

1                   A bill to be entitled  
2           An act relating to drugs, devices, and cosmetics; amending  
3           and reorganizing provisions in part I of ch. 499, F.S.;  
4           amending s. 499.002, F.S.; expanding the provisions of the  
5           section to include administration and enforcement of,  
6           exemptions from, and purpose of the part; amending and  
7           redesignating ss. 499.004, 499.0053, 499.07, 499.071, and  
8           499.081, F.S., as provisions in that section relating to  
9           such functions to conform; amending s. 499.003, F.S.;  
10          revising and providing definitions; amending and  
11          redesignating provisions in ss. 499.012, 499.029, and  
12          499.0661, F.S., relating to definitions, as provisions of  
13          that section; amending s. 499.005, F.S.; conforming  
14          provisions to changes made by the act, including the  
15          substitution of the term "prescription drug" for the term  
16          "legend drug"; amending s. 499.0051, F.S.; substituting  
17          the term "prescription drug" for the term "legend drug"  
18          with regard to criminal acts; consolidating criminal act  
19          provisions of part I of ch. 499, F.S.; amending and  
20          redesignating ss. 499.0052, 499.00535, 499.00545, 499.069,  
21          and 499.0691, F.S., as criminal offense provisions in that  
22          section; providing penalties; conforming provisions to  
23          changes made by the act; amending s. 499.0054, F.S.,  
24          relating to advertising and labeling of drugs, devices,  
25          and cosmetics to include certain exemptions; amending and  
26          redesignating ss. 499.0055 and 499.0057, F.S., as  
27          provisions relating to those functions in that section;  
28          amending s. 499.006, F.S.; conforming provisions to

29 | changes made by the act; amending s. 499.007, F.S.;

30 | conforming provisions to changes made by the act;

31 | providing that a drug or device is misbranded if it is an

32 | active pharmaceutical ingredient in bulk form and does not

33 | bear a label containing certain information; amending ss.

34 | 499.008 and 499.009, F.S.; conforming provisions to

35 | changes made by the act; amending s. 499.01, F.S.;

36 | providing that the section relates only to permits;

37 | requiring a permit to operate as a third party logistics

38 | provider and a health care clinic establishment; providing

39 | requirements for obtaining a permit to operate in certain

40 | capacities; deleting certain permit requirements;

41 | providing an exemption for a nonresident prescription drug

42 | manufacturer permit; providing requirements for such

43 | exemption; providing requirements for a third party

44 | logistics provider permit and a health care clinic

45 | establishment permit; amending and redesignating

46 | provisions of ss. 499.013, and 499.014, F.S., relating to

47 | such functions as provisions of that section; conforming

48 | provisions and cross-references to changes made by the

49 | act; amending s. 499.012, F.S.; providing that the section

50 | relates to permit application requirements; providing that

51 | a separate establishment permit is not required when a

52 | permitted prescription drug wholesale distributor operates

53 | temporary transit storage facilities for the sole purpose

54 | of storage; amending the provisions to conform; amending

55 | and redesignating provisions of s. 499.01, F.S., relating

56 | to such functions as provisions of that section;

57 conforming provisions and cross-references to changes made  
58 by the act; amending s. 499.01201, F.S.; conforming  
59 provisions to changes made by the act; amending s.  
60 499.0121, F.S., relating to storage and handling of  
61 prescription drugs and recordkeeping; directing the  
62 department to adopt rules requiring a wholesale  
63 distributor to maintain pedigree papers separate and  
64 distinct from other required records; deleting a  
65 requirement that a person who is engaged in the wholesale  
66 distribution of a prescription drug and who is not the  
67 manufacturer of that drug provide a pedigree paper to the  
68 person who receives the drug; deleting the department's  
69 requirement to adopt rules with regard to recordkeeping by  
70 affiliated groups; conforming provisions and cross-  
71 references to changes made by the act; amending and  
72 redesignating a provision of s. 499.013, F.S., relating to  
73 such functions as a provision of that section; amending s.  
74 499.01211, F.S.; conforming provisions and cross-  
75 references to changes made by the act; creating s.  
76 499.01212, F.S.; requiring a person who is engaged in the  
77 wholesale distribution of a prescription drug to provide a  
78 pedigree paper to the person who receives the drug;  
79 requiring certain information in a pedigree paper;  
80 requiring a wholesale distributor to maintain and make  
81 available to the department certain information; providing  
82 exceptions to the requirement of a pedigree paper;  
83 repealing s. 499.0122, F.S., relating to medical oxygen  
84 and veterinary legend drug retail establishments;

85 |       repealing s. 499.013, F.S., relating to manufacturers and  
86 |       repackagers of drugs, devices, and cosmetics; amending ss.  
87 |       499.015, 499.024, 499.028, 499.029, and 499.03, F.S.;  
88 |       conforming provisions and cross-references to changes made  
89 |       by the act; amending ss. 499.032 and 499.033, F.S.;  
90 |       conforming terminology to changes made by the act;  
91 |       amending s. 499.039, F.S.; conforming a provision and  
92 |       cross-reference; amending ss. 499.04, F.S.; conforming  
93 |       provisions to changes made by the act; amending s.  
94 |       499.041, F.S.; conforming provisions to changes made by  
95 |       the act; requiring the department to assess an annual fee  
96 |       for a third part logistic provider permit and a health  
97 |       care clinic establishment permit; amending s. 499.05,  
98 |       F.S.; conforming provisions to changes made by the act;  
99 |       requiring the department to adopt rules with regard to  
100 |       procedures and forms relating to pedigree paper  
101 |       requirements, alternatives to compliance with the  
102 |       requirement of certain pedigree papers, and the return of  
103 |       prescription drugs purchased before a specified date;  
104 |       amending and redesignating provisions of ss. 499.013 and  
105 |       499.0122, F.S., as provisions relating to rulemaking  
106 |       functions of that section; amending ss. 499.051, 499.052,  
107 |       499.055, and 499.06, F.S.; conforming provisions to  
108 |       changes made by the act; amending s. 499.062, F.S.;  
109 |       providing that the section relates to seizure and  
110 |       condemnation of drugs, devices, or cosmetics; conforming a  
111 |       provision to changes made by the act; amending and  
112 |       redesignating ss. 499.063 and 499.064, F.S., as provisions

113 relating to such functions in that section; amending ss.  
 114 499.065, 499.066, 499.0661, and 499.067, F.S.; conforming  
 115 provisions and cross-references to changes made by the  
 116 act; amending ss. 409.9201, 460.403, 465.0265, 794.075,  
 117 895.02, and 921.0022, F.S.; conforming provisions to  
 118 changes made by the act; conforming cross-references to  
 119 changes made by the act; providing an effective date.  
 120

121 Be It Enacted by the Legislature of the State of Florida:  
 122

123 Section 1. Section 499.002, Florida Statutes, is amended;  
 124 section 499.004, Florida Statutes, is redesignated as subsection  
 125 (2) of that section and amended; section 499.0053, Florida  
 126 Statutes, is redesignated as subsection (3) of that section and  
 127 amended; section 499.07, Florida Statutes, is redesignated as  
 128 subsection (4) of that section and amended; section 499.071,  
 129 Florida Statutes, is redesignated as subsection (5) of that  
 130 section and amended; and section 499.081, Florida Statutes, is  
 131 redesignated as subsection (6) of that section and amended, to  
 132 read:

133 499.002 Purpose, administration, and enforcement of and  
 134 exemption from this part ss. 499.001-499.081.--

135 (1) This part is Sections 499.001-499.081 are intended to:

136 (a) ~~(1)~~ Safeguard the public health and promote the public  
 137 welfare by protecting the public from injury by product use and  
 138 by merchandising deceit involving drugs, devices, and cosmetics.

139 (b) ~~(2)~~ Provide uniform legislation to be administered so  
 140 far as practicable in conformity with the provisions of, and

141 regulations issued under the authority of, the Federal Food,  
 142 Drug, and Cosmetic Act and that portion of the Federal Trade  
 143 Commission Act which expressly prohibits the false advertisement  
 144 of drugs, devices, and cosmetics.

145 (c)~~(3)~~ Promote thereby uniformity of such state and  
 146 federal laws, and their administration and enforcement,  
 147 throughout the United States.

148 (2) ~~499.004 Administration and enforcement by~~  
 149 ~~department.~~ The department of Health shall administer and  
 150 enforce this part ~~ss. 499.001-499.081~~ to prevent fraud,  
 151 adulteration, misbranding, or false advertising in the  
 152 preparation, manufacture, repackaging, or distribution of drugs,  
 153 devices, and cosmetics.

154 (3) ~~499.0053 Power to administer oaths, take depositions,~~  
 155 ~~and issue and serve subpoenas.~~ For the purpose of any  
 156 investigation or proceeding conducted by the department under  
 157 this part ~~ss. 499.001-499.081~~, the department may administer  
 158 oaths, take depositions, issue and serve subpoenas, and compel  
 159 the attendance of witnesses and the production of books, papers,  
 160 documents, or other evidence. The department shall exercise this  
 161 power on its own initiative. Challenges to, and enforcement of,  
 162 the subpoenas and orders shall be handled as provided in s.  
 163 120.569.

164 (4) ~~499.07 Duty of prosecuting officer.~~ Each state  
 165 attorney, county attorney, or municipal attorney to whom the  
 166 department or its designated agent reports any violation of this  
 167 part ~~ss. 499.001-499.081~~ shall cause appropriate proceedings to

168 be instituted in the proper courts without delay and to be  
 169 prosecuted in the manner required by law.

170 (5) ~~499.071~~ ~~Issuance of warnings for minor~~  
 171 ~~violations. This part does~~ ~~Sections 499.001-499.081~~ do not  
 172 require the department to report, for the institution of  
 173 proceedings under this part ~~ss. 499.001-499.081~~, minor  
 174 violations of this part ~~ss. 499.001-499.081~~ when it believes  
 175 that the public interest will be adequately served in the  
 176 circumstances by a suitable written notice or warning.

177 (6) ~~499.081~~ ~~Carriers in interstate commerce exempted from~~  
 178 ~~ss. 499.001-499.081.~~ Common carriers engaged in interstate  
 179 commerce are not subject to this part ~~ss. 499.001-499.081~~ if  
 180 they are engaged in the usual course of business as common  
 181 carriers.

182 Section 2. Section 499.003, Florida Statutes, is amended;  
 183 paragraphs (a) through (f) of subsection (1) of section 499.012,  
 184 Florida Statutes, are redesignated as subsections (55), (56),  
 185 (52), and (48), paragraph (c) of subsection (48), and subsection  
 186 (53), respectively, of that section and amended; paragraphs (f)  
 187 through (j) and (l) through (m) of subsection (3) of section  
 188 499.029, Florida Statutes, are redesignated as subsections (25),  
 189 (26), (27), (35), (40), and (41), and, respectively, of that  
 190 section and amended; and subsection (1) of section 499.0661,  
 191 Florida Statutes, is redesignated as subsection (38) of that  
 192 section and amended, to read:

193 499.003 Definitions of terms used in this part ~~ss.~~  
 194 ~~499.001-499.081.~~ --As used in this part ~~ss. 499.001-499.081~~, the  
 195 term:

196 (1) "Advertisement" means any representation disseminated  
 197 in any manner or by any means, other than by labeling, for the  
 198 purpose of inducing, or which is likely to induce, directly or  
 199 indirectly, the purchase of drugs, devices, or cosmetics.

200 (2) "Affiliated group" means an affiliated group as  
 201 defined by s. 1504 of the Internal Revenue Code of 1986, as  
 202 amended, which is composed of chain drug entities, including at  
 203 least 50 retail pharmacies, warehouses, or repackagers, which  
 204 are members of the same affiliated group. The affiliated group  
 205 must disclose the names of all its members to the department.

206 (3) ~~(2)~~ "Affiliated party" means:

207 (a) A director, officer, trustee, partner, or committee  
 208 member of a permittee or applicant or a subsidiary or service  
 209 corporation of the permittee or applicant;

210 (b) A person who, directly or indirectly, manages,  
 211 controls, or oversees the operation of a permittee or applicant,  
 212 regardless of whether such person is a partner, shareholder,  
 213 manager, member, officer, director, independent contractor, or  
 214 employee of the permittee or applicant;

215 (c) A person who has filed or is required to file a  
 216 personal information statement pursuant to s. 499.012(9) ~~s.~~  
 217 ~~499.012(4)~~ or is required to be identified in an application for  
 218 a permit or to renew a permit pursuant to s. 499.012(8) ~~s.~~  
 219 ~~499.012(3)~~; or

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

222 (4) ~~(3)~~ "Applicant" means a person applying for a permit or  
 223 certification under this part ~~ss. 499.001-499.081~~.



224 (5)~~(4)~~ "Authenticate" means to affirmatively verify upon  
 225 receipt before any distribution of a prescription legend drug  
 226 ~~occurs~~ that each transaction listed on the pedigree paper has  
 227 occurred.

228 (a) A wholesale distributor is not required to open a  
 229 sealed, medical convenience kit to authenticate a pedigree paper  
 230 for a prescription drug contained within the kit.

231 (b) Authentication of a prescription drug included in a  
 232 sealed, medical convenience kit shall be limited to verifying  
 233 the transaction and pedigree information received.

234 (6)~~(5)~~ "Certificate of free sale" means a document  
 235 prepared by the department which certifies a drug, device, or  
 236 cosmetic, that is registered with the department, as one that  
 237 can be legally sold in the state.

238 (7) "Chain pharmacy warehouse" means a wholesale  
 239 distributor permitted pursuant to s. 499.01 that maintains a  
 240 physical location for prescription drugs that functions solely  
 241 as a central warehouse to perform intracompany transfers of such  
 242 drugs to a member of its affiliated group.

243 (8)~~(6)~~ "Closed pharmacy" means a pharmacy that is licensed  
 244 under chapter 465 and purchases prescription drugs for use by a  
 245 limited patient population and not for wholesale distribution or  
 246 sale to the public. The term does not include retail pharmacies.

247 (9)~~(7)~~ "Color" includes black, white, and intermediate  
 248 grays.

249 (10)~~(8)~~ "Color additive" means, with the exception of any  
 250 material that has been or hereafter is exempt under the federal  
 251 act, a material that:

252 (a) Is a dye pigment, or other substance, made by a  
 253 process of synthesis or similar artifice, or extracted,  
 254 isolated, or otherwise derived, with or without intermediate or  
 255 final change of identity from a vegetable, animal, mineral, or  
 256 other source; or

257 (b) When added or applied to a drug or cosmetic or to the  
 258 human body, or any part thereof, is capable alone, or through  
 259 reaction with other substances, of imparting color thereto;

261 ~~except that the term does not include any material which has~~  
 262 ~~been or hereafter is exempt under the federal act.~~

263 (11)~~(9)~~ "Compressed medical gas" means any liquefied or  
 264 vaporized gas that is a prescription drug, whether it is alone  
 265 or in combination with other gases.

266 (12)~~(10)~~ "Contraband prescription ~~legend~~ drug" means any  
 267 adulterated drug, as defined in s. 499.006, any counterfeit  
 268 drug, as defined in this section, and also means any  
 269 prescription ~~legend~~ drug for which a pedigree paper does not  
 270 exist, or for which the pedigree paper in existence has been  
 271 forged, counterfeited, falsely created, or contains any altered,  
 272 false, or misrepresented matter.

273 (13)~~(11)~~ "Cosmetic" means an article, with the exception  
 274 of soap, that is:

275 (a) Intended to be rubbed, poured, sprinkled, or sprayed  
 276 on; introduced into; or otherwise applied to the human body or  
 277 any part thereof for cleansing, beautifying, promoting  
 278 attractiveness, or altering the appearance; or

279 (b) Intended for use as a component of any such article;

280  
 281 ~~except that the term does not include soap.~~

282       (14)~~(12)~~ "Counterfeit drug," "counterfeit device," or  
 283 "counterfeit drug, ~~counterfeit device, or counterfeit~~ cosmetic"  
 284 means a drug, device, or cosmetic which, or the container, seal,  
 285 or labeling of which, without authorization, bears the  
 286 trademark, trade name, or other identifying mark, imprint, or  
 287 device, or any likeness thereof, of a drug, device, or cosmetic  
 288 manufacturer, processor, packer, or distributor other than the  
 289 person that in fact manufactured, processed, packed, or  
 290 distributed that drug, device, or cosmetic and which thereby  
 291 falsely purports or is represented to be the product of, or to  
 292 have been packed or distributed by, that other drug, device, or  
 293 cosmetic manufacturer, processor, packer, or distributor.

294       (15)~~(13)~~ "Department" means the Department of Health.

295       (16)~~(14)~~ "Device" means any instrument, apparatus,  
 296 implement, machine, contrivance, implant, in vitro reagent, or  
 297 other similar or related article, including its components,  
 298 parts, or accessories, which is:

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

301           (b) Intended for use in the diagnosis, cure, mitigation,  
 302 treatment, therapy, or prevention of disease in humans or other  
 303 animals, or

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

306

307 and that ~~which~~ does not achieve any of its principal intended  
 308 purposes through chemical action within or on the body of humans  
 309 or other animals and which is not dependent upon being  
 310 metabolized for the achievement of any of its principal intended  
 311 purposes.

312 (17) ~~(15)~~ "Distribute ~~or distribution~~" or "distribution"  
 313 means to sell; offer to sell; give away; transfer, whether by  
 314 passage of title, physical movement, or both; deliver; or offer  
 315 to deliver. The term does not mean to administer or dispense.

316 (18) "Drop shipment" means the sale of a prescription drug  
 317 from a manufacturer to a wholesale distributor, where the  
 318 wholesale distributor takes title to, but not possession of, the  
 319 prescription drug and the manufacturer of the prescription drug  
 320 ships the prescription drug directly to a chain pharmacy  
 321 warehouse or a person authorized by law to purchase prescription  
 322 drugs for the purpose of administering or dispensing the drug,  
 323 as defined in s. 465.003.

324 ~~(16)~~ "~~Diverted from the legal channels of distribution for~~  
 325 ~~prescription drugs~~" means an adulterated drug pursuant to s.  
 326 ~~499.006(10).~~

327 (19) ~~(17)~~ "Drug" means an article that is:

328 (a) Recognized in the current edition of the United States  
 329 Pharmacopoeia and National Formulary, official Homeopathic  
 330 Pharmacopoeia of the United States, or any supplement to any of  
 331 those publications;

332 (b) Intended for use in the diagnosis, cure, mitigation,  
 333 treatment, therapy, or prevention of disease in humans or other  
 334 animals;

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

337 (d) Intended for use as a component of any article  
 338 specified in paragraph (a), paragraph (b), or paragraph (c), but  
 339 does not include devices or their components, parts, or  
 340 accessories.

341 ~~(20)~~~~(18)~~ "Establishment" means a place of business at one  
 342 general physical location.

343 ~~(21)~~~~(19)~~ "Federal act" means the Federal Food, Drug, and  
 344 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

345 ~~(22)~~~~(20)~~ "Freight forwarder" means a person who receives  
 346 prescription legend ~~legend~~ drugs which are owned by another person and  
 347 designated by that person for export, and exports those  
 348 prescription legend ~~legend~~ drugs.

349 ~~(23)~~~~(21)~~ "Health care entity" means a closed pharmacy or  
 350 any person, organization, or business entity that provides  
 351 diagnostic, medical, surgical, or dental treatment or care, or  
 352 chronic or rehabilitative care, but does not include any  
 353 wholesale distributor or retail pharmacy licensed under state  
 354 law to deal in prescription drugs.

355 ~~(24)~~~~(f)~~ "Health care facility" means a health care  
 356 facility licensed under chapter 395.

357 ~~(25)~~~~(h)~~ "Hospice" means a corporation licensed under part  
 358 IV of chapter 400.

359 ~~(26)~~~~(i)~~ "Hospital" means a facility as defined in s.  
 360 395.002 and licensed under chapter 395.

361 ~~(27)~~~~(22)~~ "Immediate container" does not include package  
 362 liners.

363        ~~(28)~~(23) "Label" means a display of written, printed, or  
 364 graphic matter upon the immediate container of any drug, device,  
 365 or cosmetic. A requirement made by or under authority of this  
 366 part ss. 499.001-499.081 or rules adopted under this part ~~these~~  
 367 ~~sections~~ that any word, statement, or other information appear  
 368 on the label is not complied with unless such word, statement,  
 369 or other information also appears on the outside container or  
 370 wrapper, if any, of the retail package of such drug, device, or  
 371 cosmetic or is easily legible through the outside container or  
 372 wrapper.

373        ~~(29)~~(24) "Labeling" means all labels and other written,  
 374 printed, or graphic matters:

375            (a) Upon a drug, device, or cosmetic, or any of its  
 376 containers or wrappers; or

377            (b) Accompanying or related to such drug, device, or  
 378 cosmetic.

379        ~~(25)~~ "Legend drug," "prescription drug," or "medicinal  
 380 drug" means any drug, including, but not limited to, finished  
 381 dosage forms, or active ingredients subject to, defined by, or  
 382 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
 383 Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or  
 384 (c).

385        ~~(26)~~ "Legend drug label" means any display of written,  
 386 printed, or graphic matter upon the immediate container of any  
 387 legend drug prior to its dispensing to an individual patient  
 388 pursuant to a prescription of a practitioner authorized by law  
 389 to prescribe.

390           ~~(30)-(27)~~ "Manufacture" means the preparation, deriving,  
 391           compounding, propagation, processing, producing, or fabrication  
 392           of any drug, device, or cosmetic.

393           ~~(31)-(28)~~ "Manufacturer" means:

394           (a) A person who prepares, derives, manufactures, or  
 395           produces a drug, device, or cosmetic.

396           (b) The holder or holders of a New Drug Application (NDA),  
 397           an Abbreviated New Drug Application (ANDA), a Biologics License  
 398           Application (BLA), or a New Animal Drug Application (NADA),  
 399           provided such application has become effective or is otherwise  
 400           approved consistent with s. 499.023; a private label distributor  
 401           for whom the private label distributor's prescription drugs are  
 402           originally manufactured and labeled for the distributor and have  
 403           not been repackaged; or the distribution point for the  
 404           manufacturer, contract manufacturer, or private label  
 405           distributor whether the establishment is a member of the  
 406           manufacturer's affiliated group or is a contract distribution  
 407           site.

408  
 409           The term excludes pharmacies that are operating in compliance  
 410           with pharmacy practice standards as defined in chapter 465 and  
 411           rules adopted under that chapter.

412           ~~(32)-(29)~~ "New drug" means:

413           (a) Any drug the composition of which is such that the  
 414           drug is not generally recognized, among experts qualified by  
 415           scientific training and experience to evaluate the safety and  
 416           effectiveness of drugs, as safe and effective for use under the

417 conditions prescribed, recommended, or suggested in the labeling  
 418 of that drug; or

419 (b) Any drug the composition of which is such that the  
 420 drug, as a result of investigations to determine its safety and  
 421 effectiveness for use under certain conditions, has been  
 422 recognized for use under such conditions, but which drug has  
 423 not, other than in those investigations, been used to a material  
 424 extent or for a material time under such conditions.

425 (33) "Normal distribution chain" means a wholesale  
 426 distribution of a prescription drug in which the wholesale  
 427 distributor or its wholly owned subsidiary purchases and  
 428 receives the specific unit of the prescription drug directly  
 429 from the manufacturer and distributes the prescription drug  
 430 directly, or through up to two intracompany transfers, to a  
 431 chain pharmacy warehouse or a person authorized by law to  
 432 purchase prescription drugs for the purpose of administering or  
 433 dispensing the drug, as defined in s. 465.003. For purposes of  
 434 this subsection, the term "intracompany" means any transaction  
 435 or transfer between any parent, division, or subsidiary wholly  
 436 owned by a corporate entity.

437 ~~(34)(j)~~ "Nursing home" means a facility licensed under  
 438 part II of chapter 400.

439 ~~(35)(30)~~ "Official compendium" means the current edition  
 440 of the official United States Pharmacopoeia and National  
 441 Formulary, or any supplement thereto.

442 ~~(36)(31)~~ "Pedigree paper" means-

443 ~~(a)~~ ~~Effective July 1, 2006,~~ A document in written or  
 444 electronic form approved by the department which contains ~~of~~



445 ~~Health and containing information required by s. 499.01212~~  
446 ~~regarding the sale and that records each distribution of any~~  
447 ~~given prescription legend drug, from sale by a pharmaceutical~~  
448 ~~manufacturer, through acquisition and sale by any wholesaler or~~  
449 ~~repackager, until final sale to a pharmacy or other person~~  
450 ~~administering or dispensing the drug. The information required~~  
451 ~~to be included on the form approved by the department pursuant~~  
452 ~~to this paragraph must at least detail the amount of the legend~~  
453 ~~drug; its dosage form and strength; its lot numbers; the name~~  
454 ~~and address of each owner of the legend drug and his or her~~  
455 ~~signature; its shipping information, including the name and~~  
456 ~~address of each person certifying delivery or receipt of the~~  
457 ~~legend drug; an invoice number, a shipping document number, or~~  
458 ~~another number uniquely identifying the transaction; and a~~  
459 ~~certification that the recipient wholesaler has authenticated~~  
460 ~~the pedigree papers. If the manufacturer or repackager has~~  
461 ~~uniquely serialized the individual legend drug unit, that~~  
462 ~~identifier must also be included on the form approved pursuant~~  
463 ~~to this paragraph. It must also include the name, address,~~  
464 ~~telephone number and, if available, e-mail contact information~~  
465 ~~of each wholesaler involved in the chain of the legend drug's~~  
466 ~~custody; or~~

467 ~~(b) A statement, under oath, in written or electronic~~  
468 ~~form, confirming that a wholesale distributor purchases and~~  
469 ~~receives the specific unit of the prescription drug directly~~  
470 ~~from the manufacturer of the prescription drug and distributes~~  
471 ~~the prescription drug directly, or through an intracompany~~  
472 ~~transfer, to a chain pharmacy warehouse or a person authorized~~

473 ~~by law to purchase prescription drugs for the purpose of~~  
474 ~~administering or dispensing the drug, as defined in s. 465.003.~~  
475 ~~For purposes of this subsection, the term "chain pharmacy~~  
476 ~~warehouse" means a wholesale distributor permitted pursuant to~~  
477 ~~s. 499.01 that maintains a physical location for prescription~~  
478 ~~drugs that functions solely as a central warehouse to perform~~  
479 ~~intracompany transfers of such drugs to a member of its~~  
480 ~~affiliated group as described in s. 499.0121(6)(f)1.~~

481 ~~1. The information required to be included pursuant to~~  
482 ~~this paragraph must include:~~

483 ~~a. The following statement: "This wholesale distributor~~  
484 ~~purchased the specific unit of the prescription drug directly~~  
485 ~~from the manufacturer."~~

486 ~~b. The manufacturer's national drug code identifier and~~  
487 ~~the name and address of the wholesaler and the purchaser of the~~  
488 ~~prescription drug.~~

489 ~~c. The name of the prescription drug as it appears on the~~  
490 ~~label.~~

491 ~~d. The quantity, dosage form, and strength of the~~  
492 ~~prescription drug.~~

493 ~~2. The wholesale distributor must also maintain and make~~  
494 ~~available to the department, upon request, the point of origin~~  
495 ~~of the prescription drugs, including intracompany transfers; the~~  
496 ~~date of the shipment from the manufacturer to the wholesale~~  
497 ~~distributor; the lot numbers of such drugs; and the invoice~~  
498 ~~numbers from the manufacturer.~~

499

500 ~~The department may adopt rules and forms relating to the~~  
 501 ~~requirements of this subsection.~~

502 ~~(37)(1) DEFINITION. As used in this section, the term~~  
 503 "Permittee" means any person holding a permit issued pursuant to  
 504 s. 499.012.

505 ~~(38)(32)~~ "Person" means any individual, child, joint  
 506 venture, syndicate, fiduciary, partnership, corporation,  
 507 division of a corporation, firm, trust, business trust, company,  
 508 estate, public or private institution, association,  
 509 organization, group, city, county, city and county, political  
 510 subdivision of this state, other governmental agency within this  
 511 state, and any representative, agent, or agency of any of the  
 512 foregoing, or any other group or combination of the foregoing.

513 ~~(39)(1)~~ "Pharmacist" means a person licensed under chapter  
 514 465.

515 ~~(40)(m)~~ "Pharmacy" means an entity licensed under chapter  
 516 465.

517 ~~(41)(33)~~ "Prepackaged drug product" means a drug that  
 518 originally was in finished packaged form sealed by a  
 519 manufacturer and that is placed in a properly labeled container  
 520 by a pharmacy or practitioner authorized to dispense pursuant to  
 521 chapter 465 for the purpose of dispensing in the establishment  
 522 in which the prepackaging occurred.

523 (42) "Prescription drug" means a prescription, medicinal,  
 524 or legend drug, including, but not limited to, finished dosage  
 525 forms or active ingredients subject to, defined by, or described  
 526 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s.

527 465.003(8), s. 499.007(13), or subsection (11), subsection (47),  
 528 or subsection (54).

529 (43) "Prescription drug label" means any display of  
 530 written, printed, or graphic matter upon the immediate container  
 531 of any prescription drug prior to its dispensing to an  
 532 individual patient pursuant to a prescription of a practitioner  
 533 authorized by law to prescribe.

534 (44)~~(34)~~ "Prescription label" means any display of  
 535 written, printed, or graphic matter upon the immediate container  
 536 of any prescription ~~legend~~ drug dispensed pursuant to a  
 537 prescription of a practitioner authorized by law to prescribe.

538 (45)~~(35)~~ "Prescription medical oxygen" means oxygen USP  
 539 which is a drug that can only be sold on the order or  
 540 prescription of a practitioner authorized by law to prescribe.  
 541 The label of prescription medical oxygen must comply with  
 542 current labeling requirements for oxygen under the Federal Food,  
 543 Drug, and Cosmetic Act.

544 (46)~~(d)~~ "Primary wholesale distributor ~~wholesaler~~" means  
 545 any wholesale distributor that:

546 (a)~~1.~~ Purchased 90 percent or more of the total dollar  
 547 volume of its purchases of prescription drugs directly from  
 548 manufacturers in the previous year; and

549 (b)~~1.2.a.~~ Directly purchased prescription drugs from not  
 550 fewer than 50 different prescription drug manufacturers in the  
 551 previous year; or

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

555            (c)~~(e)~~ For purposes of this subsection, "directly from  
 556 manufacturers ~~a manufacturer~~" means:

557            1. Purchases made by the wholesale distributor directly  
 558 from the manufacturer of prescription drugs; and

559            2. Transfers from a member of an affiliated group, as  
 560 defined in s. 1504 of the Internal Revenue Code, of which the  
 561 wholesale distributor is a member, if:

562            a. The affiliated group purchases 90 percent or more of  
 563 the total dollar volume of its purchases of prescription drugs  
 564 from the manufacturer in the previous year; and

565            b. The wholesale distributor discloses to the department  
 566 the names of all members of the affiliated group of which the  
 567 wholesale distributor is a member and the affiliated group  
 568 agrees in writing to provide records on prescription drug  
 569 purchases by the members of the affiliated group not later than  
 570 48 hours after the department requests access to such records,  
 571 regardless of the location where the records are stored.

572            (47)~~(36)~~ "Proprietary drug," or "OTC drug," means a patent  
 573 or over-the-counter drug in its unbroken, original package,  
 574 which drug is sold to the public by, or under the authority of,  
 575 the manufacturer or primary distributor thereof, is not  
 576 misbranded under the provisions of this part ~~ss. 499.001-~~  
 577 ~~499.081~~, and can be purchased without a prescription.

578            (48)~~(37)~~ "Repackage" includes repacking or otherwise  
 579 changing the container, wrapper, or labeling to further the  
 580 distribution of the drug, device, or cosmetic.

581            (49)~~(38)~~ "Repackager" means a person who repackages. The  
 582 term excludes pharmacies that are operating in compliance with

583 pharmacy practice standards as defined in chapter 465 and rules  
 584 adopted under that chapter.

585 (50)~~(e)~~ "Retail pharmacy" means a community pharmacy  
 586 licensed under chapter 465 that purchases prescription drugs at  
 587 fair market prices and provides prescription services to the  
 588 public.

589 (51)~~(f)~~ "Secondary wholesale distributor ~~wholesaler~~" means  
 590 a wholesale distributor that is not a primary wholesale  
 591 distributor ~~wholesaler~~.

592 (53)~~(39)~~ "Veterinary prescription drug" means a  
 593 prescription ~~legend~~ drug intended solely for veterinary use. The  
 594 label of the drug must bear the statement, "Caution: Federal law  
 595 restricts this drug to sale by or on the order of a licensed  
 596 veterinarian."

597 ~~(40) "Veterinary prescription drug wholesaler" means any~~  
 598 ~~person engaged in wholesale distribution of veterinary~~  
 599 ~~prescription drugs in or into this state.~~

600 (54)~~(a)~~ "Wholesale distribution" means distribution of  
 601 prescription drugs to persons other than a consumer or patient,  
 602 but does not include:

603 (a)~~1.~~ Any of the following activities, which is not a  
 604 violation of s. 499.005(21) if such activity is conducted in  
 605 accordance with s. 499.01(2)(g) ~~s. 499.014~~:

606 1.a.~~1.~~ The purchase or other acquisition by a hospital or  
 607 other health care entity that is a member of a group purchasing  
 608 organization of a prescription drug for its own use from the  
 609 group purchasing organization or from other hospitals or health  
 610 care entities that are members of that organization.

611            2.b. The sale, purchase, or trade of a prescription drug  
 612 or an offer to sell, purchase, or trade a prescription drug by a  
 613 charitable organization described in s. 501(c)(3) of the  
 614 Internal Revenue Code of 1986, as amended and revised, to a  
 615 nonprofit affiliate of the organization to the extent otherwise  
 616 permitted by law.

617            3.e. The sale, purchase, or trade of a prescription drug  
 618 or an offer to sell, purchase, or trade a prescription drug  
 619 among hospitals or other health care entities that are under  
 620 common control. For purposes of this subparagraph ~~section~~,  
 621 "common control" means the power to direct or cause the  
 622 direction of the management and policies of a person or an  
 623 organization, whether by ownership of stock, by voting rights,  
 624 by contract, or otherwise.

625            4.d. The sale, purchase, trade, or other transfer of a  
 626 prescription drug from or for any federal, state, or local  
 627 government agency or any entity eligible to purchase  
 628 prescription drugs at public health services prices pursuant to  
 629 Pub. L. No. 102-585, s. 602 to a contract provider or its  
 630 subcontractor for eligible patients of the agency or entity  
 631 under the following conditions:

632            a.(I) The agency or entity must obtain written  
 633 authorization for the sale, purchase, trade, or other transfer  
 634 of a prescription drug under this subparagraph ~~sub-subparagraph~~  
 635 from the State Surgeon General or his or her designee.

636            b.(II) The contract provider or subcontractor must be  
 637 authorized by law to administer or dispense prescription drugs.

638        ~~c.-(III)~~ In the case of a subcontractor, the agency or  
639 entity must be a party to and execute the subcontract.

640        ~~d.-(IV)~~ A contract provider or subcontractor must maintain  
641 separate and apart from other prescription drug inventory any  
642 prescription drugs of the agency or entity in its possession.

643        ~~e.-(V)~~ The contract provider and subcontractor must  
644 maintain and produce immediately for inspection all records of  
645 movement or transfer of all the prescription drugs belonging to  
646 the agency or entity, including, but not limited to, the records  
647 of receipt and disposition of prescription drugs. Each  
648 contractor and subcontractor dispensing or administering these  
649 drugs must maintain and produce records documenting the  
650 dispensing or administration. Records that are required to be  
651 maintained include, but are not limited to, a perpetual  
652 inventory itemizing drugs received and drugs dispensed by  
653 prescription number or administered by patient identifier, which  
654 must be submitted to the agency or entity quarterly.

655        ~~f.-(VI)~~ The contract provider or subcontractor may  
656 administer or dispense the prescription drugs only to the  
657 eligible patients of the agency or entity or must return the  
658 prescription drugs for or to the agency or entity. The contract  
659 provider or subcontractor must require proof from each person  
660 seeking to fill a prescription or obtain treatment that the  
661 person is an eligible patient of the agency or entity and must,  
662 at a minimum, maintain a copy of this proof as part of the  
663 records of the contractor or subcontractor required under sub-  
664 subparagraph e. ~~sub-sub-subparagraph (V).~~



665        g.~~(VII)~~ In addition to the departmental inspection  
666 authority set forth in s. 499.051, the establishment of the  
667 contract provider and subcontractor and all records pertaining  
668 to prescription drugs subject to this subparagraph ~~sub-~~  
669 ~~subparagraph~~ shall be subject to inspection by the agency or  
670 entity. All records relating to prescription drugs of a  
671 manufacturer under this subparagraph ~~sub-subparagraph~~ shall be  
672 subject to audit by the manufacturer of those drugs, without  
673 identifying individual patient information.

674        (b)2. Any of the following activities, which is not a  
675 violation of s. 499.005(21) if such activity is conducted in  
676 accordance with rules established by the department:

677        1.a. The sale, purchase, or trade of a prescription drug  
678 among federal, state, or local government health care entities  
679 that are under common control and are authorized to purchase  
680 such prescription drug.

681        2.b. The sale, purchase, or trade of a prescription drug  
682 or an offer to sell, purchase, or trade a prescription drug for  
683 emergency medical reasons. For purposes of this subparagraph  
684 ~~sub-subparagraph~~, the term "emergency medical reasons" includes  
685 transfers of prescription drugs by a retail pharmacy to another  
686 retail pharmacy to alleviate a temporary shortage.

687        3.e. The transfer of a prescription drug acquired by a  
688 medical director on behalf of a licensed emergency medical  
689 services provider to that emergency medical services provider  
690 and its transport vehicles for use in accordance with the  
691 provider's license under chapter 401.

692            ~~4.d.~~ The revocation of a sale or the return of a  
 693 prescription drug to the person's prescription drug wholesale  
 694 supplier.

695            ~~5.e.~~ The donation of a prescription drug by a health care  
 696 entity to a charitable organization that has been granted an  
 697 exemption under s. 501(c)(3) of the Internal Revenue Code of  
 698 1986, as amended, and that is authorized to possess prescription  
 699 drugs.

700            ~~6.f.~~ The transfer of a prescription drug by a person  
 701 authorized to purchase or receive prescription drugs to a person  
 702 licensed or permitted to handle reverse distributions or  
 703 destruction under the laws of the jurisdiction in which the  
 704 person handling the reverse distribution or destruction receives  
 705 the drug.

706            ~~7.g.~~ The transfer of a prescription drug by a hospital or  
 707 other health care entity to a person licensed under this part  
 708 ~~chapter~~ to repackage prescription drugs for the purpose of  
 709 repackaging the prescription drug for use by that hospital, or  
 710 other health care entity and other health care entities that are  
 711 under common control, if ownership of the prescription drugs  
 712 remains with the hospital or other health care entity at all  
 713 times. In addition to the recordkeeping requirements of s.  
 714 499.0121(6), the hospital or health care entity that transfers  
 715 prescription drugs pursuant to this subparagraph ~~sub-~~  
 716 ~~subparagraph~~ must reconcile all drugs transferred and returned  
 717 and resolve any discrepancies in a timely manner.

718            (c)~~3~~. The distribution of prescription drug samples by  
 719 manufacturers' representatives or distributors' representatives  
 720 conducted in accordance with s. 499.028.

721            (d)~~4~~. The sale, purchase, or trade of blood and blood  
 722 components intended for transfusion. As used in this paragraph  
 723 ~~subparagraph~~, the term "blood" means whole blood collected from  
 724 a single donor and processed ~~either~~ for transfusion or further  
 725 manufacturing, and the term "blood components" means that part  
 726 of the blood separated by physical or mechanical means.

727            (e)~~5~~. The lawful dispensing of a prescription drug in  
 728 accordance with chapter 465.

729            (f)~~6~~. The sale, purchase, or trade of a prescription drug  
 730 between pharmacies as a result of a sale, transfer, merger, or  
 731 consolidation of all or part of the business of the pharmacies  
 732 from or with another pharmacy, whether accomplished as a  
 733 purchase and sale of stock or of business assets.

734            (54)~~(b)~~ "Wholesale distributor" means any person engaged  
 735 in wholesale distribution of prescription drugs in or into this  
 736 state, including, but not limited to, manufacturers;  
 737 repackagers; own-label distributors; jobbers; private-label  
 738 distributors; brokers; warehouses, including manufacturers' and  
 739 distributors' warehouses, chain drug warehouses, and wholesale  
 740 drug warehouses; independent wholesale drug traders; exporters;  
 741 retail pharmacies; and the agents thereof that conduct wholesale  
 742 distributions.

743            Section 3. Subsections (4), (10), (11), (12), (14), (15),  
 744 (18), (19), (20), (22), (24), (28), and (29) of section 499.005,  
 745 Florida Statutes, are amended to read:

746           499.005 Prohibited acts.--It is unlawful for a person to  
 747 perform or cause the performance of any of the following acts in  
 748 this state:

749           (4) The sale, distribution, purchase, trade, holding, or  
 750 offering of any drug, device, or cosmetic in violation of this  
 751 part ~~ss. 499.001-499.081~~.

752           (10) Forging; counterfeiting; simulating; falsely  
 753 representing any drug, device, or cosmetic; or, without the  
 754 authority of the manufacturer, using any mark, stamp, tag,  
 755 label, or other identification device authorized or required by  
 756 rules adopted under this part ~~ss. 499.001-499.081~~.

757           (11) The use, on the labeling of any drug or in any  
 758 advertisement relating to such drug, of any representation or  
 759 suggestion that an application of the drug is effective when it  
 760 is not or that the drug complies with this part ~~ss. 499.001-~~  
 761 ~~499.081~~ when it does not.

762           (12) The possession of any drug in violation of this part  
 763 ~~ss. 499.001-499.081~~.

764           (14) The purchase or receipt of a prescription ~~legend~~ drug  
 765 from a person that is not authorized under this chapter to  
 766 distribute prescription ~~legend~~ drugs to that purchaser or  
 767 recipient.

768           (15) The sale or transfer of a prescription ~~legend~~ drug to  
 769 a person that is not authorized under the law of the  
 770 jurisdiction in which the person receives the drug to purchase  
 771 or possess prescription ~~legend~~ drugs from the person selling or  
 772 transferring the prescription ~~legend~~ drug.

773 (18) Failure to maintain records as required by this part  
 774 ~~ss. 499.001-499.081~~ and rules adopted under this part ~~those~~  
 775 ~~sections.~~

776 (19) Providing the department with false or fraudulent  
 777 records, or making false or fraudulent statements, regarding any  
 778 matter within the provisions of this part ~~chapter.~~

779 (20) The importation of a prescription ~~legend~~ drug except  
 780 as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic  
 781 Act.

782 (22) Failure to obtain a permit or registration, or  
 783 operating without a valid permit when a permit or registration  
 784 is required by this part ~~ss. 499.001-499.081~~ for that activity.

785 (24) The distribution of a prescription ~~legend~~ device to  
 786 the patient or ultimate consumer without a prescription or order  
 787 from a practitioner licensed by law to use or prescribe the  
 788 device.

789 (28) Failure to acquire ~~obtain~~ or deliver ~~pass on~~ a  
 790 pedigree paper as required under this part.

791 (29) The receipt of a prescription drug pursuant to a  
 792 wholesale distribution without having previously received or  
 793 simultaneously ~~either first~~ receiving a pedigree paper that was  
 794 attested to as accurate and complete by the wholesale  
 795 distributor as required under this part ~~or complying with the~~  
 796 ~~provisions of s. 499.0121(6)(d)5.~~

797 Section 4. Section 499.0051, Florida Statutes, is amended;  
 798 section 499.0052, Florida Statutes, is redesignated as  
 799 subsection (7) of that section and amended; section 499.00535,  
 800 Florida Statutes, is redesignated as subsection (9) of that

801 section and amended; section 499.00545, Florida Statutes, is  
 802 redesignated as subsection (10) of that section and amended;  
 803 section 499.069, Florida Statutes, is redesignated as subsection  
 804 (11) of that section and amended; and section 499.0691, Florida  
 805 Statutes, is redesignated as subsections (12) through (15) of  
 806 that section and amended, to read:

807 499.0051 Criminal acts ~~involving contraband or adulterated~~  
 808 ~~drugs~~.--

809 (1) FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.--

810 (a) A person, other than a manufacturer, engaged in the  
 811 wholesale distribution of prescription legend ~~legend~~ drugs who fails to  
 812 deliver to another person complete and accurate pedigree papers  
 813 concerning a prescription legend ~~legend~~ drug or contraband prescription  
 814 legend ~~legend~~ drug prior to, or simultaneous with, the transfer of  
 815 ~~transferring~~ the prescription legend ~~legend~~ drug or contraband  
 816 prescription legend ~~legend~~ drug to another person commits a felony of  
 817 the third degree, punishable as provided in s. 775.082, s.  
 818 775.083, or s. 775.084.

819 (b) A person engaged in the wholesale distribution of  
 820 prescription legend ~~legend~~ drugs who fails to acquire complete and  
 821 accurate pedigree papers concerning a prescription legend ~~legend~~ drug  
 822 or contraband prescription legend ~~legend~~ drug prior to, or simultaneous  
 823 with, the receipt of obtaining ~~obtaining~~ the prescription legend ~~legend~~ drug or  
 824 contraband prescription legend ~~legend~~ drug from another person commits  
 825 a felony of the third degree, punishable as provided in s.  
 826 775.082, s. 775.083, or s. 775.084.

827 (c) Any person who knowingly destroys, alters, conceals,  
 828 or fails to maintain complete and accurate pedigree papers

829 concerning any prescription ~~legend~~ drug or contraband  
830 prescription ~~legend~~ drug in his or her possession commits a  
831 felony of the third degree, punishable as provided in s.  
832 775.082, s. 775.083, or s. 775.084.

833 (2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.--Effective  
834 July 1, 2006:

835 (a) A person engaged in the wholesale distribution of  
836 prescription ~~legend~~ drugs who is in possession of pedigree  
837 papers concerning prescription ~~legend~~ drugs or contraband  
838 prescription ~~legend~~ drugs and who fails to authenticate the  
839 matters contained in the pedigree papers and who nevertheless  
840 attempts to further distribute prescription ~~legend~~ drugs or  
841 contraband prescription ~~legend~~ drugs commits a felony of the  
842 third degree, punishable as provided in s. 775.082, s. 775.083,  
843 or s. 775.084.

844 (b) A person in possession of pedigree papers concerning  
845 prescription ~~legend~~ drugs or contraband prescription ~~legend~~  
846 drugs who falsely swears or certifies that he or she has  
847 authenticated the matters contained in the pedigree papers  
848 commits a felony of the third degree, punishable as provided in  
849 s. 775.082, s. 775.083, or s. 775.084.

850 (3) KNOWING FORGERY OF PEDIGREE PAPERS.--A person who  
851 knowingly forges, counterfeits, or falsely creates any pedigree  
852 paper; who falsely represents any factual matter contained on  
853 any pedigree paper; or who knowingly omits to record material  
854 information required to be recorded in a pedigree paper, commits  
855 a felony of the second degree, punishable as provided in s.  
856 775.082, s. 775.083, or s. 775.084.

857           (4) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION ~~LEGEND~~  
 858 DRUG FROM UNAUTHORIZED PERSON.--A person who knowingly purchases  
 859 or receives from a person not authorized to distribute  
 860 prescription ~~legend~~ drugs under this chapter a prescription  
 861 ~~legend~~ drug in a wholesale distribution transaction commits a  
 862 felony of the second degree, punishable as provided in s.  
 863 775.082, s. 775.083, or s. 775.084.

864           (5) KNOWING SALE OR TRANSFER OF PRESCRIPTION ~~LEGEND~~ DRUG  
 865 TO UNAUTHORIZED PERSON.--A person who knowingly sells or  
 866 transfers to a person not authorized to purchase or possess  
 867 prescription ~~legend~~ drugs, under the law of the jurisdiction in  
 868 which the person receives the drug, a prescription ~~legend~~ drug  
 869 in a wholesale distribution transaction commits a felony of the  
 870 second degree, punishable as provided in s. 775.082, s. 775.083,  
 871 or s. 775.084.

872           (6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO  
 873 SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is  
 874 knowingly in actual or constructive possession of any amount of  
 875 contraband prescription ~~legend~~ drugs, who knowingly sells or  
 876 delivers, or who possesses with intent to sell or deliver any  
 877 amount of contraband prescription ~~legend~~ drugs, commits a felony  
 878 of the second degree, punishable as provided in s. 775.082, s.  
 879 775.083, or s. 775.084.

880           (7) ~~499.0052~~ KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION  
 881 ~~LEGEND~~ DRUGS.--A person who knowingly sells, purchases,  
 882 manufactures, delivers, or brings into this state, or who is  
 883 knowingly in actual or constructive possession of any amount of  
 884 contraband prescription ~~legend~~ drugs valued at \$25,000 or more



885 commits a felony of the first degree, punishable as provided in  
 886 s. 775.082, s. 775.083, or s. 775.084.

887 (a) Upon conviction, each defendant shall be ordered to  
 888 pay a mandatory fine according to the following schedule:

889 1.(1) If the value of contraband prescription ~~legend~~ drugs  
 890 involved is \$25,000 or more, but less than \$100,000, the  
 891 defendant shall pay a mandatory fine of \$25,000. If the  
 892 defendant is a corporation or other person that is not a natural  
 893 person, it shall pay a mandatory fine of \$75,000.

894 2.(2) If the value of contraband prescription ~~legend~~ drugs  
 895 involved is \$100,000 or more, but less than \$250,000, the  
 896 defendant shall pay a mandatory fine of \$100,000. If the  
 897 defendant is a corporation or other person that is not a natural  
 898 person, it shall pay a mandatory fine of \$300,000.

899 3.(3) If the value of contraband prescription ~~legend~~ drugs  
 900 involved is \$250,000 or more, the defendant shall pay a  
 901 mandatory fine of \$200,000. If the defendant is a corporation or  
 902 other person that is not a natural person, it shall pay a  
 903 mandatory fine of \$600,000.

904 (b) As used in this subsection ~~section~~, the term "value"  
 905 means the market value of the property at the time and place of  
 906 the offense or, if such cannot be satisfactorily ascertained,  
 907 the cost of replacement of the property within a reasonable time  
 908 after the offense. Amounts of value of separate contraband  
 909 prescription ~~legend~~ drugs involved in distinct transactions for  
 910 the distribution of the contraband prescription ~~legend~~ drugs  
 911 committed pursuant to one scheme or course of conduct, whether

912 involving the same person or several persons, may be aggregated  
 913 in determining the punishment of the offense.

914 (8)~~(7)~~ KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION  
 915 ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges,  
 916 counterfeits, or falsely creates any prescription label or  
 917 prescription legend drug label, or who falsely represents any  
 918 factual matter contained on any prescription label or  
 919 prescription legend drug label, commits a felony of the first  
 920 degree, punishable as provided in s. 775.082, s. 775.083, or s.  
 921 775.084.

922 (9)~~499.00535~~ KNOWING Sale or purchase of contraband  
 923 prescription legend drugs resulting in great bodily harm.--A  
 924 person who knowingly sells, purchases, manufactures, delivers,  
 925 or brings into this state, or who is knowingly in actual or  
 926 constructive possession of any amount of contraband prescription  
 927 ~~legend~~ drugs, and whose acts in violation of this subsection  
 928 ~~section~~ result in great bodily harm to a person, commits a  
 929 felony of the first degree, as provided in s. 775.082, s.  
 930 775.083, or s. 775.084.

931 (10)~~499.00545~~ Knowing Sale or purchase of contraband  
 932 prescription legend drugs resulting in death.--A person who  
 933 knowingly manufactures, sells, purchases, delivers, or brings  
 934 into this state, or who is knowingly in actual or constructive  
 935 possession of any amount of contraband prescription legend  
 936 drugs, and whose acts in violation of this subsection ~~section~~  
 937 result in the death of a person, commits a felony of the first  
 938 degree, punishable by a term of years not exceeding life, as  
 939 provided in s. 775.082, s. 775.083, or s. 775.084.

940 (11) 499.069 ~~Criminal punishment for~~ violations of s.  
 941 499.005 related to devices and cosmetics; dissemination of false  
 942 advertisement.--

943 (a) (1) Any person who violates any of the provisions of s.  
 944 499.005 with respect to a device or cosmetic commits a  
 945 misdemeanor of the second degree, punishable as provided in s.  
 946 775.082 or s. 775.083; but, if the violation is committed after  
 947 a conviction of such person under this subsection ~~section~~ has  
 948 become final, such person is guilty of a misdemeanor of the  
 949 first degree, punishable as provided in s. 775.082 or s. 775.083  
 950 or as otherwise provided in this part ~~ss. 499.001-499.081~~,  
 951 except that any person who violates s. 499.005(8) or (10)  
 952 ~~subsection (8) or subsection (10) of s. 499.005~~ with respect to  
 953 a device or cosmetic commits a felony of the third degree,  
 954 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,  
 955 or as otherwise provided in this part ~~ss. 499.001-499.081~~.

956 (b) (2) A publisher, radio broadcast licensee, or agency or  
 957 medium for the dissemination of an advertisement, except the  
 958 manufacturer, wholesaler, or seller of the article to which a  
 959 false advertisement relates, is not liable under this subsection  
 960 ~~section~~ by reason of the dissemination by him or her of such  
 961 false advertisement, unless he or she has refused, on the  
 962 request of the department, to furnish to the department the name  
 963 and post office address of the manufacturer, wholesaler, seller,  
 964 or advertising agency that asked him or her to disseminate such  
 965 advertisement.

966 (12) 499.0691 ADULTERATED AND MISBRANDED DRUGS; FALSE  
 967 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS

968 ~~Criminal punishment for violations related to drugs;~~  
 969 ~~dissemination of false advertisement.--(1)~~ Any person who  
 970 violates any of the following provisions commits a misdemeanor  
 971 of the second degree, punishable as provided in s. 775.082 or s.  
 972 775.083; but, if the violation is committed after a conviction  
 973 of such person under this subsection ~~section~~ has become final,  
 974 such person commits a misdemeanor of the first degree,  
 975 punishable as provided in s. 775.082 or s. 775.083, or as  
 976 otherwise provided in this part ~~ss. 499.001-499.081~~:

977 (a) The manufacture, repackaging, sale, delivery, or  
 978 holding or offering for sale of any drug that is adulterated or  
 979 misbranded or has otherwise been rendered unfit for human or  
 980 animal use.

981 (b) The adulteration or misbranding of any drug intended  
 982 for further distribution.

983 (c) The receipt of any drug that is adulterated or  
 984 misbranded, and the delivery or proffered delivery of such drug,  
 985 for pay or otherwise.

986 (d) The dissemination of any false or misleading  
 987 advertisement of a drug.

988 (e) The use, on the labeling of any drug or in any  
 989 advertisement relating to such drug, of any representation or  
 990 suggestion that an application of the drug is effective when it  
 991 is not or that the drug complies with this part ~~ss. 499.001-~~  
 992 ~~499.081~~ when it does not.

993 (f) The purchase or receipt of a compressed medical gas  
 994 from a person that is not authorized under this chapter to  
 995 distribute compressed medical gases.

996 (g) Charging a dispensing fee for dispensing,  
 997 administering, or distributing a prescription drug sample.

998 (h) The failure to maintain records related to a drug as  
 999 required by this part ~~ss. 499.001-499.081~~ and rules adopted  
 1000 under this part ~~those sections~~, except for pedigree papers,  
 1001 invoices, or shipping documents related to prescription legend  
 1002 drugs.

1003 (i) The possession of any drug in violation of this part  
 1004 ~~ss. 499.001-499.081~~, except if the violation relates to a  
 1005 deficiency in pedigree papers.

1006 (13) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR  
 1007 TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO  
 1008 PRESCRIPTION DRUGS.--(2) Any person who violates any of the  
 1009 following provisions commits a felony of the third degree,  
 1010 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,  
 1011 or as otherwise provided in this part: ~~ss. 499.001-499.081~~.

- 1012 (a) The refusal or constructive refusal to allow:
- 1013 1. The department to enter or inspect an establishment in
  - 1014 which drugs are manufactured, processed, repackaged, sold,
  - 1015 brokered, or held;
  - 1016 2. Inspection of any record of that establishment;
  - 1017 3. The department to enter and inspect any vehicle that is
  - 1018 being used to transport drugs; or
  - 1019 4. The department to take samples of any drug.

1020 (b) The sale, purchase, or trade, or the offer to sell,  
 1021 purchase, or trade, a drug sample as defined in s. 499.028; the  
 1022 distribution of a drug sample in violation of s. 499.028; or the  
 1023 failure to otherwise comply with s. 499.028.

1024 (c) Providing the department with false or fraudulent  
 1025 records, or making false or fraudulent statements, regarding any  
 1026 matter within the provisions of this part ~~chapter~~ related to a  
 1027 drug.

1028 (d) The failure to receive, maintain, or provide invoices  
 1029 and shipping documents, other than pedigree papers, if  
 1030 applicable, related to the distribution of a prescription ~~legend~~  
 1031 drug.

1032 (e) The importation of a prescription ~~legend~~ drug for  
 1033 wholesale distribution, except as provided by s. 801(d) of the  
 1034 Federal Food, Drug, and Cosmetic Act.

1035 (f) The wholesale distribution of a ~~any~~ prescription drug  
 1036 that was:

1037 1. Purchased by a public or private hospital or other  
 1038 health care entity; or

1039 2. Donated or supplied at a reduced price to a charitable  
 1040 organization.

1041 (g) The failure to obtain a permit as a prescription drug  
 1042 wholesale distributor ~~wholesaler~~ when a permit is required by  
 1043 this part ~~ss. 499.001-499.081~~ for that activity.

1044 (h) Knowingly possessing any adulterated or misbranded  
 1045 prescription ~~legend~~ drug outside of a designated quarantine  
 1046 area.

1047 (i) The purchase or sale of a prescription drug ~~drugs~~ for  
 1048 wholesale distribution in exchange for currency, as defined in  
 1049 s. 560.103(6).

1050 (14) OTHER VIOLATIONS.--(3) Any person who violates any  
 1051 of the following provisions commits a felony of the second

1052 degree, punishable as provided in s. 775.082, s. 775.083, or s.  
 1053 775.084, or as otherwise provided in this part: ~~ss. 499.001-~~  
 1054 ~~499.081.~~

1055 (a) Knowingly manufacturing, repackaging, selling,  
 1056 delivering, or holding or offering for sale any drug that is  
 1057 adulterated or misbranded or has otherwise been rendered unfit  
 1058 for human or animal use.

1059 (b) Knowingly adulterating a drug that is intended for  
 1060 further distribution.

1061 (c) Knowingly receiving a drug that is adulterated and  
 1062 delivering or proffering delivery of such drug for pay or  
 1063 otherwise.

1064 (d) Committing any act that causes a drug to be a  
 1065 counterfeit drug, or selling, dispensing, or knowingly holding  
 1066 for sale a counterfeit drug.

1067 (e) Forging, counterfeiting, simulating, or falsely  
 1068 representing any drug, or, without the authority of the  
 1069 manufacturer, using any mark, stamp, tag, label, or other  
 1070 identification device authorized or required by rules adopted  
 1071 under this part ~~ss. 499.001-499.081.~~

1072 (f) Knowingly obtaining or attempting to obtain a  
 1073 prescription drug for wholesale distribution by fraud, deceit,  
 1074 misrepresentation, or subterfuge, or engaging in  
 1075 misrepresentation or fraud in the distribution of a drug.

1076 (g) Removing a pharmacy's dispensing label from a  
 1077 dispensed prescription drug with the intent to further  
 1078 distribute the prescription drug.

1079 (h) Knowingly distributing a prescription drug that was  
 1080 previously dispensed by a licensed pharmacy, unless such  
 1081 distribution was authorized in chapter 465 or the rules adopted  
 1082 under chapter 465.

1083 (15) FALSE ADVERTISEMENT.--(4) A publisher, radio  
 1084 broadcast licensee, or agency or medium for the dissemination of  
 1085 an advertisement, except the manufacturer, repackager, wholesale  
 1086 distributor ~~wholesaler~~, or seller of the article to which a  
 1087 false advertisement relates, is not liable under subsection  
 1088 (12), subsection (13), or subsection (14) ~~this section~~ by reason  
 1089 of the dissemination by him or her of such false advertisement,  
 1090 unless he or she has refused, on the request of the department,  
 1091 to furnish to the department the name and post office address of  
 1092 the manufacturer, repackager, wholesale distributor ~~wholesaler~~,  
 1093 seller, or advertising agency that asked him or her to  
 1094 disseminate such advertisement.

1095 Section 5. Section 499.0054, Florida Statutes, is amended;  
 1096 section 499.0055, Florida Statutes, is redesignated as  
 1097 subsection (2) of that section and amended; and section  
 1098 499.0057, Florida Statutes, is redesignated as subsection (3) of  
 1099 that section and amended, to read:

1100 499.0054 Advertising and labeling of drugs, devices, and  
 1101 cosmetics; exemptions.--

1102 (1) It is a violation of the Florida Drug and Cosmetic Act  
 1103 to perform or cause the performance of any of the following  
 1104 acts:



1105        (a)~~(1)~~ The dissemination of any false advertisement of any  
 1106 drug, device, or cosmetic. An advertisement is false if it is  
 1107 false or misleading in any way.

1108        (b)~~(2)~~ The distribution in commerce of any drug, device,  
 1109 or cosmetic, if its labeling or advertising is in violation of  
 1110 this part ~~ss. 499.001-499.081~~.

1111        (c)~~(3)~~ The manufacturing, repackaging, packaging, selling,  
 1112 delivery, holding, or offering for sale of any drug, device, or  
 1113 cosmetic for which the advertising or labeling is false or  
 1114 misleading.

1115        (d)~~(4)~~ The advertising of any drug, device, or cosmetic  
 1116 that is adulterated or misbranded.

1117        (e)~~(5)~~ The receiving in commerce of any drug, device, or  
 1118 cosmetic that is falsely advertised or labeled or the delivering  
 1119 or proffering for delivery of any such drug, device, or  
 1120 cosmetic.

1121        (f)~~(6)~~ The advertising or labeling of any product  
 1122 containing ephedrine, a salt of ephedrine, an isomer of  
 1123 ephedrine, or a salt of an isomer of ephedrine, for the  
 1124 indication of stimulation, mental alertness, weight loss,  
 1125 appetite control, energy, or other indications not approved by  
 1126 the pertinent United States Food and Drug Administration Over-  
 1127 the-Counter Final or Tentative Final Monograph or approved new  
 1128 drug application under the federal act. In determining  
 1129 compliance with this requirement, the department may consider  
 1130 the following factors:

1131        1.~~(a)~~ The packaging of the product.

1132        2.~~(b)~~ The name and labeling of the product.

1133        3.~~(e)~~ The manner of distribution, advertising, and  
 1134 promotion of the product, including verbal representations at  
 1135 the point of sale.

1136        4.~~(d)~~ The duration, scope, and significance of abuse of  
 1137 the particular product.

1138        (g)~~(7)~~ The advertising of any drug or device represented  
 1139 to have any effect in any of the following conditions,  
 1140 disorders, diseases, or processes:

1141            1.~~(a)~~ Blood disorders.

1142            2.~~(b)~~ Bone or joint diseases.

1143            3.~~(c)~~ Kidney diseases or disorders.

1144            4.~~(d)~~ Cancer.

1145            5.~~(e)~~ Diabetes.

1146            6.~~(f)~~ Gall bladder diseases or disorders.

1147            7.~~(g)~~ Heart and vascular diseases.

1148            8.~~(h)~~ High blood pressure.

1149            9.~~(i)~~ Diseases or disorders of the ear or auditory  
 1150 apparatus, including hearing loss or deafness.

1151            10.~~(j)~~ Mental disease or mental retardation.

1152            11.~~(k)~~ Paralysis.

1153            12.~~(l)~~ Prostate gland disorders.

1154            13.~~(m)~~ Conditions of the scalp affecting hair loss.

1155            14.~~(n)~~ Baldness.

1156            15.~~(o)~~ Endocrine disorders.

1157            16.~~(p)~~ Sexual impotence.

1158            17.~~(q)~~ Tumors.

1159            18.~~(r)~~ Venereal diseases.

1160            19.~~(s)~~ Varicose ulcers.

- 1161        20.~~(t)~~ Breast enlargement.
- 1162        21.~~(u)~~ Purifying blood.
- 1163        22.~~(v)~~ Metabolic disorders.
- 1164        23.~~(w)~~ Immune system disorders or conditions affecting the
- 1165 immune system.
- 1166        24.~~(x)~~ Extension of life expectancy.
- 1167        25.~~(y)~~ Stress and tension.
- 1168        26.~~(z)~~ Brain stimulation or performance.
- 1169        27.~~(aa)~~ The body's natural defense mechanisms.
- 1170        28.~~(bb)~~ Blood flow.
- 1171        29.~~(cc)~~ Depression.
- 1172        30.~~(dd)~~ Human immunodeficiency virus or acquired immune
- 1173 deficiency syndrome or related disorders or conditions.
- 1174        (h)~~(8)~~ The representation or suggestion in labeling or
- 1175 advertising that an article is approved under this part ~~ss.~~
- 1176 ~~499.001-499.081~~, when such is not the case.
- 1177        (2)~~499.0055~~ ~~False or misleading advertisement.~~—In
- 1178 determining whether an advertisement is false or misleading, the
- 1179 department shall review the representations made or suggested by
- 1180 statement, word, design, device, sound, or any combination
- 1181 thereof within the advertisement and the extent to which the
- 1182 advertisement fails to reveal material facts with respect to
- 1183 consequences that can result from the use of the drug, device,
- 1184 or cosmetic to which the advertisement relates under the
- 1185 conditions of use prescribed in the labeling or advertisement.
- 1186        (3)~~499.0057~~ ~~Advertisement exemptions.~~—

1187        (a)~~(1)~~ An advertisement that is not prohibited under  
 1188 paragraph (1) (a) ~~§. 499.0054(1)~~ is not prohibited under  
 1189 paragraph (1) (g) ~~§. 499.0054(7)~~ if it is disseminated:

1190        1. To the public solely to advertise the product for those  
 1191 indications that are safe and effective indications and the  
 1192 product is safe and effective for self-medication, as  
 1193 established by the United States Food and Drug Administration;  
 1194 or

1195        2. ~~if it is disseminated~~ Only to members of the medical,  
 1196 dental, pharmaceutical, or veterinary professions or appears  
 1197 only in the scientific periodicals of these professions.

1198        (b)~~(2)~~ Compliance with this part ~~ss. 499.001-499.081~~ and  
 1199 the rules adopted under this part ~~those sections~~ creates no  
 1200 legal presumption that a drug or device is safe or effective.

1201        Section 6. Subsections (3), (10), and (11) of section  
 1202 499.006, Florida Statutes, are amended to read:

1203        499.006 Adulterated drug or device.--A drug or device is  
 1204 adulterated:

1205        (3) If it is a drug and the methods used in, or the  
 1206 facilities or controls used for, its manufacture, processing,  
 1207 packing, or holding do not conform to, or are not operated or  
 1208 administered in conformity with, current good manufacturing  
 1209 practices to assure that the drug meets the requirements of this  
 1210 part ~~ss. 499.001-499.081~~ and that the drug has the identity and  
 1211 strength, and meets the standard of quality and purity, which it  
 1212 purports or is represented to possess;

1213        (10) If it is a prescription ~~legend~~ drug for which the  
 1214 required pedigree paper is nonexistent, fraudulent, or

1215 incomplete under the requirements of this part ~~ss. 499.001-~~  
 1216 ~~499.081~~ or applicable rules, or that has been purchased, held,  
 1217 sold, or distributed at any time by a person not authorized  
 1218 under federal or state law to do so; or

1219 (11) If it is a prescription drug subject to, defined by,  
 1220 or described by s. 503(b) of the Federal Food, Drug, and  
 1221 Cosmetic Act which has been returned by a veterinarian to a  
 1222 limited prescription drug veterinary wholesale distributor  
 1223 ~~wholesaler~~.

1224 Section 7. Section 499.007, Florida Statutes, is amended  
 1225 to read:

1226 499.007 Misbranded drug or device.--A drug or device is  
 1227 misbranded:

1228 (1) If its labeling is in any way false or misleading.

1229 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a  
 1230 label containing:

1231 (a) The name and place of business of the manufacturer,  
 1232 repackager, or distributor of the finished dosage form of the  
 1233 drug. For the purpose of this paragraph, the finished dosage  
 1234 form of a prescription medicinal ~~drug~~ is that form of the drug  
 1235 which is, or is intended to be, dispensed or administered to the  
 1236 patient and requires no further manufacturing or processing  
 1237 other than packaging, reconstitution, and labeling; and

1238 (b) An accurate statement of the quantity of the contents  
 1239 in terms of weight, measure, or numerical count. ~~;~~ However, under  
 1240 this section, reasonable variations are permitted, and the  
 1241 department shall establish by rule exemptions for small  
 1242 packages.

1243           (3) If it is an active pharmaceutical ingredient in bulk  
 1244 form and does not bear a label containing:

1245           (a) The name and place of business of the manufacturer,  
 1246 repackager, or distributor; and

1247           (b) An accurate statement of the quantity of the contents  
 1248 in terms of weight, measure, or numerical count.

1249           (4)~~(3)~~ If any word, statement, or other information  
 1250 required by or under this part ~~ss. 499.001-499.081~~ to appear on  
 1251 the label or labeling is not prominently placed thereon with  
 1252 such conspicuousness as compared with other words, statements,  
 1253 designs, or devices in the labeling, and in such terms, as to  
 1254 render the word, statement, or other information likely to be  
 1255 read and understood under customary conditions of purchase and  
 1256 use.

1257           (5)~~(4)~~ If it is a drug and is not designated solely by a  
 1258 name recognized in an official compendium and, ~~unless~~ its label  
 1259 does not bear ~~bears~~:

1260           (a) The common or usual name of the drug, if any; and

1261           (b) In case it is fabricated from two or more ingredients,  
 1262 the common or usual name and quantity of each active ingredient.

1263           (6)~~(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:

1264           (a) Adequate directions for use; and

1265           (b) Adequate warnings against use in those pathological  
 1266 conditions in which its use may be dangerous to health or  
 1267 against use by children if its use may be dangerous to health,  
 1268 or against unsafe dosage or methods or duration of  
 1269 administration or application, in such manner and form as are  
 1270 necessary for the protection of users.

1271        (7)~~(6)~~ If it purports to be a drug the name of which is  
 1272 recognized in the official compendium and,~~unless~~ it is not  
 1273 packaged and labeled as prescribed therein.~~+~~ However, the method  
 1274 of packaging may be modified with the consent of the department.

1275        (8)~~(7)~~ If it has been found by the department to be a drug  
 1276 liable to deterioration and,~~unless~~ it is not packaged in such  
 1277 form and manner, and its label bears a statement of such  
 1278 precautions, as the department by rule requires as necessary to  
 1279 protect the public health. Such rule may not be established for  
 1280 any drug recognized in an official compendium until the  
 1281 department has informed the appropriate body charged with the  
 1282 revision of such compendium of the need for such packaging or  
 1283 labeling requirements and that body has failed within a  
 1284 reasonable time to prescribe such requirements.

1285        (9)~~(8)~~ If it is:

- 1286        (a) A drug and its container or finished dosage form is so
- 1287 made, formed, or filled as to be misleading;
- 1288        (b) An imitation of another drug; or
- 1289        (c) Offered for sale under the name of another drug.

1290        (10)~~(9)~~ If it is dangerous to health when used in the  
 1291 dosage or with the frequency or duration prescribed,  
 1292 recommended, or suggested in the labeling of the drug.

1293        (11)~~(10)~~ If it is, purports to be, or is represented as a  
 1294 drug composed wholly or partly of insulin and,~~unless~~:

1295        ~~(a)~~ it is not from a batch with respect to which a  
 1296 certificate has been issued pursuant to s. 506 of the federal  
 1297 act, which,~~and~~

1298        ~~(b)~~—The certificate is in effect with respect to the drug.

1299            (12)~~(11)~~ If it is, purports to be, or is represented as a  
 1300 drug composed wholly or partly of any kind of antibiotic  
 1301 requiring certification under the federal act and unless:

1302            ~~(a)~~ it is not from a batch with respect to which a  
 1303 certificate has been issued pursuant to s. 507 of the federal  
 1304 act, which, ~~and~~

1305            ~~(b)~~ the certificate is in effect with respect to the  
 1306 drug.†

1307  
 1308 However, this subsection does not apply to any drug or class of  
 1309 drugs exempted by regulations adopted under s. 507(c) or (d) of  
 1310 the federal act.

1311            (13)~~(12)~~ If it is a drug intended for use by humans which  
 1312 is a habit-forming drug or which, because of its toxicity or  
 1313 other potentiality for harmful effect, or the method of its use,  
 1314 or the collateral measures necessary to its use, is not safe for  
 1315 use except under the supervision of a practitioner licensed by  
 1316 law to administer such drugs,† or which is limited by an  
 1317 effective application under s. 505 of the federal act to use  
 1318 under the professional supervision of a practitioner licensed by  
 1319 law to prescribe such drug, if unless it is not dispensed only:

1320            (a) Upon the written prescription of a practitioner  
 1321 licensed by law to prescribe such drug;

1322            (b) Upon an oral prescription of such practitioner, which  
 1323 is reduced promptly to writing and filled by the pharmacist; or

1324            (c) By refilling any such written or oral prescription, if  
 1325 such refilling is authorized by the prescriber ~~either~~ in the



1326 original prescription or by oral order which is reduced promptly  
 1327 to writing and filled by the pharmacist.

1328  
 1329 This subsection does not relieve any person from any requirement  
 1330 prescribed by law with respect to controlled substances as  
 1331 defined in the applicable federal and state laws.

1332 ~~(14)~~~~(13)~~ If it is a drug that is subject to paragraph  
 1333 ~~(13)~~~~(12)~~(a), and if, at any time before it is dispensed, its  
 1334 label does not ~~fails to~~ bear the statement:

1335 (a) "Caution: Federal Law Prohibits Dispensing Without  
 1336 Prescription";

1337 (b) "Rx Only";

1338 (c) The prescription symbol followed by the word "Only";  
 1339 or

1340 (d) "Caution: State Law Prohibits Dispensing Without  
 1341 Prescription."

1342 ~~(15)~~~~(14)~~ If it is a drug that is not subject to paragraph  
 1343 ~~(13)~~~~(12)~~(a), if at any time before it is dispensed its label  
 1344 bears the statement of caution required in subsection ~~(14)~~ ~~(13)~~.

1345 ~~(16)~~~~(15)~~ If it is a color additive, the intended use of  
 1346 which in or on drugs is for the purpose of coloring only and  
 1347 ~~unless~~ its packaging and labeling are not in conformity with the  
 1348 packaging and labeling requirements that apply to such color  
 1349 additive and are prescribed under the federal act.

1350 (17) A drug dispensed by filling or refilling a written or  
 1351 oral prescription of a practitioner licensed by law to prescribe  
 1352 such drug is exempt from the requirements of this section,  
 1353 except subsections (1), (9) ~~(8)~~, (11) ~~(10)~~, and (12) ~~(11)~~ and

1354 the packaging requirements of subsections (7) ~~(6)~~ and (8) ~~(7)~~,  
 1355 if the drug bears a label that contains the name and address of  
 1356 the dispenser or seller, the prescription number and the date  
 1357 the prescription was written or filled, the name of the  
 1358 prescriber and the name of the patient, and the directions for  
 1359 use and cautionary statements. This exemption does not apply to  
 1360 any drug dispensed in the course of the conduct of a business of  
 1361 dispensing drugs pursuant to diagnosis by mail or to any drug  
 1362 dispensed in violation of subsection (13) ~~(12)~~. The department  
 1363 may, by rule, exempt drugs subject to s. 499.062 ~~ss. 499.062-~~  
 1364 ~~499.064~~ from subsection (13) ~~(12)~~ if compliance with that  
 1365 subsection is not necessary to protect the public health,  
 1366 safety, and welfare.

1367 Section 8. Subsection (1) of section 499.008, Florida  
 1368 Statutes, is amended and subsection (5) is added to that section  
 1369 to read:

1370 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

1371 (1) If it bears or contains any poisonous or deleterious  
 1372 substance that is injurious to users under the conditions of use  
 1373 prescribed in the labeling or advertisement thereof or under  
 1374 such conditions of use as are customary or usual; however, this  
 1375 subsection does not apply to coal-tar hair dye:

1376 (a) The label of which bears the following legend  
 1377 conspicuously displayed thereon: "Caution: This product contains  
 1378 ingredients which may cause skin irritation on certain  
 1379 individuals, and a preliminary test according to accompanying  
 1380 directions should first be made. This product must not be used

1381 for dyeing the eyelashes or eyebrows; to do so may cause  
 1382 blindness"; and

1383 (b) The labeling of which bears adequate directions for  
 1384 such preliminary testing.

1385  
 1386 ~~For the purposes of this subsection and subsection (4), the term~~  
 1387 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1388 (5) For the purposes of subsections (1) and (4), the term  
 1389 "hair dye" does not include eyelash dyes or eyebrow dyes.

1390 Section 9. Subsections (2), (3), and (5) of section  
 1391 499.009, Florida Statutes, are amended to read:

1392 499.009 Misbranded cosmetics.--A cosmetic is misbranded:

1393 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a  
 1394 label containing:

1395 (a) The name and place of business of the manufacturer,  
 1396 packer, or distributor;

1397 (b) An accurate statement of the quantity of the contents  
 1398 in terms of weight, measure, or numerical count; however, under  
 1399 this paragraph reasonable variations are permitted, and the  
 1400 department shall establish by rule exemptions for small  
 1401 packages; and

1402 (c) A declaration of ingredients in descending order of  
 1403 predominance, or as otherwise required by federal law.

1404 (3) If any word, statement, or other information required  
 1405 by or under authority of this part ~~ss. 499.001-499.081~~ to appear  
 1406 on the label or labeling is not prominently placed thereon with  
 1407 such conspicuousness as compared with other words, statements,  
 1408 designs, or devices in the labeling, and in such terms, as to

1409 render the word, statement, or other information likely to be  
 1410 read and understood by an individual under customary conditions  
 1411 of purchase and use.

1412 (5) ~~Unless,~~ If it is a color additive, its packaging and  
 1413 labeling are not in conformity with the packaging and labeling  
 1414 requirements applicable to that color additive prescribed under  
 1415 the federal act. This subsection does not apply to packages of  
 1416 color additives that, with respect to their use for cosmetics,  
 1417 are marketed and intended for use only in or on hair dyes.

1418 Section 10. Section 499.01, Florida Statutes, is amended;  
 1419 the introductory paragraph and paragraphs (a) through (h) of  
 1420 subsection (2) of section 499.012, Florida Statutes, are  
 1421 redesignated as the introductory paragraph and paragraphs (d),  
 1422 (n), (e), (f), (c), (i), (k), and (l), respectively, of  
 1423 subsection (2) of that section and amended; paragraphs (b)  
 1424 through (e) of subsection (2) of section 499.013, Florida  
 1425 Statutes, are redesignated as paragraphs (p), (o), (q), and (r),  
 1426 respectively, of subsection (2) of that section and amended; and  
 1427 section 499.014, Florida Statutes, is redesignated as paragraph  
 1428 (g) of subsection (2) of that section and amended, to read:

1429 499.01 ~~Permits, applications, renewal, general~~  
 1430 ~~requirements.~~ --

1431 (1) Prior to operating, a permit is required for each  
 1432 person and establishment that intends to operate as:

- 1433 (a) A prescription drug manufacturer;
- 1434 (b) A prescription drug repackager;
- 1435 (c) A nonresident prescription drug manufacturer;
- 1436 (d) A prescription drug wholesale distributor;

- 1437        (e) An out-of-state prescription drug wholesale
- 1438 distributor;
- 1439        (f) A retail pharmacy drug wholesale distributor;
- 1440        (g) A restricted prescription drug distributor;
- 1441        (h) A complimentary drug distributor;
- 1442        (i) A freight forwarder;
- 1443        (j) A veterinary prescription drug retail establishment;
- 1444        (k) A veterinary prescription drug wholesale distributor;
- 1445        (l) A limited prescription drug veterinary wholesale
- 1446 distributor;
- 1447        (m) A medical oxygen retail establishment;
- 1448        (n) A compressed medical gas wholesale distributor;
- 1449        (o) A compressed medical gas manufacturer;
- 1450        (p)~~(e)~~ An over-the-counter drug manufacturer;
- 1451        ~~(d) A compressed medical gas manufacturer;~~
- 1452        (q)~~(e)~~ A device manufacturer;
- 1453        (r)~~(f)~~ A cosmetic manufacturer;
- 1454        (s) A third party logistic provider; or
- 1455        (t) A health care clinic establishment.
- 1456        ~~(g) A prescription drug wholesaler;~~
- 1457        ~~(h) A veterinary prescription drug wholesaler;~~
- 1458        ~~(i) A compressed medical gas wholesaler;~~
- 1459        ~~(j) An out of state prescription drug wholesaler;~~
- 1460        ~~(k) A nonresident prescription drug manufacturer;~~
- 1461        ~~(l) A freight forwarder;~~
- 1462        ~~(m) A retail pharmacy drug wholesaler;~~
- 1463        ~~(n) A veterinary legend drug retail establishment;~~
- 1464        ~~(o) A medical oxygen retail establishment;~~

1465 ~~(p) A complimentary drug distributor,~~  
 1466 ~~(q) A restricted prescription drug distributor, or~~  
 1467 ~~(r) A limited prescription drug veterinary wholesaler.~~

1468 (2) The following ~~types of wholesaler~~ permits are  
 1469 established:

1470 (a) Prescription drug manufacturer permit.--A prescription  
 1471 drug manufacturer permit is required for any person that  
 1472 manufactures a prescription drug in this state.

1473 1. A person that operates an establishment permitted as a  
 1474 prescription drug manufacturer may engage in wholesale  
 1475 distribution of prescription drugs manufactured at that  
 1476 establishment and must comply with all the provisions of this  
 1477 part and the rules adopted under this part that apply to a  
 1478 wholesale distributor.

1479 2. A prescription drug manufacturer must comply with all  
 1480 appropriate state and federal good manufacturing practices.

1481 (b) Prescription drug repackager permit.--A prescription  
 1482 drug repackager permit is required for any person that  
 1483 repackages a prescription drug in this state.

1484 1. A person that operates an establishment permitted as a  
 1485 prescription drug repackager may engage in wholesale  
 1486 distribution of prescription drugs repackaged at that  
 1487 establishment and must comply with all the provisions of this  
 1488 part and the rules adopted under this part that apply to a  
 1489 wholesale distributor.

1490 2. A prescription drug repackager must comply with all  
 1491 appropriate state and federal good manufacturing practices.

1492            (c) ~~(e)~~ Nonresident prescription drug manufacturer  
 1493 permit.--A nonresident prescription drug manufacturer permit is  
 1494 required for any person that is a manufacturer of prescription  
 1495 drugs, or the distribution point for a manufacturer of  
 1496 prescription drugs unless permitted as a third party logistics  
 1497 provider, and located outside of this state, or that is an  
 1498 entity to whom an approved new drug application has been issued  
 1499 by the United States Food and Drug Administration, or the  
 1500 contracted manufacturer of the approved new drug application  
 1501 holder, and located outside the United States, which engages in  
 1502 the wholesale distribution in this state of the prescription  
 1503 drugs it manufactures or is responsible for manufacturing. Each  
 1504 such manufacturer or entity must be permitted by the department  
 1505 and comply with all the provisions required of a wholesale  
 1506 distributor under this part ~~ss. 499.001-499.081~~, except s.  
 1507 499.01212 ~~s. 499.0121(6)(d)~~.

1508            1. A person that distributes prescription drugs that it  
 1509 did not manufacture must also obtain an out-of-state  
 1510 prescription drug wholesale distributor ~~wholesaler~~ permit  
 1511 pursuant to this section to engage in the wholesale distribution  
 1512 of the prescription drugs manufactured by another person and  
 1513 comply with the requirements of an out-of-state prescription  
 1514 drug wholesale distributor ~~wholesaler~~.

1515            2. Any such person must comply with the licensing or  
 1516 permitting requirements of the jurisdiction in which the  
 1517 establishment is located and the federal act, and any product  
 1518 wholesaled into this state must comply with this part ~~ss.~~  
 1519 ~~499.001-499.081~~. If a person intends to import prescription

1520 drugs from a foreign country into this state, the nonresident  
1521 prescription drug manufacturer must provide to the department a  
1522 list identifying each prescription drug it intends to import and  
1523 document approval by the United States Food and Drug  
1524 Administration for such importation.

1525 3. A nonresident prescription drug manufacturer permit is  
1526 not required for a manufacturer to distribute a prescription  
1527 drug active pharmaceutical ingredient that it manufactures to a  
1528 prescription drug manufacturer permitted in this state in  
1529 limited quantities intended for research and development and not  
1530 for resale, or human use other than lawful clinical trials and  
1531 biostudies authorized and regulated by federal law. A  
1532 manufacturer claiming to be exempt from the permit requirements  
1533 of this subparagraph and the prescription drug manufacturer  
1534 purchasing and receiving the active pharmaceutical ingredient  
1535 shall comply with the recordkeeping requirements of s.  
1536 499.0121(6), but not the requirements of s. 499.01212. The  
1537 prescription drug manufacturer purchasing and receiving the  
1538 active pharmaceutical ingredient shall maintain on file a record  
1539 of the FDA registration number; the out-of-state license,  
1540 permit, or registration number; and, if available, a copy of the  
1541 most current FDA inspection report, for all manufacturers from  
1542 whom they purchase active pharmaceutical ingredients under this  
1543 section. The department shall specify by rule the allowable  
1544 number of transactions within a given period of time and the  
1545 amount of active pharmaceutical ingredients that qualify as  
1546 limited quantities for purposes of this exemption. The failure  
1547 to comply with the requirements of this subparagraph, or rules



1548 adopted by the department to administer this subparagraph, for  
 1549 the purchase of prescription drug active pharmaceutical  
 1550 ingredients is a violation of s. 499.005(14).

1551 (d) (a) A Prescription drug wholesale distributor  
 1552 ~~wholesaler's~~ permit.--A prescription drug wholesale distributor  
 1553 ~~wholesaler~~ is a wholesale distributor that may engage in the  
 1554 wholesale distribution of prescription drugs. A prescription  
 1555 drug wholesale distributor ~~wholesaler~~ that applies to the  
 1556 department for a new permit or the renewal of a permit must  
 1557 submit a bond of \$100,000, or other equivalent means of security  
 1558 acceptable to the department, such as an irrevocable letter of  
 1559 credit or a deposit in a trust account or financial institution,  
 1560 payable to the Florida Drug, Device, and Cosmetic Trust Fund.  
 1561 The purpose of the bond is to secure payment of any  
 1562 administrative penalties imposed by the department and any fees  
 1563 and costs incurred by the department regarding that permit which  
 1564 are authorized under state law and which the permittee fails to  
 1565 pay 30 days after the fine or costs become final. The department  
 1566 may make a claim against such bond or security until 1 year  
 1567 after the permittee's license ceases to be valid or until 60  
 1568 days after any administrative or legal proceeding authorized in  
 1569 this part ss. 499.001-499.081 which involves the permittee is  
 1570 concluded, including any appeal, whichever occurs later. The  
 1571 department may adopt rules for issuing a prescription drug  
 1572 wholesale distributor-broker ~~wholesaler-broker~~ permit to a  
 1573 person who engages in the wholesale distribution of prescription  
 1574 drugs and does not take physical possession of any prescription  
 1575 drugs.

1576           (e) ~~(e)~~ An Out-of-state prescription drug wholesale  
1577 distributor ~~wholesaler's~~ permit.--An out-of-state prescription  
1578 drug wholesale distributor ~~wholesaler~~ is a wholesale distributor  
1579 located outside this state which engages in the wholesale  
1580 distribution of prescription drugs into this state and which  
1581 must be permitted by the department and comply with all the  
1582 provisions required of a wholesale distributor under this part  
1583 ~~ss. 499.001-499.081~~. An out-of-state prescription drug wholesale  
1584 distributor ~~wholesaler~~ that applies to the department for a new  
1585 permit or the renewal of a permit must submit a bond of  
1586 \$100,000, or other equivalent means of security acceptable to  
1587 the department, such as an irrevocable letter of credit or a  
1588 deposit in a trust account or financial institution, payable to  
1589 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose  
1590 of the bond is to secure payment of any administrative penalties  
1591 imposed by the department and any fees and costs incurred by the  
1592 department regarding that permit which are authorized under  
1593 state law and which the permittee fails to pay 30 days after the  
1594 fine or costs become final. The department may make a claim  
1595 against such bond or security until 1 year after the permittee's  
1596 license ceases to be valid or until 60 days after any  
1597 administrative or legal proceeding authorized in this part ~~ss.~~  
1598 ~~499.001-499.081~~ which involves the permittee is concluded,  
1599 including any appeal, whichever occurs later.

1600           1. The out-of-state prescription drug wholesale  
1601 distributor ~~wholesaler~~ must maintain at all times a license or  
1602 permit to engage in the wholesale distribution of prescription

1603 drugs in compliance with laws of the state in which it is a  
 1604 resident.

1605 2. An out-of-state prescription drug wholesale distributor  
 1606 ~~wholesaler's~~ permit is not required for an intracompany sale or  
 1607 transfer of a prescription drug from an out-of-state  
 1608 establishment that is duly licensed as a prescription drug  
 1609 wholesale distributor ~~wholesaler~~, in its state of residence, to  
 1610 a licensed prescription drug wholesale distributor ~~wholesaler~~ in  
 1611 this state, if both wholesale distributors ~~wholesalers~~ conduct  
 1612 wholesale distributions of prescription drugs under the same  
 1613 business name. The recordkeeping requirements of ~~ss. s.~~  
 1614 499.0121(6) and 499.01212 must be followed for this transaction.

1615 ~~(f)-(d)~~ A Retail pharmacy drug wholesale distributor  
 1616 ~~wholesaler's~~ permit.--A retail pharmacy drug wholesale  
 1617 distributor ~~wholesaler~~ is a retail pharmacy engaged in wholesale  
 1618 distribution of prescription drugs within this state under the  
 1619 following conditions:

1620 1. The pharmacy must obtain a retail pharmacy drug  
 1621 wholesale distributor ~~wholesaler's~~ permit pursuant to this part  
 1622 ~~ss. 499.001-499.081~~ and the rules adopted under this part ~~these~~  
 1623 ~~sections~~.

1624 2. The wholesale distribution activity does not exceed 30  
 1625 percent of the total annual purchases of prescription drugs. If  
 1626 the wholesale distribution activity exceeds the 30-percent  
 1627 maximum, the pharmacy must obtain a prescription drug wholesale  
 1628 distributor ~~wholesaler's~~ permit.

1629 3. The transfer of prescription drugs that appear in any  
 1630 schedule contained in chapter 893 is subject to chapter 893 and

1631 the federal Comprehensive Drug Abuse Prevention and Control Act  
 1632 of 1970.

1633 4. The transfer is between a retail pharmacy and another  
 1634 retail pharmacy, or a Modified Class II institutional pharmacy,  
 1635 or a health care practitioner licensed in this state and  
 1636 authorized by law to dispense or prescribe prescription drugs.

1637 5. All records of sales of prescription drugs subject to  
 1638 this section must be maintained separate and distinct from other  
 1639 records and comply with the recordkeeping requirements of this  
 1640 part ss. 499.001-499.081.

1641 (g) 499.014 Restricted prescription drug distributor permit  
 1642 Distribution of legend drugs by hospitals, health care entities,  
 1643 charitable organizations, and return or destruction companies,  
 1644 permits, general requirements.--

1645 ~~(1)~~ A restricted prescription drug distributor permit is  
 1646 required for any person that engages in the distribution of a  
 1647 prescription legend drug, which distribution is not considered  
 1648 "wholesale distribution" under s. 499.003(53)(a) ~~s.~~  
 1649 ~~499.012(1)(a)1~~.

1650 1.(2) A person who engages in the receipt or distribution  
 1651 of a prescription legend drug in this state for the purpose of  
 1652 processing its return or its destruction must obtain a permit as  
 1653 a restricted prescription drug distributor if such person is not  
 1654 the person initiating the return, the prescription drug  
 1655 wholesale supplier of the person initiating the return, or the  
 1656 manufacturer of the drug.

1657 2.(3) Storage, handling, and recordkeeping of these  
 1658 distributions must comply with the requirements for wholesale

1659 distributors under s. 499.0121, but not ~~except~~ those set forth  
 1660 in s. 499.01212 ~~s. 499.0121(6)(d)~~.

1661 3.(4) A person who applies for a permit as a restricted  
 1662 prescription drug distributor, or for the renewal of such a  
 1663 permit, must provide to the department the information required  
 1664 under s. 499.012 ~~s. 499.01~~.

1665 4.(5) The department may ~~issue permits to restricted~~  
 1666 ~~prescription drug distributors and may~~ adopt rules regarding the  
 1667 distribution of prescription drugs by hospitals, health care  
 1668 entities, charitable organizations, or other persons not  
 1669 involved in wholesale distribution, which rules are necessary  
 1670 for the protection of the public health, safety, and welfare.

1671 (h) Complimentary drug distributor permit.--A  
 1672 complimentary drug distributor permit is required for any person  
 1673 that engages in the distribution of a complimentary drug,  
 1674 subject to the requirements of s. 499.028.

1675 (i)(f) Freight forwarder permit.--A freight forwarder  
 1676 permit is required for any person that engages in the  
 1677 distribution of a prescription ~~legend~~ drug as a freight  
 1678 forwarder unless the person is a common carrier. The storage,  
 1679 handling, and recordkeeping of such distributions must comply  
 1680 with the requirements for wholesale distributors under s.  
 1681 499.0121, but not ~~except~~ those set forth in s. 499.01212 ~~s.~~  
 1682 ~~499.0121(6)(d)~~. A freight forwarder must provide the source of  
 1683 the prescription ~~legend~~ drugs with a validated airway bill, bill  
 1684 of lading, or other appropriate documentation to evidence the  
 1685 exportation of the product.

1686           (j) Veterinary prescription drug retail establishment  
 1687 permit.--A veterinary prescription drug retail establishment  
 1688 permit is required for any person that sells veterinary  
 1689 prescription drugs to the public but does not include a pharmacy  
 1690 licensed under chapter 465.

1691           1. The sale to the public must be based on a valid written  
 1692 order from a veterinarian licensed in this state who has a valid  
 1693 client-veterinarian relationship with the purchaser's animal.

1694           2. Veterinary prescription drugs may not be sold in excess  
 1695 of the amount clearly indicated on the order or beyond the date  
 1696 indicated on the order.

1697           3. An order may not be valid for more than 1 year.

1698           4. A veterinary prescription drug retail establishment may  
 1699 not purchase, sell, trade, or possess human prescription drugs  
 1700 or any controlled substance as defined in chapter 893.

1701           5. A veterinary prescription drug retail establishment  
 1702 must sell a veterinary prescription drug in the original, sealed  
 1703 manufacturer's container with all labeling intact and legible.  
 1704 The department may adopt by rule additional labeling  
 1705 requirements for the sale of a veterinary prescription drug.

1706           6. A veterinary prescription drug retail establishment  
 1707 must comply with all of the wholesale distribution requirements  
 1708 of s. 499.0121.

1709           7. Prescription drugs sold by a veterinary prescription  
 1710 drug retail establishment pursuant to a practitioner's order may  
 1711 not be returned into the retail establishment's inventory.

1712           (k) ~~(g)~~ A veterinary prescription drug wholesale  
 1713 distributor ~~wholesaler~~ permit.--A veterinary prescription drug

1714 wholesale distributor ~~wholesaler~~ permit is required for any  
 1715 person that engages in the distribution of veterinary  
 1716 prescription drugs in or into this state. A veterinary  
 1717 prescription drug wholesale distributor ~~wholesaler~~ that also  
 1718 distributes prescription drugs subject to, defined by, or  
 1719 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
 1720 Act which it did not manufacture must obtain a permit as a  
 1721 prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
 1722 state prescription drug wholesale distributor ~~wholesaler~~, or a  
 1723 limited prescription drug veterinary wholesale distributor  
 1724 ~~wholesaler~~ in lieu of the veterinary prescription drug wholesale  
 1725 distributor ~~wholesaler~~ permit. A veterinary prescription drug  
 1726 wholesale distributor ~~wholesaler~~ must comply with the  
 1727 requirements for wholesale distributors under s. 499.0121, but  
 1728 not except those set forth in s. 499.01212 ~~s. 499.0121(6)(d)~~.  
 1729 (1) ~~(h)~~ Limited prescription drug veterinary wholesale  
 1730 distributor ~~wholesaler~~ permit.--Unless engaging in the  
 1731 activities of and permitted as a prescription drug manufacturer,  
 1732 nonresident prescription drug manufacturer, prescription drug  
 1733 wholesale distributor ~~wholesaler~~, or out-of-state prescription  
 1734 drug wholesale distributor ~~wholesaler~~, a limited prescription  
 1735 drug veterinary wholesale distributor ~~wholesaler~~ permit is  
 1736 required for any person that engages in the distribution in or  
 1737 into this state of veterinary prescription drugs and  
 1738 prescription drugs subject to, defined by, or described by s.  
 1739 503(b) of the Federal Food, Drug, and Cosmetic Act under the  
 1740 following conditions:

1741           1. The person is engaged in the business of wholesaling  
 1742 prescription and veterinary prescription ~~legend~~ drugs to  
 1743 persons:

1744           a. Licensed as veterinarians practicing on a full-time  
 1745 basis;

1746           b. Regularly and lawfully engaged in instruction in  
 1747 veterinary medicine;

1748           c. Regularly and lawfully engaged in law enforcement  
 1749 activities;

1750           d. For use in research not involving clinical use; or  
 1751           e. For use in chemical analysis or physical testing or for  
 1752 purposes of instruction in law enforcement activities, research,  
 1753 or testing.

1754           2. No more than 30 percent of total annual prescription  
 1755 drug sales may be prescription drugs approved for human use  
 1756 which are subject to, defined by, or described by s. 503(b) of  
 1757 the Federal Food, Drug, and Cosmetic Act.

1758           3. The person does not distribute ~~is not permitted,~~  
 1759 ~~licensed, or otherwise authorized~~ in any jurisdiction ~~state~~ to  
 1760 ~~wholesale~~ prescription drugs subject to, defined by, or  
 1761 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
 1762 Act to any person who is authorized to sell, distribute,  
 1763 purchase, trade, or use these drugs on or for humans.

1764           4. A limited prescription drug veterinary wholesale  
 1765 distributor ~~wholesaler~~ that applies to the department for a new  
 1766 permit or the renewal of a permit must submit a bond of \$20,000,  
 1767 or other equivalent means of security acceptable to the  
 1768 department, such as an irrevocable letter of credit or a deposit



1769 in a trust account or financial institution, payable to the  
1770 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of  
1771 the bond is to secure payment of any administrative penalties  
1772 imposed by the department and any fees and costs incurred by the  
1773 department regarding that permit which are authorized under  
1774 state law and which the permittee fails to pay 30 days after the  
1775 fine or costs become final. The department may make a claim  
1776 against such bond or security until 1 year after the permittee's  
1777 license ceases to be valid or until 60 days after any  
1778 administrative or legal proceeding authorized in this part ~~ss.~~  
1779 ~~499.001-499.081~~ which involves the permittee is concluded,  
1780 including any appeal, whichever occurs later.

1781 5. A limited prescription drug veterinary wholesale  
1782 distributor ~~wholesaler~~ must maintain at all times a license or  
1783 permit to engage in the wholesale distribution of prescription  
1784 drugs in compliance with laws of the state in which it is a  
1785 resident.

1786 6. A limited prescription drug veterinary wholesale  
1787 distributor ~~wholesaler~~ must comply with the requirements for  
1788 wholesale distributors under ss. s. ~~499.0121~~ and 499.01212,  
1789 except that a limited prescription drug veterinary wholesale  
1790 distributor ~~wholesaler~~ is not required to provide a pedigree  
1791 paper as required by s. 499.01212 ~~s. 499.0121(6)(d)~~ upon the  
1792 wholesale distribution of a prescription drug to a veterinarian.

1793 7. A limited prescription drug veterinary wholesale  
1794 distributor ~~wholesaler~~ may not return to inventory for  
1795 subsequent wholesale distribution any prescription drug subject  
1796 to, defined by, or described by s. 503(b) of the Federal Food,

1797 Drug, and Cosmetic Act which has been returned by a  
 1798 veterinarian.

1799 ~~8. An out-of-state prescription drug wholesaler's permit~~  
 1800 ~~or~~ A limited prescription drug veterinary wholesale distributor  
 1801 ~~wholesaler~~ permit is not required for an intracompany sale or  
 1802 transfer of a prescription drug from an out-of-state  
 1803 establishment that is duly licensed to engage in the wholesale  
 1804 distribution of prescription drugs in its state of residence to  
 1805 a licensed limited prescription drug veterinary wholesale  
 1806 distributor ~~wholesaler~~ in this state if both wholesale  
 1807 distributors ~~wholesalers~~ conduct wholesale distributions of  
 1808 prescription drugs under the same business name. The  
 1809 recordkeeping requirements of ss. s. 499.0121(6) and 499.01212  
 1810 must be followed for this transaction.

1811 (m) Medical oxygen retail establishment permit.--A medical  
 1812 oxygen retail establishment permit is required for any person  
 1813 that sells medical oxygen to patients only. The sale must be  
 1814 based on an order from a practitioner authorized by law to  
 1815 prescribe. The term does not include a pharmacy licensed under  
 1816 chapter 465.

1817 1. A medical oxygen retail establishment may not possess,  
 1818 purchase, sell, or trade any prescription drug other than  
 1819 medical oxygen.

1820 2. A medical oxygen retail establishment may refill  
 1821 medical oxygen for an individual patient based on an order from  
 1822 a practitioner authorized by law to prescribe. A medical oxygen  
 1823 retail establishment that refills medical oxygen must comply

1824 with all appropriate state and federal good manufacturing  
 1825 practices.

1826 3. A medical oxygen retail establishment must comply with  
 1827 all of the wholesale distribution requirements of s. 499.0121.

1828 4. Prescription medical oxygen sold by a medical oxygen  
 1829 retail establishment pursuant to a practitioner's order may not  
 1830 be returned into the retail establishment's inventory.

1831 (n)-(b) A compressed medical gas wholesale distributor  
 1832 wholesaler's permit.--A compressed medical gas wholesale  
 1833 distributor wholesaler is a wholesale distributor that is  
 1834 limited to the wholesale distribution of compressed medical  
 1835 gases to other than the consumer or patient. The compressed  
 1836 medical gas must be in the original sealed container that was  
 1837 purchased by that wholesale distributor wholesaler. A compressed  
 1838 medical gas wholesale distributor wholesaler may not possess or  
 1839 engage in the wholesale distribution of any prescription drug  
 1840 other than compressed medical gases. The department shall adopt  
 1841 rules that govern the wholesale distribution of prescription  
 1842 medical oxygen for emergency use. With respect to the emergency  
 1843 use of prescription medical oxygen, those rules may not be  
 1844 inconsistent with rules and regulations of federal agencies  
 1845 unless the Legislature specifically directs otherwise.

1846 (o)-(e) Compressed medical gas manufacturer permit.--A  
 1847 compressed medical gas manufacturer manufacturer's permit is  
 1848 required for any person that engages in the manufacture of  
 1849 compressed medical gases or repackages compressed medical gases  
 1850 from one container to another.

1851 1. A compressed medical gas manufacturer ~~permittee~~ may not  
 1852 manufacture or possess any prescription drug other than  
 1853 compressed medical gases.

1854 2. A compressed medical gas manufacturer ~~permittee~~ may  
 1855 engage in wholesale distribution of compressed medical gases  
 1856 manufactured at that establishment and must comply with all the  
 1857 provisions of this part ~~ss. 499.001-499.081~~ and the rules  
 1858 adopted under this part ~~those sections~~ that apply to a wholesale  
 1859 distributor.

1860 3. A compressed medical gas manufacturer ~~permittee~~ must  
 1861 comply with all appropriate state and federal good manufacturing  
 1862 practices.

1863 ~~(p)-(b)~~ Over-the-counter drug manufacturer permit.--An  
 1864 over-the-counter drug manufacturer ~~manufacturer's~~ permit is  
 1865 required for any person that engages in the manufacture or  
 1866 repackaging of an over-the-counter drug.

1867 1. An over-the-counter drug manufacturer ~~permittee~~ may not  
 1868 possess or purchase prescription drugs.

1869 2. A pharmacy is exempt from obtaining an over-the-counter  
 1870 drug manufacturer ~~manufacturer's~~ permit if it is operating in  
 1871 compliance with pharmacy practice standards as defined in  
 1872 chapter 465 and the rules adopted under that chapter.

1873 3. An over-the-counter drug manufacturer ~~permittee~~ must  
 1874 comply with all appropriate state and federal good manufacturing  
 1875 practices.

1876 ~~(g)-(d)~~ Device manufacturer permit.--A device manufacturer  
 1877 ~~manufacturer's~~ permit is required for any person that engages in  
 1878 the manufacture, repackaging, or assembly of medical devices for

1879 human use in this state, except that a permit is not required if  
 1880 the person is engaged only in manufacturing, repackaging, or  
 1881 assembling a medical device pursuant to a practitioner's order  
 1882 for a specific patient.

1883 1. A manufacturer or repackager of medical devices in this  
 1884 state must comply with all appropriate state and federal good  
 1885 manufacturing practices and quality system rules.

1886 2. The department shall adopt rules related to storage,  
 1887 handling, and recordkeeping requirements for manufacturers of  
 1888 medical devices for human use.

1889 (r) (e) Cosmetic manufacturer permit.--A cosmetic  
 1890 manufacturer ~~manufacturer's~~ permit is required for any person  
 1891 that manufactures or repackages cosmetics in this state. A  
 1892 person that only labels or changes the labeling of a cosmetic  
 1893 but does not open the container sealed by the manufacturer of  
 1894 the product is exempt from obtaining a permit under this  
 1895 paragraph.

1896 (s) Third party logistics provider permit.--A third party  
 1897 logistics provider permit is required for any person that  
 1898 contracts with a prescription drug wholesale distributor or  
 1899 prescription drug manufacturer to provide warehousing,  
 1900 distribution, or other logistics services on behalf of a  
 1901 manufacturer or wholesale distributor, but who does not take  
 1902 title to the prescription drug or have responsibility to direct  
 1903 the sale or disposition of the prescription drug. Each third  
 1904 party logistics provider permittee shall comply with the  
 1905 requirements for wholesale distributors under ss. 499.0121 and  
 1906 499.01212, with the exception of those wholesale distributions

1907 described in s. 499.01212(3)(a), and other rules that the  
 1908 department requires.

1909 (t) Health care clinic establishment permit.--Effective  
 1910 January 1, 2009, a health care clinic establishment permit is  
 1911 required for the purchase of a prescription drug by a place of  
 1912 business at one general physical location owned and operated by  
 1913 a professional corporation or professional limited liability  
 1914 company described in chapter 621, or a corporation that employs  
 1915 a veterinarian as a qualifying practitioner. For the purpose of  
 1916 this paragraph, the term "qualifying practitioner" means a  
 1917 licensed health care practitioner defined in s. 456.001 or a  
 1918 veterinarian licensed under chapter 474, who is authorized under  
 1919 the appropriate practice act to prescribe and administer a  
 1920 prescription drug.

1921 1. An establishment must provide, as part of the  
 1922 application required under s. 499.012, designation of a  
 1923 qualifying practitioner who will be responsible for complying  
 1924 with all legal and regulatory requirements related to the  
 1925 purchase, recordkeeping, storage, and handling of the  
 1926 prescription drugs. In addition, the designated qualifying  
 1927 practitioner shall be the practitioner whose name, establishment  
 1928 address, and license number is used on all distribution  
 1929 documents for prescription drugs purchased or returned by the  
 1930 health care clinic establishment. Upon initial appointment of a  
 1931 qualifying practitioner, the qualifying practitioner and the  
 1932 health care clinic establishment shall notify the department on  
 1933 a form furnished by the department within 10 days after such  
 1934 employment. In addition, the qualifying practitioner and health

1935 care clinic establishment shall notify the department within 10  
 1936 days after any subsequent change.

1937 2. The health care clinic establishment must employ a  
 1938 qualifying practitioner at each establishment.

1939 3. In addition to the remedies and penalties provided in  
 1940 this part, a violation of this chapter by the health care clinic  
 1941 establishment or qualifying practitioner constitutes grounds for  
 1942 discipline of the qualifying practitioner by the appropriate  
 1943 regulatory board.

1944 4. The purchase of prescription drugs by the health care  
 1945 clinic establishment is prohibited during any period of time  
 1946 when the establishment does not comply with this paragraph.

1947 5. A health care clinic establishment permit is not a  
 1948 pharmacy permit or otherwise subject to chapter 465. A health  
 1949 care clinic establishment that meets the criteria of a modified  
 1950 Class II institutional pharmacy under s. 465.019 is not eligible  
 1951 to be permitted under this paragraph.

1952 6. This paragraph does not prohibit a qualifying  
 1953 practitioner from purchasing prescription drugs.

1954 Section 11. Section 499.012, Florida Statutes, is amended  
 1955 and subsections (2) through (8) of section 499.01, Florida  
 1956 States, are redesignated as subsections (1) through (7) of that  
 1957 section and amended, to read:

1958 499.012 Permit application ~~Wholesale distribution;~~  
 1959 ~~definitions; permits; applications; general requirements.--~~

1960 (1) ~~As used in this section, the term:~~

1961 ~~(2)~~(a) A permit issued pursuant to this part ~~ss. 499.001-~~  
 1962 ~~499.081~~ may be issued only to a natural person who is at least

1963 18 years of age or to an applicant that is not a natural person  
 1964 if each person who, directly or indirectly, manages, controls,  
 1965 or oversees the operation of that applicant is at least 18 years  
 1966 of age.

1967 (b) An establishment that is a place of residence may not  
 1968 receive a permit and may not operate under this part ~~ss.~~  
 1969 ~~499.001-499.081.~~

1970 (c) A person that applies for or renews a permit to  
 1971 manufacture or distribute prescription ~~legend~~ drugs may not use  
 1972 a name identical to the name used by any other establishment or  
 1973 licensed person authorized to purchase prescription drugs in  
 1974 this state, except that a restricted drug distributor permit  
 1975 issued to a health care entity will be issued in the name in  
 1976 which the institutional pharmacy permit is issued and a retail  
 1977 pharmacy drug wholesale distributor ~~wholesaler~~ will be issued a  
 1978 permit in the name of its retail pharmacy permit.

1979 (d) A permit for a prescription drug manufacturer,  
 1980 prescription drug repackager, prescription drug wholesale  
 1981 distributor ~~wholesaler~~, limited prescription drug veterinary  
 1982 wholesale distributor ~~wholesaler~~, or retail pharmacy drug  
 1983 wholesale distributor ~~wholesaler~~ may not be issued to the  
 1984 address of a health care entity or to a pharmacy licensed under  
 1985 chapter 465, except as provided in this paragraph. The  
 1986 department may issue a prescription drug manufacturer permit to  
 1987 an applicant at the same address as a licensed nuclear pharmacy,  
 1988 which is a health care entity, for the purpose of manufacturing  
 1989 prescription drugs used in positron emission tomography or other  
 1990 radiopharmaceuticals, as listed in a rule adopted by the



1991 department pursuant to this paragraph. The purpose of this  
 1992 exemption is to assure availability of state-of-the-art  
 1993 pharmaceuticals that would pose a significant danger to the  
 1994 public health if manufactured at a separate establishment  
 1995 address from the nuclear pharmacy from which the prescription  
 1996 drugs are dispensed. The department may also issue a retail  
 1997 pharmacy drug wholesale distributor ~~wholesaler~~ permit to the  
 1998 address of a community pharmacy licensed under chapter 465 which  
 1999 does not meet the definition of a closed pharmacy in s. 499.003.

2000 (e) A county or municipality may not issue an occupational  
 2001 license for any licensing period beginning on or after October  
 2002 1, 2003, for any establishment that requires a permit pursuant  
 2003 to this part ~~ss. 499.001-499.081~~, unless the establishment  
 2004 exhibits a current permit issued by the department for the  
 2005 establishment. Upon presentation of the requisite permit issued  
 2006 by the department, an occupational license may be issued by the  
 2007 municipality or county in which application is made. The  
 2008 department shall furnish to local agencies responsible for  
 2009 issuing occupational licenses a current list of all  
 2010 establishments licensed pursuant to this part ~~ss. 499.001-~~  
 2011 ~~499.081~~.

2012 ~~(2)(3)~~ Notwithstanding subsection (6) ~~(7)~~, a permitted  
 2013 person in good standing may change the type of permit issued to  
 2014 that person by completing a new application for the requested  
 2015 permit, paying the amount of the difference in the permit fees  
 2016 if the fee for the new permit is more than the fee for the  
 2017 original permit, and meeting the applicable permitting  
 2018 conditions for the new permit type. The new permit expires on

2019 the expiration date of the original permit being changed;  
 2020 however, a new permit for a prescription drug wholesale  
 2021 distributor ~~wholesaler~~, an out-of-state prescription drug  
 2022 wholesale distributor ~~wholesaler~~, or a retail pharmacy drug  
 2023 wholesale distributor ~~wholesaler~~ shall expire on the expiration  
 2024 date of the original permit or 1 year after the date of issuance  
 2025 of the new permit, whichever is earlier. A refund may not be  
 2026 issued if the fee for the new permit is less than the fee that  
 2027 was paid for the original permit.

2028 (3)~~(4)~~ A written application for a permit or to renew a  
 2029 permit must be filed with the department on forms furnished by  
 2030 the department. The department shall establish, by rule, the  
 2031 form and content of the application to obtain or renew a permit.  
 2032 The applicant must submit to the department with the application  
 2033 a statement that swears or affirms that the information is true  
 2034 and correct.

2035 (4)~~(5)~~(a) Except for a permit for a prescription drug  
 2036 wholesale distributor ~~wholesaler~~ or an out-of-state prescription  
 2037 drug wholesale distributor ~~wholesaler~~, an application for a  
 2038 permit must include:

- 2039 1. The name, full business address, and telephone number  
 2040 of the applicant;
- 2041 2. All trade or business names used by the applicant;
- 2042 3. The address, telephone numbers, and the names of  
 2043 contact persons for each facility used by the applicant for the  
 2044 storage, handling, and distribution of prescription drugs;
- 2045 4. The type of ownership or operation, such as a  
 2046 partnership, corporation, or sole proprietorship; and

2047           5. The names of the owner and the operator of the  
 2048 establishment, including:

2049           a. If an individual, the name of the individual;

2050           b. If a partnership, the name of each partner and the name  
 2051 of the partnership;

2052           c. If a corporation, the name and title of each corporate  
 2053 officer and director, the corporate names, and the name of the  
 2054 state of incorporation;

2055           d. If a sole proprietorship, the full name of the sole  
 2056 proprietor and the name of the business entity;

2057           e. If a limited liability company, the name of each  
 2058 member, the name of each manager, the name of the limited  
 2059 liability company, and the name of the state in which the  
 2060 limited liability company was organized; and

2061           f. Any other relevant information that the department  
 2062 requires.

2063           (b) Upon approval of the application by the department and  
 2064 payment of the required fee, the department shall issue a permit  
 2065 to the applicant, if the applicant meets the requirements of  
 2066 this part ~~ss. 499.001-499.081~~ and rules adopted under this part  
 2067 ~~those sections~~.

2068           (c) Any change in information required under paragraph (a)  
 2069 must be submitted to the department before the change occurs.

2070           (d) The department shall consider, at a minimum, the  
 2071 following factors in reviewing the qualifications of persons to  
 2072 be permitted under this part ~~ss. 499.001-499.081~~:

2073           1. The applicant's having been found guilty, regardless of  
 2074 adjudication, in a court of this state or other jurisdiction, of

2075 a violation of a law that directly relates to a drug, device, or  
 2076 cosmetic. A plea of nolo contendere constitutes a finding of  
 2077 guilt for purposes of this subparagraph.

2078 2. The applicant's having been disciplined by a regulatory  
 2079 agency in any state for any offense that would constitute a  
 2080 violation of this part ~~ss. 499.001-499.081~~.

2081 3. Any felony conviction of the applicant under a federal,  
 2082 state, or local law;

2083 4. The applicant's past experience in manufacturing or  
 2084 distributing drugs, devices, or cosmetics;

2085 5. The furnishing by the applicant of false or fraudulent  
 2086 material in any application made in connection with  
 2087 manufacturing or distributing drugs, devices, or cosmetics;

2088 6. Suspension or revocation by a federal, state, or local  
 2089 government of any permit currently or previously held by the  
 2090 applicant for the manufacture or distribution of any drugs,  
 2091 devices, or cosmetics;

2092 7. Compliance with permitting requirements under any  
 2093 previously granted permits;

2094 8. Compliance with requirements to maintain or make  
 2095 available to the state permitting authority or to federal,  
 2096 state, or local law enforcement officials those records required  
 2097 under this section; and

2098 9. Any other factors or qualifications the department  
 2099 considers relevant to and consistent with the public health and  
 2100 safety.

2101           (5)~~(6)~~ Except for a permit ~~permits~~ for a prescription drug  
 2102 wholesale distributor ~~wholesalers~~ or an out-of-state  
 2103 prescription drug wholesale distributor ~~wholesalers~~:

2104           (a) The department shall adopt rules for the biennial  
 2105 renewal of permits.

2106           (b) The department shall renew a permit upon receipt of  
 2107 the renewal application and renewal fee if the applicant meets  
 2108 the requirements established under this part ~~ss. 499.001-499.081~~  
 2109 and the rules adopted under this part ~~those sections~~.

2110           (c) A permit, unless sooner suspended or revoked,  
 2111 automatically expires 2 years after the last day of the  
 2112 anniversary month in which the permit was originally issued. A  
 2113 permit issued under this part ~~ss. 499.001-499.081~~ may be renewed  
 2114 by making application for renewal on forms furnished by the  
 2115 department and paying the appropriate fees. If a renewal  
 2116 application and fee are submitted and postmarked after the  
 2117 expiration date of the permit, the permit may be renewed only  
 2118 upon payment of a late renewal delinquent fee of \$100, plus the  
 2119 required renewal fee, not later than 60 days after the  
 2120 expiration date.

2121           (d) Failure to renew a permit in accordance with this  
 2122 section precludes any future renewal of that permit. If a permit  
 2123 issued pursuant to this part ~~section~~ has expired and cannot be  
 2124 renewed, before an establishment may engage in activities that  
 2125 require a permit under this part ~~ss. 499.001-499.081~~, the  
 2126 establishment must submit an application for a new permit, pay  
 2127 the applicable application fee, the initial permit fee, and all

2128 applicable penalties, and be issued a new permit by the  
 2129 department.

2130 ~~(6)~~(7) A permit issued by the department is  
 2131 nontransferable. Each permit is valid only for the person or  
 2132 governmental unit to which it is issued and is not subject to  
 2133 sale, assignment, or other transfer, voluntarily or  
 2134 involuntarily; nor is a permit valid for any establishment other  
 2135 than the establishment for which it was originally issued.

2136 (a) A person permitted under this part ~~ss. 499.001-499.081~~  
 2137 must notify the department before making a change of address.  
 2138 The department shall set a change of location fee not to exceed  
 2139 \$100.

2140 (b)1. An application for a new permit is required when a  
 2141 majority of the ownership or controlling interest of a permitted  
 2142 establishment is transferred or assigned or when a lessee agrees  
 2143 to undertake or provide services to the extent that legal  
 2144 liability for operation of the establishment will rest with the  
 2145 lessee. The application for the new permit must be made before  
 2146 the date of the sale, transfer, assignment, or lease.

2147 2. A permittee that is authorized to distribute  
 2148 prescription legend ~~legend~~ drugs may transfer such drugs to the new  
 2149 owner or lessee under subparagraph 1. only after the new owner  
 2150 or lessee has been approved for a permit to distribute  
 2151 prescription legend ~~legend~~ drugs.

2152 (c) If an establishment permitted under this part ~~ss.~~  
 2153 ~~499.001-499.081~~ closes, the owner must notify the department in  
 2154 writing before the effective date of closure and must:

2155 1. Return the permit to the department;

2156           2. If the permittee is authorized to distribute  
 2157 prescription ~~legend~~ drugs, indicate the disposition of such  
 2158 drugs, including the name, address, and inventory, and provide  
 2159 the name and address of a person to contact regarding access to  
 2160 records that are required to be maintained under this part ~~ss.~~  
 2161 ~~499.001-499.081~~. Transfer of ownership of prescription ~~legend~~  
 2162 drugs may be made only to persons authorized to possess  
 2163 prescription ~~legend~~ drugs under this part ~~ss. 499.001-499.081~~.

2164  
 2165 The department may revoke the permit of any person that fails to  
 2166 comply with the requirements of this subsection.

2167           ~~(7)(8)~~ A permit must be posted in a conspicuous place on  
 2168 the licensed premises.

2169           ~~(8)(3)~~ An application for a permit or to renew a permit  
 2170 for a prescription drug wholesale distributor ~~wholesaler~~ or an  
 2171 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
 2172 submitted to the department must include:

2173           (a) The name, full business address, and telephone number  
 2174 of the applicant.

2175           (b) All trade or business names used by the applicant.

2176           (c) The address, telephone numbers, and the names of  
 2177 contact persons for each facility used by the applicant for the  
 2178 storage, handling, and distribution of prescription drugs.

2179           (d) The type of ownership or operation, such as a  
 2180 partnership, corporation, or sole proprietorship.

2181           (e) The names of the owner and the operator of the  
 2182 establishment, including:

2183           1. If an individual, the name of the individual.

2184           2. If a partnership, the name of each partner and the name  
2185 of the partnership.

2186           3. If a corporation:

2187           a. The name, address, and title of each corporate officer  
2188 and director.

2189           b. The name and address of the corporation, resident agent  
2190 of the corporation, the resident agent's address, and the  
2191 corporation's state of incorporation.

2192           c. The name and address of each shareholder of the  
2193 corporation that owns 5 percent or more of the outstanding stock  
2194 of the corporation.

2195           4. If a sole proprietorship, the full name of the sole  
2196 proprietor and the name of the business entity.

2197           5. If a limited liability company:

2198           a. The name and address of each member.

2199           b. The name and address of each manager.

2200           c. The name and address of the limited liability company,  
2201 the resident agent of the limited liability company, and the  
2202 name of the state in which the limited liability company was  
2203 organized.

2204           (f) If applicable, the name and address of each member of  
2205 the affiliated group of which the applicant is a member.

2206           (g)1. For an application for a new permit, the estimated  
2207 annual dollar volume of prescription drug sales of the  
2208 applicant, the estimated annual percentage of the applicant's  
2209 total company sales that are prescription drugs, the applicant's  
2210 estimated annual total dollar volume of purchases of  
2211 prescription drugs, and the applicant's estimated annual total



2212 dollar volume of prescription drug purchases directly from  
 2213 manufacturers.

2214         2. For an application to renew a permit, the total dollar  
 2215 volume of prescription drug sales in the previous year, the  
 2216 total dollar volume of prescription drug sales made in the  
 2217 previous 6 months, the percentage of total company sales that  
 2218 were prescription drugs in the previous year, the total dollar  
 2219 volume of purchases of prescription drugs in the previous year,  
 2220 and the total dollar volume of prescription drug purchases  
 2221 directly from manufacturers in the previous year.

2222  
 2223 Such portions of the information required pursuant to this  
 2224 paragraph which are a trade secret, as defined in s. 812.081,  
 2225 shall be maintained by the department as trade secret  
 2226 information is required to be maintained under s. 499.051.

2227         (h) The tax year of the applicant.

2228         (i) A copy of the deed for the property on which  
 2229 applicant's establishment is located, if the establishment is  
 2230 owned by the applicant, or a copy of the applicant's lease for  
 2231 the property on which applicant's establishment is located that  
 2232 has an original term of not less than 1 calendar year, if the  
 2233 establishment is not owned by the applicant.

2234         (j) A list of all licenses and permits issued to the  
 2235 applicant by any other state which authorize the applicant to  
 2236 purchase or possess prescription drugs.

2237         (k) The name of the manager of the establishment that is  
 2238 applying for the permit or to renew the permit, the next four  
 2239 highest ranking employees responsible for prescription drug

2240 wholesale operations for the establishment, and the name of all  
 2241 affiliated parties for the establishment, together with the  
 2242 personal information statement and fingerprints required  
 2243 pursuant to subsection (9) ~~(4)~~ for each of such persons.

2244 (l) The name of each of the applicant's designated  
 2245 representatives as required by subsection (16) ~~(11)~~, together  
 2246 with the personal information statement and fingerprints  
 2247 required pursuant to subsection (9) ~~(4)~~ for each such person.

2248 (m) For an applicant that is a secondary wholesale  
 2249 distributor ~~wholesaler~~, each of the following:

2250 1. A personal background information statement containing  
 2251 the background information and fingerprints required pursuant to  
 2252 subsection (9) ~~(4)~~ for each person named in the applicant's  
 2253 response to paragraphs (k) and (l) and for each affiliated party  
 2254 of the applicant.

2255 2. If any of the five largest shareholders of the  
 2256 corporation seeking the permit is a corporation, the name,  
 2257 address, and title of each corporate officer and director of  
 2258 each such corporation; the name and address of such corporation;  
 2259 the name of such corporation's resident agent, such  
 2260 corporation's resident agent's address, and such corporation's  
 2261 state of its incorporation; and the name and address of each  
 2262 shareholder of such corporation that owns 5 percent or more of  
 2263 the stock of such corporation.

2264 3. The name and address of all financial institutions in  
 2265 which the applicant has an account which is used to pay for the  
 2266 operation of the establishment or to pay for drugs purchased for  
 2267 the establishment, together with the names of all persons that

2268 are authorized signatories on such accounts. The portions of the  
 2269 information required pursuant to this subparagraph which are a  
 2270 trade secret, as defined in s. 812.081, shall be maintained by  
 2271 the department as trade secret information is required to be  
 2272 maintained under s. 499.051.

2273 4. The sources of all funds and the amounts of such funds  
 2274 used to purchase or finance purchases of prescription drugs or  
 2275 to finance the premises on which the establishment is to be  
 2276 located.

2277 5. If any of the funds identified in subparagraph 4. were  
 2278 borrowed, copies of all promissory notes or loans used to obtain  
 2279 such funds.

2280 (n) Any other relevant information that the department  
 2281 requires, including, but not limited to, any information related  
 2282 to whether the applicant satisfies the definition of a primary  
 2283 wholesale distributor ~~wholesaler~~ or a secondary wholesale  
 2284 distributor ~~wholesaler~~.

2285 (9)~~(4)~~(a) Each person required by subsection (8) ~~(3)~~ to  
 2286 provide a personal information statement and fingerprints shall  
 2287 provide the following information to the department on forms  
 2288 prescribed by the department:

- 2289 1. The person's places of residence for the past 7 years.
- 2290 2. The person's date and place of birth.
- 2291 3. The person's occupations, positions of employment, and  
 2292 offices held during the past 7 years.
- 2293 4. The principal business and address of any business,  
 2294 corporation, or other organization in which each such office of

2295 | the person was held or in which each such occupation or position  
 2296 | of employment was carried on.

2297 |         5. Whether the person has been, during the past 7 years,  
 2298 | the subject of any proceeding for the revocation of any license  
 2299 | and, if so, the nature of the proceeding and the disposition of  
 2300 | the proceeding.

2301 |         6. Whether, during the past 7 years, the person has been  
 2302 | enjoined, ~~either~~ temporarily or permanently, by a court of  
 2303 | competent jurisdiction from violating any federal or state law  
 2304 | regulating the possession, control, or distribution of  
 2305 | prescription drugs, together with details concerning any such  
 2306 | event.

2307 |         7. A description of any involvement by the person with any  
 2308 | business, including any investments, other than the ownership of  
 2309 | stock in a publicly traded company or mutual fund, during the  
 2310 | past 7 years, which manufactured, administered, prescribed,  
 2311 | distributed, or stored pharmaceutical products and any lawsuits  
 2312 | in which such businesses were named as a party.

2313 |         8. A description of any felony criminal offense of which  
 2314 | the person, as an adult, was found guilty, regardless of whether  
 2315 | adjudication of guilt was withheld or whether the person pled  
 2316 | guilty or nolo contendere. A criminal offense committed in  
 2317 | another jurisdiction which would have been a felony in this  
 2318 | state must be reported. If the person indicates that a criminal  
 2319 | conviction is under appeal and submits a copy of the notice of  
 2320 | appeal of that criminal offense, the applicant must, within 15  
 2321 | days after the disposition of the appeal, submit to the  
 2322 | department a copy of the final written order of disposition.

2323           9. A photograph of the person taken in the previous 30  
2324 days.

2325           10. A set of fingerprints for the person on a form and  
2326 under procedures specified by the department, together with  
2327 payment of an amount equal to the costs incurred by the  
2328 department for the criminal record check of the person.

2329           11. The name, address, occupation, and date and place of  
2330 birth for each member of the person's immediate family who is 18  
2331 years of age or older. As used in this subparagraph, the term  
2332 "member of the person's immediate family" includes the person's  
2333 spouse, children, parents, siblings, the spouses of the person's  
2334 children, and the spouses of the person's siblings.

2335           12. Any other relevant information that the department  
2336 requires.

2337           (b) The information required pursuant to paragraph (a)  
2338 shall be provided under oath.

2339           (c) The department shall submit the fingerprints provided  
2340 by a person for initial licensure to the Department of Law  
2341 Enforcement for a statewide criminal record check and for  
2342 forwarding to the Federal Bureau of Investigation for a national  
2343 criminal record check of the person. The department shall submit  
2344 the fingerprints provided by a person as a part of a renewal  
2345 application to the Department of Law Enforcement for a statewide  
2346 criminal record check, and for forwarding to the Federal Bureau  
2347 of Investigation for a national criminal record check, for the  
2348 initial renewal of a permit after January 1, 2004; for any  
2349 subsequent renewal of a permit, the department shall submit the  
2350 required information for a statewide and national criminal

2351 record check of the person. Any person who as a part of an  
 2352 initial permit application or initial permit renewal after  
 2353 January 1, 2004, submits to the department a set of fingerprints  
 2354 required for the criminal record check required in this  
 2355 paragraph shall not be required to provide a subsequent set of  
 2356 fingerprints for a criminal record check to the department, if  
 2357 the person has undergone a criminal record check as a condition  
 2358 of the issuance of an initial permit or the initial renewal of a  
 2359 permit of an applicant after January 1, 2004.

2360 (10)~~(5)~~ The department may deny an application for a  
 2361 permit or refuse to renew a permit for a prescription drug  
 2362 wholesale distributor ~~wholesaler~~ or an out-of-state prescription  
 2363 drug wholesale distributor ~~wholesaler~~ if:

2364 (a) The applicant has not met the requirements for the  
 2365 permit.

2366 (b) The management, officers, or directors of the  
 2367 applicant or any affiliated party are found by the department to  
 2368 be incompetent or untrustworthy.

2369 (c) The applicant is so lacking in experience in managing  
 2370 a wholesale distributor as to make the issuance of the proposed  
 2371 permit hazardous to the public health.

2372 (d) The applicant is so lacking in experience in managing  
 2373 a wholesale distributor as to jeopardize the reasonable promise  
 2374 of successful operation of the wholesale distributor.

2375 (e) The applicant is lacking in experience in the  
 2376 distribution of prescription drugs.

2377 (f) The applicant's past experience in manufacturing or  
2378 distributing prescription drugs indicates that the applicant  
2379 poses a public health risk.

2380 (g) The applicant is affiliated directly or indirectly  
2381 through ownership, control, or other business relations, with  
2382 any person or persons whose business operations are or have been  
2383 detrimental to the public health.

2384 (h) The applicant, or any affiliated party, has been found  
2385 guilty of or has pleaded guilty or nolo contendere to any felony  
2386 or crime punishable by imprisonment for 1 year or more under the  
2387 laws of the United States, any state, or any other country,  
2388 regardless of whether adjudication of guilt was withheld.

2389 (i) The applicant or any affiliated party has been charged  
2390 with a felony in a state or federal court and the disposition of  
2391 that charge is pending during the application review or renewal  
2392 review period.

2393 (j) The applicant has furnished false or fraudulent  
2394 information or material in any application made in this state or  
2395 any other state in connection with obtaining a permit or license  
2396 to manufacture or distribute drugs, devices, or cosmetics.

2397 (k) That a federal, state, or local government permit  
2398 currently or previously held by the applicant, or any affiliated  
2399 party, for the manufacture or distribution of any drugs,  
2400 devices, or cosmetics has been disciplined, suspended, or  
2401 revoked and has not been reinstated.

2402 (l) The applicant does not possess the financial or  
2403 physical resources to operate in compliance with the permit

2404 being sought, this chapter, and the rules adopted under this  
 2405 chapter.

2406 (m) The applicant or any affiliated party receives,  
 2407 directly or indirectly, financial support and assistance from a  
 2408 person who was an affiliated party of a permittee whose permit  
 2409 was subject to discipline or was suspended or revoked, other  
 2410 than through the ownership of stock in a publicly traded company  
 2411 or a mutual fund.

2412 (n) The applicant or any affiliated party receives,  
 2413 directly or indirectly, financial support and assistance from a  
 2414 person who has been found guilty of any violation of this part  
 2415 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,  
 2416 any rules adopted under any of this part ~~those sections~~ or those  
 2417 chapters, any federal or state drug law, or any felony where the  
 2418 underlying facts related to drugs, regardless of whether the  
 2419 person has been pardoned, had her or his civil rights restored,  
 2420 or had adjudication withheld, other than through the ownership  
 2421 of stock in a publicly traded company or a mutual fund.

2422 (o) The applicant for renewal of a permit under s.  
 2423 499.01(2)(d) ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph~~  
 2424 ~~(2)(e)~~ has not actively engaged in the wholesale distribution  
 2425 of prescription drugs, as demonstrated by the regular and  
 2426 systematic distribution of prescription drugs throughout the  
 2427 year as evidenced by not fewer than 12 wholesale distributions  
 2428 in the previous year and not fewer than three wholesale  
 2429 distributions in the previous 6 months.

2430 (p) Information obtained in response to s. 499.01(2)(d)  
 2431 ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~



2432 demonstrates it would not be in the best interest of the public  
 2433 health, safety, and welfare to issue a permit.

2434 (q) The applicant does not possess the financial standing  
 2435 and business experience for the successful operation of the  
 2436 applicant.

2437 (r) The applicant or any affiliated party has failed to  
 2438 comply with the requirements for manufacturing or distributing  
 2439 prescription drugs under this part ~~ss. 499.001-499.081~~, similar  
 2440 federal laws, similar laws in other states, or the rules adopted  
 2441 under such laws.

2442 ~~(11)(6)~~ Upon approval of the application by the department  
 2443 and payment of the required fee, the department shall issue or  
 2444 renew a prescription drug wholesale distributor ~~wholesaler~~ or an  
 2445 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
 2446 permit to the applicant.

2447 ~~(12)(7)~~ For a permit ~~permits~~ for a prescription drug  
 2448 wholesale distributor ~~wholesalers~~ or an out-of-state  
 2449 prescription drug wholesale distributor ~~wholesalers~~:

2450 (a) The department shall adopt rules for the annual  
 2451 renewal of permits. At least 90 days before the expiration of a  
 2452 permit, the department shall forward a permit renewal  
 2453 notification and renewal application to the prescription drug  
 2454 wholesale distributor ~~wholesaler~~ or out-of-state prescription  
 2455 drug wholesale distributor ~~wholesaler~~ at the mailing address of  
 2456 the permitted establishment on file with the department. The  
 2457 permit renewal notification must state conspicuously the date on  
 2458 which the permit for the establishment will expire and that the

2459 establishment may not operate unless the permit for the  
2460 establishment is renewed timely.

2461 (b) A permit, unless sooner suspended or revoked,  
2462 automatically expires 1 year after the last day of the  
2463 anniversary month in which the permit was originally issued. A  
2464 permit may be renewed by making application for renewal on forms  
2465 furnished by the department and paying the appropriate fees. If  
2466 a renewal application and fee are submitted and postmarked after  
2467 45 days prior to the expiration date of the permit, the permit  
2468 may be renewed only upon payment of a late renewal fee of \$100,  
2469 plus the required renewal fee. A permittee that has submitted a  
2470 renewal application in accordance with this paragraph may  
2471 continue to operate under its permit, unless the permit is  
2472 suspended or revoked, until final disposition of the renewal  
2473 application.

2474 (c) Failure to renew a permit in accordance with this  
2475 section precludes any future renewal of that permit. If a permit  
2476 issued pursuant to this section has expired and cannot be  
2477 renewed, before an establishment may engage in activities that  
2478 require a permit under this part ~~ss. 499.001-499.081~~, the  
2479 establishment must submit an application for a new permit; pay  
2480 the applicable application fee, initial permit fee, and all  
2481 applicable penalties; and be issued a new permit by the  
2482 department.

2483 (13) ~~(8)~~ A person that engages in wholesale distribution of  
2484 prescription drugs in this state must have a wholesale  
2485 distributor's permit issued by the department, except as noted

2486 in this section. Each establishment must be separately permitted  
 2487 except as noted in this subsection.

2488 (a) A separate establishment permit is not required when a  
 2489 permitted prescription drug wholesale distributor ~~wholesaler~~  
 2490 consigns a prescription drug to a pharmacy that is permitted  
 2491 under chapter 465 and located in this state, provided that:

2492 1. The consignor wholesale distributor ~~wholesaler~~ notifies  
 2493 the department in writing of the contract to consign  
 2494 prescription drugs to a pharmacy along with the identity and  
 2495 location of each consignee pharmacy;

2496 2. The pharmacy maintains its permit under chapter 465;

2497 3. The consignor wholesale distributor ~~wholesaler~~, which  
 2498 has no legal authority to dispense prescription drugs, complies  
 2499 with all wholesale distribution requirements of ss. ~~§~~ 499.0121  
 2500 and 499.01212 with respect to the consigned drugs and maintains  
 2501 records documenting the transfer of title or other completion of  
 2502 the wholesale distribution of the consigned prescription drugs;

2503 4. The distribution of the prescription drug is otherwise  
 2504 lawful under this chapter and other applicable law;

2505 5. Open packages containing prescription drugs within a  
 2506 pharmacy are the responsibility of the pharmacy, regardless of  
 2507 how the drugs are titled; and

2508 6. The pharmacy dispenses the consigned prescription drug  
 2509 in accordance with the limitations of its permit under chapter  
 2510 465 or returns the consigned prescription drug to the consignor  
 2511 wholesale distributor ~~wholesaler~~. In addition, a person who  
 2512 holds title to prescription drugs may transfer the drugs to a  
 2513 person permitted or licensed to handle the reverse distribution

2514 or destruction of drugs. Any other distribution by and means of  
 2515 the consigned prescription drug by any person, not limited to  
 2516 the consignor wholesale distributor ~~wholesaler~~ or consignee  
 2517 pharmacy, to any other person is prohibited.

2518 (b) A wholesale distributor's permit is not required for  
 2519 the one-time transfer of title of a pharmacy's lawfully acquired  
 2520 prescription drug inventory by a pharmacy with a valid permit  
 2521 issued under chapter 465 to a consignor prescription drug  
 2522 wholesale distributor ~~wholesaler~~, permitted under this chapter,  
 2523 in accordance with a written consignment agreement between the  
 2524 pharmacy and that wholesale distributor ~~wholesaler~~ if+ the  
 2525 permitted pharmacy and the permitted prescription drug wholesale  
 2526 distributor ~~wholesaler~~ comply with all of the provisions of  
 2527 paragraph (a) and the prescription drugs continue to be within  
 2528 the permitted pharmacy's inventory for dispensing in accordance  
 2529 with the limitations of the pharmacy permit under chapter 465. A  
 2530 consignor drug wholesale distributor ~~wholesaler~~ may not use the  
 2531 pharmacy as a wholesale distributor through which it distributes  
 2532 the prescription ~~legend~~ drugs to other pharmacies. Nothing in  
 2533 this section is intended to prevent a wholesale ~~drug~~ distributor  
 2534 from obtaining this inventory in the event of nonpayment by the  
 2535 pharmacy.

2536 (c) A separate establishment permit is not required when a  
 2537 permitted prescription drug wholesale distributor operates  
 2538 temporary transit storage facilities for the sole purpose of  
 2539 storage, for up to 16 hours, of a delivery of prescription drugs  
 2540 when the wholesale distributor was temporarily unable to  
 2541 complete the delivery to the recipient.

2542        (d)~~(e)~~ The department shall require information from each  
 2543 wholesale distributor as part of the permit and renewal of such  
 2544 permit, as required under ~~s. 499.01~~ or this section.

2545        (14)~~(9)~~ Personnel employed in wholesale distribution must  
 2546 have appropriate education and experience to enable them to  
 2547 perform their duties in compliance with state permitting  
 2548 requirements.

2549        (15)~~(10)~~ The name of a permittee or establishment on a  
 2550 prescription drug wholesale distributor ~~wholesaler~~ permit or an  
 2551 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
 2552 permit may not include any indicia of attainment of any  
 2553 educational degree, any indicia that the permittee or  
 2554 establishment possesses a professional license, or any name or  
 2555 abbreviation that the department determines is likely to cause  
 2556 confusion or mistake or that the department determines is  
 2557 deceptive, including that of any other entity authorized to  
 2558 purchase prescription drugs.

2559        (16)~~(11)~~(a) Each establishment that is issued an initial  
 2560 or renewal permit as a prescription drug wholesale distributor  
 2561 ~~wholesaler~~ or an out-of-state prescription drug wholesale  
 2562 distributor ~~wholesaler~~ must designate in writing to the  
 2563 department at least one natural person to serve as the  
 2564 designated representative of the wholesale distributor  
 2565 ~~wholesaler~~. Such person must have an active certification as a  
 2566 designated representative from the department.

2567        (b) To be certified as a designated representative, a  
 2568 natural person must:

- 2569           1. Submit an application on a form furnished by the  
 2570 department and pay the appropriate fees;
- 2571           2. Be at least 18 years of age;
- 2572           3. Have not less than 2 years of verifiable full-time work  
 2573 experience in a pharmacy licensed in this state or another  
 2574 state, where the person's responsibilities included, but were  
 2575 not limited to, recordkeeping for prescription drugs, or have  
 2576 not less than 2 years of verifiable full-time managerial  
 2577 experience with a prescription drug wholesale distributor  
 2578 ~~wholesaler~~ licensed in this state or in another state;
- 2579           4. Receive a passing score of at least 75 percent on an  
 2580 examination given by the department regarding federal laws  
 2581 governing distribution of prescription drugs and this part ss.  
 2582 ~~499.001-499.081~~ and the rules adopted by the department  
 2583 governing the wholesale distribution of prescription drugs. This  
 2584 requirement shall be effective 1 year after the results of the  
 2585 initial examination are mailed to the persons that took the  
 2586 examination. The department shall offer such examinations at  
 2587 least four times each calendar year; and
- 2588           5. Provide the department with a personal information  
 2589 statement and fingerprints pursuant to subsection (9)~~(4)~~.
- 2590           (c) The department may deny an application for  
 2591 certification as a designated representative or may suspend or  
 2592 revoke a certification of a designated representative pursuant  
 2593 to s. 499.067.
- 2594           (d) A designated representative:
- 2595           1. Must be actively involved in and aware of the actual  
 2596 daily operation of the wholesale distributor.

2597           2. Must be employed full time in a managerial position by  
2598 the wholesale distributor.

2599           3. Must be physically present at the establishment during  
2600 normal business hours, except for time periods when absent due  
2601 to illness, family illness or death, scheduled vacation, or  
2602 other authorized absence.

2603           4. May serve as a designated representative for only one  
2604 wholesale distributor at any one time.

2605           (e) A wholesale distributor must notify the department  
2606 when a designated representative leaves the employ of the  
2607 wholesale distributor. Such notice must be provided to the  
2608 department within 10 business days after the last day of  
2609 designated representative's employment with the wholesale  
2610 distributor.

2611           (f) A wholesale distributor may not operate under a  
2612 prescription drug wholesale distributor ~~wholesaler~~ permit or an  
2613 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2614 permit for more than 10 business days after the designated  
2615 representative leaves the employ of the wholesale distributor,  
2616 unless the wholesale distributor employs another designated  
2617 representative and notifies the department within 10 business  
2618 days of the identity of the new designated representative.

2619           Section 12. Section 499.01201, Florida Statutes, is  
2620 amended to read:

2621           499.01201 Agency for Health Care Administration review and  
2622 use of statute and rule violation or compliance  
2623 data.--Notwithstanding any other provisions of law to the  
2624 contrary, the Agency for Health Care Administration may not:

2625 (1) Review or use any violation or alleged violation of s.  
 2626 499.0121(6) or s. 499.01212, or any rules adopted under those  
 2627 sections ~~that section~~, as a ground for denying or withholding  
 2628 any payment of a Medicaid reimbursement to a pharmacy licensed  
 2629 under chapter 465; or

2630 (2) Review or use compliance with s. 499.0121(6) or s.  
 2631 499.01212, or any rules adopted under those sections ~~that~~  
 2632 ~~section~~, as the subject of any audit of Medicaid-related records  
 2633 held by a pharmacy licensed under chapter 465.

2634 Section 13. Section 499.0121, Florida Statutes, is  
 2635 amended, and subsection (4) of section 499.013, Florida  
 2636 Statutes, is redesignated as paragraph (d) of subsection (6) of  
 2637 that section and amended, to read:

2638 499.0121 Storage and handling of prescription drugs;  
 2639 recordkeeping.--The department shall adopt rules to implement  
 2640 this section as necessary to protect the public health, safety,  
 2641 and welfare. Such rules shall include, but not be limited to,  
 2642 requirements for the storage and handling of prescription drugs  
 2643 and for the establishment and maintenance of prescription drug  
 2644 distribution records.

2645 (1) ESTABLISHMENTS.--An establishment at which  
 2646 prescription drugs are stored, warehoused, handled, held,  
 2647 offered, marketed, or displayed must:

2648 (a) Be of suitable size and construction to facilitate  
 2649 cleaning, maintenance, and proper operations;

2650 (b) Have storage areas designed to provide adequate  
 2651 lighting, ventilation, temperature, sanitation, humidity, space,  
 2652 equipment, and security conditions;



2653 (c) Have a quarantine area for storage of prescription  
 2654 drugs that are outdated, damaged, deteriorated, misbranded, or  
 2655 adulterated, or that are in immediate or sealed, secondary  
 2656 containers that have been opened;

2657 (d) Be maintained in a clean and orderly condition; and

2658 (e) Be free from infestation by insects, rodents, birds,  
 2659 or vermin of any kind.

2660 (2) SECURITY.--

2661 (a) An establishment that is used for wholesale drug  
 2662 distribution must be secure from unauthorized entry.

2663 1. Access from outside the premises must be kept to a  
 2664 minimum and be well-controlled.

2665 2. The outside perimeter of the premises must be well-  
 2666 lighted.

2667 3. Entry into areas where prescription drugs are held must  
 2668 be limited to authorized personnel.

2669 (b) An establishment that is used for wholesale drug  
 2670 distribution must be equipped with:

2671 1. An alarm system to detect entry after hours; however,  
 2672 the department may exempt by rule establishments that only hold  
 2673 a permit as prescription drug wholesale distributor-brokers  
 2674 ~~wholesaler brokers~~ and establishments that only handle medical  
 2675 oxygen; and

2676 2. A security system that will provide suitable protection  
 2677 against theft and diversion. When appropriate, the security  
 2678 system must provide protection against theft or diversion that  
 2679 is facilitated or hidden by tampering with computers or  
 2680 electronic records.

2681 (c) Any vehicle that contains prescription drugs must be  
 2682 secure from unauthorized access to the prescription drugs in the  
 2683 vehicle.

2684 (3) STORAGE.--All prescription drugs shall be stored at  
 2685 appropriate temperatures and under appropriate conditions in  
 2686 accordance with requirements, if any, in the labeling of such  
 2687 drugs, or with requirements in the official compendium.

2688 (a) If no storage requirements are established for a  
 2689 prescription drug, the drug may be held at "controlled" room  
 2690 temperature, as defined in the official compendium, to help  
 2691 ensure that its identity, strength, quality, and purity are not  
 2692 adversely affected.

2693 (b) Appropriate manual, electromechanical, or electronic  
 2694 temperature and humidity recording equipment, devices, or logs  
 2695 must be used to document proper storage of prescription drugs.

2696 (c) The recordkeeping requirements in subsection (6) must  
 2697 be followed for all stored prescription drugs.

2698 (4) EXAMINATION OF MATERIALS AND RECORDS.--

2699 (a) Upon receipt, each outside shipping container must be  
 2700 visually examined for identity and to prevent the acceptance of  
 2701 contaminated prescription drugs that are otherwise unfit for  
 2702 distribution. This examination must be adequate to reveal  
 2703 container damage that would suggest possible contamination or  
 2704 other damage to the contents.

2705 (b) Each outgoing shipment must be carefully inspected for  
 2706 identity of the prescription drug products and to ensure that  
 2707 there is no delivery of prescription drugs that have expired or  
 2708 been damaged in storage or held under improper conditions.

2709 (c) The recordkeeping requirements in subsection (6) must  
 2710 be followed for all incoming and outgoing prescription drugs.

2711 (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must  
 2712 review records required under this section for the acquisition  
 2713 of prescription drugs for accuracy and completeness, considering  
 2714 the total facts and circumstances surrounding the transactions  
 2715 and the wholesale distributors involved. This includes  
 2716 authenticating each transaction listed on a pedigree paper, as  
 2717 defined in s. 499.003(35) ~~s. 499.001(31)~~.

2718 (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

2719 (a)1. Prescription drugs that are outdated, damaged,  
 2720 deteriorated, misbranded, or adulterated must be quarantined and  
 2721 physically separated from other prescription drugs until they  
 2722 are destroyed or returned to their supplier. A quarantine  
 2723 section must be separate and apart from other sections where  
 2724 prescription drugs are stored so that prescription drugs in this  
 2725 section are not confused with usable prescription drugs.

2726 2. Prescription drugs must be examined at least every 12  
 2727 months, and drugs for which the expiration date has passed must  
 2728 be removed and quarantined.

2729 (b) Any prescription drugs of which the immediate or  
 2730 sealed outer containers or sealed secondary containers have been  
 2731 opened or used must be identified as such and must be  
 2732 quarantined and physically separated from other prescription  
 2733 drugs until they are ~~either~~ destroyed or returned to the  
 2734 supplier.

2735 (c) If the conditions under which a prescription drug has  
 2736 been returned cast doubt on the drug's safety, identity,

2737 strength, quality, or purity, the drug must be destroyed or  
 2738 returned to the supplier, unless examination, testing, or other  
 2739 investigation proves that the drug meets appropriate standards  
 2740 of safety, identity, strength, quality, and purity. In  
 2741 determining whether the conditions under which a drug has been  
 2742 returned cast doubt on the drug's safety, identity, strength,  
 2743 quality, or purity, the wholesale ~~drug~~ distributor must  
 2744 consider, among other things, the conditions under which the  
 2745 drug has been held, stored, or shipped before or during its  
 2746 return and the conditions of the drug and its container, carton,  
 2747 or labeling, as a result of storage or shipping.

2748 (d) The recordkeeping requirements in subsection (6) must  
 2749 be followed for all outdated, damaged, deteriorated, misbranded,  
 2750 or adulterated prescription drugs.

2751 (6) RECORDKEEPING.--The department shall adopt rules that  
 2752 require keeping such records of prescription drugs as are  
 2753 necessary for the protection of the public health.

2754 (a) Wholesale ~~drug~~ distributors must establish and  
 2755 maintain inventories and records of all transactions regarding  
 2756 the receipt and distribution or other disposition of  
 2757 prescription drugs. These records must provide a complete audit  
 2758 trail from receipt to sale or other disposition, be readily  
 2759 retrievable for inspection, and include, at a minimum, the  
 2760 following information:

- 2761 1. The source of the drugs, including the name and  
 2762 principal address of the seller or transferor, and the address  
 2763 of the location from which the drugs were shipped;

2764           2. The name, principal address, and state license permit  
 2765 or registration number of the person authorized to purchase  
 2766 prescription drugs;

2767           3. The name, strength, dosage form, and quantity of the  
 2768 drugs received and distributed or disposed of;

2769           4. The dates of receipt and distribution or other  
 2770 disposition of the drugs; and

2771           5. Any financial documentation supporting the transaction.

2772           (b) Inventories and records must be made available for  
 2773 inspection and photocopying by authorized federal, state, or  
 2774 local officials for a period of 2 years following disposition of  
 2775 the drugs or 3 years after the creation of the records,  
 2776 whichever period is longer.

2777           (c) Records described in this section that are kept at the  
 2778 inspection site or that can be immediately retrieved by computer  
 2779 or other electronic means must be readily available for  
 2780 authorized inspection during the retention period. Records that  
 2781 are kept at a central location outside of this state and that  
 2782 are not electronically retrievable must be made available for  
 2783 inspection within 2 working days after a request by an  
 2784 authorized official of a federal, state, or local law  
 2785 enforcement agency. Records that are maintained at a central  
 2786 location within this state must be maintained at an  
 2787 establishment that is permitted pursuant to this part ~~ss.~~  
 2788 ~~499.001-499.081~~ and must be readily available.

2789           (d) ~~(4)~~ Each manufacturer or repackager of medical devices,  
 2790 over-the-counter drugs, or cosmetics must maintain records that  
 2791 include the name and principal address of the seller or

2792 transferor of the product, the address of the location from  
 2793 which the product was shipped, the date of the transaction, the  
 2794 name and quantity of the product involved, and the name and  
 2795 principal address of the person who purchased the product.

2796 (e) A wholesale distributor must maintain pedigree papers  
 2797 separate and distinct from other records required under this  
 2798 chapter.

2799 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~  
 2800 ~~the wholesale distribution of a prescription drug and who is not~~  
 2801 ~~the manufacturer of that drug must, before each wholesale~~  
 2802 ~~distribution of such drug, provide to the person who receives~~  
 2803 ~~the drug a pedigree paper as defined in s. 499.003(31).~~

2804 ~~2. A repackager must comply with this paragraph.~~

2805 ~~3. The pedigree paper requirements in this paragraph do~~  
 2806 ~~not apply to compressed medical gases or veterinary legend~~  
 2807 ~~drugs.~~

2808 ~~4. Each wholesale distributor of prescription drugs must~~  
 2809 ~~maintain separate and distinct from other required records all~~  
 2810 ~~statements that are required under subparagraph 1.~~

2811 ~~5. Subparagraph 1. is satisfied when a wholesale~~  
 2812 ~~distributor takes title to, but not possession of, a~~  
 2813 ~~prescription drug and the prescription drug's manufacturer ships~~  
 2814 ~~the prescription drug directly to a person authorized by law to~~  
 2815 ~~purchase prescription drugs for the purpose of administering or~~  
 2816 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~  
 2817 ~~affiliated group, as described in paragraph (f), with the~~  
 2818 ~~exception of a repackager.~~

2819           ~~a. The wholesale distributor must deliver to the recipient~~  
 2820 ~~of the prescription drug, within 14 days after the shipment~~  
 2821 ~~notification from the manufacturer, an invoice and the following~~  
 2822 ~~sworn statement: "This wholesale distributor purchased the~~  
 2823 ~~specific unit of the prescription drug listed on the invoice~~  
 2824 ~~directly from the manufacturer, and the specific unit of~~  
 2825 ~~prescription drug was shipped by the manufacturer directly to a~~  
 2826 ~~person authorized by law to administer or dispense the legend~~  
 2827 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~  
 2828 ~~an affiliated group, as described in s. 499.0121(6)(f), Florida~~  
 2829 ~~Statutes, with the exception of a repackager." The invoice must~~  
 2830 ~~contain a unique cross reference to the shipping document sent~~  
 2831 ~~by the manufacturer to the recipient of the prescription drug.~~

2832           ~~b. The manufacturer of the prescription drug shipped~~  
 2833 ~~directly to the recipient under this section must provide and~~  
 2834 ~~the recipient of the prescription drug must acquire, within 14~~  
 2835 ~~days after receipt of the prescription drug, a shipping document~~  
 2836 ~~from the manufacturer that contains, at a minimum:~~

2837           ~~(I) The name and address of the manufacturer, including~~  
 2838 ~~the point of origin of the shipment, and the names and addresses~~  
 2839 ~~of the wholesaler and the purchaser.~~

2840           ~~(II) The name of the prescription drug as it appears on~~  
 2841 ~~the label.~~

2842           ~~(III) The quantity, dosage form, and strength of the~~  
 2843 ~~prescription drug.~~

2844           ~~(IV) The date of the shipment from the manufacturer.~~

2845           ~~e. The wholesale distributor must also maintain and make~~  
 2846 ~~available to the department, upon request, the lot number of~~

2847 ~~such drug if not contained in the shipping document acquired by~~  
 2848 ~~the recipient.~~

2849 ~~6. Failure of the manufacturer to provide, the recipient~~  
 2850 ~~to acquire, or the wholesale distributor to deliver, the~~  
 2851 ~~documentation required under subparagraph 5. shall constitute~~  
 2852 ~~failure to acquire or deliver a pedigree paper under s.~~  
 2853 ~~499.0051. Forgery by the manufacturer, the recipient, or the~~  
 2854 ~~wholesale distributor of the documentation required to be~~  
 2855 ~~acquired or delivered under subparagraph 5. shall constitute~~  
 2856 ~~forgery of a pedigree paper under s. 499.0051.~~

2857 ~~7. The department may, by rule, specify alternatives to~~  
 2858 ~~compliance with subparagraph 1. for a prescription drug in the~~  
 2859 ~~inventory of a permitted prescription drug wholesaler as of June~~  
 2860 ~~30, 2006, and the return of a prescription drug purchased prior~~  
 2861 ~~to July 1, 2006. The department may specify time limits for such~~  
 2862 ~~alternatives.~~

2863 (7)(e) PRESCRIPTION DRUG PURCHASE LIST.--Each wholesale  
 2864 distributor, except for a manufacturer, shall annually provide  
 2865 the department with a written list of all wholesale distributors  
 2866 and manufacturers from whom the wholesale distributor purchases  
 2867 prescription drugs. A wholesale distributor, except a  
 2868 manufacturer, shall notify the department not later than 10 days  
 2869 after any change to either list. Such portions of the  
 2870 information required pursuant to this subsection ~~paragraph~~ which  
 2871 are a trade secret, as defined in s. 812.081, shall be  
 2872 maintained by the department as trade secret information is  
 2873 required to be maintained under s. 499.051.



2874 ~~(f)1. This paragraph applies only to an affiliated group,~~  
 2875 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~  
 2876 ~~amended, which is composed of chain drug entities, including at~~  
 2877 ~~least 50 retail pharmacies, warehouses, or repackagers, which~~  
 2878 ~~are members of the same affiliated group, if the affiliated~~  
 2879 ~~group:~~

2880 ~~a. Discloses to the department the names of all its~~  
 2881 ~~members; and~~

2882 ~~b. Agrees in writing to provide records on prescription~~  
 2883 ~~drug purchases by members of the affiliated group not later than~~  
 2884 ~~48 hours after the department requests such records, regardless~~  
 2885 ~~of the location where the records are stored.~~

2886 ~~2. Each warehouse within the affiliated group must comply~~  
 2887 ~~with all applicable federal and state drug wholesale permit~~  
 2888 ~~requirements and must purchase, receive, hold, and distribute~~  
 2889 ~~prescription drugs only to a retail pharmacy or warehouse within~~  
 2890 ~~the affiliated group. Such a warehouse is exempt from providing~~  
 2891 ~~a pedigree paper in accordance with paragraph (d) to its~~  
 2892 ~~affiliated group member warehouse or retail pharmacy, provided~~  
 2893 ~~that:~~

2894 ~~a. Any affiliated group member that purchases or receives~~  
 2895 ~~a prescription drug from outside the affiliated group must~~  
 2896 ~~receive a pedigree paper if the prescription drug is distributed~~  
 2897 ~~in or into this state and a pedigree paper is required under~~  
 2898 ~~this section and must authenticate the documentation as required~~  
 2899 ~~in subsection (4), regardless of whether the affiliated group~~  
 2900 ~~member is directly subject to regulation under this chapter; and~~

2901 ~~b. The affiliated group makes available to the department~~  
 2902 ~~on request all records related to the purchase or acquisition of~~  
 2903 ~~prescription drugs by members of the affiliated group,~~  
 2904 ~~regardless of the location where the records are stored, if the~~  
 2905 ~~prescription drugs were distributed in or into this state.~~

2906 ~~3. If a repackager repackages prescription drugs solely~~  
 2907 ~~for distribution to its affiliated group members for the~~  
 2908 ~~exclusive distribution to and among retail pharmacies that are~~  
 2909 ~~members of the affiliated group to which the repackager is a~~  
 2910 ~~member:~~

2911 ~~a. The repackager must:~~

2912 ~~(I) In lieu of the written statement required by paragraph~~  
 2913 ~~(d), for all repackaged prescription drugs distributed in or~~  
 2914 ~~into this state, state in writing under oath with each~~  
 2915 ~~distribution of a repackaged prescription drug to an affiliated~~  
 2916 ~~group member warehouse or repackager: "All repackaged~~  
 2917 ~~prescription drugs are purchased by the affiliated group~~  
 2918 ~~directly from the manufacturer or from a prescription drug~~  
 2919 ~~wholesaler that purchased the prescription drugs directly from~~  
 2920 ~~the manufacturer.";~~

2921 ~~(II) Purchase all prescription drugs it repackages:~~

2922 ~~(A) Directly from the manufacturer; or~~

2923 ~~(B) From a prescription drug wholesaler that purchased the~~  
 2924 ~~prescription drugs directly from the manufacturer; and~~

2925 ~~(III) Maintain records in accordance with this section to~~  
 2926 ~~document that it purchased the prescription drugs directly from~~  
 2927 ~~the manufacturer or that its prescription drug wholesale~~

2928 ~~supplier purchased the prescription drugs directly from the~~  
 2929 ~~manufacturer.~~

2930 ~~b. All members of the affiliated group must provide to~~  
 2931 ~~agents of the department on request records of purchases by all~~  
 2932 ~~members of the affiliated group of prescription drugs that have~~  
 2933 ~~been repackaged, regardless of the location where the records~~  
 2934 ~~are stored or where the repackager is located.~~

2935 (8)~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale ~~drug~~  
 2936 distributors must establish, maintain, and adhere to written  
 2937 policies and procedures, which must be followed for the receipt,  
 2938 security, storage, inventory, and distribution of prescription  
 2939 drugs, including policies and procedures for identifying,  
 2940 recording, and reporting losses or thefts, and for correcting  
 2941 all errors and inaccuracies in inventories. Wholesale ~~drug~~  
 2942 distributors must include in their written policies and  
 2943 procedures:

2944 (a) A procedure whereby the oldest approved stock of a  
 2945 prescription drug product is distributed first. The procedure  
 2946 may permit deviation from this requirement, if the deviation is  
 2947 temporary and appropriate.

2948 (b) A procedure to be followed for handling recalls and  
 2949 withdrawals of prescription drugs. Such procedure must be  
 2950 adequate to deal with recalls and withdrawals due to:

2951 1. Any action initiated at the request of the Food and  
 2952 Drug Administration or any other federal, state, or local law  
 2953 enforcement or other government agency, including the  
 2954 department.

2955           2. Any voluntary action by the manufacturer or repackager  
 2956 to remove defective or potentially defective drugs from the  
 2957 market; or

2958           3. Any action undertaken to promote public health and  
 2959 safety by replacing existing merchandise with an improved  
 2960 product or new package design.

2961           (c) A procedure to ensure that wholesale ~~drug~~ distributors  
 2962 prepare for, protect against, and handle any crisis that affects  
 2963 security or operation of any facility if a strike, fire, flood,  
 2964 or other natural disaster, or a local, state, or national  
 2965 emergency, occurs.

2966           (d) A procedure to ensure that any outdated prescription  
 2967 drugs are segregated from other drugs and ~~either~~ returned to the  
 2968 manufacturer or repackager or destroyed. This procedure must  
 2969 provide for written documentation of the disposition of outdated  
 2970 prescription drugs. This documentation must be maintained for 2  
 2971 years after disposition of the outdated drugs.

2972           (9)~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors  
 2973 must establish and maintain lists of officers, directors,  
 2974 managers, designated representatives, and other persons in  
 2975 charge of wholesale drug distribution, storage, and handling,  
 2976 including a description of their duties and a summary of their  
 2977 qualifications.

2978           (10)~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A  
 2979 wholesale ~~drug~~ distributor must operate in compliance with  
 2980 applicable federal, state, and local laws and regulations.

2981           (a) A wholesale ~~drug~~ distributor must allow the department  
 2982 and authorized federal, state, and local officials to enter and

2983 inspect its premises and delivery vehicles, and to audit its  
 2984 records and written operating procedures, at reasonable times  
 2985 and in a reasonable manner, to the extent authorized by law.

2986 (b) A wholesale ~~drug~~ distributor that deals in controlled  
 2987 substances must register with the Drug Enforcement  
 2988 Administration and must comply with all applicable state, local,  
 2989 and federal laws. A wholesale ~~drug~~ distributor that distributes  
 2990 any substance controlled under chapter 893 must notify the  
 2991 department when registering with the Drug Enforcement  
 2992 Administration pursuant to that chapter and must provide the  
 2993 department with its DEA number.

2994 (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~  
 2995 distributor is subject to any applicable federal, state, or  
 2996 local laws or regulations that relate to prescription drug  
 2997 product salvaging or reprocessing.

2998 (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person  
 2999 responsible for shipment and transportation of a prescription  
 3000 drug in a wholesale distribution may use a common carrier; its  
 3001 own vehicle or employee acting within the scope of employment if  
 3002 authorized under s. 499.03 for the possession of prescription  
 3003 drugs in this state; or, in the case of a prescription drug  
 3004 intended for domestic distribution, an independent contractor  
 3005 who must be the agent of the authorized seller or recipient  
 3006 responsible for shipping and transportation as set forth in a  
 3007 written contract between the parties. A person selling a  
 3008 prescription drug for export must obtain documentation, such as  
 3009 a validated airway bill, bill of lading, or other appropriate  
 3010 documentation that the prescription drug was exported. A person

3011 responsible for shipping or transporting prescription drugs is  
 3012 not required to maintain documentation from a common carrier  
 3013 that the designated recipient received the prescription drugs;  
 3014 however, the person must obtain such documentation from the  
 3015 common carrier and make it available to the department upon  
 3016 request of the department.

3017 (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing  
 3018 any prescription drugs from another wholesale ~~drug~~ distributor,  
 3019 a prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
 3020 state prescription drug wholesale distributor ~~wholesaler~~, or a  
 3021 prescription drug repackager must:

3022 (a) Enter an agreement with the selling wholesale ~~drug~~  
 3023 distributor by which the selling wholesale ~~drug~~ distributor will  
 3024 indemnify the purchasing wholesale ~~drug~~ distributor for any loss  
 3025 caused to the purchasing wholesale ~~drug~~ distributor related to  
 3026 the purchase of drugs from the selling wholesale ~~drug~~  
 3027 distributor which are determined to be counterfeit or to have  
 3028 been distributed in violation of any federal or state law  
 3029 governing the distribution of drugs.

3030 (b) Determine that the selling wholesale ~~drug~~ distributor  
 3031 has insurance coverage of not less than the greater of 1 percent  
 3032 of the amount of total dollar volume of the prescription drug  
 3033 sales reported to the department under s. 499.012(8)(g) ~~s.~~  
 3034 ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed  
 3035 \$2 million.

3036 (c) Obtain information from the selling wholesale ~~drug~~  
 3037 distributor, including the length of time the selling wholesale  
 3038 ~~drug~~ distributor has been licensed in this state, a copy of the

3039 selling wholesale ~~drug~~ distributor's licenses or permits, and  
 3040 background information concerning the ownership of the selling  
 3041 wholesale ~~drug~~ distributor, including the experience of the  
 3042 wholesale distributor in the wholesale distribution of  
 3043 prescription drugs.

3044 (d) Verify that the selling wholesale ~~drug~~ distributor's  
 3045 Florida permit is valid.

3046 (e) Inspect the selling wholesale ~~drug~~ distributor's  
 3047 licensed establishment to document that it has a policies and  
 3048 procedures manual relating to the distribution of drugs, the  
 3049 appropriate temperature controlled environment for drugs  
 3050 requiring temperature control, an alarm system, appropriate  
 3051 access restrictions, and procedures to ensure that records  
 3052 related to the wholesale distribution of prescription drugs are  
 3053 maintained as required by law:

3054 1. Before purchasing any drug from the wholesale ~~drug~~  
 3055 distributor, and at least once each subsequent year; or

3056 2. Before purchasing any drug from the wholesale ~~drug~~  
 3057 distributor, and each subsequent year obtain a complete copy of  
 3058 the most recent inspection report for the establishment which  
 3059 was prepared by the department or the regulatory authority  
 3060 responsible for wholesale ~~drug~~ distributors in the state in  
 3061 which the establishment is located.

3062 Section 14. Section 499.01211, Florida Statutes, is  
 3063 amended to read:

3064 499.01211 Drug Wholesale Distributor ~~Wholesaler~~ Advisory  
 3065 Council.--

3066 (1) There is created the Drug Wholesale Distributor  
 3067 ~~Wholesaler~~ Advisory Council within the department. The council  
 3068 shall meet at least once each calendar quarter. Staff for the  
 3069 council shall be provided by the department. The council shall  
 3070 consist of 11 members who shall serve without compensation. The  
 3071 council shall elect a chairperson and a vice chairperson  
 3072 annually.

3073 (2) The State Surgeon General, or his or her designee, and  
 3074 the Secretary of Health Care Administration, or her or his  
 3075 designee, shall be members of the council. The State Surgeon  
 3076 General shall appoint nine additional members to the council who  
 3077 shall be appointed to a term of 4 years each, as follows:

3078 (a) Three different persons each of whom is employed by a  
 3079 different prescription drug wholesale distributor ~~wholesaler~~  
 3080 licensed under this part ~~chapter~~ which operates nationally and  
 3081 is a primary wholesale distributor ~~wholesaler~~, as defined in s.  
 3082 499.003(46) ~~s. 499.012(1)(d)~~.

3083 (b) One person employed by a prescription drug wholesale  
 3084 distributor ~~wholesaler~~ licensed under this part ~~chapter~~ which is  
 3085 a secondary wholesale distributor ~~wholesaler~~, as defined in s.  
 3086 499.003(51) ~~s. 499.012(1)(f)~~.

3087 (c) One person employed by a retail pharmacy chain located  
 3088 in this state.

3089 (d) One person who is a member of the Board of Pharmacy  
 3090 and is a pharmacist licensed under chapter 465.

3091 (e) One person who is a physician licensed pursuant to  
 3092 chapter 458 or chapter 459.



3093 (f) One person who is an employee of a hospital licensed  
 3094 pursuant to chapter 395 and is a pharmacist licensed pursuant to  
 3095 chapter 465.

3096 (g) One person who is an employee of a pharmaceutical  
 3097 manufacturer.

3098 (3) The council shall review this part ~~ss. 499.001-499.081~~  
 3099 and the rules adopted to administer this part ~~ss. 499.001-~~  
 3100 ~~499.081~~ annually, provide input to the department regarding all  
 3101 proposed rules to administer this part ~~ss. 499.001-499.081~~, make  
 3102 recommendations to the department to improve the protection of  
 3103 the prescription drugs and public health, make recommendations  
 3104 to improve coordination with other states' regulatory agencies  
 3105 and the federal government concerning the wholesale distribution  
 3106 of drugs, and make recommendations to minimize the impact of  
 3107 regulation of the wholesale distribution industry while ensuring  
 3108 protection of the public health.

3109 Section 15. Section 499.01212, Florida Statutes, is  
 3110 created to read:

3111 499.01212 Pedigree paper.--

3112 (1) APPLICATION.--Each person who is engaged in the  
 3113 wholesale distribution of a prescription drug must, prior to or  
 3114 simultaneous with each wholesale distribution, provide a  
 3115 pedigree paper to the person who receives the drug.

3116 (2) FORMAT.--A pedigree paper must contain the following  
 3117 information:

3118 (a) For the wholesale distribution of a prescription drug  
 3119 within the normal distribution chain:

3120           1. The following statement: "This wholesale distributor  
 3121 purchased the specific unit of the prescription drug directly  
 3122 from the manufacturer."

3123           2. The manufacturer's national drug code identifier and  
 3124 the name and address of the wholesale distributor and the  
 3125 purchaser of the prescription drug.

3126           3. The name of the prescription drug as it appears on the  
 3127 label.

3128           4. The quantity, dosage form, and strength of the  
 3129 prescription drug.

3130

3131 The wholesale distributor must also maintain and make available  
 3132 to the department, upon request, the point of origin of the  
 3133 prescription drugs, including intracompany transfers, the date  
 3134 of the shipment from the manufacturer to the wholesale  
 3135 distributor, the lot numbers of such drugs, and the invoice  
 3136 numbers from the manufacturer.

3137           (b) For all other wholesale distributions of prescription  
 3138 drugs:

3139           1. The quantity, dosage form, and strength of the  
 3140 prescription drugs.

3141           2. The lot numbers of the prescription drugs.

3142           3. The name and address of each owner of the prescription  
 3143 drug and his or her signature.

3144           4. Shipping information, including the name and address of  
 3145 each person certifying delivery or receipt of the prescription  
 3146 drug.

3147 5. An invoice number, a shipping document number, or  
 3148 another number uniquely identifying the transaction.

3149 6. A certification that the recipient wholesale  
 3150 distributor has authenticated the pedigree papers.

3151 7. The unique serialization of the prescription drug, if  
 3152 the manufacturer or repackager has uniquely serialized the  
 3153 individual prescription drug unit.

3154 8. The name, address, telephone number, and, if available,  
 3155 e-mail contact information of each wholesale distributor  
 3156 involved in the chain of the prescription drug's custody.

3157 (3) EXCEPTIONS.--A pedigree paper is not required for:

3158 (a) The wholesale distribution of a prescription drug by  
 3159 the manufacturer or by a third party logistics provider  
 3160 performing a wholesale distribution of a prescription drug for a  
 3161 manufacturer.

3162 (b) The wholesale distribution of a prescription drug by a  
 3163 freight forwarder within the authority of a freight forwarder  
 3164 permit.

3165 (c) The wholesale distribution of a prescription drug by a  
 3166 limited prescription drug veterinary wholesale distributor to a  
 3167 veterinarian.

3168 (d) The wholesale distribution of a compressed medical  
 3169 gas.

3170 (e) The wholesale distribution of a veterinary  
 3171 prescription drug.

3172 (f) A drop shipment, provided:

3173 1. The wholesale distributor delivers to the recipient of  
 3174 the prescription drug, within 14 days after the shipment

3175 notification from the manufacturer, an invoice and the following  
 3176 sworn statement: "This wholesale distributor purchased the  
 3177 specific unit of the prescription drug listed on the invoice  
 3178 directly from the manufacturer, and the specific unit of  
 3179 prescription drug was shipped by the manufacturer directly to a  
 3180 person authorized by law to administer or dispense the legend  
 3181 drug, as defined in s. 465.003, Florida Statutes, or a member of  
 3182 an affiliated group, with the exception of a repackager." The  
 3183 invoice must contain a unique cross-reference to the shipping  
 3184 document sent by the manufacturer to the recipient of the  
 3185 prescription drug.

3186 2. The manufacturer of the prescription drug shipped  
 3187 directly to the recipient provides and the recipient of the  
 3188 prescription drug acquires, within 14 days after receipt of the  
 3189 prescription drug, a shipping document from the manufacturer  
 3190 that contains, at a minimum:

3191 a. The name and address of the manufacturer, including the  
 3192 point of origin of the shipment, and the names and addresses of  
 3193 the wholesale distributor and the purchaser.

3194 b. The name of the prescription drug as it appears on the  
 3195 label.

3196 c. The quantity, dosage form, and strength of the  
 3197 prescription drug.

3198 d. The date of the shipment from the manufacturer.

3199 3. The wholesale distributor maintains and makes available  
 3200 to the department, upon request, the lot number of such drug if  
 3201 not contained in the shipping document acquired by the  
 3202 recipient.

3203  
 3204 Failure of the manufacturer to provide, the recipient to  
 3205 acquire, or the wholesale distributor to deliver the  
 3206 documentation required under this paragraph shall constitute  
 3207 failure to acquire or deliver a pedigree paper under ss.  
 3208 499.005(28) and 499.0051. Forgery by the manufacturer, the  
 3209 recipient, or the wholesale distributor of the documentation  
 3210 required to be acquired or delivered under this paragraph shall  
 3211 constitute forgery of a pedigree paper under s. 499.0051.

3212 4. The wholesale distributor that takes title to, but not  
 3213 possession of, the prescription drug is not a member of the  
 3214 affiliated group that receives the prescription drug directly  
 3215 from the manufacturer.

3216 (g) The wholesale distribution of a prescription drug by a  
 3217 warehouse within an affiliated group to a warehouse or retail  
 3218 pharmacy within its affiliated group, provided:

3219 1. Any affiliated group member that purchases or receives  
 3220 a prescription drug from outside the affiliated group must  
 3221 receive a pedigree paper if the prescription drug is distributed  
 3222 in or into this state and a pedigree paper is required under  
 3223 this section and must authenticate the documentation as required  
 3224 in s. 499.0121(4), regardless of whether the affiliated group  
 3225 member is directly subject to regulation under this part; and

3226 2. The affiliated group makes available, within 48 hours,  
 3227 to the department on request to one or more of its members all  
 3228 records related to the purchase or acquisition of prescription  
 3229 drugs by members of the affiliated group, regardless of the

3230 location where the records are stored, if the prescription drugs  
 3231 were distributed in or into this state.

3232 (h) The repackaging of prescription drugs by a repackager  
 3233 solely for distribution to its affiliated group members for the  
 3234 exclusive distribution to and among retail pharmacies that are  
 3235 members of the affiliated group to which the repackager is a  
 3236 member.

3237 1. The repackager must:

3238 a. For all repackaged prescription drugs distributed in or  
 3239 into this state, state in writing under oath with each  
 3240 distribution of a repackaged prescription drug to an affiliated  
 3241 group member warehouse or repackager: "All repackaged  
 3242 prescription drugs are purchased by the affiliated group  
 3243 directly from the manufacturer or from a prescription drug  
 3244 wholesale distributor that purchased the prescription drugs  
 3245 directly from the manufacturer."

3246 b. Purchase all prescription drugs it repackages:

3247 (I) Directly from the manufacturer; or

3248 (II) From a prescription drug wholesale distributor that  
 3249 purchased the prescription drugs directly from the manufacturer.

3250 c. Maintain records in accordance with this section to  
 3251 document that it purchased the prescription drugs directly from  
 3252 the manufacturer or that its prescription drug wholesale  
 3253 supplier purchased the prescription drugs directly from the  
 3254 manufacturer.

3255 2. All members of the affiliated group must provide,  
 3256 within 48 hours, to agents of the department on request to one  
 3257 or more of its members records of purchases by all members of

3258 | the affiliated group of prescription drugs that have been  
 3259 | repackaged, regardless of the location at which the records are  
 3260 | stored or at which the repackager is located.

3261 | Section 16. Section 499.0122, Florida Statutes, is  
 3262 | repealed.

3263 | Section 17. Section 499.013, Florida Statutes, is  
 3264 | repealed.

3265 | Section 18. Subsections (1), (3), (4), (6), (8), and (9)  
 3266 | of section 499.015, Florida Statutes, are amended to read:

3267 | 499.015 Registration of drugs, devices, and cosmetics;  
 3268 | issuance of certificates of free sale.--

3269 | (1)(a) Except for those persons exempted from the  
 3270 | definition of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, any  
 3271 | person who manufactures, packages, repackages, labels, or  
 3272 | relabels a drug, device, or cosmetic in this state must register  
 3273 | such drug, device, or cosmetic biennially with the department;  
 3274 | pay a fee in accordance with the fee schedule provided by s.  
 3275 | 499.041; and comply with this section. The registrant must list  
 3276 | each separate and distinct drug, device, or cosmetic at the time  
 3277 | of registration.

3278 | (b) The department may not register any product that does  
 3279 | not comply with the Federal Food, Drug, and Cosmetic Act, as  
 3280 | amended, or Title 21 C.F.R. Registration of a product by the  
 3281 | department does not mean that the product does in fact comply  
 3282 | with all provisions of the Federal Food, Drug, and Cosmetic Act,  
 3283 | as amended.

3284 | (3) Except for those persons exempted from the definition  
 3285 | of manufacturer in s. 499.003(31) ~~s. 499.003(28)~~, a person may

3286 not sell any product that he or she has failed to register in  
 3287 conformity with this section. Such failure to register subjects  
 3288 such drug, device, or cosmetic product to seizure and  
 3289 condemnation as provided in s. 499.062 ~~ss. 499.062-499.064~~, and  
 3290 subjects such person to the penalties and remedies provided in  
 3291 this part ~~ss. 499.001-499.081~~.

3292 (4) Unless a registration is renewed, it expires 2 years  
 3293 after the last day of the month in which it was issued. The  
 3294 department may issue a stop-sale notice or order against a  
 3295 person that is subject to the requirements of this section and  
 3296 that fails to comply with this section within 31 days after the  
 3297 date the registration expires. The notice or order shall  
 3298 prohibit such person from selling or causing to be sold any  
 3299 drugs, devices, or cosmetics covered by this part ~~ss. 499.001-~~  
 3300 ~~499.081~~ until he or she complies with the requirements of this  
 3301 section.

3302 (6) The department may issue a certificate of free sale  
 3303 for any product that is required to be registered under this  
 3304 part ~~ss. 499.001-499.081~~.

3305 (8) Notwithstanding any requirements set forth in this  
 3306 part ~~ss. 499.001-499.081~~, a manufacturer of medical devices that  
 3307 is registered with the federal Food and Drug Administration is  
 3308 exempt from this section and s. 499.041(6) if:

3309 (a) The manufacturer's medical devices are approved for  
 3310 marketing by, or listed with the federal Food and Drug  
 3311 Administration in accordance with federal law for commercial  
 3312 distribution; or



3313 (b) The manufacturer subcontracts with a manufacturer of  
 3314 medical devices to manufacture components of such devices.

3315 (9) However, the manufacturer must submit evidence of such  
 3316 registration, listing, or approval with its initial application  
 3317 for a permit to do business in this state, as required in s.  
 3318 499.01 ~~s. 499.013~~ and any changes to such information previously  
 3319 submitted at the time of renewal of the permit. Evidence of  
 3320 approval, listing, and registration by the federal Food and Drug  
 3321 Administration must include:

3322 (a) For Class II devices, a copy of the pre-market  
 3323 notification letter (510K);

3324 (b) For Class III devices, a Federal Drug Administration  
 3325 pre-market approval number;

3326 (c) For a manufacturer who subcontracts with a  
 3327 manufacturer of medical devices to manufacture components of  
 3328 such devices, a Federal Drug Administration registration number;  
 3329 or

3330 (d) For a manufacturer of medical devices whose devices  
 3331 are exempt from pre-market approval by the Federal Drug  
 3332 Administration, a Federal Drug Administration registration  
 3333 number.

3334 Section 19. Subsections (3), (5), and (6) of section  
 3335 499.024, Florida Statutes, are amended to read:

3336 499.024 Drug product classification.--The State Surgeon  
 3337 General shall adopt rules to classify drug products intended for  
 3338 use by humans which the United States Food and Drug  
 3339 Administration has not classified in the federal act or the Code  
 3340 of Federal Regulations.

3341 (3) Any product that falls under the definition of drug in  
 3342 s. 499.003(19) definition, s. 499.003(17), may be classified  
 3343 under the authority of this section. This section does not  
 3344 subject portable emergency oxygen inhalators to classification;  
 3345 however, this section does not exempt any person from ss. 499.01  
 3346 and 499.015.

3347 (5) The department may by rule reclassify drugs subject to  
 3348 this part ~~ss. 499.001-499.081~~ when such classification action is  
 3349 necessary to protect the public health.

3350 (6) The department may adopt rules that exempt from any  
 3351 labeling or packaging requirements of this part ~~ss. 499.001-~~  
 3352 ~~499.081~~ drugs classified under this section if those  
 3353 requirements are not necessary to protect the public health.

3354 Section 20. Subsections (7), (12), and (15) of section  
 3355 499.028, Florida Statutes, are amended to read:

3356 499.028 Drug samples or complimentary drugs; starter  
 3357 packs; permits to distribute.--

3358 (7) A drug manufacturer or distributor must report to the  
 3359 department any conviction of itself or of its assigns, agents,  
 3360 employees, or representatives for a violation of s. 503(c)(1) of  
 3361 the federal act or of this part ~~ss. 499.001-499.081~~ because of  
 3362 the sale, purchase, or trade of a drug sample or the offer to  
 3363 sell, purchase, or trade a drug sample.

3364 (12) The department may suspend or revoke a permit issued  
 3365 under this section, after giving notice and an opportunity to be  
 3366 heard pursuant to chapter 120, when:

3367 (a) Such permit was obtained by misrepresentation or fraud  
 3368 or through a mistake of the department.

3369 (b) The holder of the permit has distributed or disposed  
 3370 of any prescription ~~legend~~ drug, directly or through its agents,  
 3371 employees, or independent contractors, to any person not  
 3372 authorized to possess such drug.

3373 (c) The holder of the permit, or its agents, employees, or  
 3374 independent contractors, has distributed or possessed any  
 3375 prescription ~~legend~~ drug except in the usual course of its  
 3376 business.

3377 (d) The holder of the permit, or its agents, employees, or  
 3378 independent contractors, has distributed any prescription ~~legend~~  
 3379 drug that is misbranded or adulterated under this part ~~ss.~~  
 3380 ~~499.001-499.081~~.

3381 (e) The holder of the permit, or its agents, employees, or  
 3382 independent contractors, has distributed any prescription ~~legend~~  
 3383 drug without written request, when a written request is required  
 3384 by this section.

3385 (f) The holder of the permit has in its employ, or uses as  
 3386 agent or independent contractor for the purpose of distributing  
 3387 or disposing of drugs, any person who has:

3388 1. Violated the requirements of this section or any rule  
 3389 adopted under this section.

3390 2. Been convicted in any of the courts of this state, the  
 3391 United States, or any other state of a felony or any other crime  
 3392 involving moral turpitude or involving those drugs named or  
 3393 described in chapter 893.

3394 (15) A person may not possess a prescription drug sample  
 3395 unless:

3396 (a) The drug sample was prescribed to her or him as  
 3397 evidenced by the label required in s. 465.0276(5).

3398 (b) She or he is the employee of a complimentary drug  
 3399 distributor that holds a permit issued under this part ~~ss.~~  
 3400 ~~499.001-499.081~~.

3401 (c) She or he is a person to whom prescription drug  
 3402 samples may be distributed pursuant to this section.

3403 (d) He or she is an officer or employee of a federal,  
 3404 state, or local government acting within the scope of his or her  
 3405 employment.

3406 Section 21. Subsections (2) and (3) of section 499.029,  
 3407 Florida Statutes, are amended to read:

3408 499.029 Cancer Drug Donation Program.--

3409 (2) There is created a Cancer Drug Donation Program within  
 3410 the department ~~of Health~~ for the purpose of authorizing and  
 3411 facilitating the donation of cancer drugs and supplies to  
 3412 eligible patients.

3413 (3) As used in this section:

3414 (a) "Cancer drug" means a prescription drug that has been  
 3415 approved under s. 505 of the federal Food, Drug, and Cosmetic  
 3416 Act and is used to treat cancer or its side effects or is used  
 3417 to treat the side effects of a prescription drug used to treat  
 3418 cancer or its side effects. "Cancer drug" does not include a  
 3419 substance listed in Schedule II, Schedule III, Schedule IV, or  
 3420 Schedule V of s. 893.03.

3421 (b) "Closed drug delivery system" means a system in which  
 3422 the actual control of the unit-dose medication package is

3423 maintained by the facility rather than by the individual  
 3424 patient.

3425 ~~(c) "Department" means the Department of Health.~~

3426 (c)~~(d)~~ "Donor" means a patient or patient representative  
 3427 who donates cancer drugs or supplies needed to administer cancer  
 3428 drugs that have been maintained within a closed drug delivery  
 3429 system; health care facilities, nursing homes, hospices, or  
 3430 hospitals with closed drug delivery systems; or pharmacies, drug  
 3431 manufacturers, medical device manufacturers or suppliers, or  
 3432 wholesalers of drugs or supplies, in accordance with this  
 3433 section. "Donor" includes a physician licensed under chapter 458  
 3434 or chapter 459 who receives cancer drugs or supplies directly  
 3435 from a drug manufacturer, wholesale distributor ~~drug wholesaler,~~  
 3436 or pharmacy.

3437 (d)~~(e)~~ "Eligible patient" means a person who the  
 3438 department determines is eligible to receive cancer drugs from  
 3439 the program.

3440 (e)~~(k)~~ "Participant facility" means a class II hospital  
 3441 pharmacy that has elected to participate in the program and that  
 3442 accepts donated cancer drugs and supplies under the rules  
 3443 adopted by the department for the program.

3444 (f)~~(n)~~ "Prescribing practitioner" means a physician  
 3445 licensed under chapter 458 or chapter 459 or any other medical  
 3446 professional with authority under state law to prescribe cancer  
 3447 medication.

3448 ~~(o) "Prescription drug" means a drug as defined in s.~~  
 3449 ~~465.003(8).~~

3450            (g)~~(p)~~ "Program" means the Cancer Drug Donation Program  
 3451 created by this section.

3452            (h)~~(q)~~ "Supplies" means any supplies used in the  
 3453 administration of a cancer drug.

3454            Section 22. Subsection (1) of section 499.03, Florida  
 3455 Statutes, is amended to read:

3456            499.03 Possession of certain drugs without prescriptions  
 3457 unlawful; exemptions and exceptions.--

3458            (1) A person may not possess, or possess with intent to  
 3459 sell, dispense, or deliver, any habit-forming, toxic, harmful,  
 3460 or new drug subject to s. 499.003(32) ~~s. 499.003(29)~~, or  
 3461 prescription legend ~~legend~~ drug as defined in s. 499.003(42) ~~s.~~  
 3462 ~~499.003(25)~~, unless the possession of the drug has been obtained  
 3463 by a valid prescription of a practitioner licensed by law to  
 3464 prescribe the drug. However, this section does not apply to the  
 3465 delivery of such drugs to persons included in any of the classes  
 3466 named in this subsection, or to the agents or employees of such  
 3467 persons, for use in the usual course of their businesses or  
 3468 practices or in the performance of their official duties, as the  
 3469 case may be; nor does this section apply to the possession of  
 3470 such drugs by those persons or their agents or employees for  
 3471 such use:

3472            (a) A licensed pharmacist or any person under the licensed  
 3473 pharmacist's supervision while acting within the scope of the  
 3474 licensed pharmacist's practice;

3475            (b) A licensed practitioner authorized by law to prescribe  
 3476 prescription legend ~~legend~~ drugs or any person under the licensed

3477 practitioner's supervision while acting within the scope of the  
 3478 licensed practitioner's practice;

3479 (c) A qualified person who uses prescription ~~legend~~ drugs  
 3480 for lawful research, teaching, or testing, and not for resale;

3481 (d) A licensed hospital or other institution that procures  
 3482 such drugs for lawful administration or dispensing by  
 3483 practitioners;

3484 (e) An officer or employee of a federal, state, or local  
 3485 government; or

3486 (f) A person that holds a valid permit issued by the  
 3487 department pursuant to this part ~~ss. 499.001-499.081~~ which  
 3488 authorizes that person to possess prescription drugs.

3489 Section 23. Section 499.032, Florida Statutes, is amended  
 3490 to read:

3491 499.032 Phenylalanine; prescription  
 3492 required.--Phenylalanine restricted formula is declared to be a  
 3493 prescription ~~legend~~ drug and may be dispensed only upon the  
 3494 prescription of a practitioner authorized by law to prescribe  
 3495 prescription ~~medicinal~~ drugs.

3496 Section 24. Subsection (1) of section 499.033, Florida  
 3497 Statutes, is amended to read:

3498 499.033 Ephedrine; prescription required.--Ephedrine is  
 3499 declared to be a prescription drug.

3500 (1) Except as provided in subsection (2), any product that  
 3501 contains any quantity of ephedrine, a salt of ephedrine, an  
 3502 optical isomer of ephedrine, or a salt of an optical isomer of  
 3503 ephedrine may be dispensed only upon the prescription of a duly

3504 licensed practitioner authorized by the laws of the state to  
 3505 prescribe prescription ~~medicinal~~ drugs.

3506 Section 25. Subsections (1) and (3) of section 499.039,  
 3507 Florida Statutes, are amended to read:

3508 499.039 Sale, distribution, or transfer of harmful  
 3509 chemical substances; penalties; authority for enforcement.--It  
 3510 is unlawful for a person to sell, deliver, or give to a person  
 3511 under the age of 18 years any compound, liquid, or chemical  
 3512 containing toluol, hexane, trichloroethylene, acetone, toluene,  
 3513 ethyl acetate, methyl ethyl ketone, trichloroethane,  
 3514 isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl  
 3515 ether acetate, cyclohexanone, nitrous oxide, diethyl ether,  
 3516 alkyl nitrites (butyl nitrite), or any similar substance for the  
 3517 purpose of inducing by breathing, inhaling, or ingesting a  
 3518 condition of intoxication or which is intended to distort or  
 3519 disturb the auditory, visual, or other physical or mental  
 3520 processes.

3521 (1) On the first violation of this section, the department  
 3522 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if  
 3523 the violation has not caused temporary or permanent physical or  
 3524 mental injury to the user.

3525 (3) The department ~~of Health~~ shall adopt rules to  
 3526 implement this section.

3527 Section 26. Section 499.04, Florida Statutes, is amended  
 3528 to read:

3529 499.04 Fee authority.--The department may collect fees for  
 3530 all drug, device, and cosmetic applications, permits, product  
 3531 registrations, and free-sale certificates. The total amount of



3532 fees collected from all permits, applications, product  
 3533 registrations, and free-sale certificates must be adequate to  
 3534 fund the expenses incurred by the department in carrying out  
 3535 this part ~~ss. 499.001-499.081~~. The department shall, by rule,  
 3536 establish a schedule of fees that are within the ranges provided  
 3537 in this section and shall adjust those fees from time to time  
 3538 based on the costs associated with administering this part ~~ss.~~  
 3539 ~~499.001-499.081~~. The fees are payable to the department to be  
 3540 deposited into the Florida Drug, Device, and Cosmetic Trust Fund  
 3541 for the sole purpose of carrying out the provisions of this part  
 3542 ~~ss. 499.001-499.081~~.

3543 Section 27. Subsections (1) through (5), (8), and (10) of  
 3544 section 499.041, Florida Statutes, are amended to read:

3545 499.041 Schedule of fees for drug, device, and cosmetic  
 3546 applications and permits, product registrations, and free-sale  
 3547 certificates.--

3548 (1) The department shall assess applicants requiring a  
 3549 manufacturing permit an annual fee within the ranges established  
 3550 in this section for the specific type of manufacturer.

3551 (a) The fee for a prescription drug manufacturer  
 3552 ~~manufacturer's~~ permit may not be less than \$500 or more than  
 3553 \$750 annually.

3554 (b) The fee for a device manufacturer ~~manufacturer's~~  
 3555 permit may not be less than \$500 or more than \$600 annually.

3556 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~  
 3557 permit may not be less than \$250 or more than \$400 annually.

3558 (d) The fee for an over-the-counter drug manufacturer  
 3559 ~~manufacturer's~~ permit may not be less than \$300 or more than  
 3560 \$400 annually.

3561 (e) The fee for a compressed medical gas manufacturer  
 3562 ~~manufacturer's~~ permit may not be less than \$400 or more than  
 3563 \$500 annually.

3564 (f) The fee for a prescription drug repackager  
 3565 ~~repackager's~~ permit may not be less than \$500 or more than \$750  
 3566 annually.

3567 (g) A manufacturer may not be required to pay more than  
 3568 one fee per establishment to obtain an additional manufacturing  
 3569 permit, but each manufacturer must pay the highest fee  
 3570 applicable to his or her operation in each establishment.

3571 (2) The department shall assess an applicant that is  
 3572 required to have a wholesaling permit an annual fee within the  
 3573 ranges established in this section for the specific type of  
 3574 wholesaling.

3575 (a) The fee for a prescription drug wholesale distributor  
 3576 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800  
 3577 annually.

3578 (b) The fee for a compressed medical gas wholesale  
 3579 distributor ~~wholesaler's~~ permit may not be less than \$200 or  
 3580 more than \$300 annually.

3581 (c) The fee for an out-of-state prescription drug  
 3582 wholesale distributor ~~wholesaler's~~ permit may not be less than  
 3583 \$300 or more than \$800 annually.

3584 (d) The fee for a nonresident prescription drug  
 3585 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or  
 3586 more than \$500 annually.

3587 (e) The fee for a retail pharmacy drug wholesale  
 3588 distributor ~~wholesaler's~~ permit may not be less than \$35 or more  
 3589 than \$50 annually.

3590 (f) The fee for a freight forwarder ~~forwarder's~~ permit may  
 3591 not be less than \$200 or more than \$300 annually.

3592 (g) The fee for a veterinary prescription drug wholesale  
 3593 distributor ~~wholesaler's~~ permit may not be less than \$300 or  
 3594 more than \$500 annually.

3595 (h) The fee for a limited prescription drug veterinary  
 3596 wholesale distributor ~~wholesaler's~~ permit may not be less than  
 3597 \$300 or more than \$500 annually.

3598 (i) The fee for a third part logistics provider permit may  
 3599 not be less than \$200 or more than \$300 annually.

3600 (3) The department shall assess an applicant that is  
 3601 required to have a retail establishment permit an annual fee  
 3602 within the ranges established in this section for the specific  
 3603 type of retail establishment.

3604 (a) The fee for a veterinary prescription ~~legend~~ drug  
 3605 retail establishment permit may not be less than \$200 or more  
 3606 than \$300 annually.

3607 (b) The fee for a medical oxygen retail establishment  
 3608 permit may not be less than \$200 or more than \$300 annually.

3609 (c) The fee for a health care clinic establishment permit  
 3610 may not be less than \$125 or more than \$250 annually.

3611 (4) The department shall assess an applicant that is  
 3612 required to have a restricted prescription drug distributor  
 3613 ~~distributor's~~ permit an annual fee of not less than \$200 or more  
 3614 than \$300.

3615 (5) In addition to the fee charged for a permit required  
 3616 by this part ~~ss. 499.001-499.081~~, the department shall assess  
 3617 applicants an initial application fee of \$150 for each new  
 3618 permit issued by the department which requires an onsite  
 3619 inspection.

3620 (8) The department shall assess an out-of-state  
 3621 prescription drug wholesale distributor ~~wholesaler~~ applicant or  
 3622 permittee an onsite inspection fee of not less than \$1,000 or  
 3623 more than \$3,000 annually, to be based on the actual cost of the  
 3624 inspection if an onsite inspection is performed by agents of the  
 3625 department.

3626 (10) The department shall assess other fees as provided in  
 3627 this part ~~ss. 499.001-499.081~~.

3628 Section 28. Section 499.05, Florida Statutes, is amended;  
 3629 subsection (3) of section 499.013, Florida Statutes, is  
 3630 redesignated as paragraph (k) of subsection (1) of that section  
 3631 and amended; paragraph (b) of subsection (2) of section  
 3632 499.0122, Florida Statutes, is redesignated as paragraph (1) of  
 3633 subsection (1) of that section and amended; and subsection (12)  
 3634 of section 499.012, Florida Statutes, is redesignated as  
 3635 paragraph (m) of subsection (1) of that section and amended, to  
 3636 read:

3637 499.05 Rules.--

3638 (1) The department shall adopt rules to implement and  
 3639 enforce this part ~~ss. 499.001-499.081~~ with respect to:

3640 (a) The definition of terms used in this part ~~ss. 499.001-~~  
 3641 ~~499.081~~, and used in the rules adopted under this part ~~ss.~~  
 3642 ~~499.001-499.081~~, when the use of the term is not its usual and  
 3643 ordinary meaning.

3644 (b) Labeling requirements for drugs, devices, and  
 3645 cosmetics.

3646 (c) The establishment of fees authorized in this part ~~ss.~~  
 3647 ~~499.001-499.081~~.

3648 (d) The identification of permits that require an initial  
 3649 application and onsite inspection or other prerequisites for  
 3650 permitting which demonstrate that the establishment and person  
 3651 are in compliance with the requirements of this part ~~ss.~~  
 3652 ~~499.001-499.081~~.

3653 (e) The application processes and forms for product  
 3654 registration.

3655 (f) Procedures for requesting and issuing certificates of  
 3656 free sale.

3657 (g) Inspections and investigations conducted under s.  
 3658 499.051, and the identification of information claimed to be a  
 3659 trade secret and exempt from the public records law as provided  
 3660 in s. 499.051(7).

3661 (h) The establishment of a range of penalties, as provided  
 3662 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of  
 3663 the potential impact of a violation of this part ~~ss. 499.001-~~  
 3664 ~~499.081~~; and a process for the uncontested settlement of alleged  
 3665 violations.

3666 (i) Additional conditions that qualify as an emergency  
3667 medical reason under s. 499.003(53)(b)2. ~~s. 499.012(1)(a)2.b.~~

3668 (j) Procedures and forms relating to the pedigree paper  
3669 requirement of s. 499.01212.

3670 ~~(k)(3) The department may adopt such rules as are~~  
3671 ~~necessary for~~ The protection of the public health, safety, and  
3672 welfare regarding good manufacturing practices that  
3673 manufacturers and repackagers must follow to ensure the safety  
3674 of the products.

3675 ~~(l)(b) The department shall adopt rules relating to~~  
3676 Information required from each retail establishment pursuant to  
3677 s. 499.012(3) ~~s. 499.01(4)~~, including requirements for  
3678 prescriptions or orders.

3679 ~~(m)(12) The department may adopt rules governing~~ The  
3680 recordkeeping, storage, and handling with respect to each of the  
3681 distributions of prescription drugs specified in s.  
3682 499.003(53)(a)-(d) subparagraphs (1)(a)1-4.

3683 (n) Alternatives to compliance with s. 499.01212 for a  
3684 prescription drug in the inventory of a permitted prescription  
3685 drug wholesale distributor as of June 30, 2006, and the return  
3686 of a prescription drug purchased prior to July 1, 2006. The  
3687 department may specify time limits for such alternatives.

3688 (2) With respect to products in interstate commerce, those  
3689 rules must not be inconsistent with rules and regulations of  
3690 federal agencies unless specifically otherwise directed by the  
3691 Legislature.

3692 (3) The department shall adopt rules regulating  
3693 recordkeeping for and the storage, handling, and distribution of

3694 medical devices and over-the-counter drugs to protect the public  
 3695 from adulterated products.

3696 Section 29. Section 499.051, Florida Statutes, is amended  
 3697 to read:

3698 499.051 Inspections and investigations.--

3699 (1) The agents of the department ~~of Health~~ and of the  
 3700 Department of Law Enforcement, after they present proper  
 3701 identification, may inspect, monitor, and investigate any  
 3702 establishment permitted pursuant to this part ~~ss. 499.001-~~  
 3703 ~~499.081~~ during business hours for the purpose of enforcing this  
 3704 part ~~ss. 499.001-499.081~~, chapters 465, 501, and 893, and the  
 3705 rules of the department that protect the public health, safety,  
 3706 and welfare.

3707 (2) In addition to the authority set forth in subsection  
 3708 (1), the department and any duly designated officer or employee  
 3709 of the department may enter and inspect any other establishment  
 3710 for the purpose of determining compliance with this part ~~ss.~~  
 3711 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~  
 3712 regarding any drug, device, or cosmetic product.

3713 (3) Any application for a permit or product registration  
 3714 or for renewal of such permit or registration made pursuant to  
 3715 this part ~~ss. 499.001-499.081~~ and rules adopted under this part  
 3716 ~~those sections~~ constitutes permission for any entry or  
 3717 inspection of the premises in order to verify compliance with  
 3718 this part ~~those sections~~ and rules; to discover, investigate,  
 3719 and determine the existence of compliance; or to elicit,  
 3720 receive, respond to, and resolve complaints and violations.

3721           (4) Any application for a permit made pursuant to s.  
 3722 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that  
 3723 section ~~those sections~~ constitutes permission for agents of the  
 3724 department ~~of Health~~ and the Department of Law Enforcement,  
 3725 after presenting proper identification, to inspect, review, and  
 3726 copy any financial document or record related to the  
 3727 manufacture, repackaging, or distribution of a drug as is  
 3728 necessary to verify compliance with this part ~~ss. 499.001-~~  
 3729 ~~499.081~~ and the rules adopted by the department to administer  
 3730 this part ~~those sections~~, in order to discover, investigate, and  
 3731 determine the existence of compliance, or to elicit, receive,  
 3732 respond to, and resolve complaints and violations.

3733           (5) The authority to inspect under this section includes  
 3734 the authority to access, review, and copy any and all financial  
 3735 documents related to the activity of manufacturing, repackaging,  
 3736 or distributing prescription drugs.

3737           (6) The authority to inspect under this section includes  
 3738 the authority to secure:

3739           (a) Samples or specimens of any drug, device, or cosmetic;  
 3740 or

3741           (b) Such other evidence as is needed for any action to  
 3742 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted  
 3743 under this part ~~those sections~~.

3744           (7) The complaint and all information obtained pursuant to  
 3745 the investigation by the department are confidential and exempt  
 3746 from ~~the provisions of~~ s. 119.07(1) and s. 24(a), Art. I of the  
 3747 State Constitution until the investigation and the enforcement  
 3748 action are completed. However, trade secret information



3749 contained therein as defined by s. 812.081(1)(c) shall remain  
 3750 confidential and exempt from the provisions of s. 119.07(1) and  
 3751 s. 24(a), Art. I of the State Constitution, as long as the  
 3752 information is retained by the department. This subsection does  
 3753 not prohibit the department from using such information for  
 3754 regulatory or enforcement proceedings under this chapter or from  
 3755 providing such information to any law enforcement agency or any  
 3756 other regulatory agency. However, the receiving agency shall  
 3757 keep such records confidential and exempt as provided in this  
 3758 subsection. In addition, this subsection is not intended to  
 3759 prevent compliance with the provisions of s. 499.01212 ~~s.~~  
 3760 ~~499.0121(6)(d)~~, and the pedigree papers required in that section  
 3761 ~~subsection~~ shall not be deemed a trade secret.

3762 Section 30. Section 499.052, Florida Statutes, is amended  
 3763 to read:

3764 499.052 Records of interstate shipment.--For the purpose  
 3765 of enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in  
 3766 interstate commerce and persons receiving drugs, devices, or  
 3767 cosmetics in interstate commerce must, upon the request, in the  
 3768 manner set out below, by an officer or employee duly designated  
 3769 by the department, permit the officer or employee to have access  
 3770 to and to copy all records showing the movement in interstate  
 3771 commerce of any drug, device, or cosmetic, and the quantity,  
 3772 shipper, and consignee thereof.

3773 Section 31. Subsection (4) of section 499.055, Florida  
 3774 Statutes, is amended to read:

3775 499.055 Reports and dissemination of information by  
 3776 department.--

3777 (4) The department shall publish on the department's  
 3778 website and update at least monthly:

3779 (a) A list of the prescription drug wholesale distributors  
 3780 ~~wholesalers~~, out-of-state prescription drug wholesale  
 3781 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
 3782 distributors ~~wholesalers~~ against whom the department has  
 3783 initiated enforcement action pursuant to this part ~~ss. 499.001-~~  
 3784 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or  
 3785 otherwise file an administrative complaint and the permit number  
 3786 of each such wholesale distributor ~~wholesaler~~.

3787 (b) A list of the prescription drug wholesale distributors  
 3788 ~~wholesalers~~, out-of-state prescription drug wholesale  
 3789 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
 3790 distributors ~~wholesalers~~ to which the department has issued a  
 3791 permit, including the date on which each permit will expire.

3792 (c) A list of the prescription drug wholesale distributor  
 3793 ~~wholesalers~~, out-of-state prescription drug wholesale  
 3794 distributor ~~wholesalers~~, and retail pharmacy drug wholesale  
 3795 distributor ~~wholesalers~~ permits that have been returned to the  
 3796 department, were suspended, were revoked, have expired, or were  
 3797 not renewed in the previous year.

3798 Section 32. Subsections (1) and (3) of section 499.06,  
 3799 Florida Statutes, are amended to read:

3800 499.06 Embargoing, detaining, or destroying article or  
 3801 processing equipment which is in violation of law or rule.--

3802 (1) When a duly authorized agent of the department finds,  
 3803 or has probable cause to believe, that any drug, device, or  
 3804 cosmetic is in violation of any provision of this part ~~ss-~~

3805 ~~499.001-499.081~~ or any rule adopted under this part ~~such~~  
 3806 ~~sections~~ so as to be dangerous, unwholesome, or fraudulent  
 3807 within the meaning of this part ~~ss. 499.001-499.081~~, she or he  
 3808 may issue and enforce a stop-sale, stop-use, removal, or hold  
 3809 order, which order gives notice that such article or processing  
 3810 equipment is, or is suspected of being, in violation and has  
 3811 been detained or embargoed, and which order warns all persons  
 3812 not to remove, use, or dispose of such article or processing  
 3813 equipment by sale or otherwise until permission for removal,  
 3814 use, or disposal is given by such agent or the court. It is  
 3815 unlawful for any person to remove, use, or dispose of such  
 3816 detained or embargoed article or processing equipment by sale or  
 3817 otherwise without such permission; and such act is a felony of  
 3818 the second degree, punishable as provided in s. 775.082, s.  
 3819 775.083, or s. 775.084.

3820 (3) If the court finds that the detained or embargoed  
 3821 article or processing equipment is in violation, such article or  
 3822 processing equipment shall, after entry of the court order, be  
 3823 destroyed or made sanitary at the expense of the claimant  
 3824 thereof, under the supervision of such agent; and all court  
 3825 costs, fees, and storage and other proper expenses shall be  
 3826 taxed against the claimant of such article or processing  
 3827 equipment or her or his agent. However, when the violation can  
 3828 be corrected by proper labeling of the article or sanitizing of  
 3829 the processing equipment, and after such costs, fees, and  
 3830 expenses have been paid and a good and sufficient bond,  
 3831 conditioned that such article be so labeled or processed or such  
 3832 processing equipment be so sanitized, has been executed, the

3833 court may by order direct that such article or processing  
 3834 equipment be delivered to the claimant thereof for such  
 3835 labeling, processing, or sanitizing, under the supervision of an  
 3836 agent of the department. The expense of such supervision shall  
 3837 be paid by the claimant. Such bond shall be returned to the  
 3838 claimant of the article or processing equipment upon  
 3839 representation to the court by the department that the article  
 3840 or processing equipment is no longer in violation of this part  
 3841 ~~ss. 499.001-499.081~~ and that the expenses of such supervision  
 3842 have been paid.

3843 Section 33. Section 499.062, Florida Statutes, is amended;  
 3844 section 499.063, Florida Statutes, is redesignated as section  
 3845 (2) of that section and amended; and section 499.064, Florida  
 3846 Statutes, is redesignated as paragraphs (a) and (b) of  
 3847 subsection (2) of that section and amended, to read:

3848 499.062 ~~Cause for~~ Seizure and condemnation of drugs,  
 3849 devices, or cosmetics.--

3850 (1) Any article of any drug, device, or cosmetic that is  
 3851 adulterated or misbranded under this part ~~ss. 499.001-499.081~~ is  
 3852 subject to seizure and condemnation by the department or by its  
 3853 duly authorized agents designated for that purpose in regard to  
 3854 drugs, devices, or cosmetics.

3855 (2) ~~499.063 Seizure; procedure; prohibition on sale or~~  
 3856 ~~disposal of article; penalty.~~ Whenever a duly authorized  
 3857 officer or employee of the department finds cause, or has  
 3858 probable cause to believe that cause exists, for the seizure of  
 3859 any drug, device, or cosmetic, as set out in this part ~~ss.~~  
 3860 ~~499.001-499.081~~, he or she shall affix to the article a tag,

3861 stamp, or other appropriate marking, giving notice that the  
3862 article is, or is suspected of being, subject to seizure under  
3863 this part ss. 499.001-499.081 and that the article has been  
3864 detained and seized by the department. Such officer or employee  
3865 shall also warn all persons not to remove or dispose of the  
3866 article, by sale or otherwise, until permission is given by the  
3867 department or the court. Any person who violates this subsection  
3868 ~~section~~ is guilty of a felony of the second degree, punishable  
3869 as provided in s. 775.082, s. 775.083, or s. 775.084.

3870 (a) 499.064 ~~Condemnation and sale; release of seized~~  
3871 ~~article.~~ ~~(1)~~ When any article detained or seized under this  
3872 subsection s. 499.063 has been found by the department to be  
3873 subject to seizure and condemnation ~~under s. 499.063~~, the  
3874 department shall petition the court for an order of condemnation  
3875 or sale, as the court directs. The proceeds of the sale of  
3876 drugs, devices, and cosmetics, less the legal costs and charges,  
3877 shall be deposited into the Florida Drug, Device, and Cosmetic  
3878 Trust Fund.

3879 (b) (2) If the department finds that any article seized  
3880 under this subsection s. 499.063 was not subject to seizure  
3881 ~~under that section~~, the department or the designated officer or  
3882 employee shall remove the tag or marking.

3883 Section 34. Section 499.065, Florida Statutes, is amended  
3884 to read:

3885 499.065 Inspections; imminent danger.--

3886 (1) Notwithstanding s. 499.051, the department shall  
3887 inspect each prescription drug wholesale distributor  
3888 establishment, prescription drug repackager establishment,

3889 veterinary prescription drug wholesale distributor  
 3890 establishment, limited prescription drug veterinary wholesale  
 3891 distributor ~~wholesaler~~ establishment, and retail pharmacy drug  
 3892 wholesale distributor ~~wholesaler~~ establishment that is required  
 3893 to be permitted under this part ~~chapter~~ as often as necessary to  
 3894 ensure compliance with applicable laws and rules. The department  
 3895 shall have the right of entry and access to these facilities at  
 3896 any reasonable time.

3897 (2) To protect the public from prescription drugs that are  
 3898 adulterated or otherwise unfit for human or animal consumption,  
 3899 the department may examine, sample, seize, and stop the sale or  
 3900 use of prescription drugs to determine the condition of those  
 3901 drugs. The department may immediately seize and remove any  
 3902 prescription drugs if the State Surgeon General or his or her  
 3903 designee determines that the prescription drugs represent a  
 3904 threat to the public health. The owner of any property seized  
 3905 under this section may, within 10 days after the seizure, apply  
 3906 to a court of competent jurisdiction for whatever relief is  
 3907 appropriate. At any time after 10 days, the department may  
 3908 destroy the drugs as contraband.

3909 (3) The department may determine that a prescription drug  
 3910 wholesale distributor establishment, prescription drug  
 3911 repackager establishment, veterinary prescription drug wholesale  
 3912 distributor establishment, limited prescription drug veterinary  
 3913 wholesale distributor ~~wholesaler~~ establishment, or retail  
 3914 pharmacy drug wholesale distributor ~~wholesaler~~ establishment  
 3915 that is required to be permitted under this part ~~chapter~~ is an  
 3916 imminent danger to the public health and shall require its

3917 immediate closure if the establishment fails to comply with  
 3918 applicable laws and rules and, because of the failure, presents  
 3919 an imminent threat to the public's health, safety, or welfare.  
 3920 Any establishment so deemed and closed shall remain closed until  
 3921 allowed by the department or by judicial order to reopen.

3922 (4) For purposes of this section, a refusal to allow entry  
 3923 to the department for inspection at reasonable times, or a  
 3924 failure or refusal to provide the department with required  
 3925 documentation for purposes of inspection, constitutes an  
 3926 imminent danger to the public health.

3927 Section 35. Subsections (1) through (4) of section  
 3928 499.066, Florida Statutes, are amended to read:

3929 499.066 Penalties; remedies.--In addition to other  
 3930 penalties and other enforcement provisions:

3931 (1) The department may institute such suits or other legal  
 3932 proceedings as are required to enforce any provision of this  
 3933 part ss. ~~499.001-499.081~~. If it appears that a person has  
 3934 violated any provision of this part ss. ~~499.001-499.081~~ for  
 3935 which criminal prosecution is provided, the department may  
 3936 provide the appropriate state attorney or other prosecuting  
 3937 agency having jurisdiction with respect to such prosecution with  
 3938 the relevant information in the department's possession.

3939 (2) If any person engaged in any activity covered by this  
 3940 part ss. ~~499.001-499.081~~ violates any provision of this part  
 3941 ~~those sections~~, any rule adopted under this part ~~those sections~~,  
 3942 or a cease and desist order as provided by this part ~~those~~  
 3943 ~~sections~~, the department may obtain an injunction in the circuit  
 3944 court of the county in which the violation occurred or in which

3945 | the person resides or has its principal place of business, and  
 3946 | may apply in that court for such temporary and permanent orders  
 3947 | as the department considers necessary to restrain the person  
 3948 | from engaging in any such activities until the person complies  
 3949 | with this part ~~ss. 499.001-499.081~~, the rules adopted under this  
 3950 | part ~~those sections~~, and the orders of the department authorized  
 3951 | by this part ~~those sections~~ or to mandate compliance with this  
 3952 | part ~~ss. 499.001-499.081~~, the rules adopted under this part  
 3953 | ~~those sections~~, and any order or permit issued by the department  
 3954 | under this part ~~those sections~~.

3955 |         (3) The department may impose an administrative fine, not  
 3956 | to exceed \$5,000 per violation per day, for the violation of any  
 3957 | provision of this part ~~ss. 499.001-499.081~~ or rules adopted  
 3958 | under this part ~~those sections~~. Each day a violation continues  
 3959 | constitutes a separate violation, and each separate violation is  
 3960 | subject to a separate fine. All amounts collected pursuant to  
 3961 | this section shall be deposited into the Florida Drug, Device,  
 3962 | and Cosmetic Trust Fund and are appropriated for the use of the  
 3963 | department in administering this part ~~ss. 499.001-499.081~~. In  
 3964 | determining the amount of the fine to be levied for a violation,  
 3965 | the department shall consider:

- 3966 |             (a) The severity of the violation;
- 3967 |             (b) Any actions taken by the person to correct the  
 3968 | violation or to remedy complaints; and
- 3969 |             (c) Any previous violations.
- 3970 |         (4) The department shall deposit any rewards, fines, or  
 3971 | collections that are due the department and which derive from  
 3972 | joint enforcement activities with other state and federal



3973 agencies which relate to this part ~~ss. 499.001-499.081~~, chapter  
 3974 893, or the federal act, into the Florida Drug, Device, and  
 3975 Cosmetic Trust Fund. The proceeds of those rewards, fines, and  
 3976 collections are appropriated for the use of the department in  
 3977 administering this part ~~ss. 499.001-499.081~~.

3978 Section 36. Section 499.0661, Florida Statutes, is amended  
 3979 to read:

3980 499.0661 Cease and desist orders; removal of certain  
 3981 persons.--

3982 (1)~~(2)~~ CEASE AND DESIST ORDERS.--

3983 (a) In addition to any authority otherwise provided in  
 3984 this chapter, the department may issue and serve a complaint  
 3985 stating charges upon any permittee or upon any affiliated party,  
 3986 whenever the department has reasonable cause to believe that the  
 3987 person or individual named therein is engaging in or has engaged  
 3988 in conduct that is:

3989 1. An act that demonstrates a lack of fitness or  
 3990 trustworthiness to engage in the business authorized under the  
 3991 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
 3992 hazardous to the public health, or constitutes business  
 3993 operations that are a detriment to the public health;

3994 2. A violation of any provision of this part ~~ss. 499.001-~~  
 3995 ~~499.081~~;

3996 3. A violation of any rule of the department;

3997 4. A violation of any order of the department; or

3998 5. A breach of any written agreement with the department.

3999 (b) The complaint must contain a statement of facts and  
 4000 notice of opportunity for a hearing pursuant to ss. 120.569 and  
 4001 120.57.

4002 (c) If a hearing is not requested within the time allowed  
 4003 by ss. 120.569 and 120.57, or if a hearing is held and the  
 4004 department finds that any of the charges are proven, the  
 4005 department may enter an order directing the permittee or the  
 4006 affiliated party named in the complaint to cease and desist from  
 4007 engaging in the conduct complained of and take corrective action  
 4008 to remedy the effects of past improper conduct and assure future  
 4009 compliance.

4010 (d) A contested or default cease and desist order is  
 4011 effective when reduced to writing and served upon the permittee  
 4012 or affiliated party named therein. An uncontested cease and  
 4013 desist order is effective as agreed.

4014 (e) Whenever the department finds that conduct described  
 4015 in paragraph (a) is likely to cause an immediate threat to the  
 4016 public health, it may issue an emergency cease and desist order  
 4017 requiring the permittee or any affiliated party to immediately  
 4018 cease and desist from engaging in the conduct complained of and  
 4019 to take corrective and remedial action. The emergency order is  
 4020 effective immediately upon service of a copy of the order upon  
 4021 the permittee or affiliated party named therein and remains  
 4022 effective for 90 days. If the department begins nonemergency  
 4023 cease and desist proceedings under this subsection, the  
 4024 emergency order remains effective until the conclusion of the  
 4025 proceedings under ss. 120.569 and 120.57.

4026 (2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

4027 (a) The department may issue and serve a complaint stating  
 4028 charges upon any affiliated party and upon the permittee  
 4029 involved whenever the department has reason to believe that an  
 4030 affiliated party is engaging in or has engaged in conduct that  
 4031 constitutes:

4032 1. An act that demonstrates a lack of fitness or  
 4033 trustworthiness to engage in the business authorized under the  
 4034 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
 4035 hazardous to the public health, or constitutes business  
 4036 operations that are a detriment to the public health;

4037 2. A willful violation of this part ~~ss. 499.001-499.081~~;  
 4038 however, if the violation constitutes a misdemeanor, a complaint  
 4039 may not be served as provided in this section until the  
 4040 affiliated party is notified in writing of the matter of the  
 4041 violation and has been afforded a reasonable period of time, as  
 4042 set forth in the notice, to correct the violation and has failed  
 4043 to do so;

4044 3. A violation of any other law involving fraud or moral  
 4045 turpitude which constitutes a felony;

4046 4. A willful violation of any rule of the department;

4047 5. A willful violation of any order of the department; or

4048 6. A material misrepresentation of fact, made knowingly  
 4049 and willfully or made with reckless disregard for the truth of  
 4050 the matter.

4051 (b) The complaint must contain a statement of facts and  
 4052 notice of opportunity for a hearing pursuant to ss. 120.569 and  
 4053 120.57.

4054 (c) If a hearing is not requested within the time allotted  
 4055 by ss. 120.569 and 120.57, or if a hearing is held and the  
 4056 department finds that any of the charges in the complaint are  
 4057 proven true, the department may enter an order removing the  
 4058 affiliated party or restricting or prohibiting participation by  
 4059 the person in the affairs of that permittee or of any other  
 4060 permittee.

4061 (d) A contested or default order of removal, restriction,  
 4062 or prohibition is effective when reduced to writing and served  
 4063 on the permittee and the affiliated party. An uncontested order  
 4064 of removal, restriction, or prohibition is effective as agreed.

4065 (e)1. The chief executive officer, designated  
 4066 representative, or the person holding the equivalent office, of  
 4067 a permittee shall promptly notify the department if she or he  
 4068 has actual knowledge that any affiliated party is charged with a  
 4069 felony in a state or federal court.

4070 2. Whenever any affiliated party is charged with a felony  
 4071 in a state or federal court or with the equivalent of a felony  
 4072 in the courts of any foreign country with which the United  
 4073 States maintains diplomatic relations, and the charge alleges  
 4074 violation of any law involving prescription drugs,  
 4075 pharmaceuticals, fraud, theft, or moral turpitude, the  
 4076 department may enter an emergency order suspending the  
 4077 affiliated party or restricting or prohibiting participation by  
 4078 the affiliated party in the affairs of the particular permittee  
 4079 or of any other permittee upon service of the order upon the  
 4080 permittee and the affiliated party charged. The order must  
 4081 contain notice of opportunity for a hearing pursuant to ss.

4082 120.569 and 120.57, where the affiliated party may request a  
 4083 postsuspension hearing to show that continued service to or  
 4084 participation in the affairs of the permittee does not pose a  
 4085 threat to the public health or the interests of the permittee  
 4086 and does not threaten to impair public confidence in the  
 4087 permittee. In accordance with applicable departmental rules, the  
 4088 department shall notify the affiliated party whether the order  
 4089 suspending or prohibiting the person from participation in the  
 4090 affairs of a permittee will be rescinded or otherwise modified.  
 4091 The emergency order remains in effect, unless otherwise modified  
 4092 by the department, until the criminal charge is disposed of. The  
 4093 acquittal of the person charged, or the final, unappealed  
 4094 dismissal of all charges against the person, dissolves the  
 4095 emergency order but does not prohibit the department from  
 4096 instituting proceedings under paragraph (a). If the person  
 4097 charged is convicted or pleads guilty or nolo contendere,  
 4098 whether or not an adjudication of guilt is entered by the court,  
 4099 the emergency order shall become final.

4100 (f) Any affiliated party removed pursuant to this section  
 4101 is not eligible for reemployment by the permittee or to be an  
 4102 affiliated party of any permittee except upon the written  
 4103 consent of the department. Any affiliated party who is removed,  
 4104 restricted, or prohibited from participating in the affairs of a  
 4105 permittee pursuant to this section may petition the department  
 4106 for modification or termination of the removal, restriction, or  
 4107 prohibition.

4108 Section 37. Section 499.067, Florida Statutes, is amended  
 4109 to read:

4110           499.067 Denial, suspension, or revocation of permit,  
4111 certification, or registration.--

4112           (1) (a) The department may deny, suspend, or revoke a  
4113 permit if it finds that there has been a substantial failure to  
4114 comply with this part ~~ss. 499.001-499.081~~ or chapter 465,  
4115 chapter 501, or chapter 893, the rules adopted under this part  
4116 ~~any of those sections~~ or those chapters, any final order of the  
4117 department, or applicable federal laws or regulations or other  
4118 state laws or rules governing drugs, devices, or cosmetics.

4119           (b) The department may deny an application for a permit or  
4120 certification, or suspend or revoke a permit or certification,  
4121 if the department finds that:

4122           1. The applicant is not of good moral character or that it  
4123 would be a danger or not in the best interest of the public  
4124 health, safety, and welfare if the applicant were issued a  
4125 permit or certification.

4126           2. The applicant has not met the requirements for the  
4127 permit or certification.

4128           3. The applicant is not eligible for a permit or  
4129 certification for any of the reasons enumerated in s. 499.012 ~~s.~~  
4130 ~~499.01~~ ~~or s. 499.012(5)~~.

4131           4. The applicant, permittee, or person certified under s.  
4132 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions  
4133 enumerated in s. 499.012 ~~s. 499.01~~ ~~or s. 499.012(5)~~.

4134           5. The applicant, permittee, or person certified under s.  
4135 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.  
4136 499.005-499.0054.

4137 (2) The department may deny, suspend, or revoke any  
 4138 registration required by the provisions of this part ~~ss.~~  
 4139 ~~499.001-499.081~~ for the violation of any provision of this part  
 4140 ~~ss. 499.001-499.081~~ or of any rules adopted under this part  
 4141 ~~those sections.~~

4142 (3) The department may revoke or suspend a permit:

4143 (a) If the permit was obtained by misrepresentation or  
 4144 fraud or through a mistake of the department;

4145 (b) If the permit was procured, or attempted to be  
 4146 procured, for any other person by making or causing to be made  
 4147 any false representation; or

4148 (c) If the permittee has violated any provision of this  
 4149 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~those~~  
 4150 ~~sections.~~

4151 (4) If any permit issued under this part ~~ss. 499.001-~~  
 4152 ~~499.081~~ is revoked or suspended, the owner, manager, operator,  
 4153 or proprietor of the establishment shall cease to operate as the  
 4154 permit authorized, from the effective date of the suspension or  
 4155 revocation until the person is again registered with the  
 4156 department and possesses the required permit. If a permit is  
 4157 revoked or suspended, the owner, manager, or proprietor shall  
 4158 remove all signs and symbols that identify the operation as  
 4159 premises permitted as a drug wholesaling establishment; drug,  
 4160 device, or cosmetic manufacturing establishment; or retail  
 4161 establishment. The department shall determine the length of time  
 4162 for which the permit is to be suspended. If a permit is revoked,  
 4163 the person that owns or operates the establishment may not apply  
 4164 for any permit under this part ~~ss. 499.001-499.081~~ for a period

4165 of 1 year after the date of the revocation. A revocation of a  
 4166 permit may be permanent if the department considers that to be  
 4167 in the best interest of the public health.

4168 (5) The department may deny, suspend, or revoke a permit  
 4169 issued under this part ~~ss. 499.001-499.081~~ which authorizes the  
 4170 permittee to purchase prescription drugs, if any owner, officer,  
 4171 employee, or other person who participates in administering or  
 4172 operating the establishment has been found guilty of any  
 4173 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,  
 4174 chapter 501, or chapter 893, any rules adopted under this part  
 4175 ~~any of those sections~~ or those chapters, or any federal or state  
 4176 drug law, regardless of whether the person has been pardoned,  
 4177 had her or his civil rights restored, or had adjudication  
 4178 withheld.

4179 (6) The department shall deny, suspend, or revoke the  
 4180 permit of any person or establishment if the assignment, sale,  
 4181 transfer, or lease of an establishment permitted under this part  
 4182 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil  
 4183 action, or criminal prosecution.

4184 (7) Notwithstanding s. 120.60(5), if a permittee fails to  
 4185 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may  
 4186 revoke the permit of the permittee and shall provide notice of  
 4187 the intended agency action by posting a notice at the  
 4188 department's headquarters and by mailing a copy of the notice of  
 4189 intended agency action by certified mail to the most recent  
 4190 mailing address on record with the department and, if the  
 4191 permittee is not a natural person, to the permittee's registered  
 4192 agent on file with the Department of State.



4193 Section 38. Paragraph (a) of subsection (1) of section  
 4194 409.9201, Florida Statutes, is amended to read:

4195 409.9201 Medicaid fraud.--

4196 (1) As used in this section, the term:

4197 (a) "Prescription Legend drug" means any drug, including,  
 4198 but not limited to, finished dosage forms or active ingredients  
 4199 that are subject to, defined by, or described by s. 503(b) of  
 4200 the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s.  
 4201 499.007(13) ~~s. 499.007(12)~~, or s. 499.003(45) or (52) ~~s.~~  
 4202 ~~499.0122(1)(b) or (c)~~.

4203  
 4204 The value of individual items of the legend drugs or goods or  
 4205 services involved in distinct transactions committed during a  
 4206 single scheme or course of conduct, whether involving a single  
 4207 person or several persons, may be aggregated when determining  
 4208 the punishment for the offense.

4209 Section 39. Paragraph (c) of subsection (9) of section  
 4210 460.403, Florida Statutes, is amended to read:

4211 460.403 Definitions.--As used in this chapter, the term:

4212 (9)

4213 (c)1. Chiropractic physicians may adjust, manipulate, or  
 4214 treat the human body by manual, mechanical, electrical, or  
 4215 natural methods; by the use of physical means or physiotherapy,  
 4216 including light, heat, water, or exercise; by the use of  
 4217 acupuncture; or by the administration of foods, food  
 4218 concentrates, food extracts, and items for which a prescription  
 4219 is not required and may apply first aid and hygiene, but  
 4220 chiropractic physicians are expressly prohibited from

4221 prescribing or administering to any person any legend drug  
 4222 except as authorized under subparagraph 2., from performing any  
 4223 surgery except as stated herein, or from practicing obstetrics.

4224 2. Notwithstanding the prohibition against prescribing and  
 4225 administering legend drugs under subparagraph 1.7 or s.  
 4226 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic  
 4227 physicians may order, store, and administer, for emergency  
 4228 purposes only at the chiropractic physician's office or place of  
 4229 business, prescription medical oxygen and may also order, store,  
 4230 and administer the following topical anesthetics in aerosol  
 4231 form:

4232 a. Any solution consisting of 25 percent ethylchloride and  
 4233 75 percent dichlorodifluoromethane.

4234 b. Any solution consisting of 15 percent  
 4235 dichlorodifluoromethane and 85 percent  
 4236 trichloromonofluoromethane.

4237  
 4238 However, this paragraph does not authorize a chiropractic  
 4239 physician to prescribe medical oxygen as defined in chapter 499.

4240 Section 40. Subsection (3) of section 465.0265, Florida  
 4241 Statutes, is amended to read:

4242 465.0265 Centralized prescription filling.--

4243 (3) The filling, delivery, and return of a prescription by  
 4244 one pharmacy for another pursuant to this section shall not be  
 4245 construed as the filling of a transferred prescription as set  
 4246 forth in s. 465.026 or as a wholesale distribution as set forth  
 4247 in s. 499.003(53) ~~s. 499.012(1)(a)~~.

4248 Section 41. Section 794.075, Florida Statutes, is amended  
 4249 to read:

4250 794.075 Sexual predators; erectile dysfunction drugs.--

4251 (1) A person may not possess a prescription drug, as  
 4252 defined in s. 499.003(42) ~~s. 499.003(25)~~, for the purpose of  
 4253 treating erectile dysfunction if the person is designated as a  
 4254 sexual predator under s. 775.21.

4255 (2) A person who violates a provision of this section for  
 4256 the first time commits a misdemeanor of the second degree,  
 4257 punishable as provided in s. 775.082 or s. 775.083. A person who  
 4258 violates a provision of this section a second or subsequent time  
 4259 commits a misdemeanor of the first degree, punishable as  
 4260 provided in s. 775.082 or s. 775.083.

4261 Section 42. Paragraph (a) of subsection (1) of section  
 4262 895.02, Florida Statutes, is amended to read:

4263 895.02 Definitions.--As used in ss. 895.01-895.08, the  
 4264 term:

4265 (1) "Racketeering activity" means to commit, to attempt to  
 4266 commit, to conspire to commit, or to solicit, coerce, or  
 4267 intimidate another person to commit:

4268 (a) Any crime that is chargeable by indictment or  
 4269 information under the following provisions of the Florida  
 4270 Statutes:

4271 1. Section 210.18, relating to evasion of payment of  
 4272 cigarette taxes.

4273 2. Section 403.727(3)(b), relating to environmental  
 4274 control.

- 4275           3. Section 409.920 or s. 409.9201, relating to Medicaid  
 4276 fraud.
- 4277           4. Section 414.39, relating to public assistance fraud.
- 4278           5. Section 440.105 or s. 440.106, relating to workers'  
 4279 compensation.
- 4280           6. Section 443.071(4), relating to creation of a  
 4281 fictitious employer scheme to commit unemployment compensation  
 4282 fraud.
- 4283           7. Section 465.0161, relating to distribution of medicinal  
 4284 drugs without a permit as an Internet pharmacy.
- 4285           8. Section 499.0051 ~~Sections 499.0051, 499.0052,~~  
 4286 ~~499.00535, 499.00545, and 499.0691,~~ relating to crimes involving  
 4287 contraband and adulterated drugs.
- 4288           9. Part IV of chapter 501, relating to telemarketing.
- 4289           10. Chapter 517, relating to sale of securities and  
 4290 investor protection.
- 4291           11. Section 550.235, s. 550.3551, or s. 550.3605, relating  
 4292 to dogracing and horseracing.
- 4293           12. Chapter 550, relating to jai alai frontons.
- 4294           13. Section 551.109, relating to slot machine gaming.
- 4295           14. Chapter 552, relating to the manufacture,  
 4296 distribution, and use of explosives.
- 4297           15. Chapter 560, relating to money transmitters, if the  
 4298 violation is punishable as a felony.
- 4299           16. Chapter 562, relating to beverage law enforcement.
- 4300           17. Section 624.401, relating to transacting insurance  
 4301 without a certificate of authority, s. 624.437(4)(c)1., relating  
 4302 to operating an unauthorized multiple-employer welfare

4303 arrangement, or s. 626.902(1)(b), relating to representing or  
 4304 aiding an unauthorized insurer.

4305 18. Section 655.50, relating to reports of currency  
 4306 transactions, when such violation is punishable as a felony.

4307 19. Chapter 687, relating to interest and usurious  
 4308 practices.

4309 20. Section 721.08, s. 721.09, or s. 721.13, relating to  
 4310 real estate timeshare plans.

4311 21. Chapter 782, relating to homicide.

4312 22. Chapter 784, relating to assault and battery.

4313 23. Chapter 787, relating to kidnapping or human  
 4314 trafficking.

4315 24. Chapter 790, relating to weapons and firearms.

4316 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.  
 4317 796.05, or s. 796.07, relating to prostitution and sex  
 4318 trafficking.

4319 26. Chapter 806, relating to arson.

4320 27. Section 810.02(2)(c), relating to specified burglary  
 4321 of a dwelling or structure.

4322 28. Chapter 812, relating to theft, robbery, and related  
 4323 crimes.

4324 29. Chapter 815, relating to computer-related crimes.

4325 30. Chapter 817, relating to fraudulent practices, false  
 4326 pretenses, fraud generally, and credit card crimes.

4327 31. Chapter 825, relating to abuse, neglect, or  
 4328 exploitation of an elderly person or disabled adult.

4329 32. Section 827.071, relating to commercial sexual  
 4330 exploitation of children.

- 4331           33. Chapter 831, relating to forgery and counterfeiting.
- 4332           34. Chapter 832, relating to issuance of worthless checks
- 4333 and drafts.
- 4334           35. Section 836.05, relating to extortion.
- 4335           36. Chapter 837, relating to perjury.
- 4336           37. Chapter 838, relating to bribery and misuse of public
- 4337 office.
- 4338           38. Chapter 843, relating to obstruction of justice.
- 4339           39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or
- 4340 s. 847.07, relating to obscene literature and profanity.
- 4341           40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.
- 4342 849.25, relating to gambling.
- 4343           41. Chapter 874, relating to criminal street gangs.
- 4344           42. Chapter 893, relating to drug abuse prevention and
- 4345 control.
- 4346           43. Chapter 896, relating to offenses related to financial
- 4347 transactions.
- 4348           44. Sections 914.22 and 914.23, relating to tampering with
- 4349 a witness, victim, or informant, and retaliation against a
- 4350 witness, victim, or informant.
- 4351           45. Sections 918.12 and 918.13, relating to tampering with
- 4352 jurors and evidence.
- 4353           Section 43. Paragraphs (d), (f), (h), (i), and (j) of
- 4354 subsection (3) of section 921.0022, Florida Statutes, are
- 4355 amended to read:
- 4356           921.0022 Criminal Punishment Code; offense severity
- 4357 ranking chart.--
- 4358           (3) OFFENSE SEVERITY RANKING CHART

4359	(d)	LEVEL 4	
4360			
	Florida	Felony	Description
	Statute	Degree	
4361			
	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.
4362			
	499.0051 (1)	3rd	Failure to maintain or deliver pedigree papers.
4363			
	499.0051 (2)	3rd	Failure to authenticate pedigree papers.
4364			
	499.0051 (6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband <u>prescription</u> <del>legend</del> drugs.
4365			
	784.07 (2) (b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4366			
	784.074 (1) (c)	3rd	Battery of sexually violent predators facility staff.
4367			

4368	784.075	3rd	Battery on detention or commitment facility staff.
4369	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
4370	784.08 (2) (c)	3rd	Battery on a person 65 years of age or older.
4371	784.081 (3)	3rd	Battery on specified official or employee.
4372	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
4373	784.083 (3)	3rd	Battery on code inspector.
4374	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
4375	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent



4376	787.04 (3)	3rd	pending custody proceedings.
4377	790.115 (1)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4378	790.115 (2) (b)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4379	790.115 (2) (c)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
4380	800.04 (7) (d)	3rd	Possessing firearm on school property.
4381	810.02 (4) (a)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4382	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
4383			Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.

4384	810.06	3rd	Burglary; possession of tools.
4385	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
4386	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4387	812.014 (2) (c) 4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4388	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4389	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
4390	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
4391	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any

4392			registered horse or cattle.
4393	837.02 (1)	3rd	Perjury in official proceedings.
4394	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4395	838.022	3rd	Official misconduct.
4396	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4397	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4398	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4399	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
4400	843.15 (1) (a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
	874.05 (1)	3rd	Encouraging or recruiting another to

4401			join a criminal street gang.
4402	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).
4403	914.14 (2)	3rd	Witnesses accepting bribes.
4404	914.22 (1)	3rd	Force, threaten, etc., witness, victim, or informant.
4405	914.23 (2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4406	918.12	3rd	Tampering with jurors.
4407	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
4408	(f)	LEVEL 6	
4409	Florida Statute	Felony Degree	Description
4410	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
4411			

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4412	499.0051 (3)	2nd	<u>Knowing</u> forgery of pedigree papers.
4413	499.0051 (4)	2nd	<u>Knowing</u> purchase or receipt of <u>prescription</u> <del>legend</del> drug from unauthorized person.
4414	499.0051 (5)	2nd	<u>Knowing</u> sale <u>or transfer</u> of <u>prescription</u> <del>legend</del> drug to unauthorized person.
4415	775.0875 (1)	3rd	Taking firearm from law enforcement officer.
4416	784.021 (1) (a)	3rd	Aggravated assault; deadly weapon without intent to kill.
4417	784.021 (1) (b)	3rd	Aggravated assault; intent to commit felony.
4418	784.041	3rd	Felony battery; domestic battery by strangulation.
4419	784.048 (3)	3rd	Aggravated stalking; credible threat.
4420	784.048 (5)	3rd	Aggravated stalking of person under 16.
4421	784.07 (2) (c)	2nd	Aggravated assault on law enforcement officer.

4422	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
4423	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
4424	784.081 (2)	2nd	Aggravated assault on specified official or employee.
4425	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
4426	784.083 (2)	2nd	Aggravated assault on code inspector.
4427	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4428	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
4429	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
4430	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.

4431	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
4432	794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
4433	794.05(1)	2nd	Unlawful sexual activity with specified minor.
4434	800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years; offender less than 18 years.
4435	800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
4436	806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
4437	810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
4438	812.014(2)(b)1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
	812.014(6)	2nd	Theft; property stolen \$3,000 or more;

coordination of others.

4439

812.015 (9) (a) 2nd Retail theft; property stolen \$300 or more; second or subsequent conviction.

4440

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

4441

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

4442

817.034 (4) (a) 1. 1st Communications fraud, value greater than \$50,000.

4443

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

4444

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

4445

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

4446

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

4447



4448	825.103 (2) (c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4449	827.03 (1)	3rd	Abuse of a child.
4450	827.03 (3) (c)	3rd	Neglect of a child.
4451	827.071 (2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
4452	836.05	2nd	Threats; extortion.
4453	836.10	2nd	Written threats to kill or do bodily injury.
4454	843.12	3rd	Aids or assists person to escape.
4455	847.0135 (2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
4456	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
	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.

4457

944.40                      2nd      Escapes.

4458

944.46                      3rd      Harboring, concealing, aiding escaped prisoners.

4459

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

4460

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

4461

4462                      (h)      LEVEL 8

4463

Florida	Felony	Description
Statute	Degree	

4464

316.193(3)(c)3.a.      2nd      DUI manslaughter.

4465

316.1935(4)(b)              1st      Aggravated fleeing or attempted eluding with serious bodily injury or death.

4466

4467	327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
4468	<u>499.0051 (8)</u> <del>499.0051 (7)</del>	1st	<u>Knowing</u> forgery of prescription labels or <u>prescription</u> legend drug labels.
4469	<u>499.0051 (7)</u> <del>499.0052</del>	1st	<u>Knowing</u> trafficking in contraband <u>prescription</u> legend drugs.
4470	560.123 (8) (b) 2.	2nd	Failure to report currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000 by money transmitter.
4471	560.125 (5) (b)	2nd	Money transmitter business by unauthorized person, currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000.
4472	655.50 (10) (b) 2.	2nd	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by financial institutions.
4473	777.03 (2) (a)	1st	Accessory after the fact, capital felony.

4474	782.04 (4)	2nd	Killing of human without design when engaged in act or attempt of any felony other than arson, sexual battery, robbery, burglary, kidnapping, aircraft piracy, or unlawfully discharging bomb.
4475	782.051 (2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04 (3).
4476	782.071 (1) (b)	1st	Committing vehicular homicide and failing to render aid or give information.
4477	782.072 (2)	1st	Committing vessel homicide and failing to render aid or give information.
4478	790.161 (3)	1st	Discharging a destructive device which results in bodily harm or property damage.
4479	794.011 (5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.

4480	794.08 (3)	2nd	Female genital mutilation, removal of a victim younger than 18 years of age from this state.
4481	800.04 (4)	2nd	Lewd or lascivious battery.
4482	806.01 (1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4483	810.02 (2) (a)	1st, PBL	Burglary with assault or battery.
4484	810.02 (2) (b)	1st, PBL	Burglary; armed with explosives or dangerous weapon.
4485	810.02 (2) (c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
4486	812.014 (2) (a) 2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st degree.
4487	812.13 (2) (b)	1st	Robbery with a weapon.
4488	812.135 (2) (c)	1st	Home-invasion robbery, no firearm, deadly weapon, or other weapon.

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4489	817.568 (6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4490	825.102 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4491	825.1025 (2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4492	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4493	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4494	837.021 (2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.
4495	860.121 (2) (c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
4496	860.16	1st	Aircraft piracy.

4497	893.13 (1) (b)	1st	Sell or deliver in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4498	893.13 (2) (b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4499	893.13 (6) (c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4500	893.135 (1) (a) 2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
4501	893.135 (1) (b) 1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
4502	893.135 (1) (c) 1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.
4503	893.135 (1) (d) 1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
4504	893.135 (1) (e) 1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.

4505	893.135 (1) (f) 1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4506	893.135 (1) (g) 1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4507	893.135 (1) (h) 1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4508	893.135 (1) (j) 1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4509	893.135 (1) (k) 2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4510	895.03 (1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
4511	895.03 (2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
	895.03 (3)	1st	Conduct or participate in any enterprise through pattern of



4512			racketeering activity.
	896.101 (5) (b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
4513			
	896.104 (4) (a) 2.	2nd	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$20,000 but less than \$100,000.
4514			
4515	(i) LEVEL 9		
4516			
	Florida Statute	Felony Degree	Description
4517			
	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
4518			
	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
4519			
	<u>499.0051 (9)</u> <del>499.00535</del>	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> <del>legend</del> drugs resulting in great bodily harm.
4520			

4521	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
4522	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
4523	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4524	775.0844	1st	Aggravated white collar crime.
4525	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
4526	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4527	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3) .

4528	782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
4529	787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
4530	787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
4531	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
4532	787.02(3)(a)	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
4533	790.161	1st	Attempted capital destructive device offense.
4534	790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.

4535	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
4536	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
4537	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4538	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
4539	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4540	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4541	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4542	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.

4543	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4544	817.568 (7)	2nd, PBL	Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.
4545	827.03 (2)	1st	Aggravated child abuse.
4546	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
4547	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
4548	859.01	1st	Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.
4549	893.135	1st	Attempted capital trafficking offense.
	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than

4550	10,000 lbs.
4551	893.135 (1) (b) 1.c. 1st Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4552	893.135 (1) (c) 1.c. 1st Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4553	893.135 (1) (d) 1.c. 1st Trafficking in phencyclidine, more than 400 grams.
4554	893.135 (1) (e) 1.c. 1st Trafficking in methaqualone, more than 25 kilograms.
4555	893.135 (1) (f) 1.c. 1st Trafficking in amphetamine, more than 200 grams.
4556	893.135 (1) (h) 1.c. 1st Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
4557	893.135 (1) (j) 1.c. 1st Trafficking in 1,4-Butanediol, 10 kilograms or more.
4558	893.135 (1) (k) 2.c. 1st Trafficking in Phenethylamines, 400 grams or more.

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4559

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

4560

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

4561

(j) LEVEL 10

4562

Florida	Felony	Description
Statute	Degree	

4563

<u>499.0051(10)</u>	1st	<u>Knowing</u> sale or purchase of contraband
<del>499.00545</del>		<u>prescription</u> <del>legend</del> drugs resulting in death.

4564

782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.
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4565

787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
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4566

787.01(3)(a)	Life	Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual battery, or lewd or
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lascivious battery, molestation,  
conduct, or exhibition.

4567

782.07(3) 1st Aggravated manslaughter of a child.

4568

794.011(3) Life Sexual battery; victim 12 years or  
older, offender uses or threatens to use  
deadly weapon or physical force to cause  
serious injury.

4569

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

4570

876.32 1st Treason against the state.

4571

4572 Section 44. This act shall take effect July 1, 2008.