 520 prescription drugs at public health services prices pursuant to

521 Pub. L. No. 102-585, s. 602 to a contract provider or its
522 subcontractor for eligible patients of the agency or entity
523 under the following conditions:

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

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

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

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

544 e. The contract provider or subcontractor may administer
545 or dispense the prescription drugs only to the eligible patients
546 of the agency or entity or must return the prescription drugs

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

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

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

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

568 2. The distribution ~~sale, purchase, or trade~~ of a
569 prescription drug or ~~an~~ offer to distribute ~~sell, purchase, or~~
570 ~~trade~~ a prescription drug for emergency medical reasons, which
571 may include. ~~For purposes of this subparagraph, The term~~
572 ~~"emergency medical reasons" includes~~ transfers of prescription

573 | drugs by a retail pharmacy to another retail pharmacy to
574 | alleviate a temporary shortage. For purposes of this
575 | subparagraph, a drug shortage not caused by a public health
576 | emergency does not constitute an emergency medical reason.

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

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

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

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

596 | ~~6.7.~~ The distribution ~~transfer~~ of a prescription drug by a
597 | hospital or other health care entity to a person licensed under
598 | this part to repackage prescription drugs for the purpose of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

677 the charitable organization to:

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

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

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

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

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

699 (49)-(54) "Wholesale distributor" means a ~~any~~ person, other
700 than a manufacturer, a manufacturer's co-licensed partner, a
701 third-party logistics provider, or a repackager, who is engaged
702 in wholesale distribution of prescription drugs in or into this

703 ~~state, including, but not limited to, manufacturers;~~
 704 ~~repackagers; own-label distributors; jobbers; private-label~~
 705 ~~distributors; brokers; warehouses, including manufacturers' and~~
 706 ~~distributors' warehouses, chain drug warehouses, and wholesale~~
 707 ~~drug warehouses; independent wholesale drug traders; exporters;~~
 708 ~~retail pharmacies; and the agents thereof that conduct wholesale~~
 709 ~~distributions.~~

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

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

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

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

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

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

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

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

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

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

738 499.0051 Criminal acts.—

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

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

752 (b) A person engaged in the ~~wholesale~~ distribution of
 753 prescription drugs who fails to acquire a complete and accurate
 754 transaction history, transaction information, or transaction

755 statement ~~pedigree papers~~ concerning a prescription drug or
756 contraband prescription drug, as required by this chapter and
757 rules adopted under this chapter, before ~~prior to~~, or
758 simultaneous with, the receipt of the prescription drug or
759 contraband prescription drug from another person commits a
760 felony of the third degree, punishable as provided in s.
761 775.082, s. 775.083, or s. 775.084.

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

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

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

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

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

786 (2)~~(3)~~ KNOWING FORGERY OF TRANSACTION HISTORY, TRANSACTION
787 INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE PAPERS~~.—A person
788 who knowingly forges, counterfeits, or falsely creates any
789 transaction history, transaction information, or transaction
790 statement ~~pedigree paper~~; who falsely represents any factual
791 matter contained on any transaction history, transaction
792 information, or transaction statement ~~pedigree paper~~; or who
793 knowingly omits to record material information required to be
794 recorded in a transaction history, transaction information, or
795 transaction statement ~~pedigree paper~~, commits a felony of the
796 second degree, punishable as provided in s. 775.082, s. 775.083,
797 or s. 775.084.

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

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

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

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

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

825 Section 4. Subsection (10) of section 499.006, Florida
 826 Statutes, is amended to read:

827 499.006 Adulterated drug or device.—A drug or device is
 828 adulterated:

829 (10) If it is a prescription drug for which the required
 830 transaction history, transaction information, or transaction
 831 statement ~~pedigree paper~~ is nonexistent, fraudulent, or
 832 incomplete under the requirements of this part or applicable

833 rules, or that has been purchased, held, sold, or distributed at
 834 any time by a person not authorized under federal or state law
 835 to do so; or

836 Section 5. Section 499.01, Florida Statutes, is amended to
 837 read:

838 499.01 Permits.—

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

841 (a) A prescription drug manufacturer;

842 (b) A prescription drug repackager;

843 (c) A nonresident prescription drug manufacturer;

844 (d) A nonresident prescription drug repackager;

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

846 (f)~~(e)~~ An out-of-state prescription drug wholesale
 847 distributor;

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

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

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

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

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

854 (l)~~(k)~~ A veterinary prescription drug wholesale
 855 distributor;

856 (m)~~(l)~~ A limited prescription drug veterinary wholesale
 857 distributor;

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

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

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

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

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

863 (2) The following permits are established:

864 (a) Prescription drug manufacturer permit.—A prescription

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

866 manufacturer of a prescription drug and that manufactures or

867 distributes such prescription drugs in this state.

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

869 prescription drug manufacturer may engage in wholesale

870 distribution of prescription drugs for which the person is the

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

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

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

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

875 department shall adopt rules for issuing a virtual prescription

876 drug manufacturer permit to a person who engages in the

877 manufacture of prescription drugs but does not make or take

878 physical possession of any prescription drugs. The rules adopted

879 by the department under this section may exempt virtual

880 manufacturers from certain establishment, security, and storage

881 requirements set forth in s. 499.0121.

882 2. A prescription drug manufacturer must comply with all

883 appropriate state and federal good manufacturing practices.

884 3. A blood establishment, as defined in s. 381.06014,

885 | operating in a manner consistent with the provisions of 21
 886 | C.F.R. parts 211 and 600-640, and manufacturing only the
 887 | prescription drugs described in s. 499.003(48)(j) ~~499.003(53)(d)~~
 888 | is not required to be permitted as a prescription drug
 889 | manufacturer under this paragraph or to register products under
 890 | s. 499.015.

891 | (b) Prescription drug repackager permit.—A prescription
 892 | drug repackager permit is required for any person that
 893 | repackages a prescription drug in this state.

894 | 1. A person that operates an establishment permitted as a
 895 | prescription drug repackager may engage in ~~wholesale~~
 896 | distribution of prescription drugs repackaged at that
 897 | establishment and must comply with all of the provisions of this
 898 | part and the rules adopted under this part that apply to a
 899 | prescription drug manufacturer ~~wholesale distributor~~.

900 | 2. A prescription drug repackager must comply with all
 901 | appropriate state and federal good manufacturing practices.

902 | (c) Nonresident prescription drug manufacturer permit.—A
 903 | nonresident prescription drug manufacturer permit is required
 904 | for any person that is a manufacturer of prescription drugs,
 905 | unless permitted as a third party logistics provider, located
 906 | outside of this state or outside the United States and that
 907 | engages in the ~~wholesale~~ distribution in this state of such
 908 | prescription drugs. Each such manufacturer must be permitted by
 909 | the department and comply with all of the provisions required of
 910 | a prescription drug manufacturer ~~wholesale distributor~~ under

911 | this part, ~~except s. 499.01212.~~ The department shall adopt rules
912 | for issuing a virtual nonresident prescription drug manufacturer
913 | permit to a person who engages in the manufacture of
914 | prescription drugs but does not make or take physical possession
915 | of any prescription drugs. The rules adopted by the department
916 | under this section may exempt virtual nonresident manufacturers
917 | from certain establishment, security, and storage requirements
918 | set forth in s. 499.0121.

919 | 1. A person that distributes prescription drugs for which
920 | the person is not the manufacturer must also obtain an out-of-
921 | state prescription drug wholesale distributor permit or third
922 | party logistics provider permit pursuant to this section to
923 | engage in the ~~wholesale~~ distribution of such prescription drugs
924 | when required by this part. This subparagraph does not apply to
925 | a manufacturer that distributes prescription drugs only for the
926 | manufacturer of the prescription drugs where both manufacturers
927 | are affiliates as defined in s. 499.003(30)(e).

928 | 2. Any such person must comply with the licensing or
929 | permitting requirements of the jurisdiction in which the
930 | establishment is located and the federal act, and any
931 | prescription drug distributed ~~product wholesaled~~ into this state
932 | must comply with this part. If a person intends to import
933 | prescription drugs from a foreign country into this state, the
934 | nonresident prescription drug manufacturer must provide to the
935 | department a list identifying each prescription drug it intends
936 | to import and document approval by the United States Food and

937 Drug Administration for such importation.

938 (d) Nonresident prescription drug repackager permit.-A
939 nonresident prescription drug repackager permit is required for
940 any person located outside of this state, but within the United
941 States or its territories, that repackages prescription drugs
942 and engages in the distribution of such prescription drugs into
943 this state.

944 1. A nonresident prescription drug repackager must comply
945 with all of the provisions of this section and the rules adopted
946 under this section that apply to a prescription drug
947 manufacturer.

948 2. A nonresident prescription drug repackager must be
949 permitted by the department and comply with all appropriate
950 state and federal good manufacturing practices.

951 3. A nonresident prescription drug repackager must be
952 registered as a drug establishment with the United States Food
953 and Drug Administration.

954 (e)-(d) Prescription drug wholesale distributor permit.-A
955 prescription drug wholesale distributor permit is required for
956 any person who is a wholesale distributor of prescription drugs
957 and that may engage in the wholesale distributes such
958 distribution of prescription drugs in this state. A prescription
959 drug wholesale distributor that applies to the department for a
960 new permit or the renewal of a permit must submit a bond of
961 \$100,000, or other equivalent means of security acceptable to
962 the department, such as an irrevocable letter of credit or a

963 ~~deposit in a trust account or financial institution, payable to~~
964 ~~the Professional Regulation Trust Fund. The purpose of the bond~~
965 ~~is to secure payment of any administrative penalties imposed by~~
966 ~~the department and any fees and costs incurred by the department~~
967 ~~regarding that permit which are authorized under state law and~~
968 ~~which the permittee fails to pay 30 days after the fine or costs~~
969 ~~become final. The department may make a claim against such bond~~
970 ~~or security until 1 year after the permittee's license ceases to~~
971 ~~be valid or until 60 days after any administrative or legal~~
972 ~~proceeding authorized in this part which involves the permittee~~
973 ~~is concluded, including any appeal, whichever occurs later. The~~
974 department may adopt rules for issuing a prescription drug
975 wholesale distributor-broker permit to a person who engages in
976 the wholesale distribution of prescription drugs and does not
977 take physical possession of any prescription drugs.

978 (f)~~(e)~~ Out-of-state prescription drug wholesale
979 distributor permit.~~An out-of-state prescription drug wholesale~~
980 distributor permit is required for any person that is a
981 wholesale distributor located outside this state, but within the
982 United States or its territories, which engages in the wholesale
983 distribution of prescription drugs into this state ~~and which~~
984 ~~must be permitted by the department and comply with all the~~
985 ~~provisions required of a wholesale distributor under this part.~~
986 ~~An out-of-state prescription drug wholesale distributor that~~
987 ~~applies to the department for a new permit or the renewal of a~~
988 ~~permit must submit a bond of \$100,000, or other equivalent means~~

989 ~~of security acceptable to the department, such as an irrevocable~~
990 ~~letter of credit or a deposit in a trust account or financial~~
991 ~~institution, payable to the Professional Regulation Trust Fund.~~
992 ~~The purpose of the bond is to secure payment of any~~
993 ~~administrative penalties imposed by the department and any fees~~
994 ~~and costs incurred by the department regarding that permit which~~
995 ~~are authorized under state law and which the permittee fails to~~
996 ~~pay 30 days after the fine or costs become final. The department~~
997 ~~may make a claim against such bond or security until 1 year~~
998 ~~after the permittee's license ceases to be valid or until 60~~
999 ~~days after any administrative or legal proceeding authorized in~~
1000 ~~this part which involves the permittee is concluded, including~~
1001 ~~any appeal, whichever occurs later. The out-of-state~~
1002 ~~prescription drug wholesale distributor must maintain at all~~
1003 ~~times a license or permit to engage in the wholesale~~
1004 ~~distribution of prescription drugs in compliance with laws of~~
1005 ~~the state in which it is a resident. If the state from which the~~
1006 ~~wholesale distributor distributes prescription drugs does not~~
1007 ~~require a license to engage in the wholesale distribution of~~
1008 ~~prescription drugs, the distributor must be licensed as a~~
1009 ~~wholesale distributor as required by the federal act.~~

1010 (g)-(f) Retail pharmacy drug wholesale distributor permit.-
1011 A retail pharmacy drug wholesale distributor is a retail
1012 pharmacy engaged in wholesale distribution of prescription drugs
1013 within this state under the following conditions:

1014 1. The pharmacy must obtain a retail pharmacy drug

1015 wholesale distributor permit pursuant to this part and ~~the~~ rules
 1016 adopted under this part.

1017 2. The wholesale distribution activity does not exceed 30
 1018 percent of the total annual purchases of prescription drugs. If
 1019 the wholesale distribution activity exceeds the 30-percent
 1020 maximum, the pharmacy must obtain a prescription drug wholesale
 1021 distributor permit.

1022 3. The transfer of prescription drugs that appear in any
 1023 schedule contained in chapter 893 is subject to chapter 893 and
 1024 the federal Comprehensive Drug Abuse Prevention and Control Act
 1025 of 1970.

1026 4. The transfer is between a retail pharmacy and another
 1027 retail pharmacy, or a Modified Class II institutional pharmacy,
 1028 or a health care practitioner licensed in this state and
 1029 authorized by law to dispense or prescribe prescription drugs.

1030 5. All records of sales of prescription drugs subject to
 1031 this section must be maintained separate and distinct from other
 1032 records and comply with the recordkeeping requirements of this
 1033 part.

1034 (h) ~~(g)~~ Restricted prescription drug distributor permit.—

1035 1. A restricted prescription drug distributor permit is
 1036 required for:

1037 a. Any person located in this state who engages in the
 1038 distribution of a prescription drug, which distribution is not
 1039 considered "wholesale distribution" under s. 499.003(48)(a)
 1040 ~~499.003(53)(a)~~.

1041 b. Any person located in this state who engages in the
 1042 receipt or distribution of a prescription drug in this state for
 1043 the purpose of processing its return or its destruction if such
 1044 person is not the person initiating the return, the prescription
 1045 drug wholesale supplier of the person initiating the return, or
 1046 the manufacturer of the drug.

1047 c. A blood establishment located in this state which
 1048 collects blood and blood components only from volunteer donors
 1049 as defined in s. 381.06014 or pursuant to an authorized
 1050 practitioner's order for medical treatment or therapy and
 1051 engages in the wholesale distribution of a prescription drug not
 1052 described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care
 1053 entity. A mobile blood unit operated by a blood establishment
 1054 permitted under this sub-subparagraph is not required to be
 1055 separately permitted. The health care entity receiving a
 1056 prescription drug distributed under this sub-subparagraph must
 1057 be licensed as a closed pharmacy or provide health care services
 1058 at that establishment. The blood establishment must operate in
 1059 accordance with s. 381.06014 and may distribute only:

- 1060 (I) Prescription drugs indicated for a bleeding or
- 1061 clotting disorder or anemia;
- 1062 (II) Blood-collection containers approved under s. 505 of
- 1063 the federal act;
- 1064 (III) Drugs that are blood derivatives, or a recombinant
- 1065 or synthetic form of a blood derivative;
- 1066 (IV) Prescription drugs that are identified in rules

1067 adopted by the department and that are essential to services
1068 performed or provided by blood establishments and authorized for
1069 distribution by blood establishments under federal law; or

1070 (V) To the extent authorized by federal law, drugs
1071 necessary to collect blood or blood components from volunteer
1072 blood donors; for blood establishment personnel to perform
1073 therapeutic procedures under the direction and supervision of a
1074 licensed physician; and to diagnose, treat, manage, and prevent
1075 any reaction of a volunteer blood donor or a patient undergoing
1076 a therapeutic procedure performed under the direction and
1077 supervision of a licensed physician,

1078
1079 as long as all of the health care services provided by the blood
1080 establishment are related to its activities as a registered
1081 blood establishment or the health care services consist of
1082 collecting, processing, storing, or administering human
1083 hematopoietic stem cells or progenitor cells or performing
1084 diagnostic testing of specimens if such specimens are tested
1085 together with specimens undergoing routine donor testing. The
1086 blood establishment may purchase and possess the drugs described
1087 in this sub-subparagraph without a health care clinic
1088 establishment permit.

1089 2. Storage, handling, and recordkeeping of these
1090 distributions by a person required to be permitted as a
1091 restricted prescription drug distributor must be in accordance
1092 with the requirements for wholesale distributors under s.

1093 499.0121, ~~but not those set forth in s. 499.01212 if the~~
 1094 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~
 1095 ~~subparagraph 1.b.~~

1096 3. A person who applies for a permit as a restricted
 1097 prescription drug distributor, or for the renewal of such a
 1098 permit, must provide to the department the information required
 1099 under s. 499.012.

1100 4. The department may adopt rules regarding the
 1101 distribution of prescription drugs by hospitals, health care
 1102 entities, charitable organizations, other persons not involved
 1103 in wholesale distribution, and blood establishments, which rules
 1104 are necessary for the protection of the public health, safety,
 1105 and welfare.

1106 (i)~~(h)~~ Complimentary drug distributor permit.—A
 1107 complimentary drug distributor permit is required for any person
 1108 that engages in the distribution of a complimentary drug,
 1109 subject to the requirements of s. 499.028.

1110 (j)~~(i)~~ Freight forwarder permit.—A freight forwarder
 1111 permit is required for any person that engages in the
 1112 distribution of a prescription drug as a freight forwarder
 1113 unless the person is a common carrier. The storage, handling,
 1114 and recordkeeping of such distributions must comply with the
 1115 requirements for wholesale distributors under s. 499.0121, ~~but~~
 1116 ~~not those set forth in s. 499.01212.~~ A freight forwarder must
 1117 provide the source of the prescription drugs with a validated
 1118 airway bill, bill of lading, or other appropriate documentation

1119 to evidence the exportation of the product.

1120 (k)~~(j)~~ Veterinary prescription drug retail establishment
 1121 permit.—A veterinary prescription drug retail establishment
 1122 permit is required for any person that sells veterinary
 1123 prescription drugs to the public but does not include a pharmacy
 1124 licensed under chapter 465.

1125 1. The sale to the public must be based on a valid written
 1126 order from a veterinarian licensed in this state who has a valid
 1127 client-veterinarian relationship with the purchaser's animal.

1128 2. Veterinary prescription drugs may not be sold in excess
 1129 of the amount clearly indicated on the order or beyond the date
 1130 indicated on the order.

1131 3. An order may not be valid for more than 1 year.

1132 4. A veterinary prescription drug retail establishment may
 1133 not purchase, sell, trade, or possess human prescription drugs
 1134 or any controlled substance as defined in chapter 893.

1135 5. A veterinary prescription drug retail establishment
 1136 must sell a veterinary prescription drug in the original, sealed
 1137 manufacturer's container with all labeling intact and legible.
 1138 The department may adopt by rule additional labeling
 1139 requirements for the sale of a veterinary prescription drug.

1140 6. A veterinary prescription drug retail establishment
 1141 must comply with all of the wholesale distribution requirements
 1142 of s. 499.0121.

1143 7. Prescription drugs sold by a veterinary prescription
 1144 drug retail establishment pursuant to a practitioner's order may

1145 not be returned into the retail establishment's inventory.
1146 (1)~~(k)~~ Veterinary prescription drug wholesale distributor
1147 permit.—A veterinary prescription drug wholesale distributor
1148 permit is required for any person that engages in the
1149 distribution of veterinary prescription drugs in or into this
1150 state. A veterinary prescription drug wholesale distributor that
1151 also distributes prescription drugs subject to, defined by, or
1152 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
1153 Act which it did not manufacture must obtain a permit as a
1154 prescription drug wholesale distributor, an out-of-state
1155 prescription drug wholesale distributor, or a limited
1156 prescription drug veterinary wholesale distributor in lieu of
1157 the veterinary prescription drug wholesale distributor permit. A
1158 veterinary prescription drug wholesale distributor must comply
1159 with the requirements for wholesale distributors under s.
1160 499.0121, ~~but not those set forth in s. 499.0122.~~

1161 (m)~~(l)~~ Limited prescription drug veterinary wholesale
1162 distributor permit.—Unless engaging in the activities of and
1163 permitted as a prescription drug manufacturer, nonresident
1164 prescription drug manufacturer, prescription drug wholesale
1165 distributor, or out-of-state prescription drug wholesale
1166 distributor, a limited prescription drug veterinary wholesale
1167 distributor permit is required for any person that engages in
1168 the distribution in or into this state of veterinary
1169 prescription drugs and prescription drugs subject to, defined
1170 by, or described by s. 503(b) of the Federal Food, Drug, and

1171 Cosmetic Act under the following conditions:

1172 1. The person is engaged in the business of wholesaling

1173 prescription and veterinary prescription drugs to persons:

1174 a. Licensed as veterinarians practicing on a full-time

1175 basis;

1176 b. Regularly and lawfully engaged in instruction in

1177 veterinary medicine;

1178 c. Regularly and lawfully engaged in law enforcement

1179 activities;

1180 d. For use in research not involving clinical use; or

1181 e. For use in chemical analysis or physical testing or for

1182 purposes of instruction in law enforcement activities, research,

1183 or testing.

1184 2. No more than 30 percent of total annual prescription

1185 drug sales may be prescription drugs approved for human use

1186 which are subject to, defined by, or described by s. 503(b) of

1187 the Federal Food, Drug, and Cosmetic Act.

1188 3. The person does not distribute in any jurisdiction

1189 prescription drugs subject to, defined by, or described by s.

1190 503(b) of the Federal Food, Drug, and Cosmetic Act to any person

1191 who is authorized to sell, distribute, purchase, trade, or use

1192 these drugs on or for humans.

1193 4. A limited prescription drug veterinary wholesale

1194 distributor that applies to the department for a new permit or

1195 the renewal of a permit must submit a bond of \$20,000, or other

1196 equivalent means of security acceptable to the department, such

1197 as an irrevocable letter of credit or a deposit in a trust
 1198 account or financial institution, payable to the Professional
 1199 Regulation Trust Fund. The purpose of the bond is to secure
 1200 payment of any administrative penalties imposed by the
 1201 department and any fees and costs incurred by the department
 1202 regarding that permit which are authorized under state law and
 1203 which the permittee fails to pay 30 days after the fine or costs
 1204 become final. The department may make a claim against such bond
 1205 or security until 1 year after the permittee's license ceases to
 1206 be valid or until 60 days after any administrative or legal
 1207 proceeding authorized in this part which involves the permittee
 1208 is concluded, including any appeal, whichever occurs later.

1209 5. A limited prescription drug veterinary wholesale
 1210 distributor must maintain at all times a license or permit to
 1211 engage in the wholesale distribution of prescription drugs in
 1212 compliance with laws of the state in which it is a resident.

1213 6. A limited prescription drug veterinary wholesale
 1214 distributor must comply with the requirements for wholesale
 1215 distributors under s. ss. 499.0121 and ~~499.01212~~, except that a
 1216 ~~limited prescription drug veterinary wholesale distributor is~~
 1217 ~~not required to provide a pedigree paper as required by s.~~
 1218 ~~499.01212 upon the wholesale distribution of a prescription drug~~
 1219 ~~to a veterinarian.~~

1220 7. A limited prescription drug veterinary wholesale
 1221 distributor may not return to inventory for subsequent wholesale
 1222 distribution any prescription drug subject to, defined by, or

1223 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
 1224 Act which has been returned by a veterinarian.

1225 8. A limited prescription drug veterinary wholesale
 1226 distributor permit is not required for an intracompany sale or
 1227 transfer of a prescription drug from an out-of-state
 1228 establishment that is duly licensed to engage in the wholesale
 1229 distribution of prescription drugs in its state of residence to
 1230 a licensed limited prescription drug veterinary wholesale
 1231 distributor in this state if both wholesale distributors conduct
 1232 wholesale distributions of prescription drugs under the same
 1233 business name. The recordkeeping requirements of s. ~~ss.~~
 1234 499.0121(6) ~~and 499.01212~~ must be followed for this transaction.

1235 (n) ~~(m)~~ Over-the-counter drug manufacturer permit.—An over-
 1236 the-counter drug manufacturer permit is required for any person
 1237 that engages in the manufacture or repackaging of an over-the-
 1238 counter drug.

1239 1. An over-the-counter drug manufacturer may not possess
 1240 or purchase prescription drugs.

1241 2. A pharmacy is exempt from obtaining an over-the-counter
 1242 drug manufacturer permit if it is operating in compliance with
 1243 pharmacy practice standards as defined in chapter 465 and ~~the~~
 1244 rules adopted under that chapter.

1245 3. An over-the-counter drug manufacturer must comply with
 1246 all appropriate state and federal good manufacturing practices.

1247 (o) ~~(n)~~ Device manufacturer permit.—

1248 1. A device manufacturer permit is required for any person

1249 that engages in the manufacture, repackaging, or assembly of
1250 medical devices for human use in this state, except that a
1251 permit is not required if:

1252 a. The person is engaged only in manufacturing,
1253 repackaging, or assembling a medical device pursuant to a
1254 practitioner's order for a specific patient; or

1255 b. The person does not manufacture, repackage, or assemble
1256 any medical devices or components for such devices, except those
1257 devices or components which are exempt from registration
1258 pursuant to s. 499.015(8).

1259 2. A manufacturer or repackager of medical devices in this
1260 state must comply with all appropriate state and federal good
1261 manufacturing practices and quality system rules.

1262 3. The department shall adopt rules related to storage,
1263 handling, and recordkeeping requirements for manufacturers of
1264 medical devices for human use.

1265 (p)~~(e)~~ Cosmetic manufacturer permit.—A cosmetic
1266 manufacturer permit is required for any person that manufactures
1267 or repackages cosmetics in this state. A person that only labels
1268 or changes the labeling of a cosmetic but does not open the
1269 container sealed by the manufacturer of the product is exempt
1270 from obtaining a permit under this paragraph.

1271 (q)~~(p)~~ Third party logistics provider permit.—A third
1272 party logistics provider permit is required for any person that
1273 contracts with a prescription drug wholesale distributor or
1274 prescription drug manufacturer to provide warehousing,

1275 distribution, or other logistics services on behalf of a
 1276 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who
 1277 does not take title to the prescription drug or have
 1278 responsibility to direct the sale or disposition of the
 1279 prescription drug. A third party logistics provider located
 1280 outside of this state, must be licensed in the state or
 1281 territory from which the prescription drug is distributed by the
 1282 third party logistics provider. If the state or territory from
 1283 which the third party logistics provider originates does not
 1284 require a license to operate as a third party logistics
 1285 provider, the third party logistic provider must be licensed as
 1286 a third party logistics provider as required by the federal act.
 1287 Each third party logistics provider permittee shall comply with
 1288 s. the requirements for wholesale distributors under ss.
 1289 499.0121 and 499.01212, with the exception of those wholesale
 1290 distributions described in s. 499.01212(3)(a), and other rules
 1291 that the department requires.

1292 (r) ~~(q)~~ Health care clinic establishment permit. ~~Effective~~
 1293 ~~January 1, 2009,~~ A health care clinic establishment permit is
 1294 required for the purchase of a prescription drug by a place of
 1295 business at one general physical location that provides health
 1296 care or veterinary services, which is owned and operated by a
 1297 business entity that has been issued a federal employer tax
 1298 identification number. For the purpose of this paragraph, the
 1299 term "qualifying practitioner" means a licensed health care
 1300 practitioner defined in s. 456.001, or a veterinarian licensed

1301 under chapter 474, who is authorized under the appropriate
1302 practice act to prescribe and administer a prescription drug.

1303 1. An establishment must provide, as part of the
1304 application required under s. 499.012, designation of a
1305 qualifying practitioner who will be responsible for complying
1306 with all legal and regulatory requirements related to the
1307 purchase, recordkeeping, storage, and handling of the
1308 prescription drugs. In addition, the designated qualifying
1309 practitioner shall be the practitioner whose name, establishment
1310 address, and license number is used on all distribution
1311 documents for prescription drugs purchased or returned by the
1312 health care clinic establishment. Upon initial appointment of a
1313 qualifying practitioner, the qualifying practitioner and the
1314 health care clinic establishment shall notify the department on
1315 a form furnished by the department within 10 days after such
1316 employment. In addition, the qualifying practitioner and health
1317 care clinic establishment shall notify the department within 10
1318 days after any subsequent change.

1319 2. The health care clinic establishment must employ a
1320 qualifying practitioner at each establishment.

1321 3. In addition to the remedies and penalties provided in
1322 this part, a violation of this chapter by the health care clinic
1323 establishment or qualifying practitioner constitutes grounds for
1324 discipline of the qualifying practitioner by the appropriate
1325 regulatory board.

1326 4. The purchase of prescription drugs by the health care

1327 clinic establishment is prohibited during any period of time
 1328 when the establishment does not comply with this paragraph.

1329 5. A health care clinic establishment permit is not a
 1330 pharmacy permit or otherwise subject to chapter 465. A health
 1331 care clinic establishment that meets the criteria of a modified
 1332 Class II institutional pharmacy under s. 465.019 is not eligible
 1333 to be permitted under this paragraph.

1334 6. This paragraph does not apply to the purchase of a
 1335 prescription drug by a licensed practitioner under his or her
 1336 license.

1337 (3) A nonresident prescription drug manufacturer permit is
 1338 not required for a manufacturer to distribute a prescription
 1339 drug active pharmaceutical ingredient that it manufactures to a
 1340 prescription drug manufacturer permitted in this state ~~in~~
 1341 ~~limited quantities~~ intended for research and development and not
 1342 for resale or human use other than lawful clinical trials and
 1343 biostudies authorized and regulated by federal law. A
 1344 manufacturer claiming to be exempt from the permit requirements
 1345 of this subsection and the prescription drug manufacturer
 1346 purchasing and receiving the active pharmaceutical ingredient
 1347 shall comply with the recordkeeping requirements of s.
 1348 499.0121(6), ~~but not the requirements of s. 499.01212.~~ The
 1349 prescription drug manufacturer purchasing and receiving the
 1350 active pharmaceutical ingredient shall maintain on file a record
 1351 of the FDA registration number; if available, the out-of-state
 1352 license, permit, or registration number; and, if available, a

1353 copy of the most current FDA inspection report, for all
1354 manufacturers from whom they purchase active pharmaceutical
1355 ingredients under this section. ~~The department shall define the~~
1356 ~~term "limited quantities" by rule, and may include the allowable~~
1357 ~~number of transactions within a given period of time and the~~
1358 ~~amount of prescription drugs distributed into the state for~~
1359 ~~purposes of this exemption.~~ The failure to comply with the
1360 requirements of this subsection, or rules adopted by the
1361 department to administer this subsection, for the purchase of
1362 prescription drug active pharmaceutical ingredients is a
1363 violation of s. 499.005(14), and a knowing failure is a
1364 violation of s. 499.0051(4).

1365 (a) The immediate package or container of a prescription
1366 drug active pharmaceutical ingredient distributed into the state
1367 that is intended for research and development under this
1368 subsection shall bear a label prominently displaying the
1369 statement: "Caution: Research and Development Only-Not for
1370 Manufacturing, Compounding, or Resale."

1371 (b) A prescription drug manufacturer that obtains a
1372 prescription drug active pharmaceutical ingredient under this
1373 subsection for use in clinical trials and or biostudies
1374 authorized and regulated by federal law must create and maintain
1375 records detailing the specific clinical trials or biostudies for
1376 which the prescription drug active pharmaceutical ingredient was
1377 obtained.

1378 (4) (a) A permit issued under this part is not required to

1379 distribute a prescription drug active pharmaceutical ingredient
1380 from an establishment located in the United States to an
1381 establishment located in this state permitted as a prescription
1382 drug manufacturer under this part for use by the recipient in
1383 preparing, deriving, processing, producing, or fabricating a
1384 prescription drug finished dosage form at the establishment in
1385 this state where the product is received under an approved and
1386 otherwise valid New Drug Approval Application, Abbreviated New
1387 Drug Application, New Animal Drug Application, or Therapeutic
1388 Biologic Application, provided that the application, active
1389 pharmaceutical ingredient, or finished dosage form has not been
1390 withdrawn or removed from the market in this country for public
1391 health reasons.

1392 1. Any distributor claiming exemption from permitting
1393 requirements pursuant to this paragraph shall maintain a
1394 license, permit, or registration to engage in the wholesale
1395 distribution of prescription drugs under the laws of the state
1396 from which the product is distributed. If the state from which
1397 the prescription drugs are distributed does not require a
1398 license to engage in the wholesale distribution of prescription
1399 drugs, the distributor must be licensed as a wholesale
1400 distributor as required by the federal act.

1401 2. Any distributor claiming exemption from permitting
1402 requirements pursuant to this paragraph and the prescription
1403 drug manufacturer purchasing and receiving the active
1404 pharmaceutical ingredient shall comply with the recordkeeping

1405 requirements of s. 499.0121(6), ~~but not the requirements of s.~~
 1406 ~~499.01212.~~

1407 (b) A permit issued under this part is not required to
 1408 distribute ~~limited quantities~~ of a prescription drug that has
 1409 not been repackaged from an establishment located in the United
 1410 States to an establishment located in this state permitted as a
 1411 prescription drug manufacturer under this part for research and
 1412 development or to a holder of a letter of exemption issued by
 1413 the department under s. 499.03(4) for research, teaching, or
 1414 testing. ~~The department shall define "limited quantities" by~~
 1415 ~~rule and may include the allowable number of transactions within~~
 1416 ~~a given period of time and the amounts of prescription drugs~~
 1417 ~~distributed into the state for purposes of this exemption.~~

1418 1. Any distributor claiming exemption from permitting
 1419 requirements pursuant to this paragraph shall maintain a
 1420 license, permit, or registration to engage in the wholesale
 1421 distribution of prescription drugs under the laws of the state
 1422 from which the product is distributed. If the state from which
 1423 the prescription drugs are distributed does not require a
 1424 license to engage in the wholesale distribution of prescription
 1425 drugs, the distributor must be licensed as a wholesale
 1426 distributor as required by the federal act.

1427 2. All purchasers and recipients of any prescription drugs
 1428 distributed pursuant to this paragraph shall ensure that the
 1429 products are not resold or used, directly or indirectly, on
 1430 humans except in lawful clinical trials and biostudies

1431 authorized and regulated by federal law.

1432 3. Any distributor claiming exemption from permitting
1433 requirements pursuant to this paragraph, and the purchaser and
1434 recipient of the prescription drug, shall comply with the
1435 recordkeeping requirements of s. 499.0121(6), ~~but not the~~
1436 ~~requirements of s. 499.01212.~~

1437 4. The immediate package or container of any active
1438 pharmaceutical ingredient distributed into the state that is
1439 intended for teaching, testing, research, and development shall
1440 bear a label prominently displaying the statement: "Caution:
1441 Research, Teaching, or Testing Only - Not for Manufacturing,
1442 Compounding, or Resale."

1443 (c) An out-of-state prescription drug wholesale
1444 distributor permit is not required for an intracompany sale or
1445 transfer of a prescription drug from an out-of-state
1446 establishment that is duly licensed as a prescription drug
1447 wholesale distributor in its state of residence to a licensed
1448 prescription drug wholesale distributor in this state, if both
1449 wholesale distributors conduct wholesale distributions of
1450 prescription drugs under the same business name. The
1451 recordkeeping requirements of s. ss. 499.0121(6) ~~and 499.01212~~
1452 must be followed for such transactions.

1453 (d) Persons receiving prescription drugs from a source
1454 claimed to be exempt from permitting requirements under this
1455 subsection shall maintain on file:

1456 1. A record of the FDA establishment registration number,

1457 | if any;

1458 | 2. The resident state or federal license, registration, or
 1459 | permit that authorizes the source to distribute prescription
 1460 | drugs ~~drug wholesale distribution license, permit, or~~
 1461 | ~~registration number~~; and

1462 | 3. A copy of the most recent resident state or FDA
 1463 | inspection report, for all distributors and establishments from
 1464 | whom they purchase or receive prescription drugs under this
 1465 | subsection.

1466 | (e) All persons claiming exemption from permitting
 1467 | requirements pursuant to this subsection who engage in the
 1468 | distribution of prescription drugs within or into the state are
 1469 | subject to this part, including ss. 499.005 and 499.0051, and
 1470 | shall make available, within 48 hours, to the department on
 1471 | request all records related to any prescription drugs
 1472 | distributed under this subsection, including those records
 1473 | described in s. 499.051(4), regardless of the location where the
 1474 | records are stored.

1475 | (f) A person purchasing and receiving a prescription drug
 1476 | from a person claimed to be exempt from licensing requirements
 1477 | pursuant to this subsection shall report to the department in
 1478 | writing within 14 days after receiving any product that is
 1479 | misbranded or adulterated or that fails to meet minimum
 1480 | standards set forth in the official compendium or state or
 1481 | federal good manufacturing practices for identity, purity,
 1482 | potency, or sterility, regardless of whether the product is

1483 thereafter rehabilitated, quarantined, returned, or destroyed.

1484 (g) The department may adopt rules to administer this
 1485 subsection which are necessary for the protection of the public
 1486 health, safety, and welfare. Failure to comply with the
 1487 requirements of this subsection, or rules adopted by the
 1488 department to administer this subsection, is a violation of s.
 1489 499.005(14), and a knowing failure is a violation of s.
 1490 499.0051(4).

1491 (h) This subsection does not relieve any person from any
 1492 requirement prescribed by law with respect to controlled
 1493 substances as defined in the applicable federal and state laws.

1494 (5) A prescription drug repackager permit issued under
 1495 this part is not required for a restricted prescription drug
 1496 distributor permitholder that is a health care entity to
 1497 repackage prescription drugs in this state for its own use or
 1498 for distribution to hospitals or other health care entities in
 1499 the state for their own use, pursuant to s. 499.003(48)(a)3.
 1500 ~~499.003(53)(a)3.~~, if:

1501 (a) The prescription drug distributor notifies the
 1502 department, in writing, of its intention to engage in
 1503 repackaging under this exemption, 30 days before engaging in the
 1504 repackaging of prescription drugs at the permitted
 1505 establishment;

1506 (b) The prescription drug distributor is under common
 1507 control with the hospitals or other health care entities to
 1508 which the prescription drug distributor is distributing

1509 prescription drugs. As used in this paragraph, "common control"
 1510 means the power to direct or cause the direction of the
 1511 management and policies of a person or an organization, whether
 1512 by ownership of stock, voting rights, contract, or otherwise;

1513 (c) The prescription drug distributor repackages the
 1514 prescription drugs in accordance with current state and federal
 1515 good manufacturing practices; and

1516 (d) The prescription drug distributor labels the
 1517 prescription drug it repackages in accordance with state and
 1518 federal laws and rules.

1519
 1520 The prescription drug distributor is exempt from the product
 1521 registration requirements of s. 499.015 with regard to the
 1522 prescription drugs that it repackages and distributes under this
 1523 subsection. A prescription drug distributor that repackages and
 1524 distributes prescription drugs under this subsection to a not-
 1525 for-profit rural hospital, as defined in s. 395.602, is not
 1526 required to comply with paragraph (c) or paragraph (d), but must
 1527 provide to each health care entity for which it repackages, for
 1528 each prescription drug that is repackaged and distributed, the
 1529 information required by department rule for labeling
 1530 prescription drugs. The prescription drug distributor shall also
 1531 provide the additional current packaging and label information
 1532 for the prescription drug by hard copy or by electronic means.

1533 Section 6. Section 499.012, Florida Statutes, is amended
 1534 to read:

1535 499.012 Permit application requirements.—

1536 (1) (a) A permit issued pursuant to this part may be issued
 1537 only to a natural person who is at least 18 years of age or to
 1538 an applicant that is not a natural person if each person who,
 1539 directly or indirectly, manages, controls, or oversees the
 1540 operation of that applicant is at least 18 years of age.

1541 (b) An establishment that is a place of residence may not
 1542 receive a permit and may not operate under this part.

1543 (c) A person that applies for or renews a permit to
 1544 manufacture or distribute prescription drugs may not use a name
 1545 identical to the name used by any other establishment or
 1546 licensed person authorized to purchase prescription drugs in
 1547 this state, except that a restricted drug distributor permit
 1548 issued to a health care entity will be issued in the name in
 1549 which the institutional pharmacy permit is issued and a retail
 1550 pharmacy drug wholesale distributor will be issued a permit in
 1551 the name of its retail pharmacy permit.

1552 (d) A permit for a prescription drug manufacturer,
 1553 prescription drug repackager, prescription drug wholesale
 1554 distributor, limited prescription drug veterinary wholesale
 1555 distributor, or retail pharmacy drug wholesale distributor may
 1556 not be issued to the address of a health care entity or to a
 1557 pharmacy licensed under chapter 465, except as provided in this
 1558 paragraph. The department may issue a prescription drug
 1559 manufacturer permit to an applicant at the same address as a
 1560 licensed nuclear pharmacy, which is a health care entity, even

1561 if the nuclear pharmacy holds a special sterile compounding
1562 permit under chapter 465, for the purpose of manufacturing
1563 prescription drugs used in positron emission tomography or other
1564 radiopharmaceuticals, as listed in a rule adopted by the
1565 department pursuant to this paragraph. The purpose of this
1566 exemption is to assure availability of state-of-the-art
1567 pharmaceuticals that would pose a significant danger to the
1568 public health if manufactured at a separate establishment
1569 address from the nuclear pharmacy from which the prescription
1570 drugs are dispensed. The department may also issue a retail
1571 pharmacy drug wholesale distributor permit to the address of a
1572 community pharmacy licensed under chapter 465, even if the
1573 community pharmacy holds a special sterile compounding permit
1574 under chapter 465, as long as the community pharmacy ~~which~~ does
1575 not meet the definition of a closed pharmacy in s. 499.003.

1576 (e) A county or municipality may not issue an occupational
1577 license for ~~any licensing period beginning on or after October~~
1578 ~~1, 2003, for~~ any establishment that requires a permit pursuant
1579 to this part, unless the establishment exhibits a current permit
1580 issued by the department for the establishment. Upon
1581 presentation of the requisite permit issued by the department,
1582 an occupational license may be issued by the municipality or
1583 county in which application is made. The department shall
1584 furnish to local agencies responsible for issuing occupational
1585 licenses a current list of all establishments licensed pursuant
1586 to this part.

1587 (2) Notwithstanding subsection (6), a permitted person in
1588 good standing may change the type of permit issued to that
1589 person by completing a new application for the requested permit,
1590 paying the amount of the difference in the permit fees if the
1591 fee for the new permit is more than the fee for the original
1592 permit, and meeting the applicable permitting conditions for the
1593 new permit type. The new permit expires on the expiration date
1594 of the original permit being changed; however, a new permit for
1595 a prescription drug wholesale distributor, an out-of-state
1596 prescription drug wholesale distributor, or a retail pharmacy
1597 drug wholesale distributor shall expire on the expiration date
1598 of the original permit or 1 year after the date of issuance of
1599 the new permit, whichever is earlier. A refund may not be issued
1600 if the fee for the new permit is less than the fee that was paid
1601 for the original permit.

1602 (3) (a) A written application for a permit or to renew a
1603 permit must be filed with the department on forms furnished by
1604 the department. The department shall establish, by rule, the
1605 form and content of the application to obtain or renew a permit.
1606 The applicant must submit to the department with the application
1607 a statement that swears or affirms that the information is true
1608 and correct.

1609 (b) Upon a determination that 2 years have elapsed since
1610 the department notified an applicant for permit, certification,
1611 or product registration of a deficiency in the application and
1612 that the applicant has failed to cure the deficiency, the

1613 application shall expire. The determination regarding the 2-year
1614 lapse of time shall be based on documentation that the
1615 department notified the applicant of the deficiency in
1616 accordance with s. 120.60.

1617 (c) Information submitted by an applicant on an
1618 application required pursuant to this subsection which is a
1619 trade secret, as defined in s. 812.081, shall be maintained by
1620 the department as trade secret information pursuant to s.
1621 499.051(7).

1622 (4) (a) Except for a permit for a prescription drug
1623 wholesale distributor or an out-of-state prescription drug
1624 wholesale distributor, an application for a permit must include:

1625 1. The name, full business address, and telephone number
1626 of the applicant;

1627 2. All trade or business names used by the applicant;

1628 3. The address, telephone numbers, and the names of
1629 contact persons for each facility used by the applicant for the
1630 storage, handling, and distribution of prescription drugs;

1631 4. The type of ownership or operation, such as a
1632 partnership, corporation, or sole proprietorship; and

1633 5. The names of the owner and the operator of the
1634 establishment, including:

1635 a. If an individual, the name of the individual;

1636 b. If a partnership, the name of each partner and the name
1637 of the partnership;

1638 c. If a corporation, the name and title of each corporate

1639 officer and director, the corporate names, and the name of the
1640 state of incorporation;

1641 d. If a sole proprietorship, the full name of the sole
1642 proprietor and the name of the business entity;

1643 e. If a limited liability company, the name of each
1644 member, the name of each manager, the name of the limited
1645 liability company, and the name of the state in which the
1646 limited liability company was organized; and

1647 f. Any other relevant information that the department
1648 requires.

1649 (b) Upon approval of the application by the department and
1650 payment of the required fee, the department shall issue a permit
1651 to the applicant, if the applicant meets the requirements of
1652 this part and rules adopted under this part.

1653 (c) Any change in information required under paragraph (a)
1654 must be submitted to the department before the change occurs.

1655 (d) The department shall consider, at a minimum, the
1656 following factors in reviewing the qualifications of persons to
1657 be permitted under this part:

1658 1. The applicant's having been found guilty, regardless of
1659 adjudication, in a court of this state or other jurisdiction, of
1660 a violation of a law that directly relates to a drug, device, or
1661 cosmetic. A plea of nolo contendere constitutes a finding of
1662 guilt for purposes of this subparagraph.

1663 2. The applicant's having been disciplined by a regulatory
1664 agency in any state for any offense that would constitute a

1665 violation of this part.

1666 3. Any felony conviction of the applicant under a federal,
1667 state, or local law;

1668 4. The applicant's past experience in manufacturing or
1669 distributing drugs, devices, or cosmetics;

1670 5. The furnishing by the applicant of false or fraudulent
1671 material in any application made in connection with
1672 manufacturing or distributing drugs, devices, or cosmetics;

1673 6. Suspension or revocation by a federal, state, or local
1674 government of any permit currently or previously held by the
1675 applicant for the manufacture or distribution of any drugs,
1676 devices, or cosmetics;

1677 7. Compliance with permitting requirements under any
1678 previously granted permits;

1679 8. Compliance with requirements to maintain or make
1680 available to the state permitting authority or to federal,
1681 state, or local law enforcement officials those records required
1682 under this section; and

1683 9. Any other factors or qualifications the department
1684 considers relevant to and consistent with the public health and
1685 safety.

1686 (5) ~~Except for a permit for a prescription drug wholesale~~
1687 ~~distributor or an out-of-state prescription drug wholesale~~
1688 ~~distributor:~~

1689 (a) The department shall adopt rules for the biennial
1690 renewal of permits; however, the department may issue up to a 4-

1691 year permit to selected permittees notwithstanding any other
1692 provision of law. Fees for such renewal may not exceed the fee
1693 caps set forth in s. 499.041 on an annualized basis as
1694 authorized by law.

1695 (b) The department shall renew a permit upon receipt of
1696 the renewal application and renewal fee if the applicant meets
1697 the requirements established under this part and ~~the~~ rules
1698 adopted under this part.

1699 (c) At least 90 days before the expiration date of a
1700 permit, the department shall forward a permit renewal
1701 notification to the permittee at the mailing address of the
1702 permitted establishment on file with the department. The permit
1703 renewal notification must state conspicuously the date on which
1704 the permit for the establishment will expire and that the
1705 establishment may not operate unless the permit for the
1706 establishment is renewed timely. A permit, unless sooner
1707 ~~suspended or revoked, automatically expires 2 years after the~~
1708 ~~last day of the anniversary month in which the permit was~~
1709 ~~originally issued.~~

1710 (d) A permit issued under this part may be renewed by
1711 making application for renewal on forms furnished by the
1712 department and paying the appropriate fees.

1713 1. If a prescription drug wholesale distributor or an out-
1714 of-state prescription drug wholesale distributor renewal
1715 application and fee are submitted and postmarked later than 45
1716 days before the expiration date of the permit, the permit may be

1717 renewed only upon payment of a late renewal fee of \$100, plus
1718 the required renewal fee.

1719 2. If any other a renewal application and fee are
1720 submitted and postmarked after the expiration date of the
1721 permit, the permit may be renewed only upon payment of a late
1722 renewal delinquent fee of \$100, plus the required renewal fee,
1723 not later than 60 days after the expiration date.

1724 3. A permittee who submits a renewal application in
1725 accordance with this paragraph may continue to operate under its
1726 permit, unless the permit is suspended or revoked, until final
1727 disposition of the renewal application.

1728 4.~~(d)~~ Failure to renew a permit in accordance with this
1729 section precludes any future renewal of that permit. If a permit
1730 issued pursuant to this part has expired and cannot be renewed,
1731 before an establishment may engage in activities that require a
1732 permit under this part, the establishment must submit an
1733 application for a new permit, pay the applicable application
1734 fee, the initial permit fee, and all applicable penalties, and
1735 be issued a new permit by the department.

1736 (6) A permit issued by the department is nontransferable.
1737 Each permit is valid only for the person or governmental unit to
1738 which it is issued and is not subject to sale, assignment, or
1739 other transfer, voluntarily or involuntarily; nor is a permit
1740 valid for any establishment other than the establishment for
1741 which it was originally issued.

1742 (a) A person permitted under this part must notify the

1743 department before making a change of address. The department
 1744 shall set a change of location fee not to exceed \$100.

1745 (b)1. An application for a new permit is required when a
 1746 majority of the ownership or controlling interest of a permitted
 1747 establishment is transferred or assigned or when a lessee agrees
 1748 to undertake or provide services to the extent that legal
 1749 liability for operation of the establishment will rest with the
 1750 lessee. The application for the new permit must be made before
 1751 the date of the sale, transfer, assignment, or lease.

1752 2. A permittee that is authorized to distribute
 1753 prescription drugs may transfer such drugs to the new owner or
 1754 lessee under subparagraph 1. only after the new owner or lessee
 1755 has been approved for a permit to distribute prescription drugs.

1756 (c) If an establishment permitted under this part closes,
 1757 the owner must notify the department in writing before the
 1758 effective date of closure and must:

- 1759 1. Return the permit to the department;
- 1760 2. If the permittee is authorized to distribute
 1761 prescription drugs, indicate the disposition of such drugs,
 1762 including the name, address, and inventory, and provide the name
 1763 and address of a person to contact regarding access to records
 1764 that are required to be maintained under this part. Transfer of
 1765 ownership of prescription drugs may be made only to persons
 1766 authorized to possess prescription drugs under this part.

1767
 1768 The department may revoke the permit of any person that fails to

1769 | comply with the requirements of this subsection.

1770 | (7) A permit must be posted in a conspicuous place on the
1771 | licensed premises.

1772 | (8) An application for a permit or to renew a permit for a
1773 | prescription drug wholesale distributor or an out-of-state
1774 | prescription drug wholesale distributor submitted to the
1775 | department must include:

1776 | (a) The name, full business address, and telephone number
1777 | of the applicant.

1778 | (b) All trade or business names used by the applicant.

1779 | (c) The address, telephone numbers, and the names of
1780 | contact persons for each facility used by the applicant for the
1781 | storage, handling, and distribution of prescription drugs.

1782 | (d) The type of ownership or operation, such as a
1783 | partnership, corporation, or sole proprietorship.

1784 | (e) The names of the owner and the operator of the
1785 | establishment, including:

1786 | 1. If an individual, the name of the individual.

1787 | 2. If a partnership, the name of each partner and the name
1788 | of the partnership.

1789 | 3. If a corporation:

1790 | a. The name, address, and title of each corporate officer
1791 | and director.

1792 | b. The name and address of the corporation, resident agent
1793 | of the corporation, the resident agent's address, and the
1794 | corporation's state of incorporation.

1795 c. The name and address of each shareholder of the
 1796 corporation that owns 5 percent or more of the outstanding stock
 1797 of the corporation.

1798 4. If a sole proprietorship, the full name of the sole
 1799 proprietor and the name of the business entity.

1800 5. If a limited liability company:

1801 a. The name and address of each member.

1802 b. The name and address of each manager.

1803 c. The name and address of the limited liability company,
 1804 the resident agent of the limited liability company, and the
 1805 name of the state in which the limited liability company was
 1806 organized.

1807 (f) If applicable, the name and address of each affiliate
 1808 ~~of member of the affiliated group of which the applicant is a~~
 1809 ~~member.~~

1810 (g)~~1.~~ The applicant's gross annual receipts attributable
 1811 to prescription drug wholesale distribution activities for the
 1812 previous tax year. ~~For an application for a new permit, the~~
 1813 ~~estimated annual dollar volume of prescription drug sales of the~~
 1814 ~~applicant, the estimated annual percentage of the applicant's~~
 1815 ~~total company sales that are prescription drugs, the applicant's~~
 1816 ~~estimated annual total dollar volume of purchases of~~
 1817 ~~prescription drugs, and the applicant's estimated annual total~~
 1818 ~~dollar volume of prescription drug purchases directly from~~
 1819 ~~manufacturers.~~

1820 ~~2. For an application to renew a permit, the total dollar~~

1821 ~~volume of prescription drug sales in the previous year, the~~
1822 ~~total dollar volume of prescription drug sales made in the~~
1823 ~~previous 6 months, the percentage of total company sales that~~
1824 ~~were prescription drugs in the previous year, the total dollar~~
1825 ~~volume of purchases of prescription drugs in the previous year,~~
1826 ~~and the total dollar volume of prescription drug purchases~~
1827 ~~directly from manufacturers in the previous year.~~

1828
1829 ~~Such portions of the information required pursuant to this~~
1830 ~~paragraph which are a trade secret, as defined in s. 812.081,~~
1831 ~~shall be maintained by the department as trade secret~~
1832 ~~information is required to be maintained under s. 499.051.~~

1833 (h) The tax year of the applicant.

1834 (i) A copy of the deed for the property on which
1835 applicant's establishment is located, if the establishment is
1836 owned by the applicant, or a copy of the applicant's lease for
1837 the property on which applicant's establishment is located that
1838 has an original term of not less than 1 calendar year, if the
1839 establishment is not owned by the applicant.

1840 (j) A list of all licenses and permits issued to the
1841 applicant by any other state which authorize the applicant to
1842 purchase or possess prescription drugs.

1843 (k) The name of the manager of the establishment that is
1844 applying for the permit or to renew the permit, the next four
1845 highest ranking employees responsible for prescription drug
1846 wholesale operations for the establishment, and the name of all

1847 affiliated parties for the establishment, together with the
 1848 personal information statement and fingerprints required
 1849 pursuant to subsection (9) for each of such persons.

1850 (l) The name of each of the applicant's designated
 1851 representatives as required by subsection (15) ~~(16)~~, together
 1852 with the personal information statement and fingerprints
 1853 required pursuant to subsection (9) for each such person.

1854 (m) Evidence of a surety bond in this state or any other
 1855 state in the United States in the amount of \$100,000. If the
 1856 annual gross receipts of the applicant's previous tax year is
 1857 \$10 million or less, evidence of a surety bond in the amount of
 1858 \$25,000. The specific language of the surety bond must include
 1859 the State of Florida as a beneficiary, payable to the
 1860 Professional Regulation Trust Fund. In lieu of the surety bond,
 1861 the applicant may provide other equivalent security, such as an
 1862 irrevocable letter of credit or a deposit in a trust account or
 1863 financial institution, that includes the State of Florida as a
 1864 beneficiary, payable to the Professional Regulation Trust Fund.
 1865 The purpose of the bond or other security is to secure payment
 1866 of any administrative penalties imposed by the department and
 1867 any fees and costs incurred by the department regarding that
 1868 permit which are authorized under state law and which the
 1869 permittee fails to pay 30 days after the fine or costs become
 1870 final. The department may make a claim against such bond or
 1871 security until 1 year after the permittee's license ceases to be
 1872 valid or until 60 days after any administrative or legal

1873 proceeding authorized in this part which involves the permittee
 1874 is concluded, including any appeal, whichever occurs later. ~~For~~
 1875 ~~an applicant that is a secondary wholesale distributor, each of~~
 1876 ~~the following:~~

1877 ~~1. A personal background information statement containing~~
 1878 ~~the background information and fingerprints required pursuant to~~
 1879 ~~subsection (9) for each person named in the applicant's response~~
 1880 ~~to paragraphs (k) and (l) and for each affiliated party of the~~
 1881 ~~applicant.~~

1882 ~~2. If any of the five largest shareholders of the~~
 1883 ~~corporation seeking the permit is a corporation, the name,~~
 1884 ~~address, and title of each corporate officer and director of~~
 1885 ~~each such corporation; the name and address of such corporation;~~
 1886 ~~the name of such corporation's resident agent, such~~
 1887 ~~corporation's resident agent's address, and such corporation's~~
 1888 ~~state of its incorporation; and the name and address of each~~
 1889 ~~shareholder of such corporation that owns 5 percent or more of~~
 1890 ~~the stock of such corporation.~~

1891 ~~3. The name and address of all financial institutions in~~
 1892 ~~which the applicant has an account which is used to pay for the~~
 1893 ~~operation of the establishment or to pay for drugs purchased for~~
 1894 ~~the establishment, together with the names of all persons that~~
 1895 ~~are authorized signatories on such accounts. The portions of the~~
 1896 ~~information required pursuant to this subparagraph which are a~~
 1897 ~~trade secret, as defined in s. 812.081, shall be maintained by~~
 1898 ~~the department as trade secret information is required to be~~

1899 ~~maintained under s. 499.051.~~

1900 ~~4. The sources of all funds and the amounts of such funds~~
 1901 ~~used to purchase or finance purchases of prescription drugs or~~
 1902 ~~to finance the premises on which the establishment is to be~~
 1903 ~~located.~~

1904 ~~5. If any of the funds identified in subparagraph 4. were~~
 1905 ~~borrowed, copies of all promissory notes or loans used to obtain~~
 1906 ~~such funds.~~

1907 (n) For establishments used in wholesale distribution,
 1908 proof of an inspection conducted by the department, the United
 1909 States Food and Drug Administration, or another governmental
 1910 entity charged with the regulation of good manufacturing
 1911 practices related to wholesale distribution of prescription
 1912 drugs, within timeframes set forth by the department in
 1913 departmental rules, which demonstrates substantial compliance
 1914 with current good manufacturing practices applicable to
 1915 wholesale distribution of prescription drugs. The department may
 1916 recognize another state's inspection of a wholesale distributor
 1917 located in that state if such state's laws are deemed to be
 1918 substantially equivalent to the law of this state by the
 1919 department. The department may accept an inspection by a third-
 1920 party accreditation or inspection service which meets the
 1921 criteria set forth in department rule.

1922 ~~(o)(n)~~ Any other relevant information that the department
 1923 requires, including, but not limited to, any information related
 1924 to whether the applicant satisfies the definition of a primary

1925 ~~wholesale distributor or a secondary wholesale distributor.~~
 1926 (p)~~(e)~~ Documentation of the credentialing policies and
 1927 procedures required by s. 499.0121(15).
 1928 (9) (a) Each person required by subsection (8) or
 1929 subsection (15) to provide a personal information statement and
 1930 fingerprints shall provide the following information to the
 1931 department on forms prescribed by the department:
 1932 1. The person's places of residence for the past 7 years.
 1933 2. The person's date and place of birth.
 1934 3. The person's occupations, positions of employment, and
 1935 offices held during the past 7 years.
 1936 4. The principal business and address of any business,
 1937 corporation, or other organization in which each such office of
 1938 the person was held or in which each such occupation or position
 1939 of employment was carried on.
 1940 5. Whether the person has been, during the past 7 years,
 1941 the subject of any proceeding for the revocation of any license
 1942 and, if so, the nature of the proceeding and the disposition of
 1943 the proceeding.
 1944 6. Whether, during the past 7 years, the person has been
 1945 enjoined, temporarily or permanently, by a court of competent
 1946 jurisdiction from violating any federal or state law regulating
 1947 the possession, control, or distribution of prescription drugs,
 1948 together with details concerning any such event.
 1949 7. A description of any involvement by the person with any
 1950 business, including any investments, other than the ownership of

1951 stock in a publicly traded company or mutual fund, during the
1952 past 4 7 years, which manufactured, administered, prescribed,
1953 distributed, or stored pharmaceutical products and any lawsuits
1954 in which such businesses were named as a party.

1955 8. A description of any felony criminal offense of which
1956 the person, as an adult, was found guilty, regardless of whether
1957 adjudication of guilt was withheld or whether the person pled
1958 guilty or nolo contendere. A criminal offense committed in
1959 another jurisdiction which would have been a felony in this
1960 state must be reported. If the person indicates that a criminal
1961 conviction is under appeal and submits a copy of the notice of
1962 appeal of that criminal offense, the applicant must, within 15
1963 days after the disposition of the appeal, submit to the
1964 department a copy of the final written order of disposition.

1965 9. A photograph of the person taken in the previous 180 ~~30~~
1966 days.

1967 10. A set of fingerprints for the person on a form and
1968 under procedures specified by the department, together with
1969 payment of an amount equal to the costs incurred by the
1970 department for the criminal record check of the person.

1971 11. The name, address, occupation, and date and place of
1972 birth for each member of the person's immediate family who is 18
1973 years of age or older. As used in this subparagraph, the term
1974 "member of the person's immediate family" includes the person's
1975 spouse, children, parents, siblings, the spouses of the person's
1976 children, and the spouses of the person's siblings.

1977 12. Any other relevant information that the department
1978 requires.

1979 (b) The information required pursuant to paragraph (a)
1980 shall be provided under oath.

1981 (c) The department shall submit the fingerprints provided
1982 by a person for initial licensure to the Department of Law
1983 Enforcement for a statewide criminal record check and for
1984 forwarding to the Federal Bureau of Investigation for a national
1985 criminal record check of the person. The department shall submit
1986 the fingerprints provided by a person as a part of a renewal
1987 application to the Department of Law Enforcement for a statewide
1988 criminal record check, and for forwarding to the Federal Bureau
1989 of Investigation for a national criminal record check, for the
1990 initial renewal of a permit after January 1, 2004; for any
1991 subsequent renewal of a permit, the department shall submit the
1992 required information for a statewide and national criminal
1993 record check of the person. Any person who as a part of an
1994 initial permit application or initial permit renewal after
1995 January 1, 2004, submits to the department a set of fingerprints
1996 required for the criminal record check required in this
1997 paragraph are ~~shall~~ not ~~be~~ required to provide a subsequent set
1998 of fingerprints for a criminal record check to the department,
1999 if the person has undergone a criminal record check as a
2000 condition of the issuance of an initial permit or the initial
2001 renewal of a permit of an applicant after January 1, 2004. The
2002 department is authorized to contract with private vendors, or

2003 enter into interagency agreements, to collect electronic
 2004 fingerprints where fingerprints are required for registration,
 2005 certification, or the licensure process or where criminal
 2006 history record checks are required.

2007 (d) For purposes of applying for renewal of a permit under
 2008 subsection (8) or certification under subsection (16), a person
 2009 may submit the following in lieu of satisfying the requirements
 2010 of paragraphs (a), (b), and (c):

2011 1. A photograph of the individual taken within 180 days;
 2012 and

2013 2. A copy of the personal information statement form most
 2014 recently submitted to the department and a certification under
 2015 oath, on a form specified by the department, that the individual
 2016 has reviewed the previously submitted personal information
 2017 statement form and that the information contained therein
 2018 remains unchanged.

2019 (10) The department may deny an application for a permit
 2020 or refuse to renew a permit for a prescription drug wholesale
 2021 distributor or an out-of-state prescription drug wholesale
 2022 distributor if:

2023 (a) The applicant has not met the requirements for the
 2024 permit.

2025 (b) The management, officers, or directors of the
 2026 applicant or any affiliated party are found by the department to
 2027 be incompetent or untrustworthy.

2028 (c) The applicant is so lacking in experience in managing

2029 a wholesale distributor as to make the issuance of the proposed
2030 permit hazardous to the public health.

2031 (d) The applicant is so lacking in experience in managing
2032 a wholesale distributor as to jeopardize the reasonable promise
2033 of successful operation of the wholesale distributor.

2034 (e) The applicant is lacking in experience in the
2035 distribution of prescription drugs.

2036 (f) The applicant's past experience in manufacturing or
2037 distributing prescription drugs indicates that the applicant
2038 poses a public health risk.

2039 (g) The applicant is affiliated directly or indirectly
2040 through ownership, control, or other business relations, with
2041 any person or persons whose business operations are or have been
2042 detrimental to the public health.

2043 (h) The applicant, or any affiliated party, has been found
2044 guilty of or has pleaded guilty or nolo contendere to any felony
2045 or crime punishable by imprisonment for 1 year or more under the
2046 laws of the United States, any state, or any other country,
2047 regardless of whether adjudication of guilt was withheld.

2048 (i) The applicant or any affiliated party has been charged
2049 with a felony in a state or federal court and the disposition of
2050 that charge is pending during the application review or renewal
2051 review period.

2052 (j) The applicant has furnished false or fraudulent
2053 information or material in any application made in this state or
2054 any other state in connection with obtaining a permit or license

2055 to manufacture or distribute drugs, devices, or cosmetics.

2056 (k) That a federal, state, or local government permit
2057 currently or previously held by the applicant, or any affiliated
2058 party, for the manufacture or distribution of any drugs,
2059 devices, or cosmetics has been disciplined, suspended, or
2060 revoked and has not been reinstated.

2061 (l) The applicant does not possess the financial or
2062 physical resources to operate in compliance with the permit
2063 being sought, this chapter, and the rules adopted under this
2064 chapter.

2065 (m) The applicant or any affiliated party receives,
2066 directly or indirectly, financial support and assistance from a
2067 person who was an affiliated party of a permittee whose permit
2068 was subject to discipline or was suspended or revoked, other
2069 than through the ownership of stock in a publicly traded company
2070 or a mutual fund.

2071 (n) The applicant or any affiliated party receives,
2072 directly or indirectly, financial support and assistance from a
2073 person who has been found guilty of any violation of this part
2074 or chapter 465, chapter 501, or chapter 893, any rules adopted
2075 under this part or those chapters, any federal or state drug
2076 law, or any felony where the underlying facts related to drugs,
2077 regardless of whether the person has been pardoned, had her or
2078 his civil rights restored, or had adjudication withheld, other
2079 than through the ownership of stock in a publicly traded company
2080 or a mutual fund.

2081 (o) The applicant for renewal of a permit under s.
 2082 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged
 2083 in the wholesale distribution of prescription drugs, as
 2084 demonstrated by the regular and systematic distribution of
 2085 prescription drugs throughout the year as evidenced by not fewer
 2086 than 12 wholesale distributions in the previous year and not
 2087 fewer than three wholesale distributions in the previous 6
 2088 months.

2089 (p) Information obtained in response to s. 499.01(2)(e) or
 2090 (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best
 2091 interest of the public health, safety, and welfare to issue a
 2092 permit.

2093 (q) The applicant does not possess the financial standing
 2094 and business experience for the successful operation of the
 2095 applicant.

2096 (r) The applicant or any affiliated party has failed to
 2097 comply with the requirements for manufacturing or distributing
 2098 prescription drugs under this part, similar federal laws,
 2099 similar laws in other states, or the rules adopted under such
 2100 laws.

2101 (11) Upon approval of the application by the department
 2102 and payment of the required fee, the department shall issue or
 2103 renew a prescription drug wholesale distributor or an out-of-
 2104 state prescription drug wholesale distributor permit to the
 2105 applicant.

2106 ~~(12) For a permit for a prescription drug wholesale~~

CS/HB 1211

2016

2107 ~~distributor or an out-of-state prescription drug wholesale~~
2108 ~~distributor:~~

2109 ~~(a) The department shall adopt rules for the annual~~
2110 ~~renewal of permits. At least 90 days before the expiration of a~~
2111 ~~permit, the department shall forward a permit renewal~~
2112 ~~notification and renewal application to the prescription drug~~
2113 ~~wholesale distributor or out-of-state prescription drug~~
2114 ~~wholesale distributor at the mailing address of the permitted~~
2115 ~~establishment on file with the department. The permit renewal~~
2116 ~~notification must state conspicuously the date on which the~~
2117 ~~permit for the establishment will expire and that the~~
2118 ~~establishment may not operate unless the permit for the~~
2119 ~~establishment is renewed timely.~~

2120 ~~(b) A permit, unless sooner suspended or revoked,~~
2121 ~~automatically expires 1 year after the last day of the~~
2122 ~~anniversary month in which the permit was originally issued. A~~
2123 ~~permit may be renewed by making application for renewal on forms~~
2124 ~~furnished by the department and paying the appropriate fees. If~~
2125 ~~a renewal application and fee are submitted and postmarked after~~
2126 ~~45 days prior to the expiration date of the permit, the permit~~
2127 ~~may be renewed only upon payment of a late renewal fee of \$100,~~
2128 ~~plus the required renewal fee. A permittee that has submitted a~~
2129 ~~renewal application in accordance with this paragraph may~~
2130 ~~continue to operate under its permit, unless the permit is~~
2131 ~~suspended or revoked, until final disposition of the renewal~~
2132 ~~application.~~

2133 ~~(c) Failure to renew a permit in accordance with this~~
 2134 ~~section precludes any future renewal of that permit. If a permit~~
 2135 ~~issued pursuant to this section has expired and cannot be~~
 2136 ~~renewed, before an establishment may engage in activities that~~
 2137 ~~require a permit under this part, the establishment must submit~~
 2138 ~~an application for a new permit; pay the applicable application~~
 2139 ~~fee, initial permit fee, and all applicable penalties; and be~~
 2140 ~~issued a new permit by the department.~~

2141 (12)~~(13)~~ A person that engages in wholesale distribution
 2142 of prescription drugs in this state must have a wholesale
 2143 distributor's permit issued by the department, except as noted
 2144 in this section. Each establishment must be separately permitted
 2145 except as noted in this subsection.

2146 (a) A separate establishment permit is not required when a
 2147 permitted prescription drug wholesale distributor consigns a
 2148 prescription drug to a pharmacy that is permitted under chapter
 2149 465 and located in this state, provided that:

2150 1. The consignor wholesale distributor notifies the
 2151 department in writing of the contract to consign prescription
 2152 drugs to a pharmacy along with the identity and location of each
 2153 consignee pharmacy;

2154 2. The pharmacy maintains its permit under chapter 465;

2155 3. The consignor wholesale distributor, which has no legal
 2156 authority to dispense prescription drugs, complies with all
 2157 wholesale distribution requirements of s. ss. 499.0121 ~~and~~
 2158 ~~499.01212~~ with respect to the consigned drugs and maintains

CS/HB 1211

2016

2159 records documenting the transfer of title or other completion of
2160 the wholesale distribution of the consigned prescription drugs;

2161 4. The distribution of the prescription drug is otherwise
2162 lawful under this chapter and other applicable law;

2163 5. Open packages containing prescription drugs within a
2164 pharmacy are the responsibility of the pharmacy, regardless of
2165 how the drugs are titled; and

2166 6. The pharmacy dispenses the consigned prescription drug
2167 in accordance with the limitations of its permit under chapter
2168 465 or returns the consigned prescription drug to the consignor
2169 wholesale distributor. In addition, a person who holds title to
2170 prescription drugs may transfer the drugs to a person permitted
2171 or licensed to handle the reverse distribution or destruction of
2172 drugs. Any other distribution by and means of the consigned
2173 prescription drug by any person, not limited to the consignor
2174 wholesale distributor or consignee pharmacy, to any other person
2175 is prohibited.

2176 (b) A wholesale distributor's permit is not required for
2177 the one-time transfer of title of a pharmacy's lawfully acquired
2178 prescription drug inventory by a pharmacy with a valid permit
2179 issued under chapter 465 to a consignor prescription drug
2180 wholesale distributor, permitted under this chapter, in
2181 accordance with a written consignment agreement between the
2182 pharmacy and that wholesale distributor if the permitted
2183 pharmacy and the permitted prescription drug wholesale
2184 distributor comply with all of the provisions of paragraph (a)

CS/HB 1211

2016

2185 and the prescription drugs continue to be within the permitted
2186 pharmacy's inventory for dispensing in accordance with the
2187 limitations of the pharmacy permit under chapter 465. A
2188 consignor drug wholesale distributor may not use the pharmacy as
2189 a wholesale distributor through which it distributes the
2190 prescription drugs to other pharmacies. Nothing in this section
2191 is intended to prevent a wholesale distributor from obtaining
2192 this inventory in the event of nonpayment by the pharmacy.

2193 (c) A separate establishment permit is not required when a
2194 permitted prescription drug wholesale distributor operates
2195 temporary transit storage facilities for the sole purpose of
2196 storage, for up to 16 hours, of a delivery of prescription drugs
2197 when the wholesale distributor was temporarily unable to
2198 complete the delivery to the recipient.

2199 (d) The department shall require information from each
2200 wholesale distributor as part of the permit and renewal of such
2201 permit, as required under this section.

2202 (13)~~(14)~~ Personnel employed in wholesale distribution must
2203 have appropriate education and experience to enable them to
2204 perform their duties in compliance with state permitting
2205 requirements.

2206 (14)~~(15)~~ The name of a permittee or establishment on a
2207 prescription drug wholesale distributor permit or an out-of-
2208 state prescription drug wholesale distributor permit may not
2209 include any indicia of attainment of any educational degree, any
2210 indicia that the permittee or establishment possesses a

2211 professional license, or any name or abbreviation that the
 2212 department determines is likely to cause confusion or mistake or
 2213 that the department determines is deceptive, including that of
 2214 any other entity authorized to purchase prescription drugs.

2215 (15)~~(16)~~(a) Each establishment that is issued an initial
 2216 or renewal permit as a prescription drug wholesale distributor
 2217 or an out-of-state prescription drug wholesale distributor must
 2218 designate in writing to the department at least one natural
 2219 person to serve as the designated representative of the
 2220 wholesale distributor. Such person must have an active
 2221 certification as a designated representative from the
 2222 department.

2223 (b) To be certified as a designated representative, a
 2224 natural person must:

- 2225 1. Submit an application on a form furnished by the
 2226 department and pay the appropriate fees.
- 2227 2. Be at least 18 years of age.
- 2228 3. Have at least 2 years of verifiable full-time:
 - 2229 a. Work experience in a pharmacy licensed in this state or
 2230 another state, where the person's responsibilities included, but
 2231 were not limited to, recordkeeping for prescription drugs;
 - 2232 b. Managerial experience with a prescription drug
 2233 wholesale distributor licensed in this state or in another
 2234 state; or
 - 2235 c. Managerial experience with the United States Armed
 2236 Forces, where the person's responsibilities included, but were

2237 not limited to, recordkeeping, warehousing, distributing, or
 2238 other logistics services pertaining to prescription drugs.

2239 4. Receive a passing score of at least 75 percent on an
 2240 examination given by the department regarding federal laws
 2241 governing distribution of prescription drugs and this part and
 2242 the rules adopted by the department governing the wholesale
 2243 distribution of prescription drugs. This requirement shall be
 2244 effective 1 year after the results of the initial examination
 2245 are mailed to the persons that took the examination. The
 2246 department shall offer such examinations at least four times
 2247 each calendar year.

2248 5. Provide the department with a personal information
 2249 statement and fingerprints pursuant to subsection (9).

2250 (c) The department may deny an application for
 2251 certification as a designated representative or may suspend or
 2252 revoke a certification of a designated representative pursuant
 2253 to s. 499.067.

2254 (d) A designated representative:

2255 1. Must be actively involved in and aware of the actual
 2256 daily operation of the wholesale distributor.

2257 2. Must be employed full time in a managerial position by
 2258 the wholesale distributor.

2259 3. Must be physically present at the establishment during
 2260 normal business hours, except for time periods when absent due
 2261 to illness, family illness or death, scheduled vacation, or
 2262 other authorized absence.

CS/HB 1211

2016

2263 4. May serve as a designated representative for only one
 2264 wholesale distributor at any one time.

2265 (e) A wholesale distributor must notify the department
 2266 when a designated representative leaves the employ of the
 2267 wholesale distributor. Such notice must be provided to the
 2268 department within 10 business days after the last day of
 2269 designated representative's employment with the wholesale
 2270 distributor.

2271 (f) A wholesale distributor may not operate under a
 2272 prescription drug wholesale distributor permit or an out-of-
 2273 state prescription drug wholesale distributor permit for more
 2274 than 10 business days after the designated representative leaves
 2275 the employ of the wholesale distributor, unless the wholesale
 2276 distributor employs another designated representative and
 2277 notifies the department within 10 business days of the identity
 2278 of the new designated representative.

2279 Section 7. Section 499.01201, Florida Statutes, is amended
 2280 to read:

2281 499.01201 Agency for Health Care Administration review and
 2282 use of statute and rule violation or compliance data.—
 2283 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~
 2284 ~~contrary~~, the Agency for Health Care Administration may not:

2285 (1) Review or use any violation or alleged violation of s.
 2286 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that
 2287 section ~~those sections~~, as a ground for denying or withholding
 2288 any payment of a Medicaid reimbursement to a pharmacy licensed

2289 under chapter 465; or

2290 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~
 2291 ~~499.01212~~, or any rules adopted under that section ~~these~~
 2292 ~~sections~~, as the subject of any audit of Medicaid-related
 2293 records held by a pharmacy licensed under chapter 465.

2294 Section 8. Paragraph (d) of subsection (4), subsection
 2295 (6), and paragraph (b) of subsection (15) of section 499.0121,
 2296 Florida Statutes, are amended to read:

2297 499.0121 Storage and handling of prescription drugs;
 2298 recordkeeping.—The department shall adopt rules to implement
 2299 this section as necessary to protect the public health, safety,
 2300 and welfare. Such rules shall include, but not be limited to,
 2301 requirements for the storage and handling of prescription drugs
 2302 and for the establishment and maintenance of prescription drug
 2303 distribution records.

2304 (4) EXAMINATION OF MATERIALS AND RECORDS.—

2305 (d) Upon receipt, a wholesale distributor must review
 2306 records required under this section for the acquisition of
 2307 prescription drugs for accuracy and completeness, considering
 2308 the total facts and circumstances surrounding the transactions
 2309 and the wholesale distributors involved. ~~This includes~~
 2310 ~~authenticating each transaction listed on a pedigree paper, as~~
 2311 ~~defined in s. 499.003(37).~~

2312 (6) RECORDKEEPING.—The department shall adopt rules that
 2313 require keeping such records of prescription drugs, including
 2314 active pharmaceutical ingredients, as are necessary for the

2315 protection of the public health.

2316 (a) ~~Wholesale~~ Distributors of prescription drugs and
 2317 active pharmaceutical ingredients must establish and maintain
 2318 inventories and records of all transactions regarding the
 2319 receipt and distribution or other disposition of prescription
 2320 drugs and active pharmaceutical ingredients. These records must
 2321 provide a complete audit trail from receipt to sale or other
 2322 disposition, be readily retrievable for inspection, and include,
 2323 at a minimum, the following information:

2324 1. The source of the prescription drugs or active
 2325 pharmaceutical ingredients, including the name and principal
 2326 address of the seller or transferor, and the address of the
 2327 location from which the prescription drugs were shipped;

2328 2. The name, principal address, and state license permit
 2329 or registration number of the person authorized to purchase
 2330 prescription drugs or active pharmaceutical ingredients;

2331 3. The name, strength, dosage form, and quantity of the
 2332 prescription drugs received and distributed or disposed of;

2333 4. The dates of receipt and distribution or other
 2334 disposition of the prescription drugs or active pharmaceutical
 2335 ingredients; and

2336 5. Any financial documentation supporting the transaction.

2337 (b) Inventories and records must be made available for
 2338 inspection and photocopying by authorized federal, state, or
 2339 local officials for a period of 2 years following disposition of
 2340 the drugs or 3 years after the creation of the records,

2341 | whichever period is longer.

2342 | (c) Records described in this section that are kept at the
 2343 | inspection site or that can be immediately retrieved by computer
 2344 | or other electronic means must be readily available for
 2345 | authorized inspection during the retention period. Records that
 2346 | are kept at a central location outside of this state and that
 2347 | are not electronically retrievable must be made available for
 2348 | inspection within 2 working days after a request by an
 2349 | authorized official of a federal, state, or local law
 2350 | enforcement agency. Records that are maintained at a central
 2351 | location within this state must be maintained at an
 2352 | establishment that is permitted pursuant to this part and must
 2353 | be readily available.

2354 | (d) Each manufacturer or repackager of medical devices,
 2355 | over-the-counter drugs, or cosmetics must maintain records that
 2356 | include the name and principal address of the seller or
 2357 | transferor of the product, the address of the location from
 2358 | which the product was shipped, the date of the transaction, the
 2359 | name and quantity of the product involved, and the name and
 2360 | principal address of the person who purchased the product.

2361 | ~~(c) When pedigree papers are required by this part, a~~
 2362 | ~~wholesale distributor must maintain the pedigree papers separate~~
 2363 | ~~and distinct from other records required under this part.~~

2364 | (15) DUE DILIGENCE OF PURCHASERS.—

2365 | (b) A wholesale distributor must take reasonable measures
 2366 | to identify its customers, understand the normal and expected

CS/HB 1211

2016

2367 transactions conducted by those customers, and identify those
2368 transactions that are suspicious in nature. A wholesale
2369 distributor must establish internal policies and procedures for
2370 identifying suspicious orders and preventing suspicious
2371 transactions. A wholesale distributor must assess orders for
2372 greater than 7,500 ~~5,000~~ unit doses of any one controlled
2373 substance in any one month to determine whether the purchase is
2374 reasonable. In making such assessments, a wholesale distributor
2375 may consider the purchasing entity's clinical business needs,
2376 location, and population served, in addition to other factors
2377 established in the distributor's policies and procedures. A
2378 wholesale distributor must report to the department any
2379 regulated transaction involving an extraordinary quantity of a
2380 listed chemical, an uncommon method of payment or delivery, or
2381 any other circumstance that the regulated person believes may
2382 indicate that the listed chemical will be used in violation of
2383 the law. The wholesale distributor shall maintain records that
2384 document the report submitted to the department in compliance
2385 with this paragraph.

2386 Section 9. Subsection (4) of section 499.015, Florida
2387 Statutes, is amended to read:

2388 499.015 Registration of drugs, devices, and cosmetics;
2389 issuance of certificates of free sale.—

2390 (4) Unless a registration is renewed, it expires 2 years
2391 after the last day of the month in which it was issued. Any
2392 product registration issued or renewed on or after July 1, 2016,

2393 shall expire on the same date as the manufacturer or repackager
 2394 permit of the person seeking to register the product. If the
 2395 first product registration issued to a person on or after July
 2396 1, 2016, expires less than 366 days after issuance, the fee for
 2397 product registration shall be \$15. If the first product
 2398 registration issued to a person on or after July 1, 2016,
 2399 expires more than 365 days after issuance, the fee for product
 2400 registration shall be \$30. The department may issue a stop-sale
 2401 notice or order against a person that is subject to the
 2402 requirements of this section and that fails to comply with this
 2403 section within 31 days after the date the registration expires.
 2404 The notice or order shall prohibit such person from selling or
 2405 causing to be sold any drugs, devices, or cosmetics covered by
 2406 this part until he or she complies with the requirements of this
 2407 section.

2408 Section 10. Subsection (1) of section 499.03, Florida
 2409 Statutes, is amended to read:

2410 499.03 Possession of certain drugs without prescriptions
 2411 unlawful; exemptions and exceptions.—

2412 (1) A person may not possess, or possess with intent to
 2413 sell, dispense, or deliver, any habit-forming, toxic, harmful,
 2414 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or
 2415 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,
 2416 unless the possession of the drug has been obtained by a valid
 2417 prescription of a practitioner licensed by law to prescribe the
 2418 drug. However, this section does not apply to the delivery of

2419 such drugs to persons included in any of the classes named in
2420 this subsection, or to the agents or employees of such persons,
2421 for use in the usual course of their businesses or practices or
2422 in the performance of their official duties, as the case may be;
2423 nor does this section apply to the possession of such drugs by
2424 those persons or their agents or employees for such use:

2425 (a) A licensed pharmacist or any person under the licensed
2426 pharmacist's supervision while acting within the scope of the
2427 licensed pharmacist's practice;

2428 (b) A licensed practitioner authorized by law to prescribe
2429 prescription drugs or any person under the licensed
2430 practitioner's supervision while acting within the scope of the
2431 licensed practitioner's practice;

2432 (c) A qualified person who uses prescription drugs for
2433 lawful research, teaching, or testing, and not for resale;

2434 (d) A licensed hospital or other institution that procures
2435 such drugs for lawful administration or dispensing by
2436 practitioners;

2437 (e) An officer or employee of a federal, state, or local
2438 government; or

2439 (f) A person that holds a valid permit issued by the
2440 department pursuant to this part which authorizes that person to
2441 possess prescription drugs.

2442 Section 11. Paragraphs (i) through (p) of subsection (1)
2443 of section 499.05, Florida Statutes, are amended to read:

2444 499.05 Rules.—

2445 (1) The department shall adopt rules to implement and
 2446 enforce this chapter with respect to:

2447 (i) Additional conditions that qualify as an emergency
 2448 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.
 2449 499.82.

2450 ~~(j) Procedures and forms relating to the pedigree paper~~
 2451 ~~requirement of s. 499.01212.~~

2452 (j)~~(k)~~ The protection of the public health, safety, and
 2453 welfare regarding good manufacturing practices that
 2454 manufacturers and repackagers must follow to ensure the safety
 2455 of the products.

2456 (k)~~(l)~~ Information required from each retail establishment
 2457 pursuant to s. 499.012(3) or s. 499.83(2)(c), including
 2458 requirements for prescriptions or orders.

2459 (l)~~(m)~~ The recordkeeping, storage, and handling with
 2460 respect to each of the distributions of prescription drugs
 2461 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.
 2462 499.82(14).

2463 ~~(n) Alternatives to compliance with s. 499.01212 for a~~
 2464 ~~prescription drug in the inventory of a permitted prescription~~
 2465 ~~drug wholesale distributor as of June 30, 2006, and the return~~
 2466 ~~of a prescription drug purchased prior to July 1, 2006. The~~
 2467 ~~department may specify time limits for such alternatives.~~

2468 (m)~~(o)~~ Wholesale distributor reporting requirements of s.
 2469 499.0121(14).

2470 (n)~~(p)~~ Wholesale distributor credentialing and

2471 distribution requirements of s. 499.0121(15).

2472 Section 12. Subsection (7) of section 499.051, Florida
 2473 Statutes, is amended to read:

2474 499.051 Inspections and investigations.—

2475 (7) The complaint and all information obtained pursuant to
 2476 the investigation by the department are confidential and exempt
 2477 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution
 2478 until the investigation and the enforcement action are
 2479 completed. However, trade secret information contained therein
 2480 as defined by s. 812.081(1)(c) shall remain confidential and
 2481 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I
 2482 of the State Constitution, as long as the information is
 2483 retained by the department. This subsection does not prohibit
 2484 the department from using such information for regulatory or
 2485 enforcement proceedings under this chapter or from providing
 2486 such information to any law enforcement agency or any other
 2487 regulatory agency. However, the receiving agency shall keep such
 2488 records confidential and exempt as provided in this subsection.
 2489 ~~In addition, this subsection is not intended to prevent~~
 2490 ~~compliance with the provisions of s. 499.01212, and the pedigree~~
 2491 ~~papers required in that section shall not be deemed a trade~~
 2492 ~~secret.~~

2493 Section 13. Subsection (8) is added to section 499.066,
 2494 Florida Statutes, to read:

2495 499.066 Penalties; remedies.—In addition to other
 2496 penalties and other enforcement provisions:

2497 (8) (a) The department shall adopt rules to permit the
2498 issuance of remedial, nondisciplinary citations. A citation
2499 shall be issued to the person alleged to have committed a
2500 violation and contain the person's name, address, and license
2501 number, if applicable, a brief factual statement, the sections
2502 of the law allegedly violated, and the monetary assessment and
2503 or other remedial measures imposed. The citation must clearly
2504 state that the person may choose, in lieu of accepting the
2505 citation, to have the department rescind the citation and
2506 conduct an investigation pursuant to s. 499.051. If the person
2507 does not dispute the matter in the citation with the department
2508 within 30 days after the citation is served, the citation
2509 becomes a final order and does not constitute discipline.

2510 (b) The department shall adopt rules designating
2511 violations for which a citation may be issued. The rules shall
2512 designate as citable those violations for which there is no
2513 substantial threat to the public health, safety, or welfare.

2514 (c) The department is entitled to recover the costs of
2515 investigation, in addition to any penalty provided according to
2516 department rule, as part of the penalty levied pursuant to the
2517 citation.

2518 (d) A citation must be issued within 12 months after the
2519 filing of the complaint that is the basis for the citation.

2520 (e) Service of a citation may be made by personal service
2521 or certified mail, restricted delivery, to the person at the
2522 person's last known address of record with the department or to

2523 the person's Florida registered agent.

2524 (f) The department has authority to, and shall adopt rules
 2525 to, designate those violations for which a person is subject to
 2526 the issuance of a citation and designate the monetary
 2527 assessments and or other remedial measures that must be taken
 2528 for those violations. The department has continuous authority to
 2529 amend its rules adopted pursuant to this section.

2530 Section 14. Subsection (14) of section 499.82, Florida
 2531 Statutes, is amended to read:

2532 499.82 Definitions.—As used in this part, the term:

2533 (14) "Wholesale distribution" means the distribution of
 2534 medical gas to a person other than a consumer or patient.

2535 Wholesale distribution of medical gases does not include:

2536 (a) The sale, purchase, or trade of a medical gas; an
 2537 offer to sell, purchase, or trade a medical gas; or the
 2538 dispensing of a medical gas pursuant to a prescription;

2539 (b) Activities exempt from the definition of wholesale
 2540 distribution in s. 499.003; or

2541 (c) The sale, purchase, or trade of a medical gas or an
 2542 offer to sell, purchase, or trade a medical gas for emergency
 2543 medical reasons; ~~or~~

2544 ~~(d) Other transactions excluded from the definition of~~
 2545 ~~wholesale distribution under the federal act or regulations~~
 2546 ~~implemented under the federal act related to medical gas.~~

2547 Section 15. Subsection (4) of section 499.89, Florida
 2548 Statutes, is amended to read:

CS/HB 1211

2016

2549 499.89 Recordkeeping.—

2550 ~~(4) A pedigree paper is not required for distributing or~~
 2551 ~~dispensing medical gas.~~

2552 Section 16. Section 499.01212, Florida Statutes, is
 2553 repealed.

2554 Section 17. Paragraph (a) of subsection (1) of section
 2555 409.9201, Florida Statutes, is amended to read:

2556 409.9201 Medicaid fraud.—

2557 (1) As used in this section, the term:

2558 (a) "Prescription drug" means any drug, including, but not
 2559 limited to, finished dosage forms or active ingredients that are
 2560 subject to, defined in, or described in s. 503(b) of the Federal
 2561 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)
 2562 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2563
 2564 The value of individual items of the legend drugs or goods or
 2565 services involved in distinct transactions committed during a
 2566 single scheme or course of conduct, whether involving a single
 2567 person or several persons, may be aggregated when determining
 2568 the punishment for the offense.

2569 Section 18. Paragraph (b) of subsection (1) of section
 2570 499.067, Florida Statutes, is amended to read:

2571 499.067 Denial, suspension, or revocation of permit,
 2572 certification, or registration.—

2573 (1)

2574 (b) The department may deny an application for a permit or

2575 certification, or suspend or revoke a permit or certification,
 2576 if the department finds that:

2577 1. The applicant is not of good moral character or that it
 2578 would be a danger or not in the best interest of the public
 2579 health, safety, and welfare if the applicant were issued a
 2580 permit or certification.

2581 2. The applicant has not met the requirements for the
 2582 permit or certification.

2583 3. The applicant is not eligible for a permit or
 2584 certification for any of the reasons enumerated in s. 499.012.

2585 4. The applicant, permittee, or person certified under s.
 2586 499.012(15) ~~499.012(16)~~ demonstrates any of the conditions
 2587 enumerated in s. 499.012.

2588 5. The applicant, permittee, or person certified under s.
 2589 499.012(15) ~~499.012(16)~~ has committed any violation of this
 2590 chapter.

2591 Section 19. Subsection (1) of section 794.075, Florida
 2592 Statutes, is amended to read:

2593 794.075 Sexual predators; erectile dysfunction drugs.—

2594 (1) A person may not possess a prescription drug, as
 2595 defined in s. 499.003 ~~499.003(43)~~, for the purpose of treating
 2596 erectile dysfunction if the person is designated as a sexual
 2597 predator under s. 775.21.

2598 Section 20. Paragraphs (d), (f), (i), and (j) of
 2599 subsection (3) of section 921.0022, Florida Statutes, are
 2600 amended to read:

CS/HB 1211

2016

2601 921.0022 Criminal Punishment Code; offense severity
 2602 ranking chart.—

2603 (3) OFFENSE SEVERITY RANKING CHART

2604 (d) LEVEL 4

2605

Florida	Felony	
Statute	Degree	Description

2606

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.
----------------	-----	--

2607

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

2608

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

2609

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

CS/HB 1211

2016

			contraband prescription drugs.
2610			
	517.07 (1)	3rd	Failure to register securities.
2611			
	517.12 (1)	3rd	Failure of dealer, associated person, or issuer of securities to register.
2612			
	784.07 (2) (b)	3rd	Battery of law enforcement officer, firefighter, etc.
2613			
	784.074 (1) (c)	3rd	Battery of sexually violent predators facility staff.
2614			
	784.075	3rd	Battery on detention or commitment facility staff.
2615			
	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
2616			
	784.08 (2) (c)	3rd	Battery on a person 65 years of age or older.
2617			
	784.081 (3)	3rd	Battery on specified official or employee.

CS/HB 1211

2016

2618	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
2619	784.083 (3)	3rd	Battery on code inspector.
2620	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
2621	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
2622	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
2623	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
2624			

CS/HB 1211

2016

2625	787.07	3rd	Human smuggling.
2626	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
2627	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
2628	790.115 (2) (c)	3rd	Possessing firearm on school property.
2629	800.04 (7) (c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
2630	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
2631	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.

CS/HB 1211

2016

2632	810.06	3rd	Burglary; possession of tools.
2633	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
2634	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
2635	812.014 (2) (c) 4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
2636	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
2637	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03 (5) drugs.
2638	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
	817.625 (2) (a)	3rd	Fraudulent use of scanning

CS/HB 1211

2016

2639			device or reencoder.
	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
2640			
	837.02 (1)	3rd	Perjury in official proceedings.
2641			
	837.021 (1)	3rd	Make contradictory statements in official proceedings.
2642			
	838.022	3rd	Official misconduct.
2643			
	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
2644			
	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Families.
2645			
	843.021	3rd	Possession of a concealed handcuff key by a person in custody.

CS/HB 1211

2016

2646	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
2647	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
2648	847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
2649	874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
2650	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).
2651	914.14(2)	3rd	Witnesses accepting bribes.
2652	914.22(1)	3rd	Force, threaten, etc., witness,

CS/HB 1211

2016

2653			victim, or informant.
	914.23 (2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
2654			
	918.12	3rd	Tampering with jurors.
2655			
	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
2656			
2657	(f)	LEVEL 6	
2658			
	Florida	Felony	
	Statute	Degree	Description
2659			
	316.027 (2) (b)	2nd	Leaving the scene of a crash involving serious bodily injury.
2660			
	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
2661			
	400.9935 (4) (c)	2nd	Operating a clinic, or offering services requiring licensure,

CS/HB 1211

2016

			without a license.
2662	<u>499.0051(2)</u> 499.0051(3)	2nd	Knowing forgery of <u>transaction history, transaction information, or transaction statement</u> pedigree papers .
2663	<u>499.0051(3)</u> 499.0051(4)	2nd	Knowing purchase or receipt of prescription drug from unauthorized person.
2664	<u>499.0051(4)</u> 499.0051(5)	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
2665	775.0875(1)	3rd	Taking firearm from law enforcement officer.
2666	784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
2667	784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
2668	784.041	3rd	Felony battery; domestic battery by strangulation.

CS/HB 1211

2016

2669	784.048 (3)	3rd	Aggravated stalking; credible threat.
2670	784.048 (5)	3rd	Aggravated stalking of person under 16.
2671	784.07 (2) (c)	2nd	Aggravated assault on law enforcement officer.
2672	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
2673	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
2674	784.081 (2)	2nd	Aggravated assault on specified official or employee.
2675	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
2676	784.083 (2)	2nd	Aggravated assault on code inspector.

CS/HB 1211

2016

2677	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
2678	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
2679	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
2680	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
2681	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
2682	794.011 (8) (a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
2683			

CS/HB 1211

2016

2684	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
2685	800.04 (5) (d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; offender less than 18 years.
2686	800.04 (6) (b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
2687	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
2688	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
2689	810.145 (8) (b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.

CS/HB 1211

2016

2690	812.014 (6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.
2691	812.015 (9) (a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
2692	812.015 (9) (b)	2nd	Retail theft; property stolen \$3,000 or more; coordination of others.
2693	812.13 (2) (c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
2694	817.4821 (5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
2695	825.102 (1)	3rd	Abuse of an elderly person or disabled adult.
2696	825.102 (3) (c)	3rd	Neglect of an elderly person or disabled adult.
2697			

CS/HB 1211

2016

2698	825.1025 (3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
2699	825.103 (3) (c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$10,000.
2700	827.03 (2) (c)	3rd	Abuse of a child.
2701	827.03 (2) (d)	3rd	Neglect of a child.
2702	827.071 (2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
2703	836.05	2nd	Threats; extortion.
2704	836.10	2nd	Written threats to kill or do bodily injury.
2705	843.12	3rd	Aids or assists person to escape.
	847.011	3rd	Distributing, offering to distribute, or possessing with

CS/HB 1211

2016

2706			intent to distribute obscene materials depicting minors.
	847.012	3rd	Knowingly using a minor in the production of materials harmful to minors.
2707			
	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
2708			
	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
2709			
	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.
2710			
	944.40	2nd	Escapes.
2711			
	944.46	3rd	Harboring, concealing, aiding escaped prisoners.

CS/HB 1211

2016

2712	944.47 (1) (a) 5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
2713	951.22 (1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
2714			
2715	(i) LEVEL 9		
2716	Florida	Felony	
	Statute	Degree	Description
2717	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
2718	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
2719	409.920 (2) (b) 1.c.	1st	Medicaid provider fraud; \$50,000 or more.
2720	<u>499.0051 (8)</u> 499.0051 (9)	1st	Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.

CS/HB 1211

2016

2721	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
2722	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
2723	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
2724	775.0844	1st	Aggravated white collar crime.
2725	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
2726	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.
2727	782.051(1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
2728	782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
2729	787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
2730	787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
2731	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
2732	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.
2733	787.06(3)(c)1.	1st	Human trafficking for labor and services of an unauthorized alien child.
2734	787.06(3)(d)	1st	Human trafficking using coercion for commercial sexual activity of an unauthorized adult alien.
2735	787.06(3)(f)1.	1st,PBL	Human trafficking for commercial sexual activity by the transfer or transport of any child from outside Florida to within the state.
2736	790.161	1st	Attempted capital destructive device offense.
2737	790.166(2)	1st,PBL	Possessing, selling, using, or

			attempting to use a weapon of mass destruction.
2738	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
2739	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
2740	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.
2741	794.011 (4) (b)	1st	Sexual battery, certain circumstances; victim and offender 18 years of age or older.
2742	794.011 (4) (c)	1st	Sexual battery, certain circumstances; victim 12 years of age or older; offender

2743	794.011 (4) (d)	1st, PBL	younger than 18 years. Sexual battery, certain circumstances; victim 12 years of age or older; prior conviction for specified sex offenses.
2744	794.011 (8) (b)	1st, PBL	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
2745	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
2746	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
2747	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
2748	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.

CS/HB 1211

2016

2749

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

2750

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

2751

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

2752

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.

2753

817.568 (7) 2nd, Fraudulent use of personal
PBL identification information of
an individual under the age of
18 by his or her parent, legal

CS/HB 1211

2016

			guardian, or person exercising custodial authority.
2754	827.03 (2) (a)	1st	Aggravated child abuse.
2755	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
2756	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
2757	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.
2758	893.135	1st	Attempted capital trafficking offense.
2759	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.

CS/HB 1211

2016

2760	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
2761	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
2762	893.135 (1) (c) 2.d.	1st	Trafficking in hydrocodone, 200 grams or more, less than 30 kilograms.
2763	893.135 (1) (c) 3.d.	1st	Trafficking in oxycodone, 100 grams or more, less than 30 kilograms.
2764	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
2765	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
2766	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more than 200 grams.
2767			

CS/HB 1211

2016

2768	893.135 (1) (h) 1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
2769	893.135 (1) (j) 1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
2770	893.135 (1) (k) 2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
2771	896.101 (5) (c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
2772	896.104 (4) (a) 3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
2773	(j) LEVEL 10		
2774			
2775	Florida Statute	Felony Degree	Description
	<u>499.0051 (9)</u>	1st	Knowing sale or purchase of

CS/HB 1211

2016

2776	499.0051(10)		contraband prescription drugs resulting in death.
2777	782.04(2)	1st, PBL	Unlawful killing of human; act is homicide, unpremeditated.
2778	782.07(3)	1st	Aggravated manslaughter of a child.
2779	787.01(1)(a)3.	1st, PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
2780	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.
2781	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.
	787.06(4)(a)	Life	Selling or buying of minors

CS/HB 1211

2016

2782			into human trafficking.
2783	794.011 (3)	Life	Sexual battery; victim 12 years or older, offender uses or threatens to use deadly weapon or physical force to cause serious injury.
2784	812.135 (2) (a)	1st, PBL	Home-invasion robbery with firearm or other deadly weapon.
2785	876.32	1st	Treason against the state.
2786	Section 21. This act shall take effect July 1, 2016.		