

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

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

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

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

90 |

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

92 |

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

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

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

105        (2)~~(1)~~ "Advertisement" means any representation  
 106        disseminated in any manner or by any means, other than by  
 107        labeling, for the purpose of inducing, or which is likely to  
 108        induce, directly or indirectly, the purchase of drugs, devices,  
 109        or cosmetics.

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

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

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

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

123        (4)~~(3)~~ "Affiliated party" means:

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

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

131 employee of the permittee or applicant;

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

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

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

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

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

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

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

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

157 | drugs between members of an affiliate ~~to a member of its~~  
 158 | ~~affiliated group.~~

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

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

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

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

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

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

183 or misrepresented matter.

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

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

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

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

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

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



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

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

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

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

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

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

235 ~~as defined in s. 465.003.~~

236 (17)~~(18)~~ "Drug" means an article that is:

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

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

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

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

259 (18)~~(19)~~ "Establishment" means a place of business which  
 260 is at one general physical location and may extend to one or

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

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

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

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

282 499.01(2)(h)1.c. ~~499.01(2)(g)1.c.~~

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

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

287 ~~(24)-(25)~~ "Hospital" means a facility as defined in s.  
 288 395.002 and licensed under chapter 395.

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

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

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

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

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

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

309 ~~(29)-(30)~~ "Manufacturer" means:

310 (a) A person who holds a New Drug Application, an  
 311 Abbreviated New Drug Application, a Biologics License  
 312 Application, or a New Animal Drug Application approved under the

313 federal act or a license issued under s. 351 of the Public  
314 Health Service Act, 42 U.S.C. s. 262, for such drug or  
315 biologics, or if such drug or biologics is not the subject of an  
316 approved application or license, the person who manufactured the  
317 drug or biologics prepares, derives, manufactures, or produces a  
318 drug, device, or cosmetic;

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

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

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

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

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

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

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

362 (30)~~(31)~~ "Medical convenience kit" means packages or units  
363 that contain combination products as defined in 21 C.F.R. s.  
364 3.2 (e) (2) .

365        (31)~~(32)~~ "Medical gas" means any liquefied or vaporized  
366 gas that is a prescription drug, whether alone or in combination  
367 with other gases, and as defined in the federal act.

368        (32)~~(33)~~ "New drug" means:

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

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

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

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

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

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

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

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

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

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

414 (38)~~(41)~~ "Pharmacy" means an entity licensed under chapter  
 415 465.

416 (39)~~(42)~~ "Prepackaged drug product" means a drug that



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

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

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

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

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

442 ~~(a) Purchased 90 percent or more of the total dollar~~

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443 ~~volume of its purchases of prescription drugs directly from~~  
444 ~~manufacturers in the previous year; and~~

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

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

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

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

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

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

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

468 ~~(43)-(47)~~ "Proprietary drug," or "OTC drug," means a patent

469 or over-the-counter drug in its unbroken, original package,  
470 which drug is sold to the public by, or under the authority of,  
471 the manufacturer or primary distributor thereof, is not  
472 misbranded under the provisions of this part, and can be  
473 purchased without a prescription.

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

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

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

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

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

492 (48)~~(53)~~ "Wholesale distribution" means the distribution  
493 of a prescription drug to a person ~~drugs to persons~~ other than a  
494 consumer or patient, or the receipt of a prescription drug by a

495 person other than the consumer or patient, but does not include:

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

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

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

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

518 4. The distribution ~~sale, purchase, trade, or other~~  
 519 ~~transfer~~ of a prescription drug from or for any federal, state,  
 520 or local government agency or any entity eligible to purchase

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

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

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

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

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

545 e. The contract provider or subcontractor may administer  
546 or dispense the prescription drugs only to the eligible patients

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

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

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

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

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

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

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

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

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

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

597 ~~6.7.~~ The distribution ~~transfer~~ of a prescription drug by a  
598 hospital or other health care entity to a person licensed under

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

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

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

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

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

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



625 prescription drug and repacks it in accordance with this part.

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

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

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

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

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

651 business assets.

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

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

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

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

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

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

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

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

675 (u) The distribution by a charitable organization  
676 described in s. 501(c) (3) of the Internal Revenue Code of

677 prescription drugs donated to or supplied at a reduced price to  
 678 the charitable organization to:

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

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

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

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

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

700 (49)-(54) "Wholesale distributor" means a ~~any~~ person, other  
 701 than a manufacturer, a manufacturer's co-licensed partner, a  
 702 third-party logistics provider, or a repackager, who is engaged

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

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

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

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

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

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

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

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

728 ~~(29) The receipt of a prescription drug pursuant to a~~

729 ~~wholesale distribution without having previously received or~~  
 730 ~~simultaneously receiving a pedigree paper that was attested to~~  
 731 ~~as accurate and complete by the wholesale distributor as~~  
 732 ~~required under this part.~~

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

739 499.0051 Criminal acts.—

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

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

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

755 transaction history, transaction information, or transaction  
756 statement ~~pedigree papers~~ concerning a prescription drug or  
757 contraband prescription drug, as required by this chapter and  
758 rules adopted under this chapter, before ~~prior to~~, or  
759 simultaneous with, the receipt of the prescription drug or  
760 contraband prescription drug from another person commits a  
761 felony of the third degree, punishable as provided in s.  
762 775.082, s. 775.083, or s. 775.084.

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

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

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

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

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

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

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807 otherwise provided in this part:

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

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

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

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

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

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

830 (10) If it is a prescription drug for which the required  
 831 transaction history, transaction information, or transaction  
 832 statement ~~pedigree paper~~ is nonexistent, fraudulent, or



833 incomplete under the requirements of this part or applicable  
 834 rules, or that has been purchased, held, sold, or distributed at  
 835 any time by a person not authorized under federal or state law  
 836 to do so; or

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

839 499.01 Permits.—

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

842 (a) A prescription drug manufacturer;

843 (b) A prescription drug repackager;

844 (c) A nonresident prescription drug manufacturer;

845 (d) A nonresident prescription drug repackager;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

864 (2) The following permits are established:

865 (a) Prescription drug manufacturer permit.—A prescription  
866 drug manufacturer permit is required for any person that is a  
867 manufacturer of a prescription drug and that manufactures or  
868 distributes such prescription drugs in this state.

869 1. A person that operates an establishment permitted as a  
870 prescription drug manufacturer may engage in wholesale  
871 distribution of prescription drugs for which the person is the  
872 manufacturer ~~manufactured at that establishment~~ and must comply  
873 with s. 499.0121 and all other ~~of the~~ provisions of this part,  
874 ~~except s. 499.01212,~~ and the rules adopted under this part,  
875 ~~except s. 499.01212, which apply to a wholesale distributor.~~ The  
876 department shall adopt rules for issuing a virtual prescription  
877 drug manufacturer permit to a person who engages in the  
878 manufacture of prescription drugs but does not make or take  
879 physical possession of any prescription drugs. The rules adopted  
880 by the department under this section may exempt virtual  
881 manufacturers from certain establishment, security, and storage  
882 requirements set forth in s. 499.0121.

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

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

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

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

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

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

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

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

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

937 to import and document approval by the United States Food and  
 938 Drug Administration for such importation.

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

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

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

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

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

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

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

989 ~~permit must submit a bond of \$100,000, or other equivalent means~~  
 990 ~~of security acceptable to the department, such as an irrevocable~~  
 991 ~~letter of credit or a deposit in a trust account or financial~~  
 992 ~~institution, payable to the Professional Regulation Trust Fund.~~  
 993 ~~The purpose of the bond is to secure payment of any~~  
 994 ~~administrative penalties imposed by the department and any fees~~  
 995 ~~and costs incurred by the department regarding that permit which~~  
 996 ~~are authorized under state law and which the permittee fails to~~  
 997 ~~pay 30 days after the fine or costs become final. The department~~  
 998 ~~may make a claim against such bond or security until 1 year~~  
 999 ~~after the permittee's license ceases to be valid or until 60~~  
 1000 ~~days after any administrative or legal proceeding authorized in~~  
 1001 ~~this part which involves the permittee is concluded, including~~  
 1002 ~~any appeal, whichever occurs later. The out-of-state~~  
 1003 ~~prescription drug wholesale distributor must maintain at all~~  
 1004 ~~times a license or permit to engage in the wholesale~~  
 1005 ~~distribution of prescription drugs in compliance with laws of~~  
 1006 ~~the state in which it is a resident. If the state from which the~~  
 1007 ~~wholesale distributor distributes prescription drugs does not~~  
 1008 ~~require a license to engage in the wholesale distribution of~~  
 1009 ~~prescription drugs, the distributor must be licensed as a~~  
 1010 ~~wholesale distributor as required by the federal act.~~

1011 (g) ~~(f)~~ Retail pharmacy drug wholesale distributor permit.—  
 1012 A retail pharmacy drug wholesale distributor is a retail  
 1013 pharmacy engaged in wholesale distribution of prescription drugs  
 1014 within this state under the following conditions:

1015 1. The pharmacy must obtain a retail pharmacy drug  
 1016 wholesale distributor permit pursuant to this part and ~~the~~ rules  
 1017 adopted under this part.

1018 2. The wholesale distribution activity does not exceed 30  
 1019 percent of the total annual purchases of prescription drugs. If  
 1020 the wholesale distribution activity exceeds the 30-percent  
 1021 maximum, the pharmacy must obtain a prescription drug wholesale  
 1022 distributor permit.

1023 3. The transfer of prescription drugs that appear in any  
 1024 schedule contained in chapter 893 is subject to chapter 893 and  
 1025 the federal Comprehensive Drug Abuse Prevention and Control Act  
 1026 of 1970.

1027 4. The transfer is between a retail pharmacy and another  
 1028 retail pharmacy, or a Modified Class II institutional pharmacy,  
 1029 or a health care practitioner licensed in this state and  
 1030 authorized by law to dispense or prescribe prescription drugs.

1031 5. All records of sales of prescription drugs subject to  
 1032 this section must be maintained separate and distinct from other  
 1033 records and comply with the recordkeeping requirements of this  
 1034 part.

1035 (h) ~~(g)~~ Restricted prescription drug distributor permit.—

1036 1. A restricted prescription drug distributor permit is  
 1037 required for:

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



1041 | ~~499.003(53)(a).~~

1042 |       b. Any person located in this state who engages in the  
 1043 | receipt or distribution of a prescription drug in this state for  
 1044 | the purpose of processing its return or its destruction if such  
 1045 | person is not the person initiating the return, the prescription  
 1046 | drug wholesale supplier of the person initiating the return, or  
 1047 | the manufacturer of the drug.

1048 |       c. A blood establishment located in this state which  
 1049 | collects blood and blood components only from volunteer donors  
 1050 | as defined in s. 381.06014 or pursuant to an authorized  
 1051 | practitioner's order for medical treatment or therapy and  
 1052 | engages in the wholesale distribution of a prescription drug not  
 1053 | described in s. 499.003(48)(j) ~~499.003(53)(d)~~ to a health care  
 1054 | entity. A mobile blood unit operated by a blood establishment  
 1055 | permitted under this sub-subparagraph is not required to be  
 1056 | separately permitted. The health care entity receiving a  
 1057 | prescription drug distributed under this sub-subparagraph must  
 1058 | be licensed as a closed pharmacy or provide health care services  
 1059 | at that establishment. The blood establishment must operate in  
 1060 | accordance with s. 381.06014 and may distribute only:

1061 |       (I) Prescription drugs indicated for a bleeding or  
 1062 | clotting disorder or anemia;

1063 |       (II) Blood-collection containers approved under s. 505 of  
 1064 | the federal act;

1065 |       (III) Drugs that are blood derivatives, or a recombinant  
 1066 | or synthetic form of a blood derivative;

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1067 (IV) Prescription drugs that are identified in rules  
1068 adopted by the department and that are essential to services  
1069 performed or provided by blood establishments and authorized for  
1070 distribution by blood establishments under federal law; or

1071 (V) To the extent authorized by federal law, drugs  
1072 necessary to collect blood or blood components from volunteer  
1073 blood donors; for blood establishment personnel to perform  
1074 therapeutic procedures under the direction and supervision of a  
1075 licensed physician; and to diagnose, treat, manage, and prevent  
1076 any reaction of a volunteer blood donor or a patient undergoing  
1077 a therapeutic procedure performed under the direction and  
1078 supervision of a licensed physician,

1079  
1080 as long as all of the health care services provided by the blood  
1081 establishment are related to its activities as a registered  
1082 blood establishment or the health care services consist of  
1083 collecting, processing, storing, or administering human  
1084 hematopoietic stem cells or progenitor cells or performing  
1085 diagnostic testing of specimens if such specimens are tested  
1086 together with specimens undergoing routine donor testing. The  
1087 blood establishment may purchase and possess the drugs described  
1088 in this sub-subparagraph without a health care clinic  
1089 establishment permit.

1090 2. Storage, handling, and recordkeeping of these  
1091 distributions by a person required to be permitted as a  
1092 restricted prescription drug distributor must be in accordance

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1093 with the requirements for wholesale distributors under s.  
 1094 499.0121, ~~but not those set forth in s. 499.01212 if the~~  
 1095 ~~distribution occurs pursuant to sub-subparagraph 1.a. or sub-~~  
 1096 ~~subparagraph 1.b.~~

1097 3. A person who applies for a permit as a restricted  
 1098 prescription drug distributor, or for the renewal of such a  
 1099 permit, must provide to the department the information required  
 1100 under s. 499.012.

1101 4. The department may adopt rules regarding the  
 1102 distribution of prescription drugs by hospitals, health care  
 1103 entities, charitable organizations, other persons not involved  
 1104 in wholesale distribution, and blood establishments, which rules  
 1105 are necessary for the protection of the public health, safety,  
 1106 and welfare.

1107 (i)~~(h)~~ Complimentary drug distributor permit.—A  
 1108 complimentary drug distributor permit is required for any person  
 1109 that engages in the distribution of a complimentary drug,  
 1110 subject to the requirements of s. 499.028.

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

1119 | airway bill, bill of lading, or other appropriate documentation  
 1120 | to evidence the exportation of the product.

1121 |        (k)~~(j)~~ Veterinary prescription drug retail establishment  
 1122 | permit.—A veterinary prescription drug retail establishment  
 1123 | permit is required for any person that sells veterinary  
 1124 | prescription drugs to the public but does not include a pharmacy  
 1125 | licensed under chapter 465.

1126 |           1. The sale to the public must be based on a valid written  
 1127 | order from a veterinarian licensed in this state who has a valid  
 1128 | client-veterinarian relationship with the purchaser's animal.

1129 |           2. Veterinary prescription drugs may not be sold in excess  
 1130 | of the amount clearly indicated on the order or beyond the date  
 1131 | indicated on the order.

1132 |           3. An order may not be valid for more than 1 year.

1133 |           4. A veterinary prescription drug retail establishment may  
 1134 | not purchase, sell, trade, or possess human prescription drugs  
 1135 | or any controlled substance as defined in chapter 893.

1136 |           5. A veterinary prescription drug retail establishment  
 1137 | must sell a veterinary prescription drug in the original, sealed  
 1138 | manufacturer's container with all labeling intact and legible.  
 1139 | The department may adopt by rule additional labeling  
 1140 | requirements for the sale of a veterinary prescription drug.

1141 |           6. A veterinary prescription drug retail establishment  
 1142 | must comply with all of the wholesale distribution requirements  
 1143 | of s. 499.0121.

1144 |           7. Prescription drugs sold by a veterinary prescription

1145 drug retail establishment pursuant to a practitioner's order may  
 1146 not be returned into the retail establishment's inventory.

1147 (l)~~(k)~~ Veterinary prescription drug wholesale distributor  
 1148 permit.—A veterinary prescription drug wholesale distributor  
 1149 permit is required for any person that engages in the  
 1150 distribution of veterinary prescription drugs in or into this  
 1151 state. A veterinary prescription drug wholesale distributor that  
 1152 also distributes prescription drugs subject to, defined by, or  
 1153 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
 1154 Act which it did not manufacture must obtain a permit as a  
 1155 prescription drug wholesale distributor, an out-of-state  
 1156 prescription drug wholesale distributor, or a limited  
 1157 prescription drug veterinary wholesale distributor in lieu of  
 1158 the veterinary prescription drug wholesale distributor permit. A  
 1159 veterinary prescription drug wholesale distributor must comply  
 1160 with the requirements for wholesale distributors under s.  
 1161 499.0121, ~~but not those set forth in s. 499.01212.~~

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

1171 by, or described by s. 503(b) of the Federal Food, Drug, and  
 1172 Cosmetic Act under the following conditions:

1173 1. The person is engaged in the business of wholesaling  
 1174 prescription and veterinary prescription drugs to persons:

1175 a. Licensed as veterinarians practicing on a full-time  
 1176 basis;

1177 b. Regularly and lawfully engaged in instruction in  
 1178 veterinary medicine;

1179 c. Regularly and lawfully engaged in law enforcement  
 1180 activities;

1181 d. For use in research not involving clinical use; or

1182 e. For use in chemical analysis or physical testing or for  
 1183 purposes of instruction in law enforcement activities, research,  
 1184 or testing.

1185 2. No more than 30 percent of total annual prescription  
 1186 drug sales may be prescription drugs approved for human use  
 1187 which are subject to, defined by, or described by s. 503(b) of  
 1188 the Federal Food, Drug, and Cosmetic Act.

1189 3. The person does not distribute in any jurisdiction  
 1190 prescription drugs subject to, defined by, or described by s.  
 1191 503(b) of the Federal Food, Drug, and Cosmetic Act to any person  
 1192 who is authorized to sell, distribute, purchase, trade, or use  
 1193 these drugs on or for humans.

1194 4. A limited prescription drug veterinary wholesale  
 1195 distributor that applies to the department for a new permit or  
 1196 the renewal of a permit must submit a bond of \$20,000, or other

1197 equivalent means of security acceptable to the department, such  
 1198 as an irrevocable letter of credit or a deposit in a trust  
 1199 account or financial institution, payable to the Professional  
 1200 Regulation Trust Fund. The purpose of the bond is to secure  
 1201 payment of any administrative penalties imposed by the  
 1202 department and any fees and costs incurred by the department  
 1203 regarding that permit which are authorized under state law and  
 1204 which the permittee fails to pay 30 days after the fine or costs  
 1205 become final. The department may make a claim against such bond  
 1206 or security until 1 year after the permittee's license ceases to  
 1207 be valid or until 60 days after any administrative or legal  
 1208 proceeding authorized in this part which involves the permittee  
 1209 is concluded, including any appeal, whichever occurs later.

1210 5. A limited prescription drug veterinary wholesale  
 1211 distributor must maintain at all times a license or permit to  
 1212 engage in the wholesale distribution of prescription drugs in  
 1213 compliance with laws of the state in which it is a resident.

1214 6. A limited prescription drug veterinary wholesale  
 1215 distributor must comply with the requirements for wholesale  
 1216 distributors under s. ss. 499.0121 and 499.01212, ~~except that a~~  
 1217 ~~limited prescription drug veterinary wholesale distributor is~~  
 1218 ~~not required to provide a pedigree paper as required by s.~~  
 1219 ~~499.01212 upon the wholesale distribution of a prescription drug~~  
 1220 ~~to a veterinarian.~~

1221 7. A limited prescription drug veterinary wholesale  
 1222 distributor may not return to inventory for subsequent wholesale

1223 distribution any prescription drug subject to, defined by, or  
 1224 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
 1225 Act which has been returned by a veterinarian.

1226 8. A limited prescription drug veterinary wholesale  
 1227 distributor permit is not required for an intracompany sale or  
 1228 transfer of a prescription drug from an out-of-state  
 1229 establishment that is duly licensed to engage in the wholesale  
 1230 distribution of prescription drugs in its state of residence to  
 1231 a licensed limited prescription drug veterinary wholesale  
 1232 distributor in this state if both wholesale distributors conduct  
 1233 wholesale distributions of prescription drugs under the same  
 1234 business name. The recordkeeping requirements of s. ss.  
 1235 499.0121(6) ~~and 499.01212~~ must be followed for this transaction.

1236 (n) ~~(m)~~ Over-the-counter drug manufacturer permit.—An over-  
 1237 the-counter drug manufacturer permit is required for any person  
 1238 that engages in the manufacture or repackaging of an over-the-  
 1239 counter drug.

1240 1. An over-the-counter drug manufacturer may not possess  
 1241 or purchase prescription drugs.

1242 2. A pharmacy is exempt from obtaining an over-the-counter  
 1243 drug manufacturer permit if it is operating in compliance with  
 1244 pharmacy practice standards as defined in chapter 465 and ~~the~~  
 1245 rules adopted under that chapter.

1246 3. An over-the-counter drug manufacturer must comply with  
 1247 all appropriate state and federal good manufacturing practices.

1248 (o) ~~(n)~~ Device manufacturer permit.—



1249 1. A device manufacturer permit is required for any person  
 1250 that engages in the manufacture, repackaging, or assembly of  
 1251 medical devices for human use in this state, except that a  
 1252 permit is not required if:

1253 a. The person is engaged only in manufacturing,  
 1254 repackaging, or assembling a medical device pursuant to a  
 1255 practitioner's order for a specific patient; or

1256 b. The person does not manufacture, repackage, or assemble  
 1257 any medical devices or components for such devices, except those  
 1258 devices or components which are exempt from registration  
 1259 pursuant to s. 499.015(8).

1260 2. A manufacturer or repackager of medical devices in this  
 1261 state must comply with all appropriate state and federal good  
 1262 manufacturing practices and quality system rules.

1263 3. The department shall adopt rules related to storage,  
 1264 handling, and recordkeeping requirements for manufacturers of  
 1265 medical devices for human use.

1266 (p)~~(e)~~ Cosmetic manufacturer permit.—A cosmetic  
 1267 manufacturer permit is required for any person that manufactures  
 1268 or repackages cosmetics in this state. A person that only labels  
 1269 or changes the labeling of a cosmetic but does not open the  
 1270 container sealed by the manufacturer of the product is exempt  
 1271 from obtaining a permit under this paragraph.

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

1275 prescription drug manufacturer to provide warehousing,  
 1276 distribution, or other logistics services on behalf of a  
 1277 manufacturer, ~~or~~ wholesale distributor, or dispenser, but who  
 1278 does not take title to the prescription drug or have  
 1279 responsibility to direct the sale or disposition of the  
 1280 prescription drug. A third party logistics provider located  
 1281 outside of this state, must be licensed in the state or  
 1282 territory from which the prescription drug is distributed by the  
 1283 third party logistics provider. If the state or territory from  
 1284 which the third party logistics provider originates does not  
 1285 require a license to operate as a third party logistics  
 1286 provider, the third party logistic provider must be licensed as  
 1287 a third party logistics provider as required by the federal act.  
 1288 Each third party logistics provider permittee shall comply with  
 1289 ~~s. the requirements for wholesale distributors under ss.~~  
 1290 ~~499.0121 and 499.01212, with the exception of those wholesale~~  
 1291 ~~distributions described in s. 499.01212(3)(a),~~ and other rules  
 1292 that the department requires.

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

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1301 practitioner defined in s. 456.001, or a veterinarian licensed  
1302 under chapter 474, who is authorized under the appropriate  
1303 practice act to prescribe and administer a prescription drug.

1304 1. An establishment must provide, as part of the  
1305 application required under s. 499.012, designation of a  
1306 qualifying practitioner who will be responsible for complying  
1307 with all legal and regulatory requirements related to the  
1308 purchase, recordkeeping, storage, and handling of the  
1309 prescription drugs. In addition, the designated qualifying  
1310 practitioner shall be the practitioner whose name, establishment  
1311 address, and license number is used on all distribution  
1312 documents for prescription drugs purchased or returned by the  
1313 health care clinic establishment. Upon initial appointment of a  
1314 qualifying practitioner, the qualifying practitioner and the  
1315 health care clinic establishment shall notify the department on  
1316 a form furnished by the department within 10 days after such  
1317 employment. In addition, the qualifying practitioner and health  
1318 care clinic establishment shall notify the department within 10  
1319 days after any subsequent change.

1320 2. The health care clinic establishment must employ a  
1321 qualifying practitioner at each establishment.

1322 3. In addition to the remedies and penalties provided in  
1323 this part, a violation of this chapter by the health care clinic  
1324 establishment or qualifying practitioner constitutes grounds for  
1325 discipline of the qualifying practitioner by the appropriate  
1326 regulatory board.

1327 4. The purchase of prescription drugs by the health care  
 1328 clinic establishment is prohibited during any period of time  
 1329 when the establishment does not comply with this paragraph.

1330 5. A health care clinic establishment permit is not a  
 1331 pharmacy permit or otherwise subject to chapter 465. A health  
 1332 care clinic establishment that meets the criteria of a modified  
 1333 Class II institutional pharmacy under s. 465.019 is not eligible  
 1334 to be permitted under this paragraph.

1335 6. This paragraph does not apply to the purchase of a  
 1336 prescription drug by a licensed practitioner under his or her  
 1337 license.

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

1353 license, permit, or registration number; and, if available, a  
1354 copy of the most current FDA inspection report, for all  
1355 manufacturers from whom they purchase active pharmaceutical  
1356 ingredients under this section. ~~The department shall define the~~  
1357 ~~term "limited quantities" by rule, and may include the allowable~~  
1358 ~~number of transactions within a given period of time and the~~  
1359 ~~amount of prescription drugs distributed into the state for~~  
1360 ~~purposes of this exemption.~~ The failure to comply with the  
1361 requirements of this subsection, or rules adopted by the  
1362 department to administer this subsection, for the purchase of  
1363 prescription drug active pharmaceutical ingredients is a  
1364 violation of s. 499.005(14), and a knowing failure is a  
1365 violation of s. 499.0051(4).

1366 (a) The immediate package or container of a prescription  
1367 drug active pharmaceutical ingredient distributed into the state  
1368 that is intended for research and development under this  
1369 subsection shall bear a label prominently displaying the  
1370 statement: "Caution: Research and Development Only—Not for  
1371 Manufacturing, Compounding, or Resale."

1372 (b) A prescription drug manufacturer that obtains a  
1373 prescription drug active pharmaceutical ingredient under this  
1374 subsection for use in clinical trials and or biostudies  
1375 authorized and regulated by federal law must create and maintain  
1376 records detailing the specific clinical trials or biostudies for  
1377 which the prescription drug active pharmaceutical ingredient was  
1378 obtained.

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1379 (4) (a) A permit issued under this part is not required to  
1380 distribute a prescription drug active pharmaceutical ingredient  
1381 from an establishment located in the United States to an  
1382 establishment located in this state permitted as a prescription  
1383 drug manufacturer under this part for use by the recipient in  
1384 preparing, deriving, processing, producing, or fabricating a  
1385 prescription drug finished dosage form at the establishment in  
1386 this state where the product is received under an approved and  
1387 otherwise valid New Drug Approval Application, Abbreviated New  
1388 Drug Application, New Animal Drug Application, or Therapeutic  
1389 Biologic Application, provided that the application, active  
1390 pharmaceutical ingredient, or finished dosage form has not been  
1391 withdrawn or removed from the market in this country for public  
1392 health reasons.

1393 1. Any distributor claiming exemption from permitting  
1394 requirements pursuant to this paragraph shall maintain a  
1395 license, permit, or registration to engage in the wholesale  
1396 distribution of prescription drugs under the laws of the state  
1397 from which the product is distributed. If the state from which  
1398 the prescription drugs are distributed does not require a  
1399 license to engage in the wholesale distribution of prescription  
1400 drugs, the distributor must be licensed as a wholesale  
1401 distributor as required by the federal act.

1402 2. Any distributor claiming exemption from permitting  
1403 requirements pursuant to this paragraph and the prescription  
1404 drug manufacturer purchasing and receiving the active

1405 pharmaceutical ingredient shall comply with the recordkeeping  
1406 requirements of s. 499.0121(6), ~~but not the requirements of s.~~  
1407 ~~499.01212.~~

1408 (b) A permit issued under this part is not required to  
1409 distribute ~~limited quantities of~~ a prescription drug that has  
1410 not been repackaged from an establishment located in the United  
1411 States to an establishment located in this state permitted as a  
1412 prescription drug manufacturer under this part for research and  
1413 development or to a holder of a letter of exemption issued by  
1414 the department under s. 499.03(4) for research, teaching, or  
1415 testing. ~~The department shall define "limited quantities" by~~  
1416 ~~rule and may include the allowable number of transactions within~~  
1417 ~~a given period of time and the amounts of prescription drugs~~  
1418 ~~distributed into the state for purposes of this exemption.~~

1419 1. Any distributor claiming exemption from permitting  
1420 requirements pursuant to this paragraph shall maintain a  
1421 license, permit, or registration to engage in the wholesale  
1422 distribution of prescription drugs under the laws of the state  
1423 from which the product is distributed. If the state from which  
1424 the prescription drugs are distributed does not require a  
1425 license to engage in the wholesale distribution of prescription  
1426 drugs, the distributor must be licensed as a wholesale  
1427 distributor as required by the federal act.

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

1431 humans except in lawful clinical trials and biostudies  
1432 authorized and regulated by federal law.

1433 3. Any distributor claiming exemption from permitting  
1434 requirements pursuant to this paragraph, and the purchaser and  
1435 recipient of the prescription drug, shall comply with the  
1436 recordkeeping requirements of s. 499.0121(6), ~~but not the~~  
1437 ~~requirements of s. 499.01212.~~

1438 4. The immediate package or container of any active  
1439 pharmaceutical ingredient distributed into the state that is  
1440 intended for teaching, testing, research, and development shall  
1441 bear a label prominently displaying the statement: "Caution:  
1442 Research, Teaching, or Testing Only - Not for Manufacturing,  
1443 Compounding, or Resale."

1444 (c) An out-of-state prescription drug wholesale  
1445 distributor permit is not required for an intracompany sale or  
1446 transfer of a prescription drug from an out-of-state  
1447 establishment that is duly licensed as a prescription drug  
1448 wholesale distributor in its state of residence to a licensed  
1449 prescription drug wholesale distributor in this state, if both  
1450 wholesale distributors conduct wholesale distributions of  
1451 prescription drugs under the same business name. The  
1452 recordkeeping requirements of s. ss. 499.0121(6) ~~and 499.01212~~  
1453 must be followed for such transactions.

1454 (d) Persons receiving prescription drugs from a source  
1455 claimed to be exempt from permitting requirements under this  
1456 subsection shall maintain on file:



1457 1. A record of the FDA establishment registration number,  
 1458 if any;

1459 2. The resident state or federal license, registration, or  
 1460 permit that authorizes the source to distribute prescription  
 1461 drugs ~~drug wholesale distribution license, permit, or~~  
 1462 ~~registration number~~; and

1463 3. A copy of the most recent resident state or FDA  
 1464 inspection report, for all distributors and establishments from  
 1465 whom they purchase or receive prescription drugs under this  
 1466 subsection.

1467 (e) All persons claiming exemption from permitting  
 1468 requirements pursuant to this subsection who engage in the  
 1469 distribution of prescription drugs within or into the state are  
 1470 subject to this part, including ss. 499.005 and 499.0051, and  
 1471 shall make available, within 48 hours, to the department on  
 1472 request all records related to any prescription drugs  
 1473 distributed under this subsection, including those records  
 1474 described in s. 499.051(4), regardless of the location where the  
 1475 records are stored.

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

1483 potency, or sterility, regardless of whether the product is  
1484 thereafter rehabilitated, quarantined, returned, or destroyed.

1485 (g) The department may adopt rules to administer this  
1486 subsection which are necessary for the protection of the public  
1487 health, safety, and welfare. Failure to comply with the  
1488 requirements of this subsection, or rules adopted by the  
1489 department to administer this subsection, is a violation of s.  
1490 499.005(14), and a knowing failure is a violation of s.  
1491 499.0051(4).

1492 (h) This subsection does not relieve any person from any  
1493 requirement prescribed by law with respect to controlled  
1494 substances as defined in the applicable federal and state laws.

1495 (5) A prescription drug repackager permit issued under  
1496 this part is not required for a restricted prescription drug  
1497 distributor permitholder that is a health care entity to  
1498 repackaging prescription drugs in this state for its own use or  
1499 for distribution to hospitals or other health care entities in  
1500 the state for their own use, pursuant to s. 499.003(48)(a)3.  
1501 ~~499.003(53)(a)3.~~, if:

1502 (a) The prescription drug distributor notifies the  
1503 department, in writing, of its intention to engage in  
1504 repackaging under this exemption, 30 days before engaging in the  
1505 repackaging of prescription drugs at the permitted  
1506 establishment;

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

1509 | which the prescription drug distributor is distributing  
 1510 | prescription drugs. As used in this paragraph, "common control"  
 1511 | means the power to direct or cause the direction of the  
 1512 | management and policies of a person or an organization, whether  
 1513 | by ownership of stock, voting rights, contract, or otherwise;

1514 |         (c) The prescription drug distributor repackages the  
 1515 | prescription drugs in accordance with current state and federal  
 1516 | good manufacturing practices; and

1517 |         (d) The prescription drug distributor labels the  
 1518 | prescription drug it repackages in accordance with state and  
 1519 | federal laws and rules.

1520 |  
 1521 | The prescription drug distributor is exempt from the product  
 1522 | registration requirements of s. 499.015 with regard to the  
 1523 | prescription drugs that it repackages and distributes under this  
 1524 | subsection. A prescription drug distributor that repackages and  
 1525 | distributes prescription drugs under this subsection to a not-  
 1526 | for-profit rural hospital, as defined in s. 395.602, is not  
 1527 | required to comply with paragraph (c) or paragraph (d), but must  
 1528 | provide to each health care entity for which it repackages, for  
 1529 | each prescription drug that is repackaged and distributed, the  
 1530 | information required by department rule for labeling  
 1531 | prescription drugs. The prescription drug distributor shall also  
 1532 | provide the additional current packaging and label information  
 1533 | for the prescription drug by hard copy or by electronic means.

1534 |         Section 6. Section 499.012, Florida Statutes, is amended

1535 to read:

1536 499.012 Permit application requirements.—

1537 (1) (a) A permit issued pursuant to this part may be issued  
 1538 only to a natural person who is at least 18 years of age or to  
 1539 an applicant that is not a natural person if each person who,  
 1540 directly or indirectly, manages, controls, or oversees the  
 1541 operation of that applicant is at least 18 years of age.

1542 (b) An establishment that is a place of residence may not  
 1543 receive a permit and may not operate under this part.

1544 (c) A person that applies for or renews a permit to  
 1545 manufacture or distribute prescription drugs may not use a name  
 1546 identical to the name used by any other establishment or  
 1547 licensed person authorized to purchase prescription drugs in  
 1548 this state, except that a restricted drug distributor permit  
 1549 issued to a health care entity will be issued in the name in  
 1550 which the institutional pharmacy permit is issued and a retail  
 1551 pharmacy drug wholesale distributor will be issued a permit in  
 1552 the name of its retail pharmacy permit.

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

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1561 licensed nuclear pharmacy, which is a health care entity, even  
1562 if the nuclear pharmacy holds a special sterile compounding  
1563 permit under chapter 465, for the purpose of manufacturing  
1564 prescription drugs used in positron emission tomography or other  
1565 radiopharmaceuticals, as listed in a rule adopted by the  
1566 department pursuant to this paragraph. The purpose of this  
1567 exemption is to assure availability of state-of-the-art  
1568 pharmaceuticals that would pose a significant danger to the  
1569 public health if manufactured at a separate establishment  
1570 address from the nuclear pharmacy from which the prescription  
1571 drugs are dispensed. The department may also issue a retail  
1572 pharmacy drug wholesale distributor permit to the address of a  
1573 community pharmacy licensed under chapter 465, even if the  
1574 community pharmacy holds a special sterile compounding permit  
1575 under chapter 465, as long as the community pharmacy ~~which~~ does  
1576 not meet the definition of a closed pharmacy in s. 499.003.

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

1587 to this part.

1588 (2) Notwithstanding subsection (6), a permitted person in  
1589 good standing may change the type of permit issued to that  
1590 person by completing a new application for the requested permit,  
1591 paying the amount of the difference in the permit fees if the  
1592 fee for the new permit is more than the fee for the original  
1593 permit, and meeting the applicable permitting conditions for the  
1594 new permit type. The new permit expires on the expiration date  
1595 of the original permit being changed; however, a new permit for  
1596 a prescription drug wholesale distributor, an out-of-state  
1597 prescription drug wholesale distributor, or a retail pharmacy  
1598 drug wholesale distributor shall expire on the expiration date  
1599 of the original permit or 1 year after the date of issuance of  
1600 the new permit, whichever is earlier. A refund may not be issued  
1601 if the fee for the new permit is less than the fee that was paid  
1602 for the original permit.

1603 (3) (a) A written application for a permit or to renew a  
1604 permit must be filed with the department on forms furnished by  
1605 the department. The department shall establish, by rule, the  
1606 form and content of the application to obtain or renew a permit.  
1607 The applicant must submit to the department with the application  
1608 a statement that swears or affirms that the information is true  
1609 and correct.

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

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1613 that the applicant has failed to cure the deficiency, the  
1614 application shall expire. The determination regarding the 2-year  
1615 lapse of time shall be based on documentation that the  
1616 department notified the applicant of the deficiency in  
1617 accordance with s. 120.60.

1618 (c) Information submitted by an applicant on an  
1619 application required pursuant to this subsection which is a  
1620 trade secret, as defined in s. 812.081, shall be maintained by  
1621 the department as trade secret information pursuant to s.  
1622 499.051(7).

1623 (4) (a) Except for a permit for a prescription drug  
1624 wholesale distributor or an out-of-state prescription drug  
1625 wholesale distributor, an application for a permit must include:

- 1626 1. The name, full business address, and telephone number  
1627 of the applicant;
- 1628 2. All trade or business names used by the applicant;
- 1629 3. The address, telephone numbers, and the names of  
1630 contact persons for each facility used by the applicant for the  
1631 storage, handling, and distribution of prescription drugs;
- 1632 4. The type of ownership or operation, such as a  
1633 partnership, corporation, or sole proprietorship; and
- 1634 5. The names of the owner and the operator of the  
1635 establishment, including:
- 1636 a. If an individual, the name of the individual;
- 1637 b. If a partnership, the name of each partner and the name  
1638 of the partnership;

1639 c. If a corporation, the name and title of each corporate  
 1640 officer and director, the corporate names, and the name of the  
 1641 state of incorporation;

1642 d. If a sole proprietorship, the full name of the sole  
 1643 proprietor and the name of the business entity;

1644 e. If a limited liability company, the name of each  
 1645 member, the name of each manager, the name of the limited  
 1646 liability company, and the name of the state in which the  
 1647 limited liability company was organized; and

1648 f. Any other relevant information that the department  
 1649 requires.

1650 (b) Upon approval of the application by the department and  
 1651 payment of the required fee, the department shall issue a permit  
 1652 to the applicant, if the applicant meets the requirements of  
 1653 this part and rules adopted under this part.

1654 (c) Any change in information required under paragraph (a)  
 1655 must be submitted to the department before the change occurs.

1656 (d) The department shall consider, at a minimum, the  
 1657 following factors in reviewing the qualifications of persons to  
 1658 be permitted under this part:

1659 1. The applicant's having been found guilty, regardless of  
 1660 adjudication, in a court of this state or other jurisdiction, of  
 1661 a violation of a law that directly relates to a drug, device, or  
 1662 cosmetic. A plea of nolo contendere constitutes a finding of  
 1663 guilt for purposes of this subparagraph.

1664 2. The applicant's having been disciplined by a regulatory



1665 agency in any state for any offense that would constitute a  
 1666 violation of this part.

1667 3. Any felony conviction of the applicant under a federal,  
 1668 state, or local law;

1669 4. The applicant's past experience in manufacturing or  
 1670 distributing drugs, devices, or cosmetics;

1671 5. The furnishing by the applicant of false or fraudulent  
 1672 material in any application made in connection with  
 1673 manufacturing or distributing drugs, devices, or cosmetics;

1674 6. Suspension or revocation by a federal, state, or local  
 1675 government of any permit currently or previously held by the  
 1676 applicant for the manufacture or distribution of any drugs,  
 1677 devices, or cosmetics;

1678 7. Compliance with permitting requirements under any  
 1679 previously granted permits;

1680 8. Compliance with requirements to maintain or make  
 1681 available to the state permitting authority or to federal,  
 1682 state, or local law enforcement officials those records required  
 1683 under this section; and

1684 9. Any other factors or qualifications the department  
 1685 considers relevant to and consistent with the public health and  
 1686 safety.

1687 (5) ~~Except for a permit for a prescription drug wholesale~~  
 1688 ~~distributor or an out-of-state prescription drug wholesale~~  
 1689 ~~distributor:~~

1690 (a) The department shall adopt rules for the biennial

1691 renewal of permits; however, the department may issue up to a 4-  
1692 year permit to selected permittees notwithstanding any other  
1693 provision of law. Fees for such renewal may not exceed the fee  
1694 caps set forth in s. 499.041 on an annualized basis as  
1695 authorized by law.

1696 (b) The department shall renew a permit upon receipt of  
1697 the renewal application and renewal fee if the applicant meets  
1698 the requirements established under this part and ~~the~~ rules  
1699 adopted under this part.

1700 (c) At least 90 days before the expiration date of a  
1701 permit, the department shall forward a permit renewal  
1702 notification to the permittee at the mailing address of the  
1703 permitted establishment on file with the department. The permit  
1704 renewal notification must state conspicuously the date on which  
1705 the permit for the establishment will expire and that the  
1706 establishment may not operate unless the permit for the  
1707 establishment is renewed timely. A permit, unless sooner  
1708 ~~suspended or revoked, automatically expires 2 years after the~~  
1709 ~~last day of the anniversary month in which the permit was~~  
1710 ~~originally issued.~~

1711 (d) A permit issued under this part may be renewed by  
1712 making application for renewal on forms furnished by the  
1713 department and paying the appropriate fees.

1714 1. If a prescription drug wholesale distributor or an out-  
1715 of-state prescription drug wholesale distributor renewal  
1716 application and fee are submitted and postmarked later than 45

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1717 days before the expiration date of the permit, the permit may be  
1718 renewed only upon payment of a late renewal fee of \$100, plus  
1719 the required renewal fee.

1720 2. If any other a renewal application and fee are  
1721 submitted and postmarked after the expiration date of the  
1722 permit, the permit may be renewed only upon payment of a late  
1723 renewal delinquent fee of \$100, plus the required renewal fee,  
1724 not later than 60 days after the expiration date.

1725 3. A permittee who submits a renewal application in  
1726 accordance with this paragraph may continue to operate under its  
1727 permit, unless the permit is suspended or revoked, until final  
1728 disposition of the renewal application.

1729 4.-(d) Failure to renew a permit in accordance with this  
1730 section precludes any future renewal of that permit. If a permit  
1731 issued pursuant to this part has expired and cannot be renewed,  
1732 before an establishment may engage in activities that require a  
1733 permit under this part, the establishment must submit an  
1734 application for a new permit, pay the applicable application  
1735 fee, the initial permit fee, and all applicable penalties, and  
1736 be issued a new permit by the department.

1737 (6) A permit issued by the department is nontransferable.  
1738 Each permit is valid only for the person or governmental unit to  
1739 which it is issued and is not subject to sale, assignment, or  
1740 other transfer, voluntarily or involuntarily; nor is a permit  
1741 valid for any establishment other than the establishment for  
1742 which it was originally issued.

1743 (a) A person permitted under this part must notify the  
 1744 department before making a change of address. The department  
 1745 shall set a change of location fee not to exceed \$100.

1746 (b)1. An application for a new permit is required when a  
 1747 majority of the ownership or controlling interest of a permitted  
 1748 establishment is transferred or assigned or when a lessee agrees  
 1749 to undertake or provide services to the extent that legal  
 1750 liability for operation of the establishment will rest with the  
 1751 lessee. The application for the new permit must be made before  
 1752 the date of the sale, transfer, assignment, or lease.

1753 2. A permittee that is authorized to distribute  
 1754 prescription drugs may transfer such drugs to the new owner or  
 1755 lessee under subparagraph 1. only after the new owner or lessee  
 1756 has been approved for a permit to distribute prescription drugs.

1757 (c) If an establishment permitted under this part closes,  
 1758 the owner must notify the department in writing before the  
 1759 effective date of closure and must:

1760 1. Return the permit to the department;

1761 2. If the permittee is authorized to distribute  
 1762 prescription drugs, indicate the disposition of such drugs,  
 1763 including the name, address, and inventory, and provide the name  
 1764 and address of a person to contact regarding access to records  
 1765 that are required to be maintained under this part. Transfer of  
 1766 ownership of prescription drugs may be made only to persons  
 1767 authorized to possess prescription drugs under this part.

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1769 The department may revoke the permit of any person that fails to  
 1770 comply with the requirements of this subsection.

1771 (7) A permit must be posted in a conspicuous place on the  
 1772 licensed premises.

1773 (8) An application for a permit or to renew a permit for a  
 1774 prescription drug wholesale distributor or an out-of-state  
 1775 prescription drug wholesale distributor submitted to the  
 1776 department must include:

1777 (a) The name, full business address, and telephone number  
 1778 of the applicant.

1779 (b) All trade or business names used by the applicant.

1780 (c) The address, telephone numbers, and the names of  
 1781 contact persons for each facility used by the applicant for the  
 1782 storage, handling, and distribution of prescription drugs.

1783 (d) The type of ownership or operation, such as a  
 1784 partnership, corporation, or sole proprietorship.

1785 (e) The names of the owner and the operator of the  
 1786 establishment, including:

1787 1. If an individual, the name of the individual.

1788 2. If a partnership, the name of each partner and the name  
 1789 of the partnership.

1790 3. If a corporation:

1791 a. The name, address, and title of each corporate officer  
 1792 and director.

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

1795 corporation's state of incorporation.

1796 c. The name and address of each shareholder of the  
 1797 corporation that owns 5 percent or more of the outstanding stock  
 1798 of the corporation.

1799 4. If a sole proprietorship, the full name of the sole  
 1800 proprietor and the name of the business entity.

1801 5. If a limited liability company:

1802 a. The name and address of each member.

1803 b. The name and address of each manager.

1804 c. The name and address of the limited liability company,  
 1805 the resident agent of the limited liability company, and the  
 1806 name of the state in which the limited liability company was  
 1807 organized.

1808 (f) If applicable, the name and address of each affiliate  
 1809 ~~of member of the affiliated group of which the applicant is a~~  
 1810 ~~member.~~

1811 (g)~~1.~~ The applicant's gross annual receipts attributable  
 1812 to prescription drug wholesale distribution activities for the  
 1813 previous tax year. ~~For an application for a new permit, the~~  
 1814 ~~estimated annual dollar volume of prescription drug sales of the~~  
 1815 ~~applicant, the estimated annual percentage of the applicant's~~  
 1816 ~~total company sales that are prescription drugs, the applicant's~~  
 1817 ~~estimated annual total dollar volume of purchases of~~  
 1818 ~~prescription drugs, and the applicant's estimated annual total~~  
 1819 ~~dollar volume of prescription drug purchases directly from~~  
 1820 ~~manufacturers.~~

1821 ~~2. For an application to renew a permit, the total dollar~~  
1822 ~~volume of prescription drug sales in the previous year, the~~  
1823 ~~total dollar volume of prescription drug sales made in the~~  
1824 ~~previous 6 months, the percentage of total company sales that~~  
1825 ~~were prescription drugs in the previous year, the total dollar~~  
1826 ~~volume of purchases of prescription drugs in the previous year,~~  
1827 ~~and the total dollar volume of prescription drug purchases~~  
1828 ~~directly from manufacturers in the previous year.~~

1829  
1830 ~~Such portions of the information required pursuant to this~~  
1831 ~~paragraph which are a trade secret, as defined in s. 812.081,~~  
1832 ~~shall be maintained by the department as trade secret~~  
1833 ~~information is required to be maintained under s. 499.051.~~

1834 (h) The tax year of the applicant.

1835 (i) A copy of the deed for the property on which  
1836 applicant's establishment is located, if the establishment is  
1837 owned by the applicant, or a copy of the applicant's lease for  
1838 the property on which applicant's establishment is located that  
1839 has an original term of not less than 1 calendar year, if the  
1840 establishment is not owned by the applicant.

1841 (j) A list of all licenses and permits issued to the  
1842 applicant by any other state which authorize the applicant to  
1843 purchase or possess prescription drugs.

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

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1847 wholesale operations for the establishment, and the name of all  
1848 affiliated parties for the establishment, together with the  
1849 personal information statement and fingerprints required  
1850 pursuant to subsection (9) for each of such persons.

1851 (l) The name of each of the applicant's designated  
1852 representatives as required by subsection (15) ~~(16)~~, together  
1853 with the personal information statement and fingerprints  
1854 required pursuant to subsection (9) for each such person.

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



1873 valid or until 60 days after any administrative or legal  
1874 proceeding authorized in this part which involves the permittee  
1875 is concluded, including any appeal, whichever occurs later. ~~For~~  
1876 ~~an applicant that is a secondary wholesale distributor, each of~~  
1877 ~~the following:~~

1878 1. ~~A personal background information statement containing~~  
1879 ~~the background information and fingerprints required pursuant to~~  
1880 ~~subsection (9) for each person named in the applicant's response~~  
1881 ~~to paragraphs (k) and (l) and for each affiliated party of the~~  
1882 ~~applicant.~~

1883 2. ~~If any of the five largest shareholders of the~~  
1884 ~~corporation seeking the permit is a corporation, the name,~~  
1885 ~~address, and title of each corporate officer and director of~~  
1886 ~~each such corporation; the name and address of such corporation;~~  
1887 ~~the name of such corporation's resident agent, such~~  
1888 ~~corporation's resident agent's address, and such corporation's~~  
1889 ~~state of its incorporation; and the name and address of each~~  
1890 ~~shareholder of such corporation that owns 5 percent or more of~~  
1891 ~~the stock of such corporation.~~

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

1899 ~~the department as trade secret information is required to be~~  
 1900 ~~maintained under s. 499.051.~~

1901 ~~4. The sources of all funds and the amounts of such funds~~  
 1902 ~~used to purchase or finance purchases of prescription drugs or~~  
 1903 ~~to finance the premises on which the establishment is to be~~  
 1904 ~~located.~~

1905 ~~5. If any of the funds identified in subparagraph 4. were~~  
 1906 ~~borrowed, copies of all promissory notes or loans used to obtain~~  
 1907 ~~such funds.~~

1908 (n) For establishments used in wholesale distribution,  
 1909 proof of an inspection conducted by the department, the United  
 1910 States Food and Drug Administration, or another governmental  
 1911 entity charged with the regulation of good manufacturing  
 1912 practices related to wholesale distribution of prescription  
 1913 drugs, within timeframes set forth by the department in  
 1914 departmental rules, which demonstrates substantial compliance  
 1915 with current good manufacturing practices applicable to  
 1916 wholesale distribution of prescription drugs. The department may  
 1917 recognize another state's inspection of a wholesale distributor  
 1918 located in that state if such state's laws are deemed to be  
 1919 substantially equivalent to the law of this state by the  
 1920 department. The department may accept an inspection by a third-  
 1921 party accreditation or inspection service which meets the  
 1922 criteria set forth in department rule.

1923 (o) ~~(n)~~ Any other relevant information that the department  
 1924 requires, including, but not limited to, any information related

1925 ~~to whether the applicant satisfies the definition of a primary~~  
 1926 ~~wholesale distributor or a secondary wholesale distributor.~~

1927 (p) ~~(e)~~ Documentation of the credentialing policies and  
 1928 procedures required by s. 499.0121(15).

1929 (9) (a) Each person required by subsection (8) or  
 1930 subsection (15) to provide a personal information statement and  
 1931 fingerprints shall provide the following information to the  
 1932 department on forms prescribed by the department:

1933 1. The person's places of residence for the past 7 years.

1934 2. The person's date and place of birth.

1935 3. The person's occupations, positions of employment, and  
 1936 offices held during the past 7 years.

1937 4. The principal business and address of any business,  
 1938 corporation, or other organization in which each such office of  
 1939 the person was held or in which each such occupation or position  
 1940 of employment was carried on.

1941 5. Whether the person has been, during the past 7 years,  
 1942 the subject of any proceeding for the revocation of any license  
 1943 and, if so, the nature of the proceeding and the disposition of  
 1944 the proceeding.

1945 6. Whether, during the past 7 years, the person has been  
 1946 enjoined, temporarily or permanently, by a court of competent  
 1947 jurisdiction from violating any federal or state law regulating  
 1948 the possession, control, or distribution of prescription drugs,  
 1949 together with details concerning any such event.

1950 7. A description of any involvement by the person with any

1951 business, including any investments, other than the ownership of  
 1952 stock in a publicly traded company or mutual fund, during the  
 1953 past 4 7 years, which manufactured, administered, prescribed,  
 1954 distributed, or stored pharmaceutical products and any lawsuits  
 1955 in which such businesses were named as a party.

1956 8. A description of any felony criminal offense of which  
 1957 the person, as an adult, was found guilty, regardless of whether  
 1958 adjudication of guilt was withheld or whether the person pled  
 1959 guilty or nolo contendere. A criminal offense committed in  
 1960 another jurisdiction which would have been a felony in this  
 1961 state must be reported. If the person indicates that a criminal  
 1962 conviction is under appeal and submits a copy of the notice of  
 1963 appeal of that criminal offense, the applicant must, within 15  
 1964 days after the disposition of the appeal, submit to the  
 1965 department a copy of the final written order of disposition.

1966 9. A photograph of the person taken in the previous 180 ~~30~~  
 1967 days.

1968 10. A set of fingerprints for the person on a form and  
 1969 under procedures specified by the department, together with  
 1970 payment of an amount equal to the costs incurred by the  
 1971 department for the criminal record check of the person.

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

1977 children, and the spouses of the person's siblings.  
 1978           12. Any other relevant information that the department  
 1979 requires.  
 1980           (b) The information required pursuant to paragraph (a)  
 1981 shall be provided under oath.  
 1982           (c) The department shall submit the fingerprints provided  
 1983 by a person for initial licensure to the Department of Law  
 1984 Enforcement for a statewide criminal record check and for  
 1985 forwarding to the Federal Bureau of Investigation for a national  
 1986 criminal record check of the person. The department shall submit  
 1987 the fingerprints provided by a person as a part of a renewal  
 1988 application to the Department of Law Enforcement for a statewide  
 1989 criminal record check, and for forwarding to the Federal Bureau  
 1990 of Investigation for a national criminal record check, for the  
 1991 initial renewal of a permit after January 1, 2004; for any  
 1992 subsequent renewal of a permit, the department shall submit the  
 1993 required information for a statewide and national criminal  
 1994 record check of the person. Any person who as a part of an  
 1995 initial permit application or initial permit renewal after  
 1996 January 1, 2004, submits to the department a set of fingerprints  
 1997 required for the criminal record check required in this  
 1998 paragraph are ~~shall~~ not be required to provide a subsequent set  
 1999 of fingerprints for a criminal record check to the department,  
 2000 if the person has undergone a criminal record check as a  
 2001 condition of the issuance of an initial permit or the initial  
 2002 renewal of a permit of an applicant after January 1, 2004. The

2003 department is authorized to contract with private vendors, or  
 2004 enter into interagency agreements, to collect electronic  
 2005 fingerprints where fingerprints are required for registration,  
 2006 certification, or the licensure process or where criminal  
 2007 history record checks are required.

2008 (d) For purposes of applying for renewal of a permit under  
 2009 subsection (8) or certification under subsection (16), a person  
 2010 may submit the following in lieu of satisfying the requirements  
 2011 of paragraphs (a), (b), and (c):

2012 1. A photograph of the individual taken within 180 days;  
 2013 and

2014 2. A copy of the personal information statement form most  
 2015 recently submitted to the department and a certification under  
 2016 oath, on a form specified by the department, that the individual  
 2017 has reviewed the previously submitted personal information  
 2018 statement form and that the information contained therein  
 2019 remains unchanged.

2020 (10) The department may deny an application for a permit  
 2021 or refuse to renew a permit for a prescription drug wholesale  
 2022 distributor or an out-of-state prescription drug wholesale  
 2023 distributor if:

2024 (a) The applicant has not met the requirements for the  
 2025 permit.

2026 (b) The management, officers, or directors of the  
 2027 applicant or any affiliated party are found by the department to  
 2028 be incompetent or untrustworthy.

2029 (c) The applicant is so lacking in experience in managing  
2030 a wholesale distributor as to make the issuance of the proposed  
2031 permit hazardous to the public health.

2032 (d) The applicant is so lacking in experience in managing  
2033 a wholesale distributor as to jeopardize the reasonable promise  
2034 of successful operation of the wholesale distributor.

2035 (e) The applicant is lacking in experience in the  
2036 distribution of prescription drugs.

2037 (f) The applicant's past experience in manufacturing or  
2038 distributing prescription drugs indicates that the applicant  
2039 poses a public health risk.

2040 (g) The applicant is affiliated directly or indirectly  
2041 through ownership, control, or other business relations, with  
2042 any person or persons whose business operations are or have been  
2043 detrimental to the public health.

2044 (h) The applicant, or any affiliated party, has been found  
2045 guilty of or has pleaded guilty or nolo contendere to any felony  
2046 or crime punishable by imprisonment for 1 year or more under the  
2047 laws of the United States, any state, or any other country,  
2048 regardless of whether adjudication of guilt was withheld.

2049 (i) The applicant or any affiliated party has been charged  
2050 with a felony in a state or federal court and the disposition of  
2051 that charge is pending during the application review or renewal  
2052 review period.

2053 (j) The applicant has furnished false or fraudulent  
2054 information or material in any application made in this state or

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2055 any other state in connection with obtaining a permit or license  
2056 to manufacture or distribute drugs, devices, or cosmetics.

2057 (k) That a federal, state, or local government permit  
2058 currently or previously held by the applicant, or any affiliated  
2059 party, for the manufacture or distribution of any drugs,  
2060 devices, or cosmetics has been disciplined, suspended, or  
2061 revoked and has not been reinstated.

2062 (l) The applicant does not possess the financial or  
2063 physical resources to operate in compliance with the permit  
2064 being sought, this chapter, and the rules adopted under this  
2065 chapter.

2066 (m) The applicant or any affiliated party receives,  
2067 directly or indirectly, financial support and assistance from a  
2068 person who was an affiliated party of a permittee whose permit  
2069 was subject to discipline or was suspended or revoked, other  
2070 than through the ownership of stock in a publicly traded company  
2071 or a mutual fund.

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



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2081 or a mutual fund.

2082 (o) The applicant for renewal of a permit under s.  
2083 499.01(2)(e) or (f) ~~499.01(2)(d) or (e)~~ has not actively engaged  
2084 in the wholesale distribution of prescription drugs, as  
2085 demonstrated by the regular and systematic distribution of  
2086 prescription drugs throughout the year as evidenced by not fewer  
2087 than 12 wholesale distributions in the previous year and not  
2088 fewer than three wholesale distributions in the previous 6  
2089 months.

2090 (p) Information obtained in response to s. 499.01(2)(e) or  
2091 (f) ~~499.01(2)(d) or (e)~~ demonstrates it would not be in the best  
2092 interest of the public health, safety, and welfare to issue a  
2093 permit.

2094 (q) The applicant does not possess the financial standing  
2095 and business experience for the successful operation of the  
2096 applicant.

2097 (r) The applicant or any affiliated party has failed to  
2098 comply with the requirements for manufacturing or distributing  
2099 prescription drugs under this part, similar federal laws,  
2100 similar laws in other states, or the rules adopted under such  
2101 laws.

2102 (11) Upon approval of the application by the department  
2103 and payment of the required fee, the department shall issue or  
2104 renew a prescription drug wholesale distributor or an out-of-  
2105 state prescription drug wholesale distributor permit to the  
2106 applicant.

2107 ~~(12) For a permit for a prescription drug wholesale~~  
 2108 ~~distributor or an out-of-state prescription drug wholesale~~  
 2109 ~~distributor:~~

2110 ~~(a) The department shall adopt rules for the annual~~  
 2111 ~~renewal of permits. At least 90 days before the expiration of a~~  
 2112 ~~permit, the department shall forward a permit renewal~~  
 2113 ~~notification and renewal application to the prescription drug~~  
 2114 ~~wholesale distributor or out-of-state prescription drug~~  
 2115 ~~wholesale distributor at the mailing address of the permitted~~  
 2116 ~~establishment on file with the department. The permit renewal~~  
 2117 ~~notification must state conspicuously the date on which the~~  
 2118 ~~permit for the establishment will expire and that the~~  
 2119 ~~establishment may not operate unless the permit for the~~  
 2120 ~~establishment is renewed timely.~~

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

2133 application.

2134 ~~(c) Failure to renew a permit in accordance with this~~  
2135 ~~section precludes any future renewal of that permit. If a permit~~  
2136 ~~issued pursuant to this section has expired and cannot be~~  
2137 ~~renewed, before an establishment may engage in activities that~~  
2138 ~~require a permit under this part, the establishment must submit~~  
2139 ~~an application for a new permit; pay the applicable application~~  
2140 ~~fee, initial permit fee, and all applicable penalties; and be~~  
2141 ~~issued a new permit by the department.~~

2142 (12) ~~(13)~~ A person that engages in wholesale distribution  
2143 of prescription drugs in this state must have a wholesale  
2144 distributor's permit issued by the department, except as noted  
2145 in this section. Each establishment must be separately permitted  
2146 except as noted in this subsection.

2147 (a) A separate establishment permit is not required when a  
2148 permitted prescription drug wholesale distributor consigns a  
2149 prescription drug to a pharmacy that is permitted under chapter  
2150 465 and located in this state, provided that:

2151 1. The consignor wholesale distributor notifies the  
2152 department in writing of the contract to consign prescription  
2153 drugs to a pharmacy along with the identity and location of each  
2154 consignee pharmacy;

2155 2. The pharmacy maintains its permit under chapter 465;

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

2159 ~~499.01212~~ with respect to the consigned drugs and maintains  
 2160 records documenting the transfer of title or other completion of  
 2161 the wholesale distribution of the consigned prescription drugs;

2162 4. The distribution of the prescription drug is otherwise  
 2163 lawful under this chapter and other applicable law;

2164 5. Open packages containing prescription drugs within a  
 2165 pharmacy are the responsibility of the pharmacy, regardless of  
 2166 how the drugs are titled; and

2167 6. The pharmacy dispenses the consigned prescription drug  
 2168 in accordance with the limitations of its permit under chapter  
 2169 465 or returns the consigned prescription drug to the consignor  
 2170 wholesale distributor. In addition, a person who holds title to  
 2171 prescription drugs may transfer the drugs to a person permitted  
 2172 or licensed to handle the reverse distribution or destruction of  
 2173 drugs. Any other distribution by and means of the consigned  
 2174 prescription drug by any person, not limited to the consignor  
 2175 wholesale distributor or consignee pharmacy, to any other person  
 2176 is prohibited.

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

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2185 distributor comply with all of the provisions of paragraph (a)  
2186 and the prescription drugs continue to be within the permitted  
2187 pharmacy's inventory for dispensing in accordance with the  
2188 limitations of the pharmacy permit under chapter 465. A  
2189 consignor drug wholesale distributor may not use the pharmacy as  
2190 a wholesale distributor through which it distributes the  
2191 prescription drugs to other pharmacies. Nothing in this section  
2192 is intended to prevent a wholesale distributor from obtaining  
2193 this inventory in the event of nonpayment by the pharmacy.

2194 (c) A separate establishment permit is not required when a  
2195 permitted prescription drug wholesale distributor operates  
2196 temporary transit storage facilities for the sole purpose of  
2197 storage, for up to 16 hours, of a delivery of prescription drugs  
2198 when the wholesale distributor was temporarily unable to  
2199 complete the delivery to the recipient.

2200 (d) The department shall require information from each  
2201 wholesale distributor as part of the permit and renewal of such  
2202 permit, as required under this section.

2203 (13)~~(14)~~ Personnel employed in wholesale distribution must  
2204 have appropriate education and experience to enable them to  
2205 perform their duties in compliance with state permitting  
2206 requirements.

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

2211 | indicia that the permittee or establishment possesses a  
 2212 | professional license, or any name or abbreviation that the  
 2213 | department determines is likely to cause confusion or mistake or  
 2214 | that the department determines is deceptive, including that of  
 2215 | any other entity authorized to purchase prescription drugs.

2216 |       (15)~~(16)~~(a) Each establishment that is issued an initial  
 2217 | or renewal permit as a prescription drug wholesale distributor  
 2218 | or an out-of-state prescription drug wholesale distributor must  
 2219 | designate in writing to the department at least one natural  
 2220 | person to serve as the designated representative of the  
 2221 | wholesale distributor. Such person must have an active  
 2222 | certification as a designated representative from the  
 2223 | department.

2224 |       (b) To be certified as a designated representative, a  
 2225 | natural person must:

2226 |           1. Submit an application on a form furnished by the  
 2227 | department and pay the appropriate fees.

2228 |           2. Be at least 18 years of age.

2229 |           3. Have at least 2 years of verifiable full-time:

2230 |           a. Work experience in a pharmacy licensed in this state or  
 2231 | another state, where the person's responsibilities included, but  
 2232 | were not limited to, recordkeeping for prescription drugs;

2233 |           b. Managerial experience with a prescription drug  
 2234 | wholesale distributor licensed in this state or in another  
 2235 | state; or

2236 |           c. Managerial experience with the United States Armed

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2237 Forces, where the person's responsibilities included, but were  
2238 not limited to, recordkeeping, warehousing, distributing, or  
2239 other logistics services pertaining to prescription drugs.

2240 4. Receive a passing score of at least 75 percent on an  
2241 examination given by the department regarding federal laws  
2242 governing distribution of prescription drugs and this part and  
2243 the rules adopted by the department governing the wholesale  
2244 distribution of prescription drugs. This requirement shall be  
2245 effective 1 year after the results of the initial examination  
2246 are mailed to the persons that took the examination. The  
2247 department shall offer such examinations at least four times  
2248 each calendar year.

2249 5. Provide the department with a personal information  
2250 statement and fingerprints pursuant to subsection (9).

2251 (c) The department may deny an application for  
2252 certification as a designated representative or may suspend or  
2253 revoke a certification of a designated representative pursuant  
2254 to s. 499.067.

2255 (d) A designated representative:

2256 1. Must be actively involved in and aware of the actual  
2257 daily operation of the wholesale distributor.

2258 2. Must be employed full time in a managerial position by  
2259 the wholesale distributor.

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

2263 other authorized absence.

2264 4. May serve as a designated representative for only one  
2265 wholesale distributor at any one time.

2266 (e) A wholesale distributor must notify the department  
2267 when a designated representative leaves the employ of the  
2268 wholesale distributor. Such notice must be provided to the  
2269 department within 10 business days after the last day of  
2270 designated representative's employment with the wholesale  
2271 distributor.

2272 (f) A wholesale distributor may not operate under a  
2273 prescription drug wholesale distributor permit or an out-of-  
2274 state prescription drug wholesale distributor permit for more  
2275 than 10 business days after the designated representative leaves  
2276 the employ of the wholesale distributor, unless the wholesale  
2277 distributor employs another designated representative and  
2278 notifies the department within 10 business days of the identity  
2279 of the new designated representative.

2280 Section 7. Section 499.01201, Florida Statutes, is amended  
2281 to read:

2282 499.01201 Agency for Health Care Administration review and  
2283 use of statute and rule violation or compliance data.—

2284 Notwithstanding any other provision ~~provisions~~ of law ~~to the~~  
2285 ~~contrary~~, the Agency for Health Care Administration may not:

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



2289 any payment of a Medicaid reimbursement to a pharmacy licensed  
 2290 under chapter 465; or

2291 (2) Review or use compliance with s. 499.0121(6) ~~or s.~~  
 2292 ~~499.01212~~, or any rules adopted under that section ~~these~~  
 2293 ~~sections~~, as the subject of any audit of Medicaid-related  
 2294 records held by a pharmacy licensed under chapter 465.

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

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

2304 (4) EXAMINATION OF MATERIALS AND RECORDS.—

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

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

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2315 protection of the public health.

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

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

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

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

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

2336 5. Any financial documentation supporting the transaction.

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

2341 | whichever period is longer.

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

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

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

2364 |       Section 9. Subsections (1), (3), (4), and (6) of section  
 2365 | 499.015, Florida Statutes, are amended to read:

2366 |       499.015 Registration of drugs, devices, and cosmetics;

2367 issuance of certificates of free sale.—

2368 (1) (a) Except for those persons exempted from the  
 2369 definition of manufacturer in s. 499.003, any person who  
 2370 manufactures, packages, repackages, labels, or relabels a drug  
 2371 or a ~~device, or cosmetic~~ in this state must register such drug  
 2372 or ~~device, or cosmetic~~ biennially with the department; pay a  
 2373 fee in accordance with the fee schedule provided by s. 499.041;  
 2374 and comply with this section. The registrant must list each  
 2375 separate and distinct drug or ~~device, or cosmetic~~ at the time  
 2376 of registration.

2377 (b) Any person who manufactures, packages, repackages,  
 2378 labels, or relabels a cosmetic in this state may voluntarily  
 2379 register such cosmetic biennially with the department. A person  
 2380 registering a cosmetic must submit a completed application to  
 2381 register the cosmetic, pay a fee in accordance with the fee  
 2382 schedule provided by s. 499.041, comply with the provisions of  
 2383 this section, and must list each separate and distinct cosmetic  
 2384 at the time of registration.

2385 (c) ~~(b)~~ The department may not register any product that  
 2386 does not comply with the Federal Food, Drug, and Cosmetic Act,  
 2387 as amended, or Title 21 C.F.R. Registration of a product by the  
 2388 department does not mean that the product does in fact comply  
 2389 with all provisions of the Federal Food, Drug, and Cosmetic Act,  
 2390 as amended.

2391 (d) A person may not register a product with the  
 2392 department if that person is not legally authorized to

2393 manufacture, package, repackage, label, or relabel the product  
2394 in this state.

2395 (3) Except for those persons exempted from the definition  
2396 of manufacturer in s. 499.003, a person may not sell any product  
2397 that he or she has failed to register in conformity with this  
2398 section. Such failure to register subjects such drug or ~~device~~  
2399 ~~or cosmetic product~~ to seizure and condemnation as provided in  
2400 s. 499.062, and subjects such person to the penalties and  
2401 remedies provided in this part.

2402 (4) Unless a registration is renewed, it expires 2 years  
2403 after the last day of the month in which it was issued. Any  
2404 product registration issued or renewed on or after July 1, 2016,  
2405 shall expire on the same date as the manufacturer or repackager  
2406 permit of the person seeking to register the product. If the  
2407 first product registration issued to a person on or after July  
2408 1, 2016, expires less than 366 days after issuance, the fee for  
2409 product registration shall be \$15. If the first product  
2410 registration issued to a person on or after July 1, 2016,  
2411 expires more than 365 days after issuance, the fee for product  
2412 registration shall be \$30. The department may issue a stop-sale  
2413 notice or order against a person that is subject to the  
2414 requirements of this section and that fails to comply with this  
2415 section within 31 days after the date the registration expires.  
2416 The notice or order shall prohibit such person from selling or  
2417 causing to be sold any drugs, devices, or cosmetics covered by  
2418 this part until he or she complies with the requirements of this

2419 section.

2420 (6) The department may only issue a certificate of free  
 2421 sale for any product that is ~~required to be~~ registered under  
 2422 this part.

2423 Section 10. Subsection (1) of section 499.03, Florida  
 2424 Statutes, is amended to read:

2425 499.03 Possession of certain drugs without prescriptions  
 2426 unlawful; exemptions and exceptions.—

2427 (1) A person may not possess, or possess with intent to  
 2428 sell, dispense, or deliver, any habit-forming, toxic, harmful,  
 2429 or new drug subject to s. 499.003(32) ~~499.003(33)~~, or  
 2430 prescription drug as defined in s. 499.003(40) ~~499.003(43)~~,  
 2431 unless the possession of the drug has been obtained by a valid  
 2432 prescription of a practitioner licensed by law to prescribe the  
 2433 drug. However, this section does not apply to the delivery of  
 2434 such drugs to persons included in any of the classes named in  
 2435 this subsection, or to the agents or employees of such persons,  
 2436 for use in the usual course of their businesses or practices or  
 2437 in the performance of their official duties, as the case may be;  
 2438 nor does this section apply to the possession of such drugs by  
 2439 those persons or their agents or employees for such use:

2440 (a) A licensed pharmacist or any person under the licensed  
 2441 pharmacist's supervision while acting within the scope of the  
 2442 licensed pharmacist's practice;

2443 (b) A licensed practitioner authorized by law to prescribe  
 2444 prescription drugs or any person under the licensed

2445 practitioner's supervision while acting within the scope of the  
 2446 licensed practitioner's practice;

2447 (c) A qualified person who uses prescription drugs for  
 2448 lawful research, teaching, or testing, and not for resale;

2449 (d) A licensed hospital or other institution that procures  
 2450 such drugs for lawful administration or dispensing by  
 2451 practitioners;

2452 (e) An officer or employee of a federal, state, or local  
 2453 government; or

2454 (f) A person that holds a valid permit issued by the  
 2455 department pursuant to this part which authorizes that person to  
 2456 possess prescription drugs.

2457 Section 11. Paragraphs (i) through (p) of subsection (1)  
 2458 of section 499.05, Florida Statutes, are amended to read:

2459 499.05 Rules.—

2460 (1) The department shall adopt rules to implement and  
 2461 enforce this chapter with respect to:

2462 (i) Additional conditions that qualify as an emergency  
 2463 medical reason under s. 499.003(48)(b)2. ~~499.003(53)(b)2.~~ or s.  
 2464 499.82.

2465 ~~(j) Procedures and forms relating to the pedigree paper~~  
 2466 ~~requirement of s. 499.01212.~~

2467 (j)(\*) The protection of the public health, safety, and  
 2468 welfare regarding good manufacturing practices that  
 2469 manufacturers and repackagers must follow to ensure the safety  
 2470 of the products.

2471 (k)~~(l)~~ Information required from each retail establishment  
 2472 pursuant to s. 499.012(3) or s. 499.83(2)(c), including  
 2473 requirements for prescriptions or orders.

2474 (l)~~(m)~~ The recordkeeping, storage, and handling with  
 2475 respect to each of the distributions of prescription drugs  
 2476 specified in s. 499.003(48)(a)-(v) ~~499.003(53)(a)-(d)~~ or s.  
 2477 499.82(14).

2478 ~~(n) Alternatives to compliance with s. 499.01212 for a~~  
 2479 ~~prescription drug in the inventory of a permitted prescription~~  
 2480 ~~drug wholesale distributor as of June 30, 2006, and the return~~  
 2481 ~~of a prescription drug purchased prior to July 1, 2006. The~~  
 2482 ~~department may specify time limits for such alternatives.~~

2483 (m)~~(o)~~ Wholesale distributor reporting requirements of s.  
 2484 499.0121(14).

2485 (n)~~(p)~~ Wholesale distributor credentialing and  
 2486 distribution requirements of s. 499.0121(15).

2487 Section 12. Subsection (7) of section 499.051, Florida  
 2488 Statutes, is amended to read:

2489 499.051 Inspections and investigations.—

2490 (7) The complaint and all information obtained pursuant to  
 2491 the investigation by the department are confidential and exempt  
 2492 from s. 119.07(1) and s. 24(a), Art. I of the State Constitution  
 2493 until the investigation and the enforcement action are  
 2494 completed. However, trade secret information contained therein  
 2495 as defined by s. 812.081(1)(c) shall remain confidential and  
 2496 exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I



2497 of the State Constitution, as long as the information is  
 2498 retained by the department. This subsection does not prohibit  
 2499 the department from using such information for regulatory or  
 2500 enforcement proceedings under this chapter or from providing  
 2501 such information to any law enforcement agency or any other  
 2502 regulatory agency. However, the receiving agency shall keep such  
 2503 records confidential and exempt as provided in this subsection.  
 2504 ~~In addition, this subsection is not intended to prevent~~  
 2505 ~~compliance with the provisions of s. 499.01212, and the pedigree~~  
 2506 ~~papers required in that section shall not be deemed a trade~~  
 2507 ~~secret.~~

2508 Section 13. Subsection (8) is added to section 499.066,  
 2509 Florida Statutes, to read:

2510 499.066 Penalties; remedies.—In addition to other  
 2511 penalties and other enforcement provisions:

2512 (8) (a) The department shall adopt rules to permit the  
 2513 issuance of remedial, nondisciplinary citations. A citation  
 2514 shall be issued to the person alleged to have committed a  
 2515 violation and contain the person's name, address, and license  
 2516 number, if applicable, a brief factual statement, the sections  
 2517 of the law allegedly violated, and the monetary assessment and  
 2518 or other remedial measures imposed. The citation must clearly  
 2519 state that the person may choose, in lieu of accepting the  
 2520 citation, to have the department rescind the citation and  
 2521 conduct an investigation pursuant to s. 499.051. If the person  
 2522 does not dispute the matter in the citation with the department

2523 within 30 days after the citation is served, the citation  
2524 becomes a final order and does not constitute discipline.

2525 (b) The department shall adopt rules designating  
2526 violations for which a citation may be issued. The rules shall  
2527 designate as citable those violations for which there is no  
2528 substantial threat to the public health, safety, or welfare.

2529 (c) The department is entitled to recover the costs of  
2530 investigation, in addition to any penalty provided according to  
2531 department rule, as part of the penalty levied pursuant to the  
2532 citation.

2533 (d) A citation must be issued within 12 months after the  
2534 filing of the complaint that is the basis for the citation.

2535 (e) Service of a citation may be made by personal service  
2536 or certified mail, restricted delivery, to the person at the  
2537 person's last known address of record with the department or to  
2538 the person's Florida registered agent.

2539 (f) The department has authority to, and shall adopt rules  
2540 to, designate those violations for which a person is subject to  
2541 the issuance of a citation and designate the monetary  
2542 assessments and or other remedial measures that must be taken  
2543 for those violations. The department has continuous authority to  
2544 amend its rules adopted pursuant to this section.

2545 Section 14. Subsection (14) of section 499.82, Florida  
2546 Statutes, is amended to read:

2547 499.82 Definitions.—As used in this part, the term:

2548 (14) "Wholesale distribution" means the distribution of

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2549 | medical gas to a person other than a consumer or patient.  
 2550 | Wholesale distribution of medical gases does not include:  
 2551 |       (a) The sale, purchase, or trade of a medical gas; an  
 2552 | offer to sell, purchase, or trade a medical gas; or the  
 2553 | dispensing of a medical gas pursuant to a prescription;  
 2554 |       (b) Activities exempt from the definition of wholesale  
 2555 | distribution in s. 499.003; or  
 2556 |       (c) The sale, purchase, or trade of a medical gas or an  
 2557 | offer to sell, purchase, or trade a medical gas for emergency  
 2558 | medical reasons; ~~or~~  
 2559 |       ~~(d) Other transactions excluded from the definition of~~  
 2560 | ~~wholesale distribution under the federal act or regulations~~  
 2561 | ~~implemented under the federal act related to medical gas.~~  
 2562 |       Section 15. Subsection (4) of section 499.89, Florida  
 2563 | Statutes, is amended to read:  
 2564 |       499.89 Recordkeeping.—  
 2565 |       ~~(4) A pedigree paper is not required for distributing or~~  
 2566 | ~~dispensing medical gas.~~  
 2567 |       Section 16. Section 499.01212, Florida Statutes, is  
 2568 | repealed.  
 2569 |       Section 17. Paragraph (a) of subsection (1) of section  
 2570 | 409.9201, Florida Statutes, is amended to read:  
 2571 |       409.9201 Medicaid fraud.—  
 2572 |       (1) As used in this section, the term:  
 2573 |       (a) "Prescription drug" means any drug, including, but not  
 2574 | limited to, finished dosage forms or active ingredients that are

2575 subject to, defined in, or described in s. 503(b) of the Federal  
 2576 Food, Drug, and Cosmetic Act or in s. 465.003(8), s. 499.003(47)  
 2577 ~~499.003(52)~~, s. 499.007(13), or s. 499.82(10).

2578  
 2579 The value of individual items of the legend drugs or goods or  
 2580 services involved in distinct transactions committed during a  
 2581 single scheme or course of conduct, whether involving a single  
 2582 person or several persons, may be aggregated when determining  
 2583 the punishment for the offense.

2584 Section 18. Subsection (1) of section 794.075, Florida  
 2585 Statutes, is amended to read:

2586 794.075 Sexual predators; erectile dysfunction drugs.—

2587 (1) A person may not possess a prescription drug, as  
 2588 defined in s. 499.003(40) ~~499.003(43)~~, for the purpose of  
 2589 treating erectile dysfunction if the person is designated as a  
 2590 sexual predator under s. 775.21.

2591 Section 19. Paragraphs (d) and (f) of subsection (3) of  
 2592 section 921.0022, Florida Statutes, are amended to read:

2593 921.0022 Criminal Punishment Code; offense severity  
 2594 ranking chart.—

2595 (3) OFFENSE SEVERITY RANKING CHART

2596 (d) LEVEL 4

2597

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

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|      |                        |     |  |
|------|------------------------|-----|--|
| 2599 | 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. |
| 2600 | 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>                            |
| 2601 | <del>499.0051(2)</del> | 3rd | <del>Failure to authenticate pedigree papers.</del>  |
| 2602 | <u>499.0051(5)</u>     | 2nd | Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.  |
| 2603 | <del>499.0051(6)</del> |     |  |
| 2603 | 517.07(1)              | 3rd | Failure to register securities.  |
| 2604 | 517.12(1)              | 3rd | Failure of dealer, associated person, or issuer of securities to register.   |

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|------|-----------------|-----|--|
| 2605 | 784.07 (2) (b)  | 3rd | Battery of law enforcement officer, firefighter, etc.  |
| 2606 | 784.074 (1) (c) | 3rd | Battery of sexually violent predators facility staff.  |
| 2607 | 784.075         | 3rd | Battery on detention or commitment facility staff.   |
| 2608 | 784.078         | 3rd | Battery of facility employee by throwing, tossing, or expelling certain fluids or materials. |
| 2609 | 784.08 (2) (c)  | 3rd | Battery on a person 65 years of age or older.  |
| 2610 | 784.081 (3)     | 3rd | Battery on specified official or employee.   |
| 2611 | 784.082 (3)     | 3rd | Battery by detained person on visitor or other detainee.                                     |
| 2612 | 784.083 (3)     | 3rd | Battery on code inspector.   |
|      | 784.085         | 3rd | Battery of child by throwing, tossing, projecting, or  |

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|------|---------------|-----|--|
| 2613 | 787.03(1)     | 3rd | expelling certain fluids or materials.   |
| 2614 | 787.04(2)     | 3rd | Interference with custody; wrongly takes minor from appointed guardian.  |
| 2615 | 787.04(3)     | 3rd | Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.                                    |
| 2616 | 787.07        | 3rd | Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person. |
| 2617 | 790.115(1)    | 3rd | Human smuggling.   |
| 2618 | 790.115(2)(b) | 3rd | Exhibiting firearm or weapon within 1,000 feet of a school.  |
|      |               |     | Possessing electric weapon or device, destructive device, or other weapon on school  |

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|      |                    |     | property.   |
| 2619 | 790.115 (2) (c)    | 3rd | Possessing firearm on school property.  |
| 2620 | 800.04 (7) (c)     | 3rd | Lewd or lascivious exhibition; offender less than 18 years.                                   |
| 2621 | 810.02 (4) (a)     | 3rd | Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.  |
| 2622 | 810.02 (4) (b)     | 3rd | Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery. |
| 2623 | 810.06             | 3rd | Burglary; possession of tools.  |
| 2624 | 810.08 (2) (c)     | 3rd | Trespass on property, armed with firearm or dangerous weapon.                                 |
| 2625 | 812.014 (2) (c) 3. | 3rd | Grand theft, 3rd degree \$10,000 or more but less than \$20,000.                              |



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| 2626 | 812.014<br>(2) (c) 4.-10. | 3rd | Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.                                   |
| 2627 | 812.0195 (2)              | 3rd | Dealing in stolen property by use of the Internet; property stolen \$300 or more.                          |
| 2628 | 817.563 (1)               | 3rd | Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03 (5) drugs.      |
| 2629 | 817.568 (2) (a)           | 3rd | Fraudulent use of personal identification information.   |
| 2630 | 817.625 (2) (a)           | 3rd | Fraudulent use of scanning device or reencoder.  |
| 2631 | 828.125 (1)               | 2nd | Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle. |
| 2632 | 837.02 (1)                | 3rd | Perjury in official  |

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|      |                |     | proceedings.  |
| 2633 | 837.021 (1)    | 3rd | Make contradictory statements in official proceedings.  |
| 2634 | 838.022        | 3rd | Official misconduct.  |
| 2635 | 839.13 (2) (a) | 3rd | Falsifying records of an individual in the care and custody of a state agency.                                    |
| 2636 | 839.13 (2) (c) | 3rd | Falsifying records of the Department of Children and Families.  |
| 2637 | 843.021        | 3rd | Possession of a concealed handcuff key by a person in custody.  |
| 2638 | 843.025        | 3rd | Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication. |
| 2639 | 843.15 (1) (a) | 3rd | Failure to appear while on bail for felony (bond estreature or  |

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|      |                   |     | bond jumping).  |
| 2640 | 847.0135 (5) (c)  | 3rd | Lewd or lascivious exhibition using computer; offender less than 18 years.                            |
| 2641 | 874.05 (1) (a)    | 3rd | Encouraging or recruiting another to join a criminal gang.  |
| 2642 | 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). |
| 2643 | 914.14 (2)        | 3rd | Witnesses accepting bribes.   |
| 2644 | 914.22 (1)        | 3rd | Force, threaten, etc., witness, victim, or informant.   |
| 2645 | 914.23 (2)        | 3rd | Retaliation against a witness, victim, or informant, no bodily injury.                                |
| 2646 | 918.12            | 3rd | Tampering with jurors.  |
| 2647 |                   |     |   |

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| 2648 | 934.215  | 3rd    | Use of two-way communications device to facilitate commission of a crime.   |
| 2649 | (f) LEVEL 6                                    |        |   |
| 2650 | Florida  | Felony |   |
| 2651 | Statute  | Degree | Description   |
| 2652 | 316.027 (2) (b)                                | 2nd    | Leaving the scene of a crash involving serious bodily injury.   |
| 2653 | 316.193 (2) (b)                                | 3rd    | Felony DUI, 4th or subsequent conviction.   |
| 2654 | 400.9935 (4) (c)                               | 2nd    | Operating a clinic, or offering services requiring licensure, without a license.  |
| 2655 | <u>499.0051 (2)</u><br><del>499.0051 (3)</del> | 2nd    | Knowing forgery of <u>transaction history, transaction information, or transaction statement</u> <del>pedigree papers</del> . |
|      | <u>499.0051 (3)</u>                            | 2nd    | Knowing purchase or receipt of  |

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| 2656 | <del>499.0051(4)</del> |     | prescription drug from<br>unauthorized person.                              |
| 2657 | <u>499.0051(4)</u>     | 2nd | Knowing sale or transfer of<br>prescription drug to<br>unauthorized person. |
| 2658 | <del>499.0051(5)</del> |     | prescription drug to<br>unauthorized person.                                |
| 2659 | 775.0875(1)            | 3rd | Taking firearm from law<br>enforcement officer.                             |
| 2660 | 784.021(1)(a)          | 3rd | Aggravated assault; deadly<br>weapon without intent to kill.                |
| 2661 | 784.021(1)(b)          | 3rd | Aggravated assault; intent to<br>commit felony.                             |
| 2662 | 784.041                | 3rd | Felony battery; domestic<br>battery by strangulation.                       |
| 2663 | 784.048(3)             | 3rd | Aggravated stalking; credible<br>threat.                                    |
| 2663 | 784.048(5)             | 3rd | Aggravated stalking of person<br>under 16.                                  |
| 2663 | 784.07(2)(c)           | 2nd | Aggravated assault on law   |

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| 2664 |                 |     | enforcement officer.  |
|      | 784.074 (1) (b) | 2nd | Aggravated assault on sexually violent predators facility staff.            |
| 2665 |                 |     |   |
|      | 784.08 (2) (b)  | 2nd | Aggravated assault on a person 65 years of age or older.                    |
| 2666 |                 |     |   |
|      | 784.081 (2)     | 2nd | Aggravated assault on specified official or employee.                       |
| 2667 |                 |     |   |
|      | 784.082 (2)     | 2nd | Aggravated assault by detained person on visitor or other detainee.         |
| 2668 |                 |     |   |
|      | 784.083 (2)     | 2nd | Aggravated assault on code inspector.                                       |
| 2669 |                 |     |   |
|      | 787.02 (2)      | 3rd | False imprisonment; restraining with purpose other than those in s. 787.01. |
| 2670 |                 |     |   |
|      | 790.115 (2) (d) | 2nd | Discharging firearm or weapon on school property.                           |
| 2671 |                 |     |   |

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| 2672 | 790.161(2)    | 2nd | Make, possess, or throw destructive device with intent to do bodily harm or damage property.                                |
| 2673 | 790.164(1)    | 2nd | False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.                |
| 2674 | 790.19        | 2nd | Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.  |
| 2675 | 794.011(8)(a) | 3rd | Solicitation of minor to participate in sexual activity by custodial adult.   |
| 2676 | 794.05(1)     | 2nd | Unlawful sexual activity with specified minor.  |
| 2677 | 800.04(5)(d)  | 3rd | Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years of age; offender less than 18 years. |

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| 2678 | 800.04 (6) (b)     | 2nd | Lewd or lascivious conduct;<br>offender 18 years of age or<br>older.                        |
| 2679 | 806.031 (2)        | 2nd | Arson resulting in great bodily<br>harm to firefighter or any<br>other person.              |
| 2680 | 810.02 (3) (c)     | 2nd | Burglary of occupied structure;<br>unarmed; no assault or battery.                          |
| 2681 | 810.145 (8) (b)    | 2nd | Video voyeurism; certain minor<br>victims; 2nd or subsequent<br>offense.                    |
| 2682 | 812.014 (2) (b) 1. | 2nd | Property stolen \$20,000 or<br>more, but less than \$100,000,<br>grand theft in 2nd degree. |
| 2683 | 812.014 (6)        | 2nd | Theft; property stolen \$3,000<br>or more; coordination of<br>others.                       |
|      | 812.015 (9) (a)    | 2nd | Retail theft; property stolen<br>\$300 or more; second or<br>subsequent conviction.         |



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| 2684 | 812.015 (9) (b) | 2nd | Retail theft; property stolen \$3,000 or more; coordination of others.                       |
| 2685 | 812.13 (2) (c)  | 2nd | Robbery, no firearm or other weapon (strong-arm robbery).                                    |
| 2686 | 817.4821 (5)    | 2nd | Possess cloning paraphernalia with intent to create cloned cellular telephones.              |
| 2687 | 825.102 (1)     | 3rd | Abuse of an elderly person or disabled adult.  |
| 2688 | 825.102 (3) (c) | 3rd | Neglect of an elderly person or disabled adult.  |
| 2689 | 825.1025 (3)    | 3rd | Lewd or lascivious molestation of an elderly person or disabled adult.                       |
| 2690 | 825.103 (3) (c) | 3rd | Exploiting an elderly person or disabled adult and property is valued at less than \$10,000. |
| 2691 |                 |     |  |

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| 2692 | 827.03 (2) (c)    | 3rd | Abuse of a child.   |
| 2693 | 827.03 (2) (d)    | 3rd | Neglect of a child.   |
| 2694 | 827.071 (2) & (3) | 2nd | Use or induce a child in a sexual performance, or promote or direct such performance.                             |
| 2695 | 836.05            | 2nd | Threats; extortion.   |
| 2696 | 836.10            | 2nd | Written threats to kill or do bodily injury.  |
| 2697 | 843.12            | 3rd | Aids or assists person to escape.   |
| 2698 | 847.011           | 3rd | Distributing, offering to distribute, or possessing with intent to distribute obscene materials depicting minors. |
| 2699 | 847.012           | 3rd | Knowingly using a minor in the production of materials harmful to minors.   |
|      | 847.0135 (2)      | 3rd | Facilitates sexual conduct of   |

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|------|-------------------|-----|---|
|      |                   |     | or with a minor or the visual depiction of such conduct.  |
| 2700 | 914.23            | 2nd | Retaliation against a witness, victim, or informant, with bodily injury.  |
| 2701 | 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. |
| 2702 | 944.40            | 2nd | Escapes.  |
| 2703 | 944.46            | 3rd | Harboring, concealing, aiding escaped prisoners.  |
| 2704 | 944.47 (1) (a) 5. | 2nd | Introduction of contraband (firearm, weapon, or explosive) into correctional facility.  |
| 2705 | 951.22 (1)        | 3rd | Intoxicating drug, firearm, or weapon introduced into county facility.  |

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2706

2707

Section 20. This act shall take effect July 1, 2016.