

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; providing rulemaking authority;  
6           amending s. 499.005, F.S.; revising prohibited acts  
7           related to the distribution of prescription drugs;  
8           conforming a cross-reference; amending s. 499.0051,  
9           F.S.; prohibiting the distribution of prescription  
10          drugs without delivering a transaction history,  
11          transaction information, and transaction statement;  
12          providing penalties; deleting provisions and revising  
13          terminology related to pedigree papers, to conform to  
14          changes made by the act; amending s. 499.006, F.S.;  
15          conforming provisions; amending s. 499.01, F.S.;  
16          requiring nonresident prescription drug repackagers to  
17          obtain an operating permit; authorizing a manufacturer  
18          to engage in the 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 | providing an exception to the restricted prescription  
30 | drug distributor permit requirements for certain  
31 | pharmacies; providing rulemaking authority; requiring  
32 | certain third party logistic providers to be licensed;  
33 | requiring research and development labeling on certain  
34 | prescription drug active pharmaceutical ingredient  
35 | packaging; requiring certain manufacturers to create  
36 | and maintain certain records; requiring certain  
37 | prescription drug distributors to provide certain  
38 | information to health care entities for which they  
39 | repackage prescription drugs; directing the department  
40 | to adopt rules concerning the safety and integrity of  
41 | certain prescription drugs; amending s. 499.012, F.S.;  
42 | providing for issuance of a prescription drug  
43 | manufacturer permit or retail pharmacy drug wholesale  
44 | distributor permit when an applicant at the same  
45 | address is a licensed nuclear pharmacy or community  
46 | pharmacy; providing for the expiration of deficient  
47 | permit applications; requiring trade secret  
48 | information submitted by an applicant to be maintained  
49 | as a trade secret; authorizing the quadrennial renewal  
50 | of permits; providing for calculation of fees for such  
51 | permit renewals; revising procedures and application  
52 | requirements for permit renewals; providing for late

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

79 changes made by the act; amending s. 499.066, F.S.;

80 authorizing the issuance of nondisciplinary citations;

81 authorizing the department to adopt rules designating

82 violations for which a citation may be issued;

83 authorizing the department to recover investigative

84 costs pursuant to the citation; specifying a time

85 limitation for issuance of a citation; providing for

86 service of a citation; amending s. 499.82, F.S.;

87 revising the definition of "wholesale distribution"

88 for purposes of medical gas requirements; amending s.

89 499.89, F.S.; conforming provisions; repealing s.

90 499.01212, F.S., relating to pedigree papers; amending

91 ss. 409.9201, 499.067, 794.075, and 921.0022, F.S.;

92 conforming provisions to changes made by the act;

93 providing an effective date.

94

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

96

97 Section 1. Section 499.003, Florida Statutes, is amended

98 to read:

99 499.003 Definitions of terms used in this part.—As used in

100 this part, the term:

101 (1) "Active pharmaceutical ingredient" includes any

102 substance or mixture of substances intended, represented, or

103 labeled for use in drug manufacturing that furnishes or is

104 intended to furnish, in a finished dosage form, any

105 pharmacological activity or other direct effect in the  
 106 diagnosis, cure, mitigation, treatment, therapy, or prevention  
 107 of disease in humans or other animals, or to affect the  
 108 structure or any function of the body of humans or animals.

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

114 (3) "Affiliate" means a business entity that has a  
 115 relationship with another business entity in which, directly or  
 116 indirectly:

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

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

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

127 (4)-(3) "Affiliated party" means:

128 (a) A director, officer, trustee, partner, or committee  
 129 member of a permittee or applicant or a subsidiary or service  
 130 corporation of the permittee or applicant;

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

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

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

142 (5)~~(4)~~ "Applicant" means a person applying for a permit or  
143 certification under this part.

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

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

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

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

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

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

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

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

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

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

179 (11) "Contraband prescription drug" means any adulterated  
 180 drug, as defined in s. 499.006, any counterfeit drug, as defined  
 181 in this section, and also means any prescription drug for which  
 182 a transaction history, transaction information, or transaction

183 statement ~~pedigree paper~~ does not exist, or for which the  
184 transaction history, transaction information, or transaction  
185 statement ~~pedigree paper~~ in existence has been forged,  
186 counterfeited, falsely created, or contains any altered, false,  
187 or misrepresented matter.

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

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

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

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

207 (14) "Department" means the Department of Business and  
208 Professional Regulation.

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

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

215 (b) Intended for use in the diagnosis, cure, mitigation,  
 216 treatment, therapy, or prevention of disease in humans or other  
 217 animals, or

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

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

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

232 ~~(17) "Drop shipment" means the sale of a prescription drug~~  
 233 ~~from a manufacturer to a wholesale distributor, where the~~  
 234 ~~wholesale distributor takes title to, but not possession of, the~~

235 ~~prescription drug, and the manufacturer of the prescription drug~~  
236 ~~ships the prescription drug directly to a chain pharmacy~~  
237 ~~warehouse or a person authorized by law to purchase prescription~~  
238 ~~drugs for the purpose of administering or dispensing the drug,~~  
239 ~~as defined in s. 465.003.~~

240 (17)~~(18)~~ "Drug" means an article that is:

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

245 (b) Intended for use in the diagnosis, cure, mitigation,  
246 treatment, therapy, or prevention of disease in humans or other  
247 animals;

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

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

261 ~~structure or any function of the body of humans or other~~  
 262 ~~animals.~~

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

272 (19)~~(20)~~ "Federal act" means the Federal Food, Drug, and  
 273 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

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

278 (21)~~(22)~~ "Health care entity" means a closed pharmacy or  
 279 any person, organization, or business entity that provides  
 280 diagnostic, medical, surgical, or dental treatment or care, or  
 281 chronic or rehabilitative care, but does not include any  
 282 wholesale distributor or retail pharmacy licensed under state  
 283 law to deal in prescription drugs. However, a blood  
 284 establishment is a health care entity that may engage in the  
 285 wholesale distribution of prescription drugs under s.  
 286 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

287        (22)~~(23)~~ "Health care facility" means a health care  
288 facility licensed under chapter 395.

289        (23)~~(24)~~ "Hospice" means a corporation licensed under part  
290 IV of chapter 400.

291        (24)~~(25)~~ "Hospital" means a facility as defined in s.  
292 395.002 and licensed under chapter 395.

293        (25)~~(26)~~ "Immediate container" does not include package  
294 liners.

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

304        (27)~~(28)~~ "Labeling" means all labels and other written,  
305 printed, or graphic matters:

306            (a) Upon a drug, device, or cosmetic, or any of its  
307 containers or wrappers; or

308            (b) Accompanying or related to such drug, device, or  
309 cosmetic.

310        (28)~~(29)~~ "Manufacture" means the preparation, deriving,  
311 compounding, propagation, processing, producing, or fabrication  
312 of any drug, device, or cosmetic.

313            (29)~~(30)~~ "Manufacturer" means:

314            (a) A person who holds a New Drug Application, an  
 315 Abbreviated New Drug Application, a Biologics License  
 316 Application, or a New Animal Drug Application approved under the  
 317 federal act or a license issued under s. 351 of the Public  
 318 Health Service Act, 42 U.S.C. s. 262, for such drug or  
 319 biologics, or if such drug or biologics is not the subject of an  
 320 approved application or license, the person who manufactured the  
 321 drug or biologics ~~prepares, derives, manufactures, or produces a~~  
 322 ~~drug, device, or cosmetic;~~

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

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

338            (d) A person that manufactures a device or a cosmetic. A

339 ~~person registered under the federal act as a manufacturer of a~~  
340 ~~prescription drug, who is described in paragraph (a), paragraph~~  
341 ~~(b), or paragraph (c), who has entered into a written agreement~~  
342 ~~with another prescription drug manufacturer that authorizes~~  
343 ~~either manufacturer to distribute the prescription drug~~  
344 ~~identified in the agreement as the manufacturer of that drug~~  
345 ~~consistent with the federal act and its implementing~~  
346 ~~regulations;~~

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

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

362

363 The term does not include a pharmacy that is operating in  
364 compliance with pharmacy practice standards as defined in

365 chapter 465 and rules adopted under that chapter.

366 (30)~~(31)~~ "Medical convenience kit" means packages or units  
367 that contain combination products as defined in 21 C.F.R. s.  
368 3.2(e)(2).

369 (31)~~(32)~~ "Medical gas" means any liquefied or vaporized  
370 gas that is a prescription drug, whether alone or in combination  
371 with other gases, and as defined in the federal act.

372 (32)~~(33)~~ "New drug" means:

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

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

385 ~~(34) "Normal distribution chain" means a wholesale~~  
386 ~~distribution of a prescription drug in which the wholesale~~  
387 ~~distributor or its wholly owned subsidiary purchases and~~  
388 ~~receives the specific unit of the prescription drug directly~~  
389 ~~from the manufacturer and distributes the prescription drug~~  
390 ~~directly, or through up to two intracompany transfers, to a~~

391 ~~chain pharmacy warehouse or a person authorized by law to~~  
392 ~~purchase prescription drugs for the purpose of administering or~~  
393 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~  
394 ~~this subsection, the term "intracompany" means any transaction~~  
395 ~~or transfer between any parent, division, or subsidiary wholly~~  
396 ~~owned by a corporate entity.~~

397 (33)~~(35)~~ "Nursing home" means a facility licensed under  
398 part II of chapter 400.

399 (34)~~(36)~~ "Official compendium" means the current edition  
400 of the official United States Pharmacopoeia and National  
401 Formulary, or any supplement thereto.

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

406 (35)~~(38)~~ "Permittee" means any person holding a permit  
407 issued under this chapter pursuant to s. 499.012.

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

416 (37)~~(40)~~ "Pharmacist" means a person licensed under

417 chapter 465.

418 (38)~~(41)~~ "Pharmacy" means an entity licensed under chapter  
419 465.

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

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

435 (41)~~(44)~~ "Prescription drug label" means any display of  
436 written, printed, or graphic matter upon the immediate container  
437 of any prescription drug before it is dispensed ~~prior to its~~  
438 ~~dispensing~~ to an individual patient pursuant to a prescription  
439 of a practitioner authorized by law to prescribe.

440 (42)~~(45)~~ "Prescription label" means any display of  
441 written, printed, or graphic matter upon the immediate container  
442 of any prescription drug dispensed pursuant to a prescription of

443 a practitioner authorized by law to prescribe.

444 ~~(46) "Primary wholesale distributor" means any wholesale~~  
 445 ~~distributor that:~~

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

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

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

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

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

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

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

465 ~~b. The wholesale distributor discloses to the department~~  
 466 ~~the names of all members of the affiliated group of which the~~  
 467 ~~wholesale distributor is a member and the affiliated group~~  
 468 ~~agrees in writing to provide records on prescription drug~~

469 ~~purchases by the members of the affiliated group not later than~~  
470 ~~48 hours after the department requests access to such records,~~  
471 ~~regardless of the location where the records are stored.~~

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

478 (44)~~(48)~~ "Repackage" includes repacking or otherwise  
479 changing the container, wrapper, or labeling to further the  
480 distribution of the drug, device, or cosmetic.

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

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

489 ~~(51) "Secondary wholesale distributor" means a wholesale~~  
490 ~~distributor that is not a primary wholesale distributor.~~

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

495 veterinarian."

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

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

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

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

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

521 rights, by contract, or otherwise.

522 4. The distribution ~~sale, purchase, trade, or other~~  
 523 ~~transfer~~ of a prescription drug from or for any federal, state,  
 524 or local government agency or any entity eligible to purchase  
 525 prescription drugs at public health services prices pursuant to  
 526 Pub. L. No. 102-585, s. 602 to a contract provider or its  
 527 subcontractor for eligible patients of the agency or entity  
 528 under the following conditions:

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

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

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

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

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

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

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

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

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

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

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

587           ~~4. The revocation of a sale or the return of a~~  
588 ~~prescription drug to the person's prescription drug wholesale~~  
589 ~~supplier.~~

590           ~~4.5.~~ The donation of a prescription drug by a health care  
591 entity to a charitable organization that has been granted an  
592 exemption under s. 501(c)(3) of the Internal Revenue Code of  
593 1986, as amended, and that is authorized to possess prescription  
594 drugs.

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

599 person handling the reverse distribution or destruction receives  
 600 the drug.

601 6.7. The distribution ~~transfer~~ of a prescription drug by a  
 602 hospital or other health care entity to a person licensed under  
 603 this part to repackage prescription drugs for the purpose of  
 604 repackaging the prescription drug for use by that hospital, or  
 605 other health care entity and other health care entities that are  
 606 under common control, if ownership of the prescription drugs  
 607 remains with the hospital or other health care entity at all  
 608 times. In addition to the recordkeeping requirements of s.  
 609 499.0121(6), the hospital or health care entity that distributes  
 610 ~~transfers~~ prescription drugs pursuant to this subparagraph must  
 611 reconcile all drugs distributed ~~transferred~~ and returned and  
 612 resolve any discrepancies in a timely manner.

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

615 (d) The distribution of a prescription drug by the  
 616 manufacturer of the prescription drug.

617 (e) ~~(e)~~ The distribution of prescription drug samples by  
 618 manufacturers' representatives or distributors' representatives  
 619 conducted in accordance with s. 499.028.

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

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

630        (h) The purchase or other acquisition by a dispenser,  
631 hospital, or other health care entity of a prescription drug for  
632 use by such dispenser, hospital, or other health care entity.

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

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

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

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

651 prescription drug between pharmacies as a result of a sale,  
652 transfer, merger, or consolidation of all or part of the  
653 business of the pharmacies from or with another pharmacy,  
654 whether accomplished as a purchase and sale of stock or of  
655 business assets.

656 (m) The distribution of minimal quantities of prescription  
657 drugs by a licensed retail pharmacy to a licensed practitioner  
658 for office use in compliance with chapter 465 and rules adopted  
659 thereunder. The department shall adopt rules specifying when  
660 quantities of prescription drugs are considered minimal  
661 quantities, but, until such rules are adopted, minimal  
662 quantities distributed may not exceed 3 percent of the total  
663 annual purchases of prescription drugs.

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

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

671 (p) The distribution of a prescription drug that is  
672 intended for irrigation or sterile water, whether intended for  
673 such purposes or for injection.

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

676 (r) A common carrier that transports a prescription drug,

677 if the common carrier does not take ownership of the  
678 prescription drug.

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

680 (t) Facilitating the distribution of a prescription drug  
681 by providing solely administrative services, including  
682 processing of orders and payments.

683 (u) The distribution by a charitable organization  
684 described in s. 501(c)(3) of the Internal Revenue Code of  
685 prescription drugs donated to or supplied at a reduced price to  
686 the charitable organization to:

687 1. A licensed health care practitioner, as defined in s.  
688 456.001, who is authorized under the appropriate practice act to  
689 prescribe and administer prescription drugs;

690 2. A health care clinic establishment permitted pursuant  
691 to chapter 499; or

692 3. The Department of Health or the licensed medical  
693 director of a government agency health care entity, authorized  
694 to possess prescription drugs, for storage and use in the  
695 treatment of persons in need of emergency medical services,  
696 including controlling communicable diseases or providing  
697 protection from unsafe conditions that pose an imminent threat  
698 to public health,

699  
700 if the distributor and the receiving entity receive no direct or  
701 indirect financial benefit other than tax benefits related to  
702 charitable contributions. Distributions under this section that

703 involve controlled substances must comply with all state and  
704 federal regulations pertaining to the handling of controlled  
705 substances.

706 (v) The distribution of medical gas pursuant to part III  
707 of this chapter.

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

719 Section 2. Subsections (21), (28), and (29) of section  
720 499.005, Florida Statutes, are amended to read:

721 499.005 Prohibited acts.—It is unlawful for a person to  
722 perform or cause the performance of any of the following acts in  
723 this state:

724 (21) The wholesale distribution of any prescription drug  
725 that was:

726 (a) Purchased by a public or private hospital or other  
727 health care entity; or

728 (b) Donated or supplied at a reduced price to a charitable

729 organization,

730

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

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

736 ~~(29) The receipt of a prescription drug pursuant to a~~  
 737 ~~wholesale distribution without having previously received or~~  
 738 ~~simultaneously receiving a pedigree paper that was attested to~~  
 739 ~~as accurate and complete by the wholesale distributor as~~  
 740 ~~required under this part.~~

741 Section 3. Subsections (4) through (17) of section  
 742 499.0051, Florida Statutes, are renumbered as subsections (3)  
 743 through (16), respectively, and subsections (1) and (2), present  
 744 subsection (3), paragraphs (h) and (i) of present subsection  
 745 (12), and paragraph (d) of present subsection (13) of that  
 746 section are amended, to read:

747 499.0051 Criminal acts.—

748 (1) FAILURE TO MAINTAIN OR DELIVER TRANSACTION HISTORY,  
 749 TRANSACTION INFORMATION, OR TRANSACTION STATEMENT ~~PEDIGREE~~  
 750 ~~PAPERS.~~—

751 (a) A person, ~~other than a manufacturer,~~ engaged in the  
 752 ~~wholesale~~ distribution of prescription drugs who fails to  
 753 deliver to another person a complete and accurate transaction  
 754 history, transaction information, or transaction statement

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

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

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

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

781 ~~(a) A person engaged in the wholesale distribution of~~  
 782 ~~prescription drugs who is in possession of pedigree papers~~  
 783 ~~concerning prescription drugs or contraband prescription drugs~~  
 784 ~~and who fails to authenticate the matters contained in the~~  
 785 ~~pedigree papers and who nevertheless attempts to further~~  
 786 ~~distribute prescription drugs or contraband prescription drugs~~  
 787 ~~commits a felony of the third degree, punishable as provided in~~  
 788 ~~s. 775.082, s. 775.083, or s. 775.084.~~

789 ~~(b) A person in possession of pedigree papers concerning~~  
 790 ~~prescription drugs or contraband prescription drugs who falsely~~  
 791 ~~swears or certifies that he or she has authenticated the matters~~  
 792 ~~contained in the pedigree papers commits a felony of the third~~  
 793 ~~degree, punishable as provided in s. 775.082, s. 775.083, or s.~~  
 794 ~~775.084.~~

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

807            ~~(11)-(12)~~ ADULTERATED AND MISBRANDED DRUGS; FALSE  
 808 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—  
 809 Any person who violates any of the following provisions commits  
 810 a misdemeanor of the second degree, punishable as provided in s.  
 811 775.082 or s. 775.083; but, if the violation is committed after  
 812 a conviction of such person under this subsection has become  
 813 final, such person commits a misdemeanor of the first degree,  
 814 punishable as provided in s. 775.082 or s. 775.083, or as  
 815 otherwise provided in this part:

816            (h) The failure to maintain records related to a drug as  
 817 required by this part and rules adopted under this part, except  
 818 for transaction histories, transaction information, or  
 819 transaction statements ~~pedigree papers~~, invoices, or shipping  
 820 documents related to prescription drugs.

821            (i) The possession of any drug in violation of this part,  
 822 except if the violation relates to a deficiency in transaction  
 823 histories, transaction information, or transaction statements  
 824 ~~pedigree papers~~.

825            ~~(12)-(13)~~ REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING,  
 826 OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO  
 827 PRESCRIPTION DRUGS.—Any person who violates any of the following  
 828 provisions commits a felony of the third degree, punishable as  
 829 provided in s. 775.082, s. 775.083, or s. 775.084, or as  
 830 otherwise provided in this part:

831            (d) The failure to receive, maintain, or provide invoices  
 832 and shipping documents, ~~other than pedigree papers~~, if

833 applicable, related to the distribution of a prescription drug.

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

836 499.006 Adulterated drug or device.—A drug or device is  
837 adulterated:

838 (10) If it is a prescription drug for which the required  
839 transaction history, transaction information, or transaction  
840 statement ~~pedigree paper~~ is nonexistent, fraudulent, or  
841 incomplete under the requirements of this part or applicable  
842 rules, or that has been purchased, held, sold, or distributed at  
843 any time by a person not authorized under federal or state law  
844 to do so; or

845 Section 5. Section 499.01, Florida Statutes, is amended to  
846 read:

847 499.01 Permits.—

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

850 (a) A prescription drug manufacturer;

851 (b) A prescription drug repackager;

852 (c) A nonresident prescription drug manufacturer;

853 (d) A nonresident prescription drug repackager;

854 (e)-(d) A prescription drug wholesale distributor;

855 (f)-(e) An out-of-state prescription drug wholesale  
856 distributor;

857 (g)-(f) A retail pharmacy drug wholesale distributor;

858 (h)-(g) A restricted prescription drug distributor;

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

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

861            (k)~~(j)~~ A veterinary prescription drug retail

862 establishment;

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

864 distributor;

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

866 distributor;

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

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

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

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

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

872            (2) The following permits are established:

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

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

875 manufacturer of a prescription drug and that manufactures or

876 distributes such prescription drugs in this state.

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

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

879 distribution of prescription drugs for which the person is the

880 manufacturer manufactured at that establishment and must comply

881 with s. 499.0121 and all other ~~of the~~ provisions of this part,<sup>7</sup>

882 ~~except s. 499.01212,~~ and the rules adopted under this part,<sup>7</sup>

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

884 department shall adopt rules for issuing a virtual prescription

885 drug manufacturer permit to a person who engages in the  
886 manufacture of prescription drugs but does not make or take  
887 physical possession of any prescription drugs. The rules adopted  
888 by the department under this section may exempt virtual  
889 manufacturers from certain establishment, security, and storage  
890 requirements set forth in s. 499.0121.

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

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

900 (b) Prescription drug repackager permit.—A prescription  
901 drug repackager permit is required for any person that  
902 repackages a prescription drug in this state.

903 1. A person that operates an establishment permitted as a  
904 prescription drug repackager may engage in ~~wholesale~~  
905 distribution of prescription drugs repackaged at that  
906 establishment and must comply with all of the provisions of this  
907 part and the rules adopted under this part that apply to a  
908 prescription drug manufacturer ~~wholesale distributor~~.

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

911 (c) Nonresident prescription drug manufacturer permit.—A  
912 nonresident prescription drug manufacturer permit is required  
913 for any person that is a manufacturer of prescription drugs,  
914 unless permitted as a third party logistics provider, located  
915 outside of this state or outside the United States and that  
916 engages in the ~~wholesale~~ distribution in this state of such  
917 prescription drugs. Each such manufacturer must be permitted by  
918 the department and comply with all of the provisions required of  
919 a prescription drug manufacturer ~~wholesale distributor~~ under  
920 this part, ~~except s. 499.01212~~. The department shall adopt rules  
921 for issuing a virtual nonresident prescription drug manufacturer  
922 permit to a person who engages in the manufacture of  
923 prescription drugs but does not make or take physical possession  
924 of any prescription drugs. The rules adopted by the department  
925 under this section may exempt virtual nonresident manufacturers  
926 from certain establishment, security, and storage requirements  
927 set forth in s. 499.0121.

928 1. A person that distributes prescription drugs for which  
929 the person is not the manufacturer must also obtain an out-of-  
930 state prescription drug wholesale distributor permit or third  
931 party logistics provider permit pursuant to this section to  
932 engage in the ~~wholesale~~ distribution of such prescription drugs  
933 when required by this part. This subparagraph does not apply to  
934 a manufacturer that distributes prescription drugs only for the  
935 manufacturer of the prescription drugs where both manufacturers  
936 are affiliates as defined in s. 499.003(30)(e).

937           2. Any such person must comply with the licensing or  
938 permitting requirements of the jurisdiction in which the  
939 establishment is located and the federal act, and any  
940 prescription drug distributed ~~product-wholesaled~~ into this state  
941 must comply with this part. If a person intends to import  
942 prescription drugs from a foreign country into this state, the  
943 nonresident prescription drug manufacturer must provide to the  
944 department a list identifying each prescription drug it intends  
945 to import and document approval by the United States Food and  
946 Drug Administration for such importation.

947           (d) Nonresident prescription drug repackager permit.-A  
948 nonresident prescription drug repackager permit is required for  
949 any person located outside of this state, but within the United  
950 States or its territories, that repackages prescription drugs  
951 and engages in the distribution of such prescription drugs into  
952 this state.

953           1. A nonresident prescription drug repackager must comply  
954 with all of the provisions of this section and the rules adopted  
955 under this section that apply to a prescription drug  
956 manufacturer.

957           2. A nonresident prescription drug repackager must be  
958 permitted by the department and comply with all appropriate  
959 state and federal good manufacturing practices.

960           3. A nonresident prescription drug repackager must be  
961 registered as a drug establishment with the United States Food  
962 and Drug Administration.

963        (e)~~(d)~~ Prescription drug wholesale distributor permit.—A  
964 prescription drug wholesale distributor permit is required for  
965 any person who is a wholesale distributor of prescription drugs  
966 and that may engage in the wholesale distributes such  
967 distribution of prescription drugs in this state. A prescription  
968 drug wholesale distributor that applies to the department for a  
969 new permit or the renewal of a permit must submit a bond of  
970 \$100,000, or other equivalent means of security acceptable to  
971 the department, such as an irrevocable letter of credit or a  
972 deposit in a trust account or financial institution, payable to  
973 the Professional Regulation Trust Fund. The purpose of the bond  
974 is to secure payment of any administrative penalties imposed by  
975 the department and any fees and costs incurred by the department  
976 regarding that permit which are authorized under state law and  
977 which the permittee fails to pay 30 days after the fine or costs  
978 become final. The department may make a claim against such bond  
979 or security until 1 year after the permittee's license ceases to  
980 be valid or until 60 days after any administrative or legal  
981 proceeding authorized in this part which involves the permittee  
982 is concluded, including any appeal, whichever occurs later. The  
983 department may adopt rules for issuing a prescription drug  
984 wholesale distributor-broker permit to a person who engages in  
985 the wholesale distribution of prescription drugs and does not  
986 take physical possession of any prescription drugs.

987        (f)~~(e)~~ Out-of-state prescription drug wholesale  
988 distributor permit.—An out-of-state prescription drug wholesale

989 distributor permit is required for any person that is a  
990 wholesale distributor located outside this state, but within the  
991 United States or its territories, which engages in the wholesale  
992 distribution of prescription drugs into this state ~~and which~~  
993 ~~must be permitted by the department and comply with all the~~  
994 ~~provisions required of a wholesale distributor under this part.~~  
995 ~~An out-of-state prescription drug wholesale distributor that~~  
996 ~~applies to the department for a new permit or the renewal of a~~  
997 ~~permit must submit a bond of \$100,000, or other equivalent means~~  
998 ~~of security acceptable to the department, such as an irrevocable~~  
999 ~~letter of credit or a deposit in a trust account or financial~~  
1000 ~~institution, payable to the Professional Regulation Trust Fund.~~  
1001 ~~The purpose of the bond is to secure payment of any~~  
1002 ~~administrative penalties imposed by the department and any fees~~  
1003 ~~and costs incurred by the department regarding that permit which~~  
1004 ~~are authorized under state law and which the permittee fails to~~  
1005 ~~pay 30 days after the fine or costs become final. The department~~  
1006 ~~may make a claim against such bond or security until 1 year~~  
1007 ~~after the permittee's license ceases to be valid or until 60~~  
1008 ~~days after any administrative or legal proceeding authorized in~~  
1009 ~~this part which involves the permittee is concluded, including~~  
1010 ~~any appeal, whichever occurs later. The out-of-state~~  
1011 prescription drug wholesale distributor must maintain at all  
1012 times a license or permit to engage in the wholesale  
1013 distribution of prescription drugs in compliance with laws of  
1014 the state in which it is a resident. If the state from which the

1015 wholesale distributor distributes prescription drugs does not  
 1016 require a license to engage in the wholesale distribution of  
 1017 prescription drugs, the distributor must be licensed as a  
 1018 wholesale distributor as required by the federal act.

1019 (g) ~~(f)~~ Retail pharmacy drug wholesale distributor permit.-

1020 A retail pharmacy drug wholesale distributor is a retail  
 1021 pharmacy engaged in wholesale distribution of prescription drugs  
 1022 within this state under the following conditions:

1023 1. The pharmacy must obtain a retail pharmacy drug  
 1024 wholesale distributor permit pursuant to this part and ~~the~~ rules  
 1025 adopted under this part.

1026 2. The wholesale distribution activity does not exceed 30  
 1027 percent of the total annual purchases of prescription drugs. If  
 1028 the wholesale distribution activity exceeds the 30-percent  
 1029 maximum, the pharmacy must obtain a prescription drug wholesale  
 1030 distributor permit.

1031 3. The transfer of prescription drugs that appear in any  
 1032 schedule contained in chapter 893 is subject to chapter 893 and  
 1033 the federal Comprehensive Drug Abuse Prevention and Control Act  
 1034 of 1970.

1035 4. The transfer is between a retail pharmacy and another  
 1036 retail pharmacy, or a Modified Class II institutional pharmacy,  
 1037 or a health care practitioner licensed in this state and  
 1038 authorized by law to dispense or prescribe prescription drugs.

1039 5. All records of sales of prescription drugs subject to  
 1040 this section must be maintained separate and distinct from other

1041 records and comply with the recordkeeping requirements of this  
 1042 part.

1043 (h)~~(g)~~ Restricted prescription drug distributor permit.—

1044 1. A restricted prescription drug distributor permit is  
 1045 required for:

1046 a. Any person located in this state who engages in the  
 1047 distribution of a prescription drug, which distribution is not  
 1048 considered "wholesale distribution" under s. 499.003(48)(a)  
 1049 ~~499.003(53)(a)~~.

1050 b. Any person located in this state who engages in the  
 1051 receipt or distribution of a prescription drug in this state for  
 1052 the purpose of processing its return or its destruction if such  
 1053 person is not the person initiating the return, the prescription  
 1054 drug wholesale supplier of the person initiating the return, or  
 1055 the manufacturer of the drug.

1056 c. A blood establishment located in this state which  
 1057 collects blood and blood components only from volunteer donors  
 1058 as defined in s. 381.06014 or pursuant to an authorized  
 1059 practitioner's order for medical treatment or therapy and  
 1060 engages in the wholesale distribution of a prescription drug not  
 1061 described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care  
 1062 entity. A mobile blood unit operated by a blood establishment  
 1063 permitted under this sub-subparagraph is not required to be  
 1064 separately permitted. The health care entity receiving a  
 1065 prescription drug distributed under this sub-subparagraph must  
 1066 be licensed as a closed pharmacy or provide health care services

1067 at that establishment. The blood establishment must operate in  
1068 accordance with s. 381.06014 and may distribute only:

1069 (I) Prescription drugs indicated for a bleeding or  
1070 clotting disorder or anemia;

1071 (II) Blood-collection containers approved under s. 505 of  
1072 the federal act;

1073 (III) Drugs that are blood derivatives, or a recombinant  
1074 or synthetic form of a blood derivative;

1075 (IV) Prescription drugs that are identified in rules  
1076 adopted by the department and that are essential to services  
1077 performed or provided by blood establishments and authorized for  
1078 distribution by blood establishments under federal law; or

1079 (V) To the extent authorized by federal law, drugs  
1080 necessary to collect blood or blood components from volunteer  
1081 blood donors; for blood establishment personnel to perform  
1082 therapeutic procedures under the direction and supervision of a  
1083 licensed physician; and to diagnose, treat, manage, and prevent  
1084 any reaction of a volunteer blood donor or a patient undergoing  
1085 a therapeutic procedure performed under the direction and  
1086 supervision of a licensed physician,

1087  
1088 as long as all of the health care services provided by the blood  
1089 establishment are related to its activities as a registered  
1090 blood establishment or the health care services consist of  
1091 collecting, processing, storing, or administering human  
1092 hematopoietic stem cells or progenitor cells or performing

1093 diagnostic testing of specimens if such specimens are tested  
 1094 together with specimens undergoing routine donor testing. The  
 1095 blood establishment may purchase and possess the drugs described  
 1096 in this sub-subparagraph without a health care clinic  
 1097 establishment permit.

1098 2. Storage, handling, and recordkeeping of these  
 1099 distributions by a person required to be permitted as a  
 1100 restricted prescription drug distributor must be in accordance  
 1101 with the requirements for wholesale distributors under s.  
 1102 ~~499.0121, but not those set forth in s. 499.01212 if the~~  
 1103 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~  
 1104 ~~subparagraph 1.b.~~

1105 3. A person who applies for a permit as a restricted  
 1106 prescription drug distributor, or for the renewal of such a  
 1107 permit, must provide to the department the information required  
 1108 under s. 499.012.

1109 4. The department may adopt rules regarding the  
 1110 distribution of prescription drugs by hospitals, health care  
 1111 entities, charitable organizations, other persons not involved  
 1112 in wholesale distribution, and blood establishments, which rules  
 1113 are necessary for the protection of the public health, safety,  
 1114 and welfare.

1115 5. A restricted prescription drug distributor permit is  
 1116 not required for distributions between pharmacies that each hold  
 1117 an active permit under chapter 465, have a common ownership, and  
 1118 are operating in a freestanding end-stage renal dialysis clinic,

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1119 if such distributions are made to meet the immediate emergency  
1120 medical needs of specifically identified patients and do not  
1121 occur with such frequency as to amount to the regular and  
1122 systematic supplying of that drug between the pharmacies. The  
1123 department shall adopt rules establishing criteria for  
1124 determining when the distribution of a prescription drug under  
1125 this subparagraph amounts to the regular and systematic  
1126 supplying of that drug.

1127 (i)~~(h)~~ Complimentary drug distributor permit.—A  
1128 complimentary drug distributor permit is required for any person  
1129 that engages in the distribution of a complimentary drug,  
1130 subject to the requirements of s. 499.028.

1131 (j)~~(i)~~ Freight forwarder permit.—A freight forwarder  
1132 permit is required for any person that engages in the  
1133 distribution of a prescription drug as a freight forwarder  
1134 unless the person is a common carrier. The storage, handling,  
1135 and recordkeeping of such distributions must comply with the  
1136 requirements for wholesale distributors under s. 499.0121, ~~but~~  
1137 ~~not those set forth in s. 499.01212.~~ A freight forwarder must  
1138 provide the source of the prescription drugs with a validated  
1139 airway bill, bill of lading, or other appropriate documentation  
1140 to evidence the exportation of the product.

1141 (k)~~(j)~~ Veterinary prescription drug retail establishment  
1142 permit.—A veterinary prescription drug retail establishment  
1143 permit is required for any person that sells veterinary  
1144 prescription drugs to the public but does not include a pharmacy

1145 licensed under chapter 465.

1146 1. The sale to the public must be based on a valid written  
 1147 order from a veterinarian licensed in this state who has a valid  
 1148 client-veterinarian relationship with the purchaser's animal.

1149 2. Veterinary prescription drugs may not be sold in excess  
 1150 of the amount clearly indicated on the order or beyond the date  
 1151 indicated on the order.

1152 3. An order may not be valid for more than 1 year.

1153 4. A veterinary prescription drug retail establishment may  
 1154 not purchase, sell, trade, or possess human prescription drugs  
 1155 or any controlled substance as defined in chapter 893.

1156 5. A veterinary prescription drug retail establishment  
 1157 must sell a veterinary prescription drug in the original, sealed  
 1158 manufacturer's container with all labeling intact and legible.  
 1159 The department may adopt by rule additional labeling  
 1160 requirements for the sale of a veterinary prescription drug.

1161 6. A veterinary prescription drug retail establishment  
 1162 must comply with all of the wholesale distribution requirements  
 1163 of s. 499.0121.

1164 7. Prescription drugs sold by a veterinary prescription  
 1165 drug retail establishment pursuant to a practitioner's order may  
 1166 not be returned into the retail establishment's inventory.

1167 (1)~~(\*)~~ Veterinary prescription drug wholesale distributor  
 1168 permit.—A veterinary prescription drug wholesale distributor  
 1169 permit is required for any person that engages in the  
 1170 distribution of veterinary prescription drugs in or into this

1171 state. A veterinary prescription drug wholesale distributor that  
 1172 also distributes prescription drugs subject to, defined by, or  
 1173 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
 1174 Act which it did not manufacture must obtain a permit as a  
 1175 prescription drug wholesale distributor, an out-of-state  
 1176 prescription drug wholesale distributor, or a limited  
 1177 prescription drug veterinary wholesale distributor in lieu of  
 1178 the veterinary prescription drug wholesale distributor permit. A  
 1179 veterinary prescription drug wholesale distributor must comply  
 1180 with the requirements for wholesale distributors under s.  
 1181 499.0121, ~~but not those set forth in s. 499.01212.~~

1182 (m)~~(l)~~ Limited prescription drug veterinary wholesale  
 1183 distributor permit.—Unless engaging in the activities of and  
 1184 permitted as a prescription drug manufacturer, nonresident  
 1185 prescription drug manufacturer, prescription drug wholesale  
 1186 distributor, or out-of-state prescription drug wholesale  
 1187 distributor, a limited prescription drug veterinary wholesale  
 1188 distributor permit is required for any person that engages in  
 1189 the distribution in or into this state of veterinary  
 1190 prescription drugs and prescription drugs subject to, defined  
 1191 by, or described by s. 503(b) of the Federal Food, Drug, and  
 1192 Cosmetic Act under the following conditions:

- 1193 1. The person is engaged in the business of wholesaling  
 1194 prescription and veterinary prescription drugs to persons:
  - 1195 a. Licensed as veterinarians practicing on a full-time  
 1196 basis;

1197           b. Regularly and lawfully engaged in instruction in  
 1198 veterinary medicine;

1199           c. Regularly and lawfully engaged in law enforcement  
 1200 activities;

1201           d. For use in research not involving clinical use; or  
 1202           e. For use in chemical analysis or physical testing or for  
 1203 purposes of instruction in law enforcement activities, research,  
 1204 or testing.

1205           2. No more than 30 percent of total annual prescription  
 1206 drug sales may be prescription drugs approved for human use  
 1207 which are subject to, defined by, or described by s. 503(b) of  
 1208 the Federal Food, Drug, and Cosmetic Act.

1209           3. The person does not distribute in any jurisdiction  
 1210 prescription drugs subject to, defined by, or described by s.  
 1211 503(b) of the Federal Food, Drug, and Cosmetic Act to any person  
 1212 who is authorized to sell, distribute, purchase, trade, or use  
 1213 these drugs on or for humans.

1214           4. A limited prescription drug veterinary wholesale  
 1215 distributor that applies to the department for a new permit or  
 1216 the renewal of a permit must submit a bond of \$20,000, or other  
 1217 equivalent means of security acceptable to the department, such  
 1218 as an irrevocable letter of credit or a deposit in a trust  
 1219 account or financial institution, payable to the Professional  
 1220 Regulation Trust Fund. The purpose of the bond is to secure  
 1221 payment of any administrative penalties imposed by the  
 1222 department and any fees and costs incurred by the department

1223 regarding that permit which are authorized under state law and  
1224 which the permittee fails to pay 30 days after the fine or costs  
1225 become final. The department may make a claim against such bond  
1226 or security until 1 year after the permittee's license ceases to  
1227 be valid or until 60 days after any administrative or legal  
1228 proceeding authorized in this part which involves the permittee  
1229 is concluded, including any appeal, whichever occurs later.

1230 5. A limited prescription drug veterinary wholesale  
1231 distributor must maintain at all times a license or permit to  
1232 engage in the wholesale distribution of prescription drugs in  
1233 compliance with laws of the state in which it is a resident.

1234 6. A limited prescription drug veterinary wholesale  
1235 distributor must comply with the requirements for wholesale  
1236 distributors under s. ss. 499.0121 and ~~499.01212~~, ~~except that a~~  
1237 ~~limited prescription drug veterinary wholesale distributor is~~  
1238 ~~not required to provide a pedigree paper as required by s.~~  
1239 ~~499.01212 upon the wholesale distribution of a prescription drug~~  
1240 ~~to a veterinarian.~~

1241 7. A limited prescription drug veterinary wholesale  
1242 distributor may not return to inventory for subsequent wholesale  
1243 distribution any prescription drug subject to, defined by, or  
1244 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
1245 Act which has been returned by a veterinarian.

1246 8. A limited prescription drug veterinary wholesale  
1247 distributor permit is not required for an intracompany sale or  
1248 transfer of a prescription drug from an out-of-state

1249 establishment that is duly licensed to engage in the wholesale  
 1250 distribution of prescription drugs in its state of residence to  
 1251 a licensed limited prescription drug veterinary wholesale  
 1252 distributor in this state if both wholesale distributors conduct  
 1253 wholesale distributions of prescription drugs under the same  
 1254 business name. The recordkeeping requirements of s. ss.  
 1255 499.0121(6) ~~and 499.01212~~ must be followed for this transaction.

1256 (n) ~~(m)~~ Over-the-counter drug manufacturer permit.—An over-  
 1257 the-counter drug manufacturer permit is required for any person  
 1258 that engages in the manufacture or repackaging of an over-the-  
 1259 counter drug.

1260 1. An over-the-counter drug manufacturer may not possess  
 1261 or purchase prescription drugs.

1262 2. A pharmacy is exempt from obtaining an over-the-counter  
 1263 drug manufacturer permit if it is operating in compliance with  
 1264 pharmacy practice standards as defined in chapter 465 and ~~the~~  
 1265 rules adopted under that chapter.

1266 3. An over-the-counter drug manufacturer must comply with  
 1267 all appropriate state and federal good manufacturing practices.

1268 (o) ~~(n)~~ Device manufacturer permit.—

1269 1. A device manufacturer permit is required for any person  
 1270 that engages in the manufacture, repackaging, or assembly of  
 1271 medical devices for human use in this state, except that a  
 1272 permit is not required if:

1273 a. The person is engaged only in manufacturing,  
 1274 repackaging, or assembling a medical device pursuant to a

1275 practitioner's order for a specific patient; or

1276       b. The person does not manufacture, repackage, or assemble  
 1277 any medical devices or components for such devices, except those  
 1278 devices or components which are exempt from registration  
 1279 pursuant to s. 499.015(8).

1280       2. A manufacturer or repackager of medical devices in this  
 1281 state must comply with all appropriate state and federal good  
 1282 manufacturing practices and quality system rules.

1283       3. The department shall adopt rules related to storage,  
 1284 handling, and recordkeeping requirements for manufacturers of  
 1285 medical devices for human use.

1286       (p)~~(e)~~ Cosmetic manufacturer permit.—A cosmetic  
 1287 manufacturer permit is required for any person that manufactures  
 1288 or repackages cosmetics in this state. A person that only labels  
 1289 or changes the labeling of a cosmetic but does not open the  
 1290 container sealed by the manufacturer of the product is exempt  
 1291 from obtaining a permit under this paragraph.

1292       (q)~~(p)~~ Third party logistics provider permit.—A third  
 1293 party logistics provider permit is required for any person that  
 1294 contracts with a prescription drug wholesale distributor or  
 1295 prescription drug manufacturer to provide warehousing,  
 1296 distribution, or other logistics services on behalf of a  
 1297 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who  
 1298 does not take title to the prescription drug or have  
 1299 responsibility to direct the sale or disposition of the  
 1300 prescription drug. A third party logistics provider located

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1301 outside of this state, must be licensed in the state or  
1302 territory from which the prescription drug is distributed by the  
1303 third party logistics provider. If the state or territory from  
1304 which the third party logistics provider originates does not  
1305 require a license to operate as a third party logistics  
1306 provider, the third party logistic provider must be licensed as  
1307 a third party logistics provider as required by the federal act.  
1308 Each third party logistics provider permittee shall comply with  
1309 s. the requirements for wholesale distributors under ss.  
1310 499.0121 and 499.01212, with the exception of those wholesale  
1311 distributions described in s. 499.01212(3)(a), and other rules  
1312 that the department requires.

1313 (r)(q) Health care clinic establishment permit. ~~Effective~~  
1314 ~~January 1, 2009,~~ A health care clinic establishment permit is  
1315 required for the purchase of a prescription drug by a place of  
1316 business at one general physical location that provides health  
1317 care or veterinary services, which is owned and operated by a  
1318 business entity that has been issued a federal employer tax  
1319 identification number. For the purpose of this paragraph, the  
1320 term "qualifying practitioner" means a licensed health care  
1321 practitioner defined in s. 456.001, or a veterinarian licensed  
1322 under chapter 474, who is authorized under the appropriate  
1323 practice act to prescribe and administer a prescription drug.

1324 1. An establishment must provide, as part of the  
1325 application required under s. 499.012, designation of a  
1326 qualifying practitioner who will be responsible for complying

1327 with all legal and regulatory requirements related to the  
1328 purchase, recordkeeping, storage, and handling of the  
1329 prescription drugs. In addition, the designated qualifying  
1330 practitioner shall be the practitioner whose name, establishment  
1331 address, and license number is used on all distribution  
1332 documents for prescription drugs purchased or returned by the  
1333 health care clinic establishment. Upon initial appointment of a  
1334 qualifying practitioner, the qualifying practitioner and the  
1335 health care clinic establishment shall notify the department on  
1336 a form furnished by the department within 10 days after such  
1337 employment. In addition, the qualifying practitioner and health  
1338 care clinic establishment shall notify the department within 10  
1339 days after any subsequent change.

1340 2. The health care clinic establishment must employ a  
1341 qualifying practitioner at each establishment.

1342 3. In addition to the remedies and penalties provided in  
1343 this part, a violation of this chapter by the health care clinic  
1344 establishment or qualifying practitioner constitutes grounds for  
1345 discipline of the qualifying practitioner by the appropriate  
1346 regulatory board.

1347 4. The purchase of prescription drugs by the health care  
1348 clinic establishment is prohibited during any period of time  
1349 when the establishment does not comply with this paragraph.

1350 5. A health care clinic establishment permit is not a  
1351 pharmacy permit or otherwise subject to chapter 465. A health  
1352 care clinic establishment that meets the criteria of a modified

1353 Class II institutional pharmacy under s. 465.019 is not eligible  
1354 to be permitted under this paragraph.

1355 6. This paragraph does not apply to the purchase of a  
1356 prescription drug by a licensed practitioner under his or her  
1357 license.

1358 (3) A nonresident prescription drug manufacturer permit is  
1359 not required for a manufacturer to distribute a prescription  
1360 drug active pharmaceutical ingredient that it manufactures to a  
1361 prescription drug manufacturer permitted in this state ~~in~~  
1362 ~~limited quantities~~ intended for research and development and not  
1363 for resale or human use other than lawful clinical trials and  
1364 biostudies authorized and regulated by federal law. A  
1365 manufacturer claiming to be exempt from the permit requirements  
1366 of this subsection and the prescription drug manufacturer  
1367 purchasing and receiving the active pharmaceutical ingredient  
1368 shall comply with the recordkeeping requirements of s.  
1369 499.0121(6), ~~but not the requirements of s. 499.01212.~~ The  
1370 prescription drug manufacturer purchasing and receiving the  
1371 active pharmaceutical ingredient shall maintain on file a record  
1372 of the FDA registration number; if available, the out-of-state  
1373 license, permit, or registration number; and, if available, a  
1374 copy of the most current FDA inspection report, for all  
1375 manufacturers from whom they purchase active pharmaceutical  
1376 ingredients under this section. ~~The department shall define the~~  
1377 ~~term "limited quantities" by rule, and may include the allowable~~  
1378 ~~number of transactions within a given period of time and the~~

1379 ~~amount of prescription drugs distributed into the state for~~  
1380 ~~purposes of this exemption.~~ The failure to comply with the  
1381 requirements of this subsection, or rules adopted by the  
1382 department to administer this subsection, for the purchase of  
1383 prescription drug active pharmaceutical ingredients is a  
1384 violation of s. 499.005(14), and a knowing failure is a  
1385 violation of s. 499.0051(4).

1386 (a) The immediate package or container of a prescription  
1387 drug active pharmaceutical ingredient distributed into the state  
1388 that is intended for research and development under this  
1389 subsection shall bear a label prominently displaying the  
1390 statement: "Caution: Research and Development Only—Not for  
1391 Manufacturing, Compounding, or Resale."

1392 (b) A prescription drug manufacturer that obtains a  
1393 prescription drug active pharmaceutical ingredient under this  
1394 subsection for use in clinical trials and or biostudies  
1395 authorized and regulated by federal law must create and maintain  
1396 records detailing the specific clinical trials or biostudies for  
1397 which the prescription drug active pharmaceutical ingredient was  
1398 obtained.

1399 (4) (a) A permit issued under this part is not required to  
1400 distribute a prescription drug active pharmaceutical ingredient  
1401 from an establishment located in the United States to an  
1402 establishment located in this state permitted as a prescription  
1403 drug manufacturer under this part for use by the recipient in  
1404 preparing, deriving, processing, producing, or fabricating a

1405 prescription drug finished dosage form at the establishment in  
1406 this state where the product is received under an approved and  
1407 otherwise valid New Drug Approval Application, Abbreviated New  
1408 Drug Application, New Animal Drug Application, or Therapeutic  
1409 Biologic Application, provided that the application, active  
1410 pharmaceutical ingredient, or finished dosage form has not been  
1411 withdrawn or removed from the market in this country for public  
1412 health reasons.

1413 1. Any distributor claiming exemption from permitting  
1414 requirements pursuant to this paragraph shall maintain a  
1415 license, permit, or registration to engage in the wholesale  
1416 distribution of prescription drugs under the laws of the state  
1417 from which the product is distributed. If the state from which  
1418 the prescription drugs are distributed does not require a  
1419 license to engage in the wholesale distribution of prescription  
1420 drugs, the distributor must be licensed as a wholesale  
1421 distributor as required by the federal act.

1422 2. Any distributor claiming exemption from permitting  
1423 requirements pursuant to this paragraph and the prescription  
1424 drug manufacturer purchasing and receiving the active  
1425 pharmaceutical ingredient shall comply with the recordkeeping  
1426 requirements of s. 499.0121(6), ~~but not the requirements of s.~~  
1427 ~~499.01212.~~

1428 (b) A permit issued under this part is not required to  
1429 distribute ~~limited quantities of~~ a prescription drug that has  
1430 not been repackaged from an establishment located in the United

1431 States to an establishment located in this state permitted as a  
1432 prescription drug manufacturer under this part for research and  
1433 development or to a holder of a letter of exemption issued by  
1434 the department under s. 499.03(4) for research, teaching, or  
1435 testing. ~~The department shall define "limited quantities" by~~  
1436 ~~rule and may include the allowable number of transactions within~~  
1437 ~~a given period of time and the amounts of prescription drugs~~  
1438 ~~distributed into the state for purposes of this exemption.~~

1439 1. Any distributor claiming exemption from permitting  
1440 requirements pursuant to this paragraph shall maintain a  
1441 license, permit, or registration to engage in the wholesale  
1442 distribution of prescription drugs under the laws of the state  
1443 from which the product is distributed. If the state from which  
1444 the prescription drugs are distributed does not require a  
1445 license to engage in the wholesale distribution of prescription  
1446 drugs, the distributor must be licensed as a wholesale  
1447 distributor as required by the federal act.

1448 2. All purchasers and recipients of any prescription drugs  
1449 distributed pursuant to this paragraph shall ensure that the  
1450 products are not resold or used, directly or indirectly, on  
1451 humans except in lawful clinical trials and biostudies  
1452 authorized and regulated by federal law.

1453 3. Any distributor claiming exemption from permitting  
1454 requirements pursuant to this paragraph, and the purchaser and  
1455 recipient of the prescription drug, shall comply with the  
1456 recordkeeping requirements of s. 499.0121(6), ~~but not the~~

1457 ~~requirements of s. 499.01212.~~

1458         4. The immediate package or container of any active  
1459 pharmaceutical ingredient distributed into the state that is  
1460 intended for teaching, testing, research, and development shall  
1461 bear a label prominently displaying the statement: "Caution:  
1462 Research, Teaching, or Testing Only - Not for Manufacturing,  
1463 Compounding, or Resale."

1464         (c) An out-of-state prescription drug wholesale  
1465 distributor permit is not required for an intracompany sale or  
1466 transfer of a prescription drug from an out-of-state  
1467 establishment that is duly licensed as a prescription drug  
1468 wholesale distributor in its state of residence to a licensed  
1469 prescription drug wholesale distributor in this state, if both  
1470 wholesale distributors conduct wholesale distributions of  
1471 prescription drugs under the same business name. The  
1472 recordkeeping requirements of s. ss. 499.0121(6) and ~~499.01212~~  
1473 must be followed for such transactions.

1474         (d) Persons receiving prescription drugs from a source  
1475 claimed to be exempt from permitting requirements under this  
1476 subsection shall maintain on file:

1477             1. A record of the FDA establishment registration number,  
1478 if any;

1479             2. The resident state or federal license, registration, or  
1480 permit that authorizes the source to distribute prescription  
1481 drugs ~~drug wholesale distribution license, permit, or~~  
1482 ~~registration number;~~ and

1483           3. A copy of the most recent resident state or FDA  
1484 inspection report, for all distributors and establishments from  
1485 whom they purchase or receive prescription drugs under this  
1486 subsection.

1487           (e) All persons claiming exemption from permitting  
1488 requirements pursuant to this subsection who engage in the  
1489 distribution of prescription drugs within or into the state are  
1490 subject to this part, including ss. 499.005 and 499.0051, and  
1491 shall make available, within 48 hours, to the department on  
1492 request all records related to any prescription drugs  
1493 distributed under this subsection, including those records  
1494 described in s. 499.051(4), regardless of the location where the  
1495 records are stored.

1496           (f) A person purchasing and receiving a prescription drug  
1497 from a person claimed to be exempt from licensing requirements  
1498 pursuant to this subsection shall report to the department in  
1499 writing within 14 days after receiving any product that is  
1500 misbranded or adulterated or that fails to meet minimum  
1501 standards set forth in the official compendium or state or  
1502 federal good manufacturing practices for identity, purity,  
1503 potency, or sterility, regardless of whether the product is  
1504 thereafter rehabilitated, quarantined, returned, or destroyed.

1505           (g) The department may adopt rules to administer this  
1506 subsection which are necessary for the protection of the public  
1507 health, safety, and welfare. Failure to comply with the  
1508 requirements of this subsection, or rules adopted by the

1509 department to administer this subsection, is a violation of s.  
 1510 499.005(14), and a knowing failure is a violation of s.  
 1511 499.0051(4).

1512 (h) This subsection does not relieve any person from any  
 1513 requirement prescribed by law with respect to controlled  
 1514 substances as defined in the applicable federal and state laws.

1515 (5) A prescription drug repackager permit issued under  
 1516 this part is not required for a restricted prescription drug  
 1517 distributor permitholder that is a health care entity to  
 1518 repackage prescription drugs in this state for its own use or  
 1519 for distribution to hospitals or other health care entities in  
 1520 the state for their own use, pursuant to s. 499.003(48)(a)3.  
 1521 ~~499.003(53)(a)3.~~, if:

1522 (a) The prescription drug distributor notifies the  
 1523 department, in writing, of its intention to engage in  
 1524 repackaging under this exemption, 30 days before engaging in the  
 1525 repackaging of prescription drugs at the permitted  
 1526 establishment;

1527 (b) The prescription drug distributor is under common  
 1528 control with the hospitals or other health care entities to  
 1529 which the prescription drug distributor is distributing  
 1530 prescription drugs. As used in this paragraph, "common control"  
 1531 means the power to direct or cause the direction of the  
 1532 management and policies of a person or an organization, whether  
 1533 by ownership of stock, voting rights, contract, or otherwise;

1534 (c) The prescription drug distributor repackages the

1535 prescription drugs in accordance with current state and federal  
 1536 good manufacturing practices; and

1537 (d) The prescription drug distributor labels the  
 1538 prescription drug it repackages in accordance with state and  
 1539 federal laws and rules.

1540  
 1541 The prescription drug distributor is exempt from the product  
 1542 registration requirements of s. 499.015 with regard to the  
 1543 prescription drugs that it repackages and distributes under this  
 1544 subsection. A prescription drug distributor that repackages and  
 1545 distributes prescription drugs under this subsection to a not-  
 1546 for-profit rural hospital, as defined in s. 395.602, is not  
 1547 required to comply with paragraph (c) or paragraph (d), but must  
 1548 provide to each health care entity for which it repackages, for  
 1549 each prescription drug that is repackaged and distributed, the  
 1550 information required by department rule for labeling  
 1551 prescription drugs. The department shall adopt rules to ensure  
 1552 the safety and integrity of prescription drugs repackaged and  
 1553 distributed under this subsection, including manufacturing and  
 1554 labeling requirements.

1555 Section 6. Section 499.012, Florida Statutes, is amended  
 1556 to read:

1557 499.012 Permit application requirements.—

1558 (1) (a) A permit issued pursuant to this part may be issued  
 1559 only to a natural person who is at least 18 years of age or to  
 1560 an applicant that is not a natural person if each person who,

1561 directly or indirectly, manages, controls, or oversees the  
 1562 operation of that applicant is at least 18 years of age.

1563 (b) An establishment that is a place of residence may not  
 1564 receive a permit and may not operate under this part.

1565 (c) A person that applies for or renews a permit to  
 1566 manufacture or distribute prescription drugs may not use a name  
 1567 identical to the name used by any other establishment or  
 1568 licensed person authorized to purchase prescription drugs in  
 1569 this state, except that a restricted drug distributor permit  
 1570 issued to a health care entity will be issued in the name in  
 1571 which the institutional pharmacy permit is issued and a retail  
 1572 pharmacy drug wholesale distributor will be issued a permit in  
 1573 the name of its retail pharmacy permit.

1574 (d) A permit for a prescription drug manufacturer,  
 1575 prescription drug repackager, prescription drug wholesale  
 1576 distributor, limited prescription drug veterinary wholesale  
 1577 distributor, or retail pharmacy drug wholesale distributor may  
 1578 not be issued to the address of a health care entity or to a  
 1579 pharmacy licensed under chapter 465, except as provided in this  
 1580 paragraph. The department may issue a prescription drug  
 1581 manufacturer permit to an applicant at the same address as a  
 1582 licensed nuclear pharmacy, which is a health care entity, even  
 1583 if the nuclear pharmacy holds a special sterile compounding  
 1584 permit under chapter 465, for the purpose of manufacturing  
 1585 prescription drugs used in positron emission tomography or other  
 1586 radiopharmaceuticals, as listed in a rule adopted by the

1587 department pursuant to this paragraph. The purpose of this  
1588 exemption is to assure availability of state-of-the-art  
1589 pharmaceuticals that would pose a significant danger to the  
1590 public health if manufactured at a separate establishment  
1591 address from the nuclear pharmacy from which the prescription  
1592 drugs are dispensed. The department may also issue a retail  
1593 pharmacy drug wholesale distributor permit to the address of a  
1594 community pharmacy licensed under chapter 465, even if the  
1595 community pharmacy holds a special sterile compounding permit  
1596 under chapter 465, as long as the community pharmacy ~~which~~ does  
1597 not meet the definition of a closed pharmacy in s. 499.003.

1598 (e) A county or municipality may not issue an occupational  
1599 license for ~~any licensing period beginning on or after October~~  
1600 ~~1, 2003, for~~ any establishment that requires a permit pursuant  
1601 to this part, unless the establishment exhibits a current permit  
1602 issued by the department for the establishment. Upon  
1603 presentation of the requisite permit issued by the department,  
1604 an occupational license may be issued by the municipality or  
1605 county in which application is made. The department shall  
1606 furnish to local agencies responsible for issuing occupational  
1607 licenses a current list of all establishments licensed pursuant  
1608 to this part.

1609 (2) Notwithstanding subsection (6), a permitted person in  
1610 good standing may change the type of permit issued to that  
1611 person by completing a new application for the requested permit,  
1612 paying the amount of the difference in the permit fees if the

1613 fee for the new permit is more than the fee for the original  
1614 permit, and meeting the applicable permitting conditions for the  
1615 new permit type. The new permit expires on the expiration date  
1616 of the original permit being changed; however, a new permit for  
1617 a prescription drug wholesale distributor, an out-of-state  
1618 prescription drug wholesale distributor, or a retail pharmacy  
1619 drug wholesale distributor shall expire on the expiration date  
1620 of the original permit or 1 year after the date of issuance of  
1621 the new permit, whichever is earlier. A refund may not be issued  
1622 if the fee for the new permit is less than the fee that was paid  
1623 for the original permit.

1624 (3) (a) A written application for a permit or to renew a  
1625 permit must be filed with the department on forms furnished by  
1626 the department. The department shall establish, by rule, the  
1627 form and content of the application to obtain or renew a permit.  
1628 The applicant must submit to the department with the application  
1629 a statement that swears or affirms that the information is true  
1630 and correct.

1631 (b) Upon a determination that 2 years have elapsed since  
1632 the department notified an applicant for permit, certification,  
1633 or product registration of a deficiency in the application and  
1634 that the applicant has failed to cure the deficiency, the  
1635 application shall expire. The determination regarding the 2-year  
1636 lapse of time shall be based on documentation that the  
1637 department notified the applicant of the deficiency in  
1638 accordance with s. 120.60.

1639           (c) Information submitted by an applicant on an  
 1640 application required pursuant to this subsection which is a  
 1641 trade secret, as defined in s. 812.081, shall be maintained by  
 1642 the department as trade secret information pursuant to s.  
 1643 499.051(7).

1644           (4) (a) Except for a permit for a prescription drug  
 1645 wholesale distributor or an out-of-state prescription drug  
 1646 wholesale distributor, an application for a permit must include:

1647           1. The name, full business address, and telephone number  
 1648 of the applicant;

1649           2. All trade or business names used by the applicant;

1650           3. The address, telephone numbers, and the names of  
 1651 contact persons for each facility used by the applicant for the  
 1652 storage, handling, and distribution of prescription drugs;

1653           4. The type of ownership or operation, such as a  
 1654 partnership, corporation, or sole proprietorship; and

1655           5. The names of the owner and the operator of the  
 1656 establishment, including:

1657           a. If an individual, the name of the individual;

1658           b. If a partnership, the name of each partner and the name  
 1659 of the partnership;

1660           c. If a corporation, the name and title of each corporate  
 1661 officer and director, the corporate names, and the name of the  
 1662 state of incorporation;

1663           d. If a sole proprietorship, the full name of the sole  
 1664 proprietor and the name of the business entity;

1665 e. If a limited liability company, the name of each  
1666 member, the name of each manager, the name of the limited  
1667 liability company, and the name of the state in which the  
1668 limited liability company was organized; and

1669 f. Any other relevant information that the department  
1670 requires.

1671 (b) Upon approval of the application by the department and  
1672 payment of the required fee, the department shall issue a permit  
1673 to the applicant, if the applicant meets the requirements of  
1674 this part and rules adopted under this part.

1675 (c) Any change in information required under paragraph (a)  
1676 must be submitted to the department before the change occurs.

1677 (d) The department shall consider, at a minimum, the  
1678 following factors in reviewing the qualifications of persons to  
1679 be permitted under this part:

1680 1. The applicant's having been found guilty, regardless of  
1681 adjudication, in a court of this state or other jurisdiction, of  
1682 a violation of a law that directly relates to a drug, device, or  
1683 cosmetic. A plea of nolo contendere constitutes a finding of  
1684 guilt for purposes of this subparagraph.

1685 2. The applicant's having been disciplined by a regulatory  
1686 agency in any state for any offense that would constitute a  
1687 violation of this part.

1688 3. Any felony conviction of the applicant under a federal,  
1689 state, or local law;

1690 4. The applicant's past experience in manufacturing or

1691 distributing drugs, devices, or cosmetics;

1692 5. The furnishing by the applicant of false or fraudulent  
 1693 material in any application made in connection with  
 1694 manufacturing or distributing drugs, devices, or cosmetics;

1695 6. Suspension or revocation by a federal, state, or local  
 1696 government of any permit currently or previously held by the  
 1697 applicant for the manufacture or distribution of any drugs,  
 1698 devices, or cosmetics;

1699 7. Compliance with permitting requirements under any  
 1700 previously granted permits;

1701 8. Compliance with requirements to maintain or make  
 1702 available to the state permitting authority or to federal,  
 1703 state, or local law enforcement officials those records required  
 1704 under this section; and

1705 9. Any other factors or qualifications the department  
 1706 considers relevant to and consistent with the public health and  
 1707 safety.

1708 (5) ~~Except for a permit for a prescription drug wholesale~~  
 1709 ~~distributor or an out-of-state prescription drug wholesale~~  
 1710 ~~distributor:~~

1711 (a) The department shall adopt rules for the biennial  
 1712 renewal of permits; however, the department may issue up to a 4-  
 1713 year permit to selected permittees notwithstanding any other  
 1714 provision of law. Fees for such renewal may not exceed the fee  
 1715 caps set forth in s. 499.041 on an annualized basis as  
 1716 authorized by law.

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1717 (b) The department shall renew a permit upon receipt of  
1718 the renewal application and renewal fee if the applicant meets  
1719 the requirements established under this part and ~~the~~ rules  
1720 adopted under this part.

1721 (c) At least 90 days before the expiration date of a  
1722 permit, the department shall forward a permit renewal  
1723 notification to the permittee at the mailing address of the  
1724 permitted establishment on file with the department. The permit  
1725 renewal notification must state conspicuously the date on which  
1726 the permit for the establishment will expire and that the  
1727 establishment may not operate unless the permit for the  
1728 establishment is renewed timely. A permit, unless sooner  
1729 suspended or revoked, automatically expires 2 years after the  
1730 last day of the anniversary month in which the permit was  
1731 originally issued.

1732 (d) A permit issued under this part may be renewed by  
1733 making application for renewal on forms furnished by the  
1734 department and paying the appropriate fees.

1735 1. If a prescription drug wholesale distributor or an out-  
1736 of-state prescription drug wholesale distributor renewal  
1737 application and fee are submitted and postmarked later than 45  
1738 days before the expiration date of the permit, the permit may be  
1739 renewed only upon payment of a late renewal fee of \$100, plus  
1740 the required renewal fee.

1741 2. If any other a renewal application and fee are  
1742 submitted and postmarked after the expiration date of the

1743 permit, the permit may be renewed only upon payment of a late  
1744 renewal delinquent fee of \$100, plus the required renewal fee,  
1745 not later than 60 days after the expiration date.

1746 3. A permittee who submits a renewal application in  
1747 accordance with this paragraph may continue to operate under its  
1748 permit, unless the permit is suspended or revoked, until final  
1749 disposition of the renewal application.

1750 4. ~~(d)~~ Failure to renew a permit in accordance with this  
1751 section precludes any future renewal of that permit. If a permit  
1752 issued pursuant to this part has expired and cannot be renewed,  
1753 before an establishment may engage in activities that require a  
1754 permit under this part, the establishment must submit an  
1755 application for a new permit, pay the applicable application  
1756 fee, the initial permit fee, and all applicable penalties, and  
1757 be issued a new permit by the department.

1758 (6) A permit issued by the department is nontransferable.  
1759 Each permit is valid only for the person or governmental unit to  
1760 which it is issued and is not subject to sale, assignment, or  
1761 other transfer, voluntarily or involuntarily; nor is a permit  
1762 valid for any establishment other than the establishment for  
1763 which it was originally issued.

1764 (a) A person permitted under this part must notify the  
1765 department before making a change of address. The department  
1766 shall set a change of location fee not to exceed \$100.

1767 (b)1. An application for a new permit is required when a  
1768 majority of the ownership or controlling interest of a permitted

1769 establishment is transferred or assigned or when a lessee agrees  
 1770 to undertake or provide services to the extent that legal  
 1771 liability for operation of the establishment will rest with the  
 1772 lessee. The application for the new permit must be made before  
 1773 the date of the sale, transfer, assignment, or lease.

1774 2. A permittee that is authorized to distribute  
 1775 prescription drugs may transfer such drugs to the new owner or  
 1776 lessee under subparagraph 1. only after the new owner or lessee  
 1777 has been approved for a permit to distribute prescription drugs.

1778 (c) If an establishment permitted under this part closes,  
 1779 the owner must notify the department in writing before the  
 1780 effective date of closure and must:

1781 1. Return the permit to the department;

1782 2. If the permittee is authorized to distribute  
 1783 prescription drugs, indicate the disposition of such drugs,  
 1784 including the name, address, and inventory, and provide the name  
 1785 and address of a person to contact regarding access to records  
 1786 that are required to be maintained under this part. Transfer of  
 1787 ownership of prescription drugs may be made only to persons  
 1788 authorized to possess prescription drugs under this part.

1789  
 1790 The department may revoke the permit of any person that fails to  
 1791 comply with the requirements of this subsection.

1792 (7) A permit must be posted in a conspicuous place on the  
 1793 licensed premises.

1794 (8) An application for a permit or to renew a permit for a

1795 prescription drug wholesale distributor or an out-of-state  
 1796 prescription drug wholesale distributor submitted to the  
 1797 department must include:

1798       (a) The name, full business address, and telephone number  
 1799 of the applicant.

1800       (b) All trade or business names used by the applicant.

1801       (c) The address, telephone numbers, and the names of  
 1802 contact persons for each facility used by the applicant for the  
 1803 storage, handling, and distribution of prescription drugs.

1804       (d) The type of ownership or operation, such as a  
 1805 partnership, corporation, or sole proprietorship.

1806       (e) The names of the owner and the operator of the  
 1807 establishment, including:

1808           1. If an individual, the name of the individual.

1809           2. If a partnership, the name of each partner and the name  
 1810 of the partnership.

1811           3. If a corporation:

1812               a. The name, address, and title of each corporate officer  
 1813 and director.

1814               b. The name and address of the corporation, resident agent  
 1815 of the corporation, the resident agent's address, and the  
 1816 corporation's state of incorporation.

1817               c. The name and address of each shareholder of the  
 1818 corporation that owns 5 percent or more of the outstanding stock  
 1819 of the corporation.

1820           4. If a sole proprietorship, the full name of the sole

1821 proprietor and the name of the business entity.

1822 5. If a limited liability company:

1823 a. The name and address of each member.

1824 b. The name and address of each manager.

1825 c. The name and address of the limited liability company,  
 1826 the resident agent of the limited liability company, and the  
 1827 name of the state in which the limited liability company was  
 1828 organized.

1829 (f) If applicable, the name and address of each affiliate  
 1830 ~~of member of the affiliated group of which the applicant is a~~  
 1831 ~~member.~~

1832 (g)~~1.~~ The applicant's gross annual receipts attributable  
 1833 to prescription drug wholesale distribution activities for the  
 1834 previous tax year. ~~For an application for a new permit, the~~  
 1835 ~~estimated annual dollar volume of prescription drug sales of the~~  
 1836 ~~applicant, the estimated annual percentage of the applicant's~~  
 1837 ~~total company sales that are prescription drugs, the applicant's~~  
 1838 ~~estimated annual total dollar volume of purchases of~~  
 1839 ~~prescription drugs, and the applicant's estimated annual total~~  
 1840 ~~dollar volume of prescription drug purchases directly from~~  
 1841 ~~manufacturers.~~

1842 ~~2. For an application to renew a permit, the total dollar~~  
 1843 ~~volume of prescription drug sales in the previous year, the~~  
 1844 ~~total dollar volume of prescription drug sales made in the~~  
 1845 ~~previous 6 months, the percentage of total company sales that~~  
 1846 ~~were prescription drugs in the previous year, the total dollar~~

1847 ~~volume of purchases of prescription drugs in the previous year,~~  
1848 ~~and the total dollar volume of prescription drug purchases~~  
1849 ~~directly from manufacturers in the previous year.~~

1850

1851 ~~Such portions of the information required pursuant to this~~  
1852 ~~paragraph which are a trade secret, as defined in s. 812.081,~~  
1853 ~~shall be maintained by the department as trade secret~~  
1854 ~~information is required to be maintained under s. 499.051.~~

1855 (h) The tax year of the applicant.

1856 (i) A copy of the deed for the property on which  
1857 applicant's establishment is located, if the establishment is  
1858 owned by the applicant, or a copy of the applicant's lease for  
1859 the property on which applicant's establishment is located that  
1860 has an original term of not less than 1 calendar year, if the  
1861 establishment is not owned by the applicant.

1862 (j) A list of all licenses and permits issued to the  
1863 applicant by any other state which authorize the applicant to  
1864 purchase or possess prescription drugs.

1865 (k) The name of the manager of the establishment that is  
1866 applying for the permit or to renew the permit, the next four  
1867 highest ranking employees responsible for prescription drug  
1868 wholesale operations for the establishment, and the name of all  
1869 affiliated parties for the establishment, together with the  
1870 personal information statement and fingerprints required  
1871 pursuant to subsection (9) for each of such persons.

1872 (l) The name of each of the applicant's designated

1873 representatives as required by subsection (15) ~~(16)~~, together  
1874 with the personal information statement and fingerprints  
1875 required pursuant to subsection (9) for each such person.

1876 (m) Evidence of a surety bond in this state or any other  
1877 state in the United States in the amount of \$100,000. If the  
1878 annual gross receipts of the applicant's previous tax year is  
1879 \$10 million or less, evidence of a surety bond in the amount of  
1880 \$25,000. The specific language of the surety bond must include  
1881 the State of Florida as a beneficiary, payable to the  
1882 Professional Regulation Trust Fund. In lieu of the surety bond,  
1883 the applicant may provide other equivalent security, such as an  
1884 irrevocable letter of credit or a deposit in a trust account or  
1885 financial institution, that includes the State of Florida as a  
1886 beneficiary, payable to the Professional Regulation Trust Fund.  
1887 The purpose of the bond or other security is to secure payment  
1888 of any administrative penalties imposed by the department and  
1889 any fees and costs incurred by the department regarding that  
1890 permit which are authorized under state law and which the  
1891 permittee fails to pay 30 days after the fine or costs become  
1892 final. The department may make a claim against such bond or  
1893 security until 1 year after the permittee's license ceases to be  
1894 valid or until 60 days after any administrative or legal  
1895 proceeding authorized in this part which involves the permittee  
1896 is concluded, including any appeal, whichever occurs later. For  
1897 ~~an applicant that is a secondary wholesale distributor, each of~~  
1898 ~~the following:~~

1899           1. ~~A personal background information statement containing~~  
 1900 ~~the background information and fingerprints required pursuant to~~  
 1901 ~~subsection (9) for each person named in the applicant's response~~  
 1902 ~~to paragraphs (k) and (l) and for each affiliated party of the~~  
 1903 ~~applicant.~~

1904           2. ~~If any of the five largest shareholders of the~~  
 1905 ~~corporation seeking the permit is a corporation, the name,~~  
 1906 ~~address, and title of each corporate officer and director of~~  
 1907 ~~each such corporation; the name and address of such corporation;~~  
 1908 ~~the name of such corporation's resident agent, such~~  
 1909 ~~corporation's resident agent's address, and such corporation's~~  
 1910 ~~state of its incorporation; and the name and address of each~~  
 1911 ~~shareholder of such corporation that owns 5 percent or more of~~  
 1912 ~~the stock of such corporation.~~

1913           3. ~~The name and address of all financial institutions in~~  
 1914 ~~which the applicant has an account which is used to pay for the~~  
 1915 ~~operation of the establishment or to pay for drugs purchased for~~  
 1916 ~~the establishment, together with the names of all persons that~~  
 1917 ~~are authorized signatories on such accounts. The portions of the~~  
 1918 ~~information required pursuant to this subparagraph which are a~~  
 1919 ~~trade secret, as defined in s. 812.081, shall be maintained by~~  
 1920 ~~the department as trade secret information is required to be~~  
 1921 ~~maintained under s. 499.051.~~

1922           4. ~~The sources of all funds and the amounts of such funds~~  
 1923 ~~used to purchase or finance purchases of prescription drugs or~~  
 1924 ~~to finance the premises on which the establishment is to be~~

1925 ~~located.~~

1926 ~~5. If any of the funds identified in subparagraph 4. were~~  
 1927 ~~borrowed, copies of all promissory notes or loans used to obtain~~  
 1928 ~~such funds.~~

1929 (n) For establishments used in wholesale distribution,  
 1930 proof of an inspection conducted by the department, the United  
 1931 States Food and Drug Administration, or another governmental  
 1932 entity charged with the regulation of good manufacturing  
 1933 practices related to wholesale distribution of prescription  
 1934 drugs, within timeframes set forth by the department in  
 1935 departmental rules, which demonstrates substantial compliance  
 1936 with current good manufacturing practices applicable to  
 1937 wholesale distribution of prescription drugs. The department may  
 1938 recognize another state's inspection of a wholesale distributor  
 1939 located in that state if such state's laws are deemed to be  
 1940 substantially equivalent to the law of this state by the  
 1941 department. The department may accept an inspection by a third-  
 1942 party accreditation or inspection service which meets the  
 1943 criteria set forth in department rule.

1944 ~~(o) (n)~~ Any other relevant information that the department  
 1945 requires, including, but not limited to, any information related  
 1946 to whether the applicant satisfies the definition of a primary  
 1947 wholesale distributor or a secondary wholesale distributor.

1948 ~~(p) (o)~~ Documentation of the credentialing policies and  
 1949 procedures required by s. 499.0121(15).

1950 (9) (a) Each person required by subsection (8) or

1951 subsection (15) to provide a personal information statement and  
1952 fingerprints shall provide the following information to the  
1953 department on forms prescribed by the department:

1954 1. The person's places of residence for the past 7 years.

1955 2. The person's date and place of birth.

1956 3. The person's occupations, positions of employment, and  
1957 offices held during the past 7 years.

1958 4. The principal business and address of any business,  
1959 corporation, or other organization in which each such office of  
1960 the person was held or in which each such occupation or position  
1961 of employment was carried on.

1962 5. Whether the person has been, during the past 7 years,  
1963 the subject of any proceeding for the revocation of any license  
1964 and, if so, the nature of the proceeding and the disposition of  
1965 the proceeding.

1966 6. Whether, during the past 7 years, the person has been  
1967 enjoined, temporarily or permanently, by a court of competent  
1968 jurisdiction from violating any federal or state law regulating  
1969 the possession, control, or distribution of prescription drugs,  
1970 together with details concerning any such event.

1971 7. A description of any involvement by the person with any  
1972 business, including any investments, other than the ownership of  
1973 stock in a publicly traded company or mutual fund, during the  
1974 past 4 7 years, which manufactured, administered, prescribed,  
1975 distributed, or stored pharmaceutical products and any lawsuits  
1976 in which such businesses were named as a party.

1977 8. A description of any felony criminal offense of which  
 1978 the person, as an adult, was found guilty, regardless of whether  
 1979 adjudication of guilt was withheld or whether the person pled  
 1980 guilty or nolo contendere. A criminal offense committed in  
 1981 another jurisdiction which would have been a felony in this  
 1982 state must be reported. If the person indicates that a criminal  
 1983 conviction is under appeal and submits a copy of the notice of  
 1984 appeal of that criminal offense, the applicant must, within 15  
 1985 days after the disposition of the appeal, submit to the  
 1986 department a copy of the final written order of disposition.

1987 9. A photograph of the person taken in the previous 180 ~~30~~  
 1988 days.

1989 10. A set of fingerprints for the person on a form and  
 1990 under procedures specified by the department, together with  
 1991 payment of an amount equal to the costs incurred by the  
 1992 department for the criminal record check of the person.

1993 11. The name, address, occupation, and date and place of  
 1994 birth for each member of the person's immediate family who is 18  
 1995 years of age or older. As used in this subparagraph, the term  
 1996 "member of the person's immediate family" includes the person's  
 1997 spouse, children, parents, siblings, the spouses of the person's  
 1998 children, and the spouses of the person's siblings.

1999 12. Any other relevant information that the department  
 2000 requires.

2001 (b) The information required pursuant to paragraph (a)  
 2002 shall be provided under oath.

2003 (c) The department shall submit the fingerprints provided  
 2004 by a person for initial licensure to the Department of Law  
 2005 Enforcement for a statewide criminal record check and for  
 2006 forwarding to the Federal Bureau of Investigation for a national  
 2007 criminal record check of the person. The department shall submit  
 2008 the fingerprints provided by a person as a part of a renewal  
 2009 application to the Department of Law Enforcement for a statewide  
 2010 criminal record check, and for forwarding to the Federal Bureau  
 2011 of Investigation for a national criminal record check, for the  
 2012 initial renewal of a permit after January 1, 2004; for any  
 2013 subsequent renewal of a permit, the department shall submit the  
 2014 required information for a statewide and national criminal  
 2015 record check of the person. Any person who as a part of an  
 2016 initial permit application or initial permit renewal after  
 2017 January 1, 2004, submits to the department a set of fingerprints  
 2018 required for the criminal record check required in this  
 2019 paragraph are ~~shall~~ not be required to provide a subsequent set  
 2020 of fingerprints for a criminal record check to the department,  
 2021 if the person has undergone a criminal record check as a  
 2022 condition of the issuance of an initial permit or the initial  
 2023 renewal of a permit of an applicant after January 1, 2004. The  
 2024 department is authorized to contract with private vendors, or  
 2025 enter into interagency agreements, to collect electronic  
 2026 fingerprints where fingerprints are required for registration,  
 2027 certification, or the licensure process or where criminal  
 2028 history record checks are required.

2029        (d) For purposes of applying for renewal of a permit under  
2030 subsection (8) or certification under subsection (16), a person  
2031 may submit the following in lieu of satisfying the requirements  
2032 of paragraphs (a), (b), and (c):

2033        1. A photograph of the individual taken within 180 days;  
2034 and

2035        2. A copy of the personal information statement form most  
2036 recently submitted to the department and a certification under  
2037 oath, on a form specified by the department, that the individual  
2038 has reviewed the previously submitted personal information  
2039 statement form and that the information contained therein  
2040 remains unchanged.

2041        (10) The department may deny an application for a permit  
2042 or refuse to renew a permit for a prescription drug wholesale  
2043 distributor or an out-of-state prescription drug wholesale  
2044 distributor if:

2045        (a) The applicant has not met the requirements for the  
2046 permit.

2047        (b) The management, officers, or directors of the  
2048 applicant or any affiliated party are found by the department to  
2049 be incompetent or untrustworthy.

2050        (c) The applicant is so lacking in experience in managing  
2051 a wholesale distributor as to make the issuance of the proposed  
2052 permit hazardous to the public health.

2053        (d) The applicant is so lacking in experience in managing  
2054 a wholesale distributor as to jeopardize the reasonable promise

2055 of successful operation of the wholesale distributor.

2056 (e) The applicant is lacking in experience in the  
2057 distribution of prescription drugs.

2058 (f) The applicant's past experience in manufacturing or  
2059 distributing prescription drugs indicates that the applicant  
2060 poses a public health risk.

2061 (g) The applicant is affiliated directly or indirectly  
2062 through ownership, control, or other business relations, with  
2063 any person or persons whose business operations are or have been  
2064 detrimental to the public health.

2065 (h) The applicant, or any affiliated party, has been found  
2066 guilty of or has pleaded guilty or nolo contendere to any felony  
2067 or crime punishable by imprisonment for 1 year or more under the  
2068 laws of the United States, any state, or any other country,  
2069 regardless of whether adjudication of guilt was withheld.

2070 (i) The applicant or any affiliated party has been charged  
2071 with a felony in a state or federal court and the disposition of  
2072 that charge is pending during the application review or renewal  
2073 review period.

2074 (j) The applicant has furnished false or fraudulent  
2075 information or material in any application made in this state or  
2076 any other state in connection with obtaining a permit or license  
2077 to manufacture or distribute drugs, devices, or cosmetics.

2078 (k) That a federal, state, or local government permit  
2079 currently or previously held by the applicant, or any affiliated  
2080 party, for the manufacture or distribution of any drugs,

2081 devices, or cosmetics has been disciplined, suspended, or  
 2082 revoked and has not been reinstated.

2083 (l) The applicant does not possess the financial or  
 2084 physical resources to operate in compliance with the permit  
 2085 being sought, this chapter, and the rules adopted under this  
 2086 chapter.

2087 (m) The applicant or any affiliated party receives,  
 2088 directly or indirectly, financial support and assistance from a  
 2089 person who was an affiliated party of a permittee whose permit  
 2090 was subject to discipline or was suspended or revoked, other  
 2091 than through the ownership of stock in a publicly traded company  
 2092 or a mutual fund.

2093 (n) The applicant or any affiliated party receives,  
 2094 directly or indirectly, financial support and assistance from a  
 2095 person who has been found guilty of any violation of this part  
 2096 or chapter 465, chapter 501, or chapter 893, any rules adopted  
 2097 under this part or those chapters, any federal or state drug  
 2098 law, or any felony where the underlying facts related to drugs,  
 2099 regardless of whether the person has been pardoned, had her or  
 2100 his civil rights restored, or had adjudication withheld, other  
 2101 than through the ownership of stock in a publicly traded company  
 2102 or a mutual fund.

2103 (o) The applicant for renewal of a permit under s.  
 2104 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged  
 2105 in the wholesale distribution of prescription drugs, as  
 2106 demonstrated by the regular and systematic distribution of

2107 prescription drugs throughout the year as evidenced by not fewer  
 2108 than 12 wholesale distributions in the previous year and not  
 2109 fewer than three wholesale distributions in the previous 6  
 2110 months.

2111 (p) Information obtained in response to s. 499.01(2)(e) or  
 2112 (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best  
 2113 interest of the public health, safety, and welfare to issue a  
 2114 permit.

2115 (q) The applicant does not possess the financial standing  
 2116 and business experience for the successful operation of the  
 2117 applicant.

2118 (r) The applicant or any affiliated party has failed to  
 2119 comply with the requirements for manufacturing or distributing  
 2120 prescription drugs under this part, similar federal laws,  
 2121 similar laws in other states, or the rules adopted under such  
 2122 laws.

2123 (11) Upon approval of the application by the department  
 2124 and payment of the required fee, the department shall issue or  
 2125 renew a prescription drug wholesale distributor or an out-of-  
 2126 state prescription drug wholesale distributor permit to the  
 2127 applicant.

2128 ~~(12) For a permit for a prescription drug wholesale~~  
 2129 ~~distributor or an out-of-state prescription drug wholesale~~  
 2130 ~~distributor:~~

2131 ~~(a) The department shall adopt rules for the annual~~  
 2132 ~~renewal of permits. At least 90 days before the expiration of a~~

2133 ~~permit, the department shall forward a permit renewal~~  
2134 ~~notification and renewal application to the prescription drug~~  
2135 ~~wholesale distributor or out-of-state prescription drug~~  
2136 ~~wholesale distributor at the mailing address of the permitted~~  
2137 ~~establishment on file with the department. The permit renewal~~  
2138 ~~notification must state conspicuously the date on which the~~  
2139 ~~permit for the establishment will expire and that the~~  
2140 ~~establishment may not operate unless the permit for the~~  
2141 ~~establishment is renewed timely.~~

2142 ~~(b) A permit, unless sooner suspended or revoked,~~  
2143 ~~automatically expires 1 year after the last day of the~~  
2144 ~~anniversary month in which the permit was originally issued. A~~  
2145 ~~permit may be renewed by making application for renewal on forms~~  
2146 ~~furnished by the department and paying the appropriate fees. If~~  
2147 ~~a renewal application and fee are submitted and postmarked after~~  
2148 ~~45 days prior to the expiration date of the permit, the permit~~  
2149 ~~may be renewed only upon payment of a late renewal fee of \$100,~~  
2150 ~~plus the required renewal fee. A permittee that has submitted a~~  
2151 ~~renewal application in accordance with this paragraph may~~  
2152 ~~continue to operate under its permit, unless the permit is~~  
2153 ~~suspended or revoked, until final disposition of the renewal~~  
2154 ~~application.~~

2155 ~~(c) Failure to renew a permit in accordance with this~~  
2156 ~~section precludes any future renewal of that permit. If a permit~~  
2157 ~~issued pursuant to this section has expired and cannot be~~  
2158 ~~renewed, before an establishment may engage in activities that~~

2159 ~~require a permit under this part, the establishment must submit~~  
 2160 ~~an application for a new permit; pay the applicable application~~  
 2161 ~~fee, initial permit fee, and all applicable penalties; and be~~  
 2162 ~~issued a new permit by the department.~~

2163 (12)~~(13)~~ A person that engages in wholesale distribution  
 2164 of prescription drugs in this state must have a wholesale  
 2165 distributor's permit issued by the department, except as noted  
 2166 in this section. Each establishment must be separately permitted  
 2167 except as noted in this subsection.

2168 (a) A separate establishment permit is not required when a  
 2169 permitted prescription drug wholesale distributor consigns a  
 2170 prescription drug to a pharmacy that is permitted under chapter  
 2171 465 and located in this state, provided that:

2172 1. The consignor wholesale distributor notifies the  
 2173 department in writing of the contract to consign prescription  
 2174 drugs to a pharmacy along with the identity and location of each  
 2175 consignee pharmacy;

2176 2. The pharmacy maintains its permit under chapter 465;

2177 3. The consignor wholesale distributor, which has no legal  
 2178 authority to dispense prescription drugs, complies with all  
 2179 wholesale distribution requirements of s. 499.0121 ~~and~~  
 2180 ~~499.01212~~ with respect to the consigned drugs and maintains  
 2181 records documenting the transfer of title or other completion of  
 2182 the wholesale distribution of the consigned prescription drugs;

2183 4. The distribution of the prescription drug is otherwise  
 2184 lawful under this chapter and other applicable law;

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2185           5. Open packages containing prescription drugs within a  
2186 pharmacy are the responsibility of the pharmacy, regardless of  
2187 how the drugs are titled; and

2188           6. The pharmacy dispenses the consigned prescription drug  
2189 in accordance with the limitations of its permit under chapter  
2190 465 or returns the consigned prescription drug to the consignor  
2191 wholesale distributor. In addition, a person who holds title to  
2192 prescription drugs may transfer the drugs to a person permitted  
2193 or licensed to handle the reverse distribution or destruction of  
2194 drugs. Any other distribution by and means of the consigned  
2195 prescription drug by any person, not limited to the consignor  
2196 wholesale distributor or consignee pharmacy, to any other person  
2197 is prohibited.

2198           (b) A wholesale distributor's permit is not required for  
2199 the one-time transfer of title of a pharmacy's lawfully acquired  
2200 prescription drug inventory by a pharmacy with a valid permit  
2201 issued under chapter 465 to a consignor prescription drug  
2202 wholesale distributor, permitted under this chapter, in  
2203 accordance with a written consignment agreement between the  
2204 pharmacy and that wholesale distributor if the permitted  
2205 pharmacy and the permitted prescription drug wholesale  
2206 distributor comply with all of the provisions of paragraph (a)  
2207 and the prescription drugs continue to be within the permitted  
2208 pharmacy's inventory for dispensing in accordance with the  
2209 limitations of the pharmacy permit under chapter 465. A  
2210 consignor drug wholesale distributor may not use the pharmacy as

2211 a wholesale distributor through which it distributes the  
2212 prescription drugs to other pharmacies. Nothing in this section  
2213 is intended to prevent a wholesale distributor from obtaining  
2214 this inventory in the event of nonpayment by the pharmacy.

2215 (c) A separate establishment permit is not required when a  
2216 permitted prescription drug wholesale distributor operates  
2217 temporary transit storage facilities for the sole purpose of  
2218 storage, for up to 16 hours, of a delivery of prescription drugs  
2219 when the wholesale distributor was temporarily unable to  
2220 complete the delivery to the recipient.

2221 (d) The department shall require information from each  
2222 wholesale distributor as part of the permit and renewal of such  
2223 permit, as required under this section.

2224 (13)~~(14)~~ Personnel employed in wholesale distribution must  
2225 have appropriate education and experience to enable them to  
2226 perform their duties in compliance with state permitting  
2227 requirements.

2228 (14)~~(15)~~ The name of a permittee or establishment on a  
2229 prescription drug wholesale distributor permit or an out-of-  
2230 state prescription drug wholesale distributor permit may not  
2231 include any indicia of attainment of any educational degree, any  
2232 indicia that the permittee or establishment possesses a  
2233 professional license, or any name or abbreviation that the  
2234 department determines is likely to cause confusion or mistake or  
2235 that the department determines is deceptive, including that of  
2236 any other entity authorized to purchase prescription drugs.

2237        (15)~~(16)~~(a) Each establishment that is issued an initial  
 2238 or renewal permit as a prescription drug wholesale distributor  
 2239 or an out-of-state prescription drug wholesale distributor must  
 2240 designate in writing to the department at least one natural  
 2241 person to serve as the designated representative of the  
 2242 wholesale distributor. Such person must have an active  
 2243 certification as a designated representative from the  
 2244 department.

2245        (b) To be certified as a designated representative, a  
 2246 natural person must:

2247            1. Submit an application on a form furnished by the  
 2248 department and pay the appropriate fees.

2249            2. Be at least 18 years of age.

2250            3. Have at least 2 years of verifiable full-time:

2251                a. Work experience in a pharmacy licensed in this state or  
 2252 another state, where the person's responsibilities included, but  
 2253 were not limited to, recordkeeping for prescription drugs;

2254                b. Managerial experience with a prescription drug  
 2255 wholesale distributor licensed in this state or in another  
 2256 state; or

2257                c. Managerial experience with the United States Armed  
 2258 Forces, where the person's responsibilities included, but were  
 2259 not limited to, recordkeeping, warehousing, distributing, or  
 2260 other logistics services pertaining to prescription drugs.

2261            4. Receive a passing score of at least 75 percent on an  
 2262 examination given by the department regarding federal laws

2263 governing distribution of prescription drugs and this part and  
2264 the rules adopted by the department governing the wholesale  
2265 distribution of prescription drugs. This requirement shall be  
2266 effective 1 year after the results of the initial examination  
2267 are mailed to the persons that took the examination. The  
2268 department shall offer such examinations at least four times  
2269 each calendar year.

2270 5. Provide the department with a personal information  
2271 statement and fingerprints pursuant to subsection (9).

2272 (c) The department may deny an application for  
2273 certification as a designated representative or may suspend or  
2274 revoke a certification of a designated representative pursuant  
2275 to s. 499.067.

2276 (d) A designated representative:

2277 1. Must be actively involved in and aware of the actual  
2278 daily operation of the wholesale distributor.

2279 2. Must be employed full time in a managerial position by  
2280 the wholesale distributor.

2281 3. Must be physically present at the establishment during  
2282 normal business hours, except for time periods when absent due  
2283 to illness, family illness or death, scheduled vacation, or  
2284 other authorized absence.

2285 4. May serve as a designated representative for only one  
2286 wholesale distributor at any one time.

2287 (e) A wholesale distributor must notify the department  
2288 when a designated representative leaves the employ of the

2289 wholesale distributor. Such notice must be provided to the  
 2290 department within 10 business days after the last day of  
 2291 designated representative's employment with the wholesale  
 2292 distributor.

2293 (f) A wholesale distributor may not operate under a  
 2294 prescription drug wholesale distributor permit or an out-of-  
 2295 state prescription drug wholesale distributor permit for more  
 2296 than 10 business days after the designated representative leaves  
 2297 the employ of the wholesale distributor, unless the wholesale  
 2298 distributor employs another designated representative and  
 2299 notifies the department within 10 business days of the identity  
 2300 of the new designated representative.

2301 Section 7. Section 499.01201, Florida Statutes, is amended  
 2302 to read:

2303 499.01201 Agency for Health Care Administration review and  
 2304 use of statute and rule violation or compliance data.—  
 2305 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~  
 2306 ~~contrary~~, the Agency for Health Care Administration may not:

2307 (1) Review or use any violation or alleged violation of s.  
 2308 499.0121(6) ~~or s. 499.01212~~, or any rules adopted under that  
 2309 section ~~those sections~~, as a ground for denying or withholding  
 2310 any payment of a Medicaid reimbursement to a pharmacy licensed  
 2311 under chapter 465; or

2312 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~  
 2313 ~~499.01212~~, or any rules adopted under that section ~~those~~  
 2314 ~~sections~~, as the subject of any audit of Medicaid-related

2315 records held by a pharmacy licensed under chapter 465.

2316 Section 8. Paragraph (d) of subsection (4), subsection  
 2317 (6), and paragraph (b) of subsection (15) of section 499.0121,  
 2318 Florida Statutes, are amended to read:

2319 499.0121 Storage and handling of prescription drugs;  
 2320 recordkeeping.—The department shall adopt rules to implement  
 2321 this section as necessary to protect the public health, safety,  
 2322 and welfare. Such rules shall include, but not be limited to,  
 2323 requirements for the storage and handling of prescription drugs  
 2324 and for the establishment and maintenance of prescription drug  
 2325 distribution records.

2326 (4) EXAMINATION OF MATERIALS AND RECORDS.—

2327 (d) Upon receipt, a wholesale distributor must review  
 2328 records required under this section for the acquisition of  
 2329 prescription drugs for accuracy and completeness, considering  
 2330 the total facts and circumstances surrounding the transactions  
 2331 and the wholesale distributors involved. ~~This includes~~  
 2332 ~~authenticating each transaction listed on a pedigree paper, as~~  
 2333 ~~defined in s. 499.003(37).~~

2334 (6) RECORDKEEPING.—The department shall adopt rules that  
 2335 require keeping such records of prescription drugs, including  
 2336 active pharmaceutical ingredients, as are necessary for the  
 2337 protection of the public health.

2338 (a) ~~Wholesale~~ Distributors of prescription drugs and  
 2339 active pharmaceutical ingredients must establish and maintain  
 2340 inventories and records of all transactions regarding the

2341 receipt and distribution or other disposition of prescription  
2342 drugs and active pharmaceutical ingredients. These records must  
2343 provide a complete audit trail from receipt to sale or other  
2344 disposition, be readily retrievable for inspection, and include,  
2345 at a minimum, the following information:

2346 1. The source of the prescription drugs or active  
2347 pharmaceutical ingredients, including the name and principal  
2348 address of the seller or transferor, and the address of the  
2349 location from which the prescription drugs were shipped;

2350 2. The name, principal address, and state license permit  
2351 or registration number of the person authorized to purchase  
2352 prescription drugs or active pharmaceutical ingredients;

2353 3. The name, strength, dosage form, and quantity of the  
2354 prescription drugs received and distributed or disposed of;

2355 4. The dates of receipt and distribution or other  
2356 disposition of the prescription drugs or active pharmaceutical  
2357 ingredients; and

2358 5. Any financial documentation supporting the transaction.

2359 (b) Inventories and records must be made available for  
2360 inspection and photocopying by authorized federal, state, or  
2361 local officials for a period of 2 years following disposition of  
2362 the drugs or 3 years after the creation of the records,  
2363 whichever period is longer.

2364 (c) Records described in this section that are kept at the  
2365 inspection site or that can be immediately retrieved by computer  
2366 or other electronic means must be readily available for

2367 authorized inspection during the retention period. Records that  
 2368 are kept at a central location outside of this state and that  
 2369 are not electronically retrievable must be made available for  
 2370 inspection within 2 working days after a request by an  
 2371 authorized official of a federal, state, or local law  
 2372 enforcement agency. Records that are maintained at a central  
 2373 location within this state must be maintained at an  
 2374 establishment that is permitted pursuant to this part and must  
 2375 be readily available.

2376 (d) Each manufacturer or repackager of medical devices,  
 2377 over-the-counter drugs, or cosmetics must maintain records that  
 2378 include the name and principal address of the seller or  
 2379 transferor of the product, the address of the location from  
 2380 which the product was shipped, the date of the transaction, the  
 2381 name and quantity of the product involved, and the name and  
 2382 principal address of the person who purchased the product.

2383 ~~(c) When pedigree papers are required by this part, a~~  
 2384 ~~wholesale distributor must maintain the pedigree papers separate~~  
 2385 ~~and distinct from other records required under this part.~~

2386 (15) DUE DILIGENCE OF PURCHASERS.—

2387 (b) A wholesale distributor must take reasonable measures  
 2388 to identify its customers, understand the normal and expected  
 2389 transactions conducted by those customers, and identify those  
 2390 transactions that are suspicious in nature. A wholesale  
 2391 distributor must establish internal policies and procedures for  
 2392 identifying suspicious orders and preventing suspicious

2393 transactions. A wholesale distributor must assess orders for  
2394 greater than 7,500 ~~5,000~~ unit doses of any one controlled  
2395 substance in any one month to determine whether the purchase is  
2396 reasonable. In making such assessments, a wholesale distributor  
2397 may consider the purchasing entity's clinical business needs,  
2398 location, and population served, in addition to other factors  
2399 established in the distributor's policies and procedures. A  
2400 wholesale distributor must report to the department any  
2401 regulated transaction involving an extraordinary quantity of a  
2402 listed chemical, an uncommon method of payment or delivery, or  
2403 any other circumstance that the regulated person believes may  
2404 indicate that the listed chemical will be used in violation of  
2405 the law. The wholesale distributor shall maintain records that  
2406 document the report submitted to the department in compliance  
2407 with this paragraph.

2408 Section 9. Subsection (4) of section 499.015, Florida  
2409 Statutes, is amended to read:

2410 499.015 Registration of drugs, devices, and cosmetics;  
2411 issuance of certificates of free sale.-

2412 (4) Unless a registration is renewed, it expires 2 years  
2413 after the last day of the month in which it was issued. Any  
2414 product registration issued or renewed on or after July 1, 2016,  
2415 shall expire on the same date as the manufacturer or repackager  
2416 permit of the person seeking to register the product. If the  
2417 first product registration issued to a person on or after July  
2418 1, 2016, expires less than 366 days after issuance, the fee for

2419 product registration shall be \$15. If the first product  
 2420 registration issued to a person on or after July 1, 2016,  
 2421 expires more than 365 days after issuance, the fee for product  
 2422 registration shall be \$30. The department may issue a stop-sale  
 2423 notice or order against a person that is subject to the  
 2424 requirements of this section and that fails to comply with this  
 2425 section within 31 days after the date the registration expires.  
 2426 The notice or order shall prohibit such person from selling or  
 2427 causing to be sold any drugs, devices, or cosmetics covered by  
 2428 this part until he or she complies with the requirements of this  
 2429 section.

2430 Section 10. Subsection (1) of section 499.03, Florida  
 2431 Statutes, is amended to read:

2432 499.03 Possession of certain drugs without prescriptions  
 2433 unlawful; exemptions and exceptions.—

2434 (1) A person may not possess, or possess with intent to  
 2435 sell, dispense, or deliver, any habit-forming, toxic, harmful,  
 2436 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or  
 2437 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,  
 2438 unless the possession of the drug has been obtained by a valid  
 2439 prescription of a practitioner licensed by law to prescribe the  
 2440 drug. However, this section does not apply to the delivery of  
 2441 such drugs to persons included in any of the classes named in  
 2442 this subsection, or to the agents or employees of such persons,  
 2443 for use in the usual course of their businesses or practices or  
 2444 in the performance of their official duties, as the case may be;

2445 nor does this section apply to the possession of such drugs by  
 2446 those persons or their agents or employees for such use:

2447 (a) A licensed pharmacist or any person under the licensed  
 2448 pharmacist's supervision while acting within the scope of the  
 2449 licensed pharmacist's practice;

2450 (b) A licensed practitioner authorized by law to prescribe  
 2451 prescription drugs or any person under the licensed  
 2452 practitioner's supervision while acting within the scope of the  
 2453 licensed practitioner's practice;

2454 (c) A qualified person who uses prescription drugs for  
 2455 lawful research, teaching, or testing, and not for resale;

2456 (d) A licensed hospital or other institution that procures  
 2457 such drugs for lawful administration or dispensing by  
 2458 practitioners;

2459 (e) An officer or employee of a federal, state, or local  
 2460 government; or

2461 (f) A person that holds a valid permit issued by the  
 2462 department pursuant to this part which authorizes that person to  
 2463 possess prescription drugs.

2464 Section 11. Paragraphs (i) through (p) of subsection (1)  
 2465 of section 499.05, Florida Statutes, are amended to read:

2466 499.05 Rules.—

2467 (1) The department shall adopt rules to implement and  
 2468 enforce this chapter with respect to:

2469 (i) Additional conditions that qualify as an emergency  
 2470 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.

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2471 499.82.

2472 ~~(j) Procedures and forms relating to the pedigree paper~~  
2473 ~~requirement of s. 499.01212.~~

2474 (j)~~(k)~~ The protection of the public health, safety, and  
2475 welfare regarding good manufacturing practices that  
2476 manufacturers and repackagers must follow to ensure the safety  
2477 of the products.

2478 (k)~~(l)~~ Information required from each retail establishment  
2479 pursuant to s. 499.012(3) or s. 499.83(2)(c), including  
2480 requirements for prescriptions or orders.

2481 (l)~~(m)~~ The recordkeeping, storage, and handling with  
2482 respect to each of the distributions of prescription drugs  
2483 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.  
2484 499.82(14).

2485 ~~(n) Alternatives to compliance with s. 499.01212 for a~~  
2486 ~~prescription drug in the inventory of a permitted prescription~~  
2487 ~~drug wholesale distributor as of June 30, 2006, and the return~~  
2488 ~~of a prescription drug purchased prior to July 1, 2006. The~~  
2489 ~~department may specify time limits for such alternatives.~~

2490 (m)~~(o)~~ Wholesale distributor reporting requirements of s.  
2491 499.0121(14).

2492 (n)~~(p)~~ Wholesale distributor credentialing and  
2493 distribution requirements of s. 499.0121(15).

2494 Section 12. Subsection (7) of section 499.051, Florida  
2495 Statutes, is amended to read:

2496 499.051 Inspections and investigations.—

2497 (7) The complaint and all information obtained pursuant to  
 2498 the investigation by the department are confidential and exempt  
 2499 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution  
 2500 until the investigation and the enforcement action are  
 2501 completed. However, trade secret information contained therein  
 2502 as defined by s. 812.081(1)(c) shall remain confidential and  
 2503 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I  
 2504 of the State Constitution, as long as the information is  
 2505 retained by the department. This subsection does not prohibit  
 2506 the department from using such information for regulatory or  
 2507 enforcement proceedings under this chapter or from providing  
 2508 such information to any law enforcement agency or any other  
 2509 regulatory agency. However, the receiving agency shall keep such  
 2510 records confidential and exempt as provided in this subsection.  
 2511 ~~In addition, this subsection is not intended to prevent~~  
 2512 ~~compliance with the provisions of s. 499.01212, and the pedigree~~  
 2513 ~~papers required in that section shall not be deemed a trade~~  
 2514 ~~secret.~~

2515 Section 13. Subsection (8) is added to section 499.066,  
 2516 Florida Statutes, to read:

2517 499.066 Penalties; remedies.—In addition to other  
 2518 penalties and other enforcement provisions:

2519 (8) (a) The department shall adopt rules to permit the  
 2520 issuance of remedial, nondisciplinary citations. A citation  
 2521 shall be issued to the person alleged to have committed a  
 2522 violation and contain the person's name, address, and license

2523 number, if applicable, a brief factual statement, the sections  
2524 of the law allegedly violated, and the monetary assessment and  
2525 or other remedial measures imposed. The citation must clearly  
2526 state that the person may choose, in lieu of accepting the  
2527 citation, to have the department rescind the citation and  
2528 conduct an investigation pursuant to s. 499.051. If the person  
2529 does not dispute the matter in the citation with the department  
2530 within 30 days after the citation is served, the citation  
2531 becomes a final order and does not constitute discipline.

2532 (b) The department shall adopt rules designating  
2533 violations for which a citation may be issued. The rules shall  
2534 designate as citable those violations for which there is no  
2535 substantial threat to the public health, safety, or welfare.

2536 (c) The department is entitled to recover the costs of  
2537 investigation, in addition to any penalty provided according to  
2538 department rule, as part of the penalty levied pursuant to the  
2539 citation.

2540 (d) A citation must be issued within 12 months after the  
2541 filing of the complaint that is the basis for the citation.

2542 (e) Service of a citation may be made by personal service  
2543 or certified mail, restricted delivery, to the person at the  
2544 person's last known address of record with the department or to  
2545 the person's Florida registered agent.

2546 (f) The department has authority to, and shall adopt rules  
2547 to, designate those violations for which a person is subject to  
2548 the issuance of a citation and designate the monetary

2549 assessments and or other remedial measures that must be taken  
 2550 for those violations. The department has continuous authority to  
 2551 amend its rules adopted pursuant to this section.

2552 Section 14. Subsection (14) of section 499.82, Florida  
 2553 Statutes, is amended to read:

2554 499.82 Definitions.—As used in this part, the term:

2555 (14) "Wholesale distribution" means the distribution of  
 2556 medical gas to a person other than a consumer or patient.  
 2557 Wholesale distribution of medical gases does not include:

2558 (a) The sale, purchase, or trade of a medical gas; an  
 2559 offer to sell, purchase, or trade a medical gas; or the  
 2560 dispensing of a medical gas pursuant to a prescription;

2561 (b) Activities exempt from the definition of wholesale  
 2562 distribution in s. 499.003; or

2563 (c) The sale, purchase, or trade of a medical gas or an  
 2564 offer to sell, purchase, or trade a medical gas for emergency  
 2565 medical reasons; ~~or~~

2566 ~~(d) Other transactions excluded from the definition of~~  
 2567 ~~wholesale distribution under the federal act or regulations~~  
 2568 ~~implemented under the federal act related to medical gas.~~

2569 Section 15. Subsection (4) of section 499.89, Florida  
 2570 Statutes, is amended to read:

2571 499.89 Recordkeeping.—

2572 ~~(4) A pedigree paper is not required for distributing or~~  
 2573 ~~dispensing medical gas.~~

2574 Section 16. Section 499.01212, Florida Statutes, is

2575 repealed.

2576 Section 17. Paragraph (a) of subsection (1) of section  
2577 409.9201, Florida Statutes, is amended to read:

2578 409.9201 Medicaid fraud.—

2579 (1) As used in this section, the term:

2580 (a) "Prescription drug" means any drug, including, but not  
2581 limited to, finished dosage forms or active ingredients that are  
2582 subject to, defined in, or described in s. 503(b) of the Federal  
2583 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)  
2584 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2585  
2586 The value of individual items of the legend drugs or goods or  
2587 services involved in distinct transactions committed during a  
2588 single scheme or course of conduct, whether involving a single  
2589 person or several persons, may be aggregated when determining  
2590 the punishment for the offense.

2591 Section 18. Paragraph (b) of subsection (1) of section  
2592 499.067, Florida Statutes, is amended to read:

2593 499.067 Denial, suspension, or revocation of permit,  
2594 certification, or registration.—

2595 (1)

2596 (b) The department may deny an application for a permit or  
2597 certification, or suspend or revoke a permit or certification,  
2598 if the department finds that:

2599 1. The applicant is not of good moral character or that it  
2600 would be a danger or not in the best interest of the public

2601 health, safety, and welfare if the applicant were issued a  
 2602 permit or certification.

2603 2. The applicant has not met the requirements for the  
 2604 permit or certification.

2605 3. The applicant is not eligible for a permit or  
 2606 certification for any of the reasons enumerated in s. 499.012.

2607 4. The applicant, permittee, or person certified under s.  
 2608 499.012(15) ~~499.012(16)~~ demonstrates any of the conditions  
 2609 enumerated in s. 499.012.

2610 5. The applicant, permittee, or person certified under s.  
 2611 499.012(15) ~~499.012(16)~~ has committed any violation of this  
 2612 chapter.

2613 Section 19. Subsection (1) of section 794.075, Florida  
 2614 Statutes, is amended to read:

2615 794.075 Sexual predators; erectile dysfunction drugs.—

2616 (1) A person may not possess a prescription drug, as  
 2617 defined in s. 499.003 ~~499.003(43)~~, for the purpose of treating  
 2618 erectile dysfunction if the person is designated as a sexual  
 2619 predator under s. 775.21.

2620 Section 20. Paragraphs (d), (f), (i), and (j) of  
 2621 subsection (3) of section 921.0022, Florida Statutes, are  
 2622 amended to read:

2623 921.0022 Criminal Punishment Code; offense severity  
 2624 ranking chart.—

2625 (3) OFFENSE SEVERITY RANKING CHART

2626 (d) LEVEL 4

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2627	Florida	Felony	Description
2628	Statute	Degree	Description
2628	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.
2629	499.0051 (1)	3rd	Failure to maintain or deliver <u>transaction history,</u> <u>transaction information,</u> or <u>transaction statements</u> <del>pedigree papers.</del>
2630	<del>499.0051 (2)</del>	<del>3rd</del>	<del>Failure to authenticate pedigree papers.</del>
2631	<u>499.0051 (5)</u> <del>499.0051 (6)</del>	2nd	Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.
2632	517.07 (1)	3rd	Failure to register securities.
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2634	517.12 (1)	3rd	Failure of dealer, associated person, or issuer of securities to register.
2635	784.07 (2) (b)	3rd	Battery of law enforcement officer, firefighter, etc.
2636	784.074 (1) (c)	3rd	Battery of sexually violent predators facility staff.
2637	784.075	3rd	Battery on detention or commitment facility staff.
2638	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
2639	784.08 (2) (c)	3rd	Battery on a person 65 years of age or older.
2640	784.081 (3)	3rd	Battery on specified official or employee.
2641	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.

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2642	784.083 (3)	3rd	Battery on code inspector.
2643	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
2644	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
2645	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
2646	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
2647	787.07	3rd	Human smuggling.
	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.

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2648	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
2649	790.115 (2) (c)	3rd	Possessing firearm on school property.
2650	800.04 (7) (c)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
2651	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
2652	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
2653	810.06	3rd	Burglary; possession of tools.
2654	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous

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			weapon.
2655	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
2656	812.014 (2) (c) 4.-10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
2657	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
2658	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03 (5) drugs.
2659	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
2660	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
2661	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent

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2662	837.02 (1)	3rd	breeding disability to any registered horse or cattle. Perjury in official proceedings.
2663	837.021 (1)	3rd	Make contradictory statements in official proceedings.
2664	838.022	3rd	Official misconduct.
2665	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
2666	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Families.
2667	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
2668	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of

			protection or communication.
2669	843.15(1)(a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
2670	847.0135(5)(c)	3rd	Lewd or lascivious exhibition using computer; offender less than 18 years.
2671	874.05(1)(a)	3rd	Encouraging or recruiting another to join a criminal gang.
2672	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).
2673	914.14(2)	3rd	Witnesses accepting bribes.
2674	914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
2675	914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily

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2676			injury.
2677	918.12	3rd	Tampering with jurors.
2678	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
2679	(f) LEVEL 6		
2680	Florida Statute	Felony Degree	Description
2681	316.027 (2) (b)	2nd	Leaving the scene of a crash involving serious bodily injury.
2682	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
2683	400.9935 (4) (c)	2nd	Operating a clinic, or offering services requiring licensure, without a license.
2684	<u>499.0051 (2)</u> <del>499.0051 (3)</del>	2nd	Knowing forgery of <u>transaction history, transaction</u>

			<u>information, or transaction</u> <u>statement</u> <del>pedigree papers.</del>
2685	<u>499.0051(3)</u> <del>499.0051(4)</del>	2nd	Knowing purchase or receipt of prescription drug from unauthorized person.
2686	<u>499.0051(4)</u> <del>499.0051(5)</del>	2nd	Knowing sale or transfer of prescription drug to unauthorized person.
2687	775.0875(1)	3rd	Taking firearm from law enforcement officer.
2688	784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
2689	784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
2690	784.041	3rd	Felony battery; domestic battery by strangulation.
2691	784.048(3)	3rd	Aggravated stalking; credible threat.
2692			

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2693	784.048 (5)	3rd	Aggravated stalking of person under 16.
2694	784.07 (2) (c)	2nd	Aggravated assault on law enforcement officer.
2695	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
2696	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
2697	784.081 (2)	2nd	Aggravated assault on specified official or employee.
2698	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
2699	784.083 (2)	2nd	Aggravated assault on code inspector.
	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.

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2700	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
2701	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
2702	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
2703	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
2704	794.011 (8) (a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
2705	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
2706	800.04 (5) (d)	3rd	Lewd or lascivious molestation;

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2707			victim 12 years of age or older but less than 16 years of age; offender less than 18 years.
	800.04 (6) (b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
2708			
	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
2709			
	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
2710			
	810.145 (8) (b)	2nd	Video voyeurism; certain minor victims; 2nd or subsequent offense.
2711			
	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
2712			
	812.014 (6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.

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2713	812.015 (9) (a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
2714	812.015 (9) (b)	2nd	Retail theft; property stolen \$3,000 or more; coordination of others.
2715	812.13 (2) (c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
2716	817.4821 (5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
2717	825.102 (1)	3rd	Abuse of an elderly person or disabled adult.
2718	825.102 (3) (c)	3rd	Neglect of an elderly person or disabled adult.
2719	825.1025 (3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
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2721	825.103 (3) (c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$10,000.
2722	827.03 (2) (c)	3rd	Abuse of a child.
2723	827.03 (2) (d)	3rd	Neglect of a child.
2724	827.071 (2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
2725	836.05	2nd	Threats; extortion.
2726	836.10	2nd	Written threats to kill or do bodily injury.
2727	843.12	3rd	Aids or assists person to escape.
2728	847.011	3rd	Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors.
	847.012	3rd	Knowingly using a minor in the

			production of materials harmful to minors.
2729	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
2730	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
2731	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.
2732	944.40	2nd	Escapes.
2733	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
2734	944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.

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2735	951.22 (1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
2736			
2737	(i) LEVEL 9		
2738			
	Florida	Felony	
	Statute	Degree	Description
2739			
	316.193	1st	DUI manslaughter; failing to render aid or give information.
	(3) (c) 3.b.		
2740			
	327.35	1st	BUI manslaughter; failing to render aid or give information.
	(3) (c) 3.b.		
2741			
	409.920	1st	Medicaid provider fraud; \$50,000 or more.
	(2) (b) 1.c.		
2742			
	<u>499.0051 (8)</u>	1st	Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.
	<del>499.0051 (9)</del>		
2743			
	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money

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2744			transmitter.
	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
2745			
	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
2746			
	775.0844	1st	Aggravated white collar crime.
2747			
	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
2748			
	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.
2749			
	782.051 (1)	1st	Attempted felony murder while

			perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
2750	782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
2751	787.01(1)(a)1.	1st, PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
2752	787.01(1)(a)2.	1st, PBL	Kidnapping with intent to commit or facilitate commission of any felony.
2753	787.01(1)(a)4.	1st, PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
2754	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.
2755	787.06(3)(c)1.	1st	Human trafficking for labor and services of an unauthorized alien child.
2756	787.06(3)(d)	1st	Human trafficking using coercion for commercial sexual activity of an unauthorized adult alien.
2757	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.
2758	790.161	1st	Attempted capital destructive device offense.
2759	790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
2760	794.011(2)	1st	Attempted sexual battery;

			victim less than 12 years of age.
2761	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
2762	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.
2763	794.011 (4) (b)	1st	Sexual battery, certain circumstances; victim and offender 18 years of age or older.
2764	794.011 (4) (c)	1st	Sexual battery, certain circumstances; victim 12 years of age or older; offender younger than 18 years.
2765	794.011 (4) (d)	1st, PBL	Sexual battery, certain circumstances; victim 12 years

			of age or older; prior conviction for specified sex offenses.
2766	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.
2767	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
2768	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
2769	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
2770	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
2771	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
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2773	817.535 (3) (b)	1st	Filing false lien or other unauthorized document; second or subsequent offense; property owner is a public officer or employee.
2774	817.535 (4) (a) 2.	1st	Filing false claim or other unauthorized document; defendant is incarcerated or under supervision.
2775	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.
2776	817.568 (7)	2nd, PBL	Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.
	827.03 (2) (a)	1st	Aggravated child abuse.

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2777	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
2778	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
2779	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.
2780	893.135	1st	Attempted capital trafficking offense.
2781	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
2782	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.

2783	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
2784	893.135 (1) (c) 2.d.	1st	Trafficking in hydrocodone, 200 grams or more, less than 30 kilograms.
2785	893.135 (1) (c) 3.d.	1st	Trafficking in oxycodone, 100 grams or more, less than 30 kilograms.
2786	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
2787	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
2788	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more than 200 grams.
2789	893.135 (1) (h) 1.c.	1st	Trafficking in gamma- hydroxybutyric acid (GHB), 10 kilograms or more.

2790

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2791	893.135 (1) (j) 1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
2792	893.135 (1) (k) 2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
2793	896.101 (5) (c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
2794	896.104 (4) (a) 3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
2795	(j) LEVEL 10		
2796	Florida	Felony	
2797	Statute	Degree	Description
2798	<u>499.0051(9)</u> <del>499.0051(10)</del>	1st	Knowing sale or purchase of contraband prescription drugs resulting in death.
	782.04 (2)	1st, PBL	Unlawful killing of human; act

2799			is homicide, unpremeditated.
	782.07 (3)	1st	Aggravated manslaughter of a child.
2800			
	787.01 (1) (a) 3.	1st, PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
2801			
	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.
2802			
	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.
2803			
	787.06 (4) (a)	Life	Selling or buying of minors into human trafficking.
2804			
	794.011 (3)	Life	Sexual battery; victim 12 years or older, offender uses or

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threatens to use deadly weapon  
or physical force to cause  
serious injury.

2805

812.135 (2) (a)      1st, PBL      Home-invasion robbery with  
firearm or other deadly weapon.

2806

876.32                      1st      Treason against the state.

2807

2808              Section 21.      This act shall take effect July 1, 2016.