

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 | providing requirements for obtaining a permit to operate

38 | in certain capacities; deleting certain permit

39 | requirements; amending and redesignating provisions of ss.

40 | 499.012, 499.013, and 499.014, F.S., relating to such

41 | functions as provisions of that section; conforming

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

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

44 | relates to permit application requirements; amending the

45 | provisions to conform; amending and redesignating

46 | provisions of s. 499.01, F.S., relating to such functions

47 | as provisions of that section; conforming provisions and

48 | cross-references to changes made by the act; amending s.

49 | 499.01201, F.S.; conforming provisions to changes made by

50 | the act; amending s. 499.0121, F.S., relating to storage

51 | and handling of prescription drugs and recordkeeping;

52 | directing the department to adopt rules requiring a

53 | wholesale distributor to maintain pedigree papers separate

54 | and distinct from other required records; deleting a

55 | requirement that a person who is engaged in the wholesale

56 | distribution of a prescription drug and who is not the

57 manufacturer of that drug provide a pedigree paper to the
58 person who receives the drug; deleting the department's
59 requirement to adopt rules with regard to recordkeeping by
60 affiliated groups; conforming provisions and cross-
61 references to changes made by the act; amending and
62 redesignating a provision of s. 499.013, F.S., relating to
63 such functions as a provision of that section; amending s.
64 499.01211, F.S.; conforming provisions and cross-
65 references to changes made by the act; creating s.
66 499.01212, F.S.; requiring a person who is engaged in the
67 wholesale distribution of a prescription drug to provide a
68 pedigree paper to the person who receives the drug;
69 requiring certain information in a pedigree paper;
70 requiring a wholesale distributor to maintain and make
71 available to the department certain information; providing
72 exceptions to the requirement of a pedigree paper;
73 repealing s. 499.0122, F.S., relating to medical oxygen
74 and veterinary legend drug retail establishments;
75 repealing s. 499.013, F.S., relating to manufacturers and
76 repackagers of drugs, devices, and cosmetics; amending ss.
77 499.015, 499.024, 499.028, 499.029, and 499.03, F.S.;
78 conforming provisions and cross-references to changes made
79 by the act; amending ss. 499.032 and 499.033, F.S.;
80 conforming terminology to changes made by the act;
81 amending s. 499.039, F.S.; conforming a provision and
82 cross-reference; amending ss. 499.04 and 499.041, F.S.;
83 conforming provisions to changes made by the act; amending
84 s. 499.05, F.S.; conforming provisions to changes made by

85 the act; requiring the department to adopt rules with
86 regard to procedures and forms relating to pedigree paper
87 requirements, alternatives to compliance with the
88 requirement of certain pedigree papers, and the return of
89 prescription drugs purchased before a specified date;
90 amending and redesignating provisions of ss. 499.013 and
91 499.0122, F.S., as provisions relating to rulemaking
92 functions of that section; amending ss. 499.051, 499.052,
93 499.055, and 499.06, F.S.; conforming provisions to
94 changes made by the act; amending s. 499.062, F.S.;
95 providing that the section relates to seizure and
96 condemnation of drugs, devices, or cosmetics; conforming a
97 provision to changes made by the act; amending and
98 redesignating ss. 499.063 and 499.064, F.S., as provisions
99 relating to such functions in that section; amending ss.
100 499.065, 499.066, 499.0661, and 499.067, F.S.; conforming
101 provisions and cross-references to changes made by the
102 act; amending ss. 409.9201, 460.403, 465.0265, 794.075,
103 895.02, and 921.0022, F.S.; conforming cross-references to
104 changes made by the act; providing an effective date.

105
106 Be It Enacted by the Legislature of the State of Florida:
107

108 Section 1. Section 499.002, Florida Statutes, is amended;
109 section 499.004, Florida Statutes, is redesignated as subsection
110 (2) of that section and amended; section 499.0053, Florida
111 Statutes, is redesignated as subsection (3) of that section and
112 amended; section 499.07, Florida Statutes, is redesignated as

113 subsection (4) of that section and amended; section 499.071,
 114 Florida Statutes, is redesignated as subsection (5) of that
 115 section and amended; and section 499.081, Florida Statutes, is
 116 redesignated as subsection (6) of that section and amended, to
 117 read:

118 499.002 Purpose, administration, and enforcement of and
 119 exemption from this part ss. ~~499.001-499.081~~.--

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

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

124 (b)~~(2)~~ Provide uniform legislation to be administered so
 125 far as practicable in conformity with the provisions of, and
 126 regulations issued under the authority of, the Federal Food,
 127 Drug, and Cosmetic Act and that portion of the Federal Trade
 128 Commission Act which expressly prohibits the false advertisement
 129 of drugs, devices, and cosmetics.

130 (c)~~(3)~~ Promote thereby uniformity of such state and
 131 federal laws, and their administration and enforcement,
 132 throughout the United States.

133 (2) ~~499.004 Administration and enforcement by~~
 134 ~~department.~~The department of Health shall administer and
 135 enforce this part ss. ~~499.001-499.081~~ to prevent fraud,
 136 adulteration, misbranding, or false advertising in the
 137 preparation, manufacture, repackaging, or distribution of drugs,
 138 devices, and cosmetics.

139 (3) ~~499.0053 Power to administer oaths, take depositions,~~
 140 ~~and issue and serve subpoenas.~~For the purpose of any

141 investigation or proceeding conducted by the department under
 142 this part ss. 499.001-499.081, the department may administer
 143 oaths, take depositions, issue and serve subpoenas, and compel
 144 the attendance of witnesses and the production of books, papers,
 145 documents, or other evidence. The department shall exercise this
 146 power on its own initiative. Challenges to, and enforcement of,
 147 the subpoenas and orders shall be handled as provided in s.
 148 120.569.

149 (4) 499.07 ~~Duty of prosecuting officer.~~ Each state
 150 attorney, county attorney, or municipal attorney to whom the
 151 department or its designated agent reports any violation of this
 152 part ss. 499.001-499.081 shall cause appropriate proceedings to
 153 be instituted in the proper courts without delay and to be
 154 prosecuted in the manner required by law.

155 (5) 499.071 ~~Issuance of warnings for minor~~
 156 ~~violations.~~ This part does ~~Sections 499.001-499.081~~ do not
 157 require the department to report, for the institution of
 158 proceedings under this part ss. 499.001-499.081, minor
 159 violations of this part ss. 499.001-499.081 when it believes
 160 that the public interest will be adequately served in the
 161 circumstances by a suitable written notice or warning.

162 (6) 499.081 ~~Carriers in interstate commerce exempted from~~
 163 ~~ss. 499.001-499.081.~~ Carriers engaged in interstate commerce
 164 are not subject to this part ss. 499.001-499.081 if they are
 165 engaged in the usual course of business as carriers.

166 Section 2. Section 499.003, Florida Statutes, is amended;
 167 paragraphs (a) through (f) of subsection (1) of section 499.012,
 168 Florida Statutes, are redesignated as subsections (55), (56),

169 (52), and (48), paragraph (c) of subsection (48), and subsection
 170 (53), respectively, of that section and amended; paragraphs (f)
 171 through (j) and (l) through (n) of subsection (3) of section
 172 499.029, Florida Statutes, are redesignated as subsections (25),
 173 (23), (26), (27), (35), (40), (41), and (43), respectively, of
 174 that section and amended; and subsection (1) of section
 175 499.0661, Florida Statutes, is redesignated as subsection (38)
 176 of that section and amended, to read:

177 499.003 Definitions of terms used in this part ~~ss.~~
 178 ~~499.001-499.081.~~--As used in this part ~~ss. 499.001-499.081~~, the
 179 term:

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

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

190 ~~(3)-(2)~~ "Affiliated party" means:

191 (a) A director, officer, trustee, partner, or committee
 192 member of a permittee or applicant or a subsidiary or service
 193 corporation of the permittee or applicant;

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

197 manager, member, officer, director, independent contractor, or
 198 employee of the permittee or applicant;

199 (c) A person who has filed or is required to file a
 200 personal information statement pursuant to s. 499.012(9) ~~s.~~
 201 ~~499.012(4)~~ or is required to be identified in an application for
 202 a permit or to renew a permit pursuant to s. 499.012(8) ~~s.~~
 203 ~~499.012(3)~~; or

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

206 ~~(4)(3)~~ "Applicant" means a person applying for a permit or
 207 certification under this part ~~ss. 499.001-499.081~~.

208 ~~(5)(4)~~ "Authenticate" means to affirmatively verify upon
 209 receipt before any distribution of a prescription legend drug
 210 ~~occurs~~ that each transaction listed on the pedigree paper has
 211 occurred. A wholesale distributor is not required to open a
 212 sealed, medical convenience kit to authenticate a pedigree paper
 213 for a prescription drug contained within the kit.

214 ~~(6)(5)~~ "Certificate of free sale" means a document
 215 prepared by the department which certifies a drug, device, or
 216 cosmetic, that is registered with the department, as one that
 217 can be legally sold in the state.

218 (7) "Chain pharmacy warehouse" means a wholesale
 219 distributor permitted pursuant to s. 499.01 that maintains a
 220 physical location for prescription drugs that functions solely
 221 as a central warehouse to perform intracompany transfers of such
 222 drugs to a member of its affiliated group.

223 ~~(8)(6)~~ "Closed pharmacy" means a pharmacy that is licensed
 224 under chapter 465 and purchases prescription drugs for use by a

225 limited patient population and not for wholesale distribution or
 226 sale to the public. The term does not include retail pharmacies.

227 ~~(9)(7)~~ "Color" includes black, white, and intermediate
 228 grays.

229 ~~(10)(8)~~ "Color additive" means, with the exception of any
 230 material that has been or hereafter is exempt under the federal
 231 act, a material that:

232 (a) Is a dye pigment, or other substance, made by a
 233 process of synthesis or similar artifice, or extracted,
 234 isolated, or otherwise derived, with or without intermediate or
 235 final change of identity from a vegetable, animal, mineral, or
 236 other source; or

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

240
 241 ~~except that the term does not include any material which has~~
 242 ~~been or hereafter is exempt under the federal act.~~

243 ~~(11)(9)~~ "Compressed medical gas" means any liquefied or
 244 vaporized gas that is a prescription drug, whether it is alone
 245 or in combination with other gases.

246 ~~(12)(10)~~ "Contraband prescription legend drug" means any
 247 adulterated drug, as defined in s. 499.006, any counterfeit
 248 drug, as defined in this section, and also means any
 249 prescription legend drug for which a pedigree paper does not
 250 exist, or for which the pedigree paper in existence has been
 251 forged, counterfeited, falsely created, or contains any altered,
 252 false, or misrepresented matter.

253 (13)~~(11)~~ "Cosmetic" means an article, with the exception
 254 of soap, that is:

255 (a) Intended to be rubbed, poured, sprinkled, or sprayed
 256 on; introduced into; or otherwise applied to the human body or
 257 any part thereof for cleansing, beautifying, promoting
 258 attractiveness, or altering the appearance; or

259 (b) Intended for use as a component of any such article;
 260
 261 ~~except that the term does not include soap.~~

262 (14)~~(12)~~ "Counterfeit drug," "counterfeit device," or
 263 "counterfeit drug, counterfeit device, or counterfeit cosmetic"
 264 means a drug, device, or cosmetic which, or the container, seal,
 265 or labeling of which, without authorization, bears the
 266 trademark, trade name, or other identifying mark, imprint, or
 267 device, or any likeness thereof, of a drug, device, or cosmetic
 268 manufacturer, processor, packer, or distributor other than the
 269 person that in fact manufactured, processed, packed, or
 270 distributed that drug, device, or cosmetic and which thereby
 271 falsely purports or is represented to be the product of, or to
 272 have been packed or distributed by, that other drug, device, or
 273 cosmetic manufacturer, processor, packer, or distributor.

274 (15)~~(13)~~ "Department" means the Department of Health.

275 (16)~~(14)~~ "Device" means any instrument, apparatus,
 276 implement, machine, contrivance, implant, in vitro reagent, or
 277 other similar or related article, including its components,
 278 parts, or accessories, which is:

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

281 (b) Intended for use in the diagnosis, cure, mitigation,
 282 treatment, therapy, or prevention of disease in humans or other
 283 animals, or

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

286
 287 and that ~~which~~ does not achieve any of its principal intended
 288 purposes through chemical action within or on the body of humans
 289 or other animals and which is not dependent upon being
 290 metabolized for the achievement of any of its principal intended
 291 purposes.

292 ~~(17)-(15)~~ "Distribute or distribution" or "distribution"
 293 means to sell; offer to sell; give away; transfer, whether by
 294 passage of title, physical movement, or both; deliver; or offer
 295 to deliver. The term does not mean to administer or dispense.

296 (18) "Drop shipment" means the sale of a prescription drug
 297 from a manufacturer to a wholesale distributor, where the
 298 wholesale distributor takes title to, but not possession of, the
 299 prescription drug and the manufacturer of the prescription drug
 300 ships the prescription drug directly to a chain pharmacy
 301 warehouse or a person authorized by law to purchase prescription
 302 drugs for the purpose of administering or dispensing the drug,
 303 as defined in s. 465.003.

304 ~~(16) "Diverted from the legal channels of distribution for~~
 305 ~~prescription drugs" means an adulterated drug pursuant to s.~~
 306 ~~499.006(10).~~

307 (19)-(17) "Drug" means an article that is:

308 (a) Recognized in the current edition of the United States
 309 Pharmacopoeia and National Formulary, official Homeopathic
 310 Pharmacopoeia of the United States, or any supplement to any of
 311 those publications;

312 (b) Intended for use in the diagnosis, cure, mitigation,
 313 treatment, therapy, or prevention of disease in humans or other
 314 animals;

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

317 (d) Intended for use as a component of any article
 318 specified in paragraph (a), paragraph (b), or paragraph (c), but
 319 does not include devices or their components, parts, or
 320 accessories.

321 (20)~~(18)~~ "Establishment" means a place of business at one
 322 general physical location.

323 (21)~~(19)~~ "Federal act" means the Federal Food, Drug, and
 324 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

325 (22)~~(20)~~ "Freight forwarder" means a person who receives
 326 prescription ~~legend~~ drugs which are owned by another person and
 327 designated by that person for export, and exports those
 328 prescription ~~legend~~ drugs.

329 (23)~~(9)~~ "Health care clinic" means a health care clinic
 330 licensed under part X of chapter 400.

331 (24)~~(21)~~ "Health care entity" means a closed pharmacy or
 332 any person, organization, or business entity that provides
 333 diagnostic, medical, surgical, or dental treatment or care, or
 334 chronic or rehabilitative care, but does not include any

335 wholesale distributor or retail pharmacy licensed under state
 336 law to deal in prescription drugs.

337 (25)~~(f)~~ "Health care facility" means a health care
 338 facility licensed under chapter 395.

339 (26)~~(h)~~ "Hospice" means a corporation licensed under part
 340 IV of chapter 400.

341 (27)~~(i)~~ "Hospital" means a facility as defined in s.
 342 395.002 and licensed under chapter 395.

343 (28)~~(22)~~ "Immediate container" does not include package
 344 liners.

345 (29)~~(23)~~ "Label" means a display of written, printed, or
 346 graphic matter upon the immediate container of any drug, device,
 347 or cosmetic. A requirement made by or under authority of this
 348 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~
 349 ~~sections~~ that any word, statement, or other information appear
 350 on the label is not complied with unless such word, statement,
 351 or other information also appears on the outside container or
 352 wrapper, if any, of the retail package of such drug, device, or
 353 cosmetic or is easily legible through the outside container or
 354 wrapper.

355 (30)~~(24)~~ "Labeling" means all labels and other written,
 356 printed, or graphic matters:

357 (a) Upon a drug, device, or cosmetic, or any of its
 358 containers or wrappers; or

359 (b) Accompanying or related to such drug, device, or
 360 cosmetic.

361 ~~(25) "Legend drug," "prescription drug," or "medicinal~~
 362 ~~drug" means any drug, including, but not limited to, finished~~

363 ~~dosage forms, or active ingredients subject to, defined by, or~~
 364 ~~described by s. 503(b) of the Federal Food, Drug, and Cosmetic~~
 365 ~~Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or~~
 366 ~~(e).~~

367 ~~(26) "Legend drug label" means any display of written,~~
 368 ~~printed, or graphic matter upon the immediate container of any~~
 369 ~~legend drug prior to its dispensing to an individual patient~~
 370 ~~pursuant to a prescription of a practitioner authorized by law~~
 371 ~~to prescribe.~~

372 ~~(31)-(27)~~ "Manufacture" means the preparation, deriving,
 373 compounding, propagation, processing, producing, or fabrication
 374 of any drug, device, or cosmetic.

375 ~~(32)-(28)~~ "Manufacturer" means:

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

378 (b) The holder or holders of a New Drug Application (NDA),
 379 an Abbreviated New Drug Application (ANDA), a Biologics License
 380 Application (BLA), or a New Animal Drug Application (NADA),
 381 provided such application has become effective or is otherwise
 382 approved consistent with s. 499.023; a private label distributor
 383 for whom the private label distributor's prescription drugs are
 384 originally manufactured and labeled for the distributor and have
 385 not been repackaged; or the distribution point for the
 386 manufacturer, contract manufacturer, or private label
 387 distributor whether the establishment is a member of the
 388 manufacturer's affiliated group or is a contract distribution
 389 site.

390

391 The term excludes pharmacies that are operating in compliance
 392 with pharmacy practice standards as defined in chapter 465 and
 393 rules adopted under that chapter.

394 ~~(33)-(29)~~ "New drug" means:

395 (a) Any drug the composition of which is such that the
 396 drug is not generally recognized, among experts qualified by
 397 scientific training and experience to evaluate the safety and
 398 effectiveness of drugs, as safe and effective for use under the
 399 conditions prescribed, recommended, or suggested in the labeling
 400 of that drug; or

401 (b) Any drug the composition of which is such that the
 402 drug, as a result of investigations to determine its safety and
 403 effectiveness for use under certain conditions, has been
 404 recognized for use under such conditions, but which drug has
 405 not, other than in those investigations, been used to a material
 406 extent or for a material time under such conditions.

407 (34) "Normal distribution chain" means a wholesale
 408 distribution of a prescription drug in which the wholesale
 409 distributor purchases and receives the specific unit of the
 410 prescription drug directly from the manufacturer and distributes
 411 the prescription drug directly, or through one or more
 412 intracompany transfers, to a chain pharmacy warehouse or a
 413 person authorized by law to purchase prescription drugs for the
 414 purpose of administering or dispensing the drug, as defined in
 415 s. 465.003. For purposes of this subsection, the term
 416 "intracompany" means any transaction or transfer between any
 417 parent, division, or subsidiary wholly owned by a corporate
 418 entity.

419 ~~(35)(j)~~ "Nursing home" means a facility licensed under
 420 part II of chapter 400.

421 ~~(36)(30)~~ "Official compendium" means the current edition
 422 of the official United States Pharmacopoeia and National
 423 Formulary, or any supplement thereto.

424 ~~(37)(31)~~ "Pedigree paper" means+

425 ~~(a) Effective July 1, 2006, a document in written or
 426 electronic form approved by the department that contains of
 427 ~~Health and containing~~ information required by s. 499.01212
 428 regarding the sale and that records each distribution of any
 429 given prescription legend drug, ~~from sale by a pharmaceutical~~
 430 ~~manufacturer, through acquisition and sale by any wholesaler or~~
 431 ~~repackager, until final sale to a pharmacy or other person~~
 432 ~~administering or dispensing the drug. The information required~~
 433 ~~to be included on the form approved by the department pursuant~~
 434 ~~to this paragraph must at least detail the amount of the legend~~
 435 ~~drug; its dosage form and strength; its lot numbers; the name~~
 436 ~~and address of each owner of the legend drug and his or her~~
 437 ~~signature; its shipping information, including the name and~~
 438 ~~address of each person certifying delivery or receipt of the~~
 439 ~~legend drug; an invoice number, a shipping document number, or~~
 440 ~~another number uniquely identifying the transaction; and a~~
 441 ~~certification that the recipient wholesaler has authenticated~~
 442 ~~the pedigree papers. If the manufacturer or repackager has~~
 443 ~~uniquely serialized the individual legend drug unit, that~~
 444 ~~identifier must also be included on the form approved pursuant~~
 445 ~~to this paragraph. It must also include the name, address,~~
 446 ~~telephone number and, if available, e-mail contact information~~~~

447 ~~of each wholesaler involved in the chain of the legend drug's~~
448 ~~custody; or~~

449 ~~(b) A statement, under oath, in written or electronic~~
450 ~~form, confirming that a wholesale distributor purchases and~~
451 ~~receives the specific unit of the prescription drug directly~~
452 ~~from the manufacturer of the prescription drug and distributes~~
453 ~~the prescription drug directly, or through an intracompany~~
454 ~~transfer, to a chain pharmacy warehouse or a person authorized~~
455 ~~by law to purchase prescription drugs for the purpose of~~
456 ~~administering or dispensing the drug, as defined in s. 465.003.~~
457 ~~For purposes of this subsection, the term "chain pharmacy~~
458 ~~warehouse" means a wholesale distributor permitted pursuant to~~
459 ~~s. 499.01 that maintains a physical location for prescription~~
460 ~~drugs that functions solely as a central warehouse to perform~~
461 ~~intracompany transfers of such drugs to a member of its~~
462 ~~affiliated group as described in s. 499.0121(6)(f)1.~~

463 ~~1. The information required to be included pursuant to~~
464 ~~this paragraph must include:~~

465 ~~a. The following statement: "This wholesale distributor~~
466 ~~purchased the specific unit of the prescription drug directly~~
467 ~~from the manufacturer."~~

468 ~~b. The manufacturer's national drug code identifier and~~
469 ~~the name and address of the wholesaler and the purchaser of the~~
470 ~~prescription drug.~~

471 ~~c. The name of the prescription drug as it appears on the~~
472 ~~label.~~

473 ~~d. The quantity, dosage form, and strength of the~~
474 ~~prescription drug.~~

475 ~~2. The wholesale distributor must also maintain and make~~
 476 ~~available to the department, upon request, the point of origin~~
 477 ~~of the prescription drugs, including intracompany transfers; the~~
 478 ~~date of the shipment from the manufacturer to the wholesale~~
 479 ~~distributor; the lot numbers of such drugs; and the invoice~~
 480 ~~numbers from the manufacturer.~~

481
 482 ~~The department may adopt rules and forms relating to the~~
 483 ~~requirements of this subsection.~~

484 ~~(38)(1) DEFINITION. As used in this section, the term~~
 485 ~~"Permittee" means any person holding a permit issued pursuant to~~
 486 ~~s. 499.012.~~

487 ~~(39)(32)~~ "Person" means any individual, child, joint
 488 venture, syndicate, fiduciary, partnership, corporation,
 489 division of a corporation, firm, trust, business trust, company,
 490 estate, public or private institution, association,
 491 organization, group, city, county, city and county, political
 492 subdivision of this state, other governmental agency within this
 493 state, and any representative, agent, or agency of any of the
 494 foregoing, or any other group or combination of the foregoing.

495 ~~(40)(1)~~ "Pharmacist" means a person licensed under chapter
 496 465.

497 ~~(41)(m)~~ "Pharmacy" means an entity licensed under chapter
 498 465.

499 ~~(42)(33)~~ "Prepackaged drug product" means a drug that
 500 originally was in finished packaged form sealed by a
 501 manufacturer and that is placed in a properly labeled container
 502 by a pharmacy or practitioner authorized to dispense pursuant to

503 chapter 465 for the purpose of dispensing in the establishment
 504 in which the prepackaging occurred.

505 ~~(43)(n)~~ "Prescribing practitioner" means a physician
 506 licensed under chapter 458 or chapter 459 or any other medical
 507 professional with authority under state law to prescribe cancer
 508 medication.

509 (44) "Prescription drug" means a prescription, medicinal,
 510 or legend drug, including, but not limited to, finished dosage
 511 forms or active ingredients subject to, defined by, or described
 512 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s.
 513 465.003(8), s. 499.007(13), or subsection (11), subsection (47),
 514 or subsection (54).

515 (45) "Prescription drug label" means any display of
 516 written, printed, or graphic matter upon the immediate container
 517 of any prescription drug prior to its dispensing to an
 518 individual patient pursuant to a prescription of a practitioner
 519 authorized by law to prescribe.

520 ~~(46)(34)~~ "Prescription label" means any display of
 521 written, printed, or graphic matter upon the immediate container
 522 of any prescription ~~legend~~ drug dispensed pursuant to a
 523 prescription of a practitioner authorized by law to prescribe.

524 ~~(47)(35)~~ "Prescription medical oxygen" means oxygen USP
 525 which is a drug that can only be sold on the order or
 526 prescription of a practitioner authorized by law to prescribe.
 527 The label of prescription medical oxygen must comply with
 528 current labeling requirements for oxygen under the Federal Food,
 529 Drug, and Cosmetic Act.

530 ~~(48)(d)~~ "Primary wholesale distributor ~~wholesaler~~" means
531 any wholesale distributor that:

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

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

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

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

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

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

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

551 b. The wholesale distributor discloses to the department
552 the names of all members of the affiliated group of which the
553 wholesale distributor is a member and the affiliated group
554 agrees in writing to provide records on prescription drug
555 purchases by the members of the affiliated group not later than
556 48 hours after the department requests access to such records,
557 regardless of the location where the records are stored.

558 ~~(49)(36)~~ "Proprietary drug," or "OTC drug," means a patent
 559 or over-the-counter drug in its unbroken, original package,
 560 which drug is sold to the public by, or under the authority of,
 561 the manufacturer or primary distributor thereof, is not
 562 misbranded under the provisions of this part ~~ss. 499.001-~~
 563 ~~499.081~~, and can be purchased without a prescription.

564 ~~(50)(37)~~ "Repackage" includes repacking or otherwise
 565 changing the container, wrapper, or labeling to further the
 566 distribution of the drug, device, or cosmetic.

567 ~~(51)(38)~~ "Repackager" means a person who repackages. The
 568 term excludes pharmacies that are operating in compliance with
 569 pharmacy practice standards as defined in chapter 465 and rules
 570 adopted under that chapter.

571 ~~(52)(e)~~ "Retail pharmacy" means a community pharmacy
 572 licensed under chapter 465 that purchases prescription drugs at
 573 fair market prices and provides prescription services to the
 574 public.

575 ~~(53)(f)~~ "Secondary wholesale distributor ~~wholesaler~~" means
 576 a wholesale distributor that is not a primary wholesale
 577 distributor ~~wholesaler~~.

578 ~~(54)(39)~~ "Veterinary prescription drug" means a
 579 prescription ~~legend~~ drug intended solely for veterinary use. The
 580 label of the drug must bear the statement, "Caution: Federal law
 581 restricts this drug to sale by or on the order of a licensed
 582 veterinarian."

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

586 ~~(55)(a)~~ "Wholesale distribution" means distribution of
 587 prescription drugs to persons other than a consumer or patient,
 588 but does not include:

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

592 ~~1.a.~~ The purchase or other acquisition by a hospital or
 593 other health care entity that is a member of a group purchasing
 594 organization of a prescription drug for its own use from the
 595 group purchasing organization or from other hospitals or health
 596 care entities that are members of that organization.

597 ~~2.b.~~ The sale, purchase, or trade of a prescription drug
 598 or an offer to sell, purchase, or trade a prescription drug by a
 599 charitable organization described in s. 501(c)(3) of the
 600 Internal Revenue Code of 1986, as amended and revised, to a
 601 nonprofit affiliate of the organization to the extent otherwise
 602 permitted by law.

603 ~~3.e.~~ The sale, purchase, or trade of a prescription drug
 604 or an offer to sell, purchase, or trade a prescription drug
 605 among hospitals or other health care entities that are under
 606 common control. For purposes of this subparagraph ~~section~~,
 607 "common control" means the power to direct or cause the
 608 direction of the management and policies of a person or an
 609 organization, whether by ownership of stock, by voting rights,
 610 by contract, or otherwise.

611 ~~4.d.~~ The sale, purchase, trade, or other transfer of a
 612 prescription drug from or for any federal, state, or local
 613 government agency or any entity eligible to purchase

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

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

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

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

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

629 e.~~(V)~~ The contract provider and subcontractor must
 630 maintain and produce immediately for inspection all records of
 631 movement or transfer of all the prescription drugs belonging to
 632 the agency or entity, including, but not limited to, the records
 633 of receipt and disposition of prescription drugs. Each
 634 contractor and subcontractor dispensing or administering these
 635 drugs must maintain and produce records documenting the
 636 dispensing or administration. Records that are required to be
 637 maintained include, but are not limited to, a perpetual
 638 inventory itemizing drugs received and drugs dispensed by
 639 prescription number or administered by patient identifier, which
 640 must be submitted to the agency or entity quarterly.

641 f. ~~(VI)~~ The contract provider or subcontractor may
642 administer or dispense the prescription drugs only to the
643 eligible patients of the agency or entity or must return the
644 prescription drugs for or to the agency or entity. The contract
645 provider or subcontractor must require proof from each person
646 seeking to fill a prescription or obtain treatment that the
647 person is an eligible patient of the agency or entity and must,
648 at a minimum, maintain a copy of this proof as part of the
649 records of the contractor or subcontractor required under sub-
650 subparagraph e. ~~sub-subparagraph (V).~~

651 g. ~~(VII)~~ In addition to the departmental inspection
652 authority set forth in s. 499.051, the establishment of the
653 contract provider and subcontractor and all records pertaining
654 to prescription drugs subject to this subparagraph ~~sub-~~
655 ~~subparagraph~~ shall be subject to inspection by the agency or
656 entity. All records relating to prescription drugs of a
657 manufacturer under this subparagraph ~~sub-subparagraph~~ shall be
658 subject to audit by the manufacturer of those drugs, without
659 identifying individual patient information.

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

663 1.a. The sale, purchase, or trade of a prescription drug
664 among federal, state, or local government health care entities
665 that are under common control and are authorized to purchase
666 such prescription drug.

667 2.b. The sale, purchase, or trade of a prescription drug
668 or an offer to sell, purchase, or trade a prescription drug for

669 emergency medical reasons. For purposes of this subparagraph
670 ~~sub-subparagraph~~, the term "emergency medical reasons" includes
671 transfers of prescription drugs by a retail pharmacy to another
672 retail pharmacy to alleviate a temporary shortage.

673 3.e. The transfer of a prescription drug acquired by a
674 medical director on behalf of a licensed emergency medical
675 services provider to that emergency medical services provider
676 and its transport vehicles for use in accordance with the
677 provider's license under chapter 401.

678 4.d. The revocation of a sale or the return of a
679 prescription drug to the person's prescription drug wholesale
680 supplier.

681 5.e. The donation of a prescription drug by a health care
682 entity to a charitable organization that has been granted an
683 exemption under s. 501(c)(3) of the Internal Revenue Code of
684 1986, as amended, and that is authorized to possess prescription
685 drugs.

686 6.f. The transfer of a prescription drug by a person
687 authorized to purchase or receive prescription drugs to a person
688 licensed or permitted to handle reverse distributions or
689 destruction under the laws of the jurisdiction in which the
690 person handling the reverse distribution or destruction receives
691 the drug.

692 7.g. The transfer of a prescription drug by a hospital or
693 other health care entity to a person licensed under this part
694 ~~chapter~~ to repackage prescription drugs for the purpose of
695 repackaging the prescription drug for use by that hospital, or
696 other health care entity and other health care entities that are

697 under common control, if ownership of the prescription drugs
 698 remains with the hospital or other health care entity at all
 699 times. In addition to the recordkeeping requirements of s.
 700 499.0121(6), the hospital or health care entity that transfers
 701 prescription drugs pursuant to this subparagraph ~~sub-~~
 702 ~~subparagraph~~ must reconcile all drugs transferred and returned
 703 and resolve any discrepancies in a timely manner.

704 (c)3- The distribution of prescription drug samples by
 705 manufacturers' representatives or distributors' representatives
 706 conducted in accordance with s. 499.028.

707 (d)4- The sale, purchase, or trade of blood and blood
 708 components intended for transfusion. As used in this paragraph
 709 ~~subparagraph~~, the term "blood" means whole blood collected from
 710 a single donor and processed either for transfusion or further
 711 manufacturing, and the term "blood components" means that part
 712 of the blood separated by physical or mechanical means.

713 (e)5- The lawful dispensing of a prescription drug in
 714 accordance with chapter 465.

715 (f)6- The sale, purchase, or trade of a prescription drug
 716 between pharmacies as a result of a sale, transfer, merger, or
 717 consolidation of all or part of the business of the pharmacies
 718 from or with another pharmacy, whether accomplished as a
 719 purchase and sale of stock or of business assets.

720 (56)(b)- "Wholesale distributor" means any person engaged
 721 in wholesale distribution of prescription drugs in or into this
 722 state, including, but not limited to, manufacturers;
 723 repackagers; own-label distributors; jobbers; private-label
 724 distributors; brokers; warehouses, including manufacturers' and

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

729 Section 3. Subsections (4), (10), (11), (12), (14), (15),
730 (18), (19), (20), (22), (24), (28), and (29) of section 499.005,
731 Florida Statutes, are amended to read:

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

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

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

743 (11) The use, on the labeling of any drug or in any
744 advertisement relating to such drug, of any representation or
745 suggestion that an application of the drug is effective when it
746 is not or that the drug complies with this part ~~ss. 499.001-~~
747 ~~499.081~~ when it does not.

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

750 (14) The purchase or receipt of a prescription ~~legend~~ drug
751 from a person that is not authorized under this chapter to

752 distribute prescription ~~legend~~ drugs to that purchaser or
 753 recipient.

754 (15) The sale or transfer of a prescription ~~legend~~ drug to
 755 a person that is not authorized under the law of the
 756 jurisdiction in which the person receives the drug to purchase
 757 or possess prescription ~~legend~~ drugs from the person selling or
 758 transferring the prescription ~~legend~~ drug.

759 (18) Failure to maintain records as required by this part
 760 ~~ss. 499.001-499.081~~ and rules adopted under this part ~~these~~
 761 ~~sections~~.

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

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

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

771 (24) The distribution of a prescription ~~legend~~ device to
 772 the patient or ultimate consumer without a prescription or order
 773 from a practitioner licensed by law to use or prescribe the
 774 device.

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

777 (29) The receipt of a prescription drug pursuant to a
 778 wholesale distribution without having previously received or
 779 simultaneously ~~either first~~ receiving a pedigree paper that was

780 attested to as accurate and complete by the wholesale
 781 distributor as required under this part ~~or complying with the~~
 782 ~~provisions of s. 499.0121(6)(d)5.~~

783 Section 4. Section 499.0051, Florida Statutes, is amended;
 784 section 499.0052, Florida Statutes, is redesignated as
 785 subsection (7) of that section and amended; section 499.00535,
 786 Florida Statutes, is redesignated as subsection (9) of that
 787 section and amended; section 499.00545, Florida Statutes, is
 788 redesignated as subsection (10) of that section and amended;
 789 section 499.069, Florida Statutes, is redesignated as subsection
 790 (11) of that section and amended; and section 499.0691, Florida
 791 Statutes, is redesignated as subsections (12) through (15) of
 792 that section and amended, to read:

793 499.0051 Criminal acts ~~involving contraband or adulterated~~
 794 ~~drugs.~~--

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

796 (a) A person, other than a manufacturer, engaged in the
 797 wholesale distribution of prescription legend ~~legend~~ drugs who fails to
 798 deliver to another person complete and accurate pedigree papers
 799 concerning a prescription legend ~~legend~~ drug or contraband prescription
 800 ~~legend~~ drug prior to, or simultaneous with, the transfer of
 801 ~~transferring~~ the prescription legend ~~legend~~ drug or contraband
 802 prescription legend ~~legend~~ drug to another person commits a felony of
 803 the third degree, punishable as provided in s. 775.082, s.
 804 775.083, or s. 775.084.

805 (b) A person engaged in the wholesale distribution of
 806 prescription legend ~~legend~~ drugs who fails to acquire complete and
 807 accurate pedigree papers concerning a prescription legend ~~legend~~ drug

808 or contraband prescription ~~legend~~ drug prior to, or simultaneous
 809 with, the receipt of ~~obtaining~~ the prescription ~~legend~~ drug or
 810 contraband prescription ~~legend~~ drug from another person commits
 811 a felony of the third degree, punishable as provided in s.
 812 775.082, s. 775.083, or s. 775.084.

813 (c) Any person who knowingly destroys, alters, conceals,
 814 or fails to maintain complete and accurate pedigree papers
 815 concerning any prescription ~~legend~~ drug or contraband
 816 prescription ~~legend~~ drug in his or her possession commits a
 817 felony of the third degree, punishable as provided in s.
 818 775.082, s. 775.083, or s. 775.084.

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

821 (a) A person engaged in the wholesale distribution of
 822 prescription ~~legend~~ drugs who is in possession of pedigree
 823 papers concerning prescription ~~legend~~ drugs or contraband
 824 prescription ~~legend~~ drugs and who fails to authenticate the
 825 matters contained in the pedigree papers and who nevertheless
 826 attempts to further distribute prescription ~~legend~~ drugs or
 827 contraband prescription ~~legend~~ drugs commits a felony of the
 828 third degree, punishable as provided in s. 775.082, s. 775.083,
 829 or s. 775.084.

830 (b) A person in possession of pedigree papers concerning
 831 prescription ~~legend~~ drugs or contraband prescription ~~legend~~
 832 drugs who falsely swears or certifies that he or she has
 833 authenticated the matters contained in the pedigree papers
 834 commits a felony of the third degree, punishable as provided in
 835 s. 775.082, s. 775.083, or s. 775.084.

836 (3) KNOWING FORGERY OF PEDIGREE PAPERS.--A person who
 837 knowingly forges, counterfeits, or falsely creates any pedigree
 838 paper; who falsely represents any factual matter contained on
 839 any pedigree paper; or who knowingly omits to record material
 840 information required to be recorded in a pedigree paper, commits
 841 a felony of the second degree, punishable as provided in s.
 842 775.082, s. 775.083, or s. 775.084.

843 (4) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION ~~LEGEND~~
 844 DRUG FROM UNAUTHORIZED PERSON.--A person who knowingly purchases
 845 or receives from a person not authorized to distribute
 846 prescription ~~legend~~ drugs under this chapter a prescription
 847 ~~legend~~ drug in a wholesale distribution transaction commits a
 848 felony of the second degree, punishable as provided in s.
 849 775.082, s. 775.083, or s. 775.084.

850 (5) KNOWING SALE OR TRANSFER OF PRESCRIPTION ~~LEGEND~~ DRUG
 851 TO UNAUTHORIZED PERSON.--A person who knowingly sells or
 852 transfers to a person not authorized to purchase or possess
 853 prescription ~~legend~~ drugs, under the law of the jurisdiction in
 854 which the person receives the drug, a prescription ~~legend~~ drug
 855 in a wholesale distribution transaction commits a felony of the
 856 second degree, punishable as provided in s. 775.082, s. 775.083,
 857 or s. 775.084.

858 (6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO
 859 SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is
 860 knowingly in actual or constructive possession of any amount of
 861 contraband prescription ~~legend~~ drugs, who knowingly sells or
 862 delivers, or who possesses with intent to sell or deliver any
 863 amount of contraband prescription ~~legend~~ drugs, commits a felony

864 of the second degree, punishable as provided in s. 775.082, s.
 865 775.083, or s. 775.084.

866 ~~(7)499.0052~~ KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION
 867 ~~LEGEND~~ DRUGS.--A person who knowingly sells, purchases,
 868 manufactures, delivers, or brings into this state, or who is
 869 knowingly in actual or constructive possession of any amount of
 870 contraband prescription ~~legend~~ drugs valued at \$25,000 or more
 871 commits a felony of the first degree, punishable as provided in
 872 s. 775.082, s. 775.083, or s. 775.084.

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

875 1.~~(1)~~ If the value of contraband prescription ~~legend~~ drugs
 876 involved is \$25,000 or more, but less than \$100,000, the
 877 defendant shall pay a mandatory fine of \$25,000. If the
 878 defendant is a corporation or other person that is not a natural
 879 person, it shall pay a mandatory fine of \$75,000.

880 2.~~(2)~~ If the value of contraband prescription ~~legend~~ drugs
 881 involved is \$100,000 or more, but less than \$250,000, the
 882 defendant shall pay a mandatory fine of \$100,000. If the
 883 defendant is a corporation or other person that is not a natural
 884 person, it shall pay a mandatory fine of \$300,000.

885 3.~~(3)~~ If the value of contraband prescription ~~legend~~ drugs
 886 involved is \$250,000 or more, the defendant shall pay a
 887 mandatory fine of \$200,000. If the defendant is a corporation or
 888 other person that is not a natural person, it shall pay a
 889 mandatory fine of \$600,000.

890 (b) As used in this subsection ~~section~~, the term "value"
 891 means the market value of the property at the time and place of

892 the offense or, if such cannot be satisfactorily ascertained,
 893 the cost of replacement of the property within a reasonable time
 894 after the offense. Amounts of value of separate contraband
 895 prescription legend drugs involved in distinct transactions for
 896 the distribution of the contraband prescription legend drugs
 897 committed pursuant to one scheme or course of conduct, whether
 898 involving the same person or several persons, may be aggregated
 899 in determining the punishment of the offense.

900 ~~(8)~~ ~~(7)~~ KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION
 901 ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges,
 902 counterfeits, or falsely creates any prescription label or
 903 prescription legend drug label, or who falsely represents any
 904 factual matter contained on any prescription label or
 905 prescription legend drug label, commits a felony of the first
 906 degree, punishable as provided in s. 775.082, s. 775.083, or s.
 907 775.084.

908 ~~(9)~~ ~~499.00535~~ KNOWING SALE OR PURCHASE OF CONTRABAND
 909 PRESCRIPTION LEGEND DRUGS RESULTING IN GREAT BODILY HARM.--A
 910 person who knowingly sells, purchases, manufactures, delivers,
 911 or brings into this state, or who is knowingly in actual or
 912 constructive possession of any amount of contraband prescription
 913 ~~legend~~ drugs, and whose acts in violation of this subsection
 914 ~~section~~ result in great bodily harm to a person, commits a
 915 felony of the first degree, as provided in s. 775.082, s.
 916 775.083, or s. 775.084.

917 ~~(10)~~ ~~499.00545~~ KNOWING SALE OR PURCHASE OF CONTRABAND
 918 PRESCRIPTION LEGEND DRUGS RESULTING IN DEATH.--A person who
 919 knowingly manufactures, sells, purchases, delivers, or brings

920 into this state, or who is knowingly in actual or constructive
 921 possession of any amount of contraband prescription legend
 922 drugs, and whose acts in violation of this subsection ~~section~~
 923 result in the death of a person, commits a felony of the first
 924 degree, punishable by a term of years not exceeding life, as
 925 provided in s. 775.082, s. 775.083, or s. 775.084.

926 ~~(11) 499.069 CRIMINAL PUNISHMENT FOR VIOLATIONS OF S.~~
 927 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE
 928 ADVERTISEMENT.--

929 ~~(a)(1)~~ Any person who violates any of the provisions of s.
 930 499.005 with respect to a device or cosmetic commits a
 931 misdemeanor of the second degree, punishable as provided in s.
 932 775.082 or s. 775.083; but, if the violation is committed after
 933 a conviction of such person under this subsection ~~section~~ has
 934 become final, such person is guilty of a misdemeanor of the
 935 first degree, punishable as provided in s. 775.082 or s. 775.083
 936 or as otherwise provided in this part ~~ss. 499.001 499.081~~,
 937 except that any person who violates s. 499.005(8) or (10)
 938 ~~subsection (8) or subsection (10) of s. 499.005~~ with respect to
 939 a device or cosmetic commits a felony of the third degree,
 940 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,
 941 or as otherwise provided in this part ~~ss. 499.001 499.081~~.

942 ~~(b)(2)~~ A publisher, radio broadcast licensee, or agency or
 943 medium for the dissemination of an advertisement, except the
 944 manufacturer, wholesaler, or seller of the article to which a
 945 false advertisement relates, is not liable under this subsection
 946 ~~section~~ by reason of the dissemination by him or her of such
 947 false advertisement, unless he or she has refused, on the

948 request of the department, to furnish to the department the name
 949 and post office address of the manufacturer, wholesaler, seller,
 950 or advertising agency that asked him or her to disseminate such
 951 advertisement.

952 (12) 499.0691 ADULTERATED AND MISBRANDED DRUGS; FALSE
 953 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS

954 ~~Criminal punishment for violations related to drugs;~~
 955 ~~dissemination of false advertisement.--(1)~~ Any person who
 956 violates any of the following provisions commits a misdemeanor
 957 of the second degree, punishable as provided in s. 775.082 or s.
 958 775.083; but, if the violation is committed after a conviction
 959 of such person under this subsection ~~section~~ has become final,
 960 such person commits a misdemeanor of the first degree,
 961 punishable as provided in s. 775.082 or s. 775.083, or as
 962 otherwise provided in this part ~~ss. 499.001-499.081~~:

963 (a) The manufacture, repackaging, sale, delivery, or
 964 holding or offering for sale of any drug that is adulterated or
 965 misbranded or has otherwise been rendered unfit for human or
 966 animal use.

967 (b) The adulteration or misbranding of any drug intended
 968 for further distribution.

969 (c) The receipt of any drug that is adulterated or
 970 misbranded, and the delivery or proffered delivery of such drug,
 971 for pay or otherwise.

972 (d) The dissemination of any false or misleading
 973 advertisement of a drug.

974 (e) The use, on the labeling of any drug or in any
 975 advertisement relating to such drug, of any representation or

976 suggestion that an application of the drug is effective when it
 977 is not or that the drug complies with this part ~~ss. 499.001-~~
 978 ~~499.081~~ when it does not.

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

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

984 (h) The failure to maintain records related to a drug as
 985 required by this part ~~ss. 499.001-499.081~~ and rules adopted
 986 under this part ~~these sections~~, except for pedigree papers,
 987 invoices, or shipping documents related to prescription legend
 988 drugs.

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

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

998 (a) The refusal or constructive refusal to allow:

999 1. The department to enter or inspect an establishment in
 1000 which drugs are manufactured, processed, repackaged, sold,
 1001 brokered, or held;

1002 2. Inspection of any record of that establishment;

1003 3. The department to enter and inspect any vehicle that is
1004 being used to transport drugs; or

1005 4. The department to take samples of any drug.

1006 (b) The sale, purchase, or trade, or the offer to sell,
1007 purchase, or trade, a drug sample as defined in s. 499.028; the
1008 distribution of a drug sample in violation of s. 499.028; or the
1009 failure to otherwise comply with s. 499.028.

1010 (c) Providing the department with false or fraudulent
1011 records, or making false or fraudulent statements, regarding any
1012 matter within the provisions of this part ~~chapter~~ related to a
1013 drug.

1014 (d) The failure to receive, maintain, or provide invoices
1015 and shipping documents, other than pedigree papers, if
1016 applicable, related to the distribution of a prescription legend
1017 drug.

1018 (e) The importation of a prescription legend drug for
1019 wholesale distribution, except as provided by s. 801(d) of the
1020 Federal Food, Drug, and Cosmetic Act.

1021 (f) The wholesale distribution of a ~~any~~ prescription drug
1022 that was:

1023 1. Purchased by a public or private hospital or other
1024 health care entity; or

1025 2. Donated or supplied at a reduced price to a charitable
1026 organization.

1027 (g) The failure to obtain a permit as a prescription drug
1028 wholesale distributor ~~wholesaler~~ when a permit is required by
1029 this part ~~ss. 499.001-499.081~~ for that activity.

1030 (h) Knowingly possessing any adulterated or misbranded
 1031 prescription ~~legend~~ drug outside of a designated quarantine
 1032 area.

1033 (i) The purchase or sale of a prescription drug ~~drugs~~ for
 1034 wholesale distribution in exchange for currency, as defined in
 1035 s. 560.103(6).

1036 (14) OTHER VIOLATIONS. ~~--(3)~~ Any person who violates any
 1037 of the following provisions commits a felony of the second
 1038 degree, punishable as provided in s. 775.082, s. 775.083, or s.
 1039 775.084, or as otherwise provided in this part: ~~ss. 499.001-~~
 1040 ~~499.081.~~

1041 (a) Knowingly manufacturing, repackaging, selling,
 1042 delivering, or holding or offering for sale any drug that is
 1043 adulterated or misbranded or has otherwise been rendered unfit
 1044 for human or animal use.

1045 (b) Knowingly adulterating a drug that is intended for
 1046 further distribution.

1047 (c) Knowingly receiving a drug that is adulterated and
 1048 delivering or proffering delivery of such drug for pay or
 1049 otherwise.

1050 (d) Committing any act that causes a drug to be a
 1051 counterfeit drug, or selling, dispensing, or knowingly holding
 1052 for sale a counterfeit drug.

1053 (e) Forging, counterfeiting, simulating, or falsely
 1054 representing any drug, or, without the authority of the
 1055 manufacturer, using any mark, stamp, tag, label, or other
 1056 identification device authorized or required by rules adopted
 1057 under this part ~~ss. 499.001-499.081.~~

1058 (f) Knowingly obtaining or attempting to obtain a
 1059 prescription drug for wholesale distribution by fraud, deceit,
 1060 misrepresentation, or subterfuge, or engaging in
 1061 misrepresentation or fraud in the distribution of a drug.

1062 (g) Removing a pharmacy's dispensing label from a
 1063 dispensed prescription drug with the intent to further
 1064 distribute the prescription drug.

1065 (h) Knowingly distributing a prescription drug that was
 1066 previously dispensed by a licensed pharmacy, unless such
 1067 distribution was authorized in chapter 465 or the rules adopted
 1068 under chapter 465.

1069 (15) FALSE ADVERTISEMENT.--(4) A publisher, radio
 1070 broadcast licensee, or agency or medium for the dissemination of
 1071 an advertisement, except the manufacturer, repackager, wholesale
 1072 distributor ~~wholesaler~~, or seller of the article to which a
 1073 false advertisement relates, is not liable under subsection
 1074 (12), subsection (13), or subsection (14) ~~this section~~ by reason
 1075 of the dissemination by him or her of such false advertisement,
 1076 unless he or she has refused, on the request of the department,
 1077 to furnish to the department the name and post office address of
 1078 the manufacturer, repackager, wholesale distributor ~~wholesaler~~,
 1079 seller, or advertising agency that asked him or her to
 1080 disseminate such advertisement.

1081 Section 5. Section 499.0054, Florida Statutes, is amended;
 1082 section 499.0055, Florida Statutes, is redesignated as
 1083 subsection (2) of that section and amended; and section
 1084 499.0057, Florida Statutes, is redesignated as subsection (3) of
 1085 that section and amended, to read:

1086 499.0054 Advertising and labeling of drugs, devices, and
 1087 cosmetics; exemptions.--

1088 (1) It is a violation of the Florida Drug and Cosmetic Act
 1089 to perform or cause the performance of any of the following
 1090 acts:

1091 (a)~~(1)~~ The dissemination of any false advertisement of any
 1092 drug, device, or cosmetic. An advertisement is false if it is
 1093 false or misleading in any way.

1094 (b)~~(2)~~ The distribution in commerce of any drug, device,
 1095 or cosmetic, if its labeling or advertising is in violation of
 1096 this part ~~ss. 499.001-499.081~~.

1097 (c)~~(3)~~ The manufacturing, repackaging, packaging, selling,
 1098 delivery, holding, or offering for sale of any drug, device, or
 1099 cosmetic for which the advertising or labeling is false or
 1100 misleading.

1101 (d)~~(4)~~ The advertising of any drug, device, or cosmetic
 1102 that is adulterated or misbranded.

1103 (e)~~(5)~~ The receiving in commerce of any drug, device, or
 1104 cosmetic that is falsely advertised or labeled or the delivering
 1105 or proffering for delivery of any such drug, device, or
 1106 cosmetic.

1107 (f)~~(6)~~ The advertising or labeling of any product
 1108 containing ephedrine, a salt of ephedrine, an isomer of
 1109 ephedrine, or a salt of an isomer of ephedrine, for the
 1110 indication of stimulation, mental alertness, weight loss,
 1111 appetite control, energy, or other indications not approved by
 1112 the pertinent United States Food and Drug Administration Over-
 1113 the-Counter Final or Tentative Final Monograph or approved new

1114 drug application under the federal act. In determining
 1115 compliance with this requirement, the department may consider
 1116 the following factors:

- 1117 1.~~(a)~~ The packaging of the product.
- 1118 2.~~(b)~~ The name and labeling of the product.
- 1119 3.~~(c)~~ The manner of distribution, advertising, and
 1120 promotion of the product, including verbal representations at
 1121 the point of sale.

1122 4.~~(d)~~ The duration, scope, and significance of abuse of
 1123 the particular product.

1124 (g)~~(7)~~ The advertising of any drug or device represented
 1125 to have any effect in any of the following conditions,
 1126 disorders, diseases, or processes:

- 1127 1.~~(a)~~ Blood disorders.
- 1128 2.~~(b)~~ Bone or joint diseases.
- 1129 3.~~(c)~~ Kidney diseases or disorders.
- 1130 4.~~(d)~~ Cancer.
- 1131 5.~~(e)~~ Diabetes.
- 1132 6.~~(f)~~ Gall bladder diseases or disorders.
- 1133 7.~~(g)~~ Heart and vascular diseases.
- 1134 8.~~(h)~~ High blood pressure.
- 1135 9.~~(i)~~ Diseases or disorders of the ear or auditory
 1136 apparatus, including hearing loss or deafness.
- 1137 10.~~(j)~~ Mental disease or mental retardation.
- 1138 11.~~(k)~~ Paralysis.
- 1139 12.~~(l)~~ Prostate gland disorders.
- 1140 13.~~(m)~~ Conditions of the scalp affecting hair loss.
- 1141 14.~~(n)~~ Baldness.

- 1142 15.~~(o)~~ Endocrine disorders.
- 1143 16.~~(p)~~ Sexual impotence.
- 1144 17.~~(q)~~ Tumors.
- 1145 18.~~(r)~~ Venereal diseases.
- 1146 19.~~(s)~~ Varicose ulcers.
- 1147 20.~~(t)~~ Breast enlargement.
- 1148 21.~~(u)~~ Purifying blood.
- 1149 22.~~(v)~~ Metabolic disorders.
- 1150 23.~~(w)~~ Immune system disorders or conditions affecting the
- 1151 immune system.
- 1152 24.~~(x)~~ Extension of life expectancy.
- 1153 25.~~(y)~~ Stress and tension.
- 1154 26.~~(z)~~ Brain stimulation or performance.
- 1155 27.~~(aa)~~ The body's natural defense mechanisms.
- 1156 28.~~(bb)~~ Blood flow.
- 1157 29.~~(cc)~~ Depression.
- 1158 30.~~(dd)~~ Human immunodeficiency virus or acquired immune
- 1159 deficiency syndrome or related disorders or conditions.
- 1160 (h)~~(8)~~ The representation or suggestion in labeling or
- 1161 advertising that an article is approved under this part ~~ss.~~
- 1162 ~~499.001-499.081~~, when such is not the case.
- 1163 (2)~~499.0055~~ ~~False or misleading advertisement.~~—In
- 1164 determining whether an advertisement is false or misleading, the
- 1165 department shall review the representations made or suggested by
- 1166 statement, word, design, device, sound, or any combination
- 1167 thereof within the advertisement and the extent to which the
- 1168 advertisement fails to reveal material facts with respect to
- 1169 consequences that can result from the use of the drug, device,

1170 or cosmetic to which the advertisement relates under the
 1171 conditions of use prescribed in the labeling or advertisement.

1172 ~~(3) 499.0057 Advertisement exemptions.~~

1173 ~~(a) (1)~~ An advertisement that is not prohibited under
 1174 paragraph (1) (a) ~~s. 499.0054(1)~~ is not prohibited under
 1175 paragraph (1) (g) ~~s. 499.0054(7)~~ if it is disseminated:

1176 1. To the public solely to advertise the product for those
 1177 indications that are safe and effective indications and the
 1178 product is safe and effective for self-medication, as
 1179 established by the United States Food and Drug Administration;
 1180 or

1181 2. ~~if it is disseminated~~ Only to members of the medical,
 1182 dental, pharmaceutical, or veterinary professions or appears
 1183 only in the scientific periodicals of these professions.

1184 ~~(b) (2)~~ Compliance with this part ~~ss. 499.001-499.081~~ and
 1185 the rules adopted under this part ~~those sections~~ creates no
 1186 legal presumption that a drug or device is safe or effective.

1187 Section 6. Subsections (3), (10), and (11) of section
 1188 499.006, Florida Statutes, are amended to read:

1189 499.006 Adulterated drug or device.--A drug or device is
 1190 adulterated:

1191 (3) If it is a drug and the methods used in, or the
 1192 facilities or controls used for, its manufacture, processing,
 1193 packing, or holding do not conform to, or are not operated or
 1194 administered in conformity with, current good manufacturing
 1195 practices to assure that the drug meets the requirements of this
 1196 part ~~ss. 499.001-499.081~~ and that the drug has the identity and

1197 strength, and meets the standard of quality and purity, which it
 1198 purports or is represented to possess;

1199 (10) If it is a prescription ~~legend~~ drug for which the
 1200 required pedigree paper is nonexistent, fraudulent, or
 1201 incomplete under the requirements of this part ~~ss. 499.001-~~
 1202 ~~499.081~~ or applicable rules, or that has been purchased, held,
 1203 sold, or distributed at any time by a person not authorized
 1204 under federal or state law to do so; or

1205 (11) If it is a prescription drug subject to, defined by,
 1206 or described by s. 503(b) of the Federal Food, Drug, and
 1207 Cosmetic Act which has been returned by a veterinarian to a
 1208 limited prescription drug veterinary wholesale distributor
 1209 ~~wholesaler~~.

1210 Section 7. Section 499.007, Florida Statutes, is amended
 1211 to read:

1212 499.007 Misbranded drug or device.--A drug or device is
 1213 misbranded:

1214 (1) If its labeling is in any way false or misleading.

1215 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
 1216 label containing:

1217 (a) The name and place of business of the manufacturer,
 1218 repackager, or distributor of the finished dosage form of the
 1219 drug. For the purpose of this paragraph, the finished dosage
 1220 form of a prescription ~~medicinal~~ drug is that form of the drug
 1221 which is, or is intended to be, dispensed or administered to the
 1222 patient and requires no further manufacturing or processing
 1223 other than packaging, reconstitution, and labeling; and

1224 (b) An accurate statement of the quantity of the contents
 1225 in terms of weight, measure, or numerical count. ~~+~~ However, under
 1226 this section, reasonable variations are permitted, and the
 1227 department shall establish by rule exemptions for small
 1228 packages.

1229 (3) If it is an active pharmaceutical ingredient in bulk
 1230 form and does not bear a label containing:

1231 (a) The name and place of business of the manufacturer,
 1232 repackager, or distributor; and

1233 (b) An accurate statement of the quantity of the contents
 1234 in terms of weight, measure, or numerical count.

1235 (4)~~(3)~~ If any word, statement, or other information
 1236 required by or under this part ~~ss. 499.001-499.081~~ to appear on
 1237 the label or labeling is not prominently placed thereon with
 1238 such conspicuousness as compared with other words, statements,
 1239 designs, or devices in the labeling, and in such terms, as to
 1240 render the word, statement, or other information likely to be
 1241 read and understood under customary conditions of purchase and
 1242 use.

1243 (5)~~(4)~~ If it is a drug and is not designated solely by a
 1244 name recognized in an official compendium and, ~~unless~~ its label
 1245 does not bear ~~bears~~:

1246 (a) The common or usual name of the drug, if any; and

1247 (b) In case it is fabricated from two or more ingredients,
 1248 the common or usual name and quantity of each active ingredient.

1249 (6)~~(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:

1250 (a) Adequate directions for use; and

1251 (b) Adequate warnings against use in those pathological
 1252 conditions in which its use may be dangerous to health or
 1253 against use by children if its use may be dangerous to health,
 1254 or against unsafe dosage or methods or duration of
 1255 administration or application, in such manner and form as are
 1256 necessary for the protection of users.

1257 (7)~~(6)~~ If it purports to be a drug the name of which is
 1258 recognized in the official compendium and~~, unless~~ it is not
 1259 packaged and labeled as prescribed therein.⁷ However, the method
 1260 of packaging may be modified with the consent of the department.

1261 (8)~~(7)~~ If it has been found by the department to be a drug
 1262 liable to deterioration and~~, unless~~ it is not packaged in such
 1263 form and manner, and its label bears a statement of such
 1264 precautions, as the department by rule requires as necessary to
 1265 protect the public health. Such rule may not be established for
 1266 any drug recognized in an official compendium until the
 1267 department has informed the appropriate body charged with the
 1268 revision of such compendium of the need for such packaging or
 1269 labeling requirements and that body has failed within a
 1270 reasonable time to prescribe such requirements.

1271 (9)~~(8)~~ If it is:

1272 (a) A drug and its container or finished dosage form is so
 1273 made, formed, or filled as to be misleading;

1274 (b) An imitation of another drug; or

1275 (c) Offered for sale under the name of another drug.

1276 (10)~~(9)~~ If it is dangerous to health when used in the
 1277 dosage or with the frequency or duration prescribed,
 1278 recommended, or suggested in the labeling of the drug.

1279 ~~(11)~~~~(10)~~ If it is, purports to be, or is represented as a
 1280 drug composed wholly or partly of insulin and, ~~unless~~

1281 ~~(a)~~ it is not from a batch with respect to which a
 1282 certificate has been issued pursuant to s. 506 of the federal
 1283 act, which, ~~and~~

1284 ~~(b)~~ ~~The~~ certificate is in effect with respect to the drug.

1285 ~~(12)~~~~(11)~~ If it is, purports to be, or is represented as a
 1286 drug composed wholly or partly of any kind of antibiotic
 1287 requiring certification under the federal act and ~~unless~~

1288 ~~(a)~~ it is not from a batch with respect to which a
 1289 certificate has been issued pursuant to s. 507 of the federal
 1290 act, which, ~~and~~

1291 ~~(b)~~ the certificate is in effect with respect to the
 1292 drug. ~~†~~

1293
 1294 However, this subsection does not apply to any drug or class of
 1295 drugs exempted by regulations adopted under s. 507(c) or (d) of
 1296 the federal act.

1297 ~~(13)~~~~(12)~~ If it is a drug intended for use by humans which
 1298 is a habit-forming drug or which, because of its toxicity or
 1299 other potentiality for harmful effect, or the method of its use,
 1300 or the collateral measures necessary to its use, is not safe for
 1301 use except under the supervision of a practitioner licensed by
 1302 law to administer such drugs, ~~†~~ or which is limited by an
 1303 effective application under s. 505 of the federal act to use
 1304 under the professional supervision of a practitioner licensed by
 1305 law to prescribe such drug, if ~~unless~~ it is not dispensed only:

- 1306 (a) Upon the written prescription of a practitioner
 1307 licensed by law to prescribe such drug;
 1308 (b) Upon an oral prescription of such practitioner, which
 1309 is reduced promptly to writing and filled by the pharmacist; or
 1310 (c) By refilling any such written or oral prescription, if
 1311 such refilling is authorized by the prescriber either in the
 1312 original prescription or by oral order which is reduced promptly
 1313 to writing and filled by the pharmacist.

1314
 1315 This subsection does not relieve any person from any requirement
 1316 prescribed by law with respect to controlled substances as
 1317 defined in the applicable federal and state laws.

1318 ~~(14)-(13)~~ If it is a drug that is subject to paragraph
 1319 ~~(13)-(12)~~(a), and if, at any time before it is dispensed, its
 1320 label does not ~~fails to~~ bear the statement:

1321 (a) "Caution: Federal Law Prohibits Dispensing Without
 1322 Prescription";

1323 (b) "Rx Only";

1324 (c) The prescription symbol followed by the word "Only";
 1325 or

1326 (d) "Caution: State Law Prohibits Dispensing Without
 1327 Prescription."

1328 ~~(15)-(14)~~ If it is a drug that is not subject to paragraph
 1329 ~~(13)-(12)~~(a), if at any time before it is dispensed its label
 1330 bears the statement of caution required in subsection ~~(14)~~ ~~(13)~~.

1331 ~~(16)-(15)~~ If it is a color additive, the intended use of
 1332 which in or on drugs is for the purpose of coloring only and,
 1333 ~~unless~~ its packaging and labeling are not in conformity with the

1334 packaging and labeling requirements that apply to such color
 1335 additive and are prescribed under the federal act.

1336 (17) A drug dispensed by filling or refilling a written or
 1337 oral prescription of a practitioner licensed by law to prescribe
 1338 such drug is exempt from the requirements of this section,
 1339 except subsections (1), (9) ~~(8)~~, (11) ~~(10)~~, and (12) ~~(11)~~ and
 1340 the packaging requirements of subsections (7) ~~(6)~~ and (8) ~~(7)~~,
 1341 if the drug bears a label that contains the name and address of
 1342 the dispenser or seller, the prescription number and the date
 1343 the prescription was written or filled, the name of the
 1344 prescriber and the name of the patient, and the directions for
 1345 use and cautionary statements. This exemption does not apply to
 1346 any drug dispensed in the course of the conduct of a business of
 1347 dispensing drugs pursuant to diagnosis by mail or to any drug
 1348 dispensed in violation of subsection (13) ~~(12)~~. The department
 1349 may, by rule, exempt drugs subject to s. 499.062 ~~ss. 499.062-~~
 1350 ~~499.064~~ from subsection (13) ~~(12)~~ if compliance with that
 1351 subsection is not necessary to protect the public health,
 1352 safety, and welfare.

1353 Section 8. Subsection (1) of section 499.008, Florida
 1354 Statutes, is amended and subsection (5) is added to that section
 1355 to read:

1356 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

1357 (1) If it bears or contains any poisonous or deleterious
 1358 substance that is injurious to users under the conditions of use
 1359 prescribed in the labeling or advertisement thereof or under
 1360 such conditions of use as are customary or usual; however, this
 1361 subsection does not apply to coal-tar hair dye:

1362 (a) The label of which bears the following legend
 1363 conspicuously displayed thereon: "Caution: This product contains
 1364 ingredients which may cause skin irritation on certain
 1365 individuals, and a preliminary test according to accompanying
 1366 directions should first be made. This product must not be used
 1367 for dyeing the eyelashes or eyebrows; to do so may cause
 1368 blindness"; and

1369 (b) The labeling of which bears adequate directions for
 1370 such preliminary testing.

1371

1372 ~~For the purposes of this subsection and subsection (4), the term~~
 1373 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1374 (5) For the purposes of subsections (1) and (4), the term
 1375 "hair dye" does not include eyelash dyes or eyebrow dyes.

1376 Section 9. Subsections (2), (3), and (5) of section
 1377 499.009, Florida Statutes, are amended to read:

1378 499.009 Misbranded cosmetics.--A cosmetic is misbranded:

1379 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a
 1380 label containing:

1381 (a) The name and place of business of the manufacturer,
 1382 packer, or distributor;

1383 (b) An accurate statement of the quantity of the contents
 1384 in terms of weight, measure, or numerical count; however, under
 1385 this paragraph reasonable variations are permitted, and the
 1386 department shall establish by rule exemptions for small
 1387 packages; and

1388 (c) A declaration of ingredients in descending order of
 1389 predominance, or as otherwise required by federal law.

1390 (3) If any word, statement, or other information required
 1391 by or under authority of this part ~~ss. 499.001-499.081~~ to appear
 1392 on the label or labeling is not prominently placed thereon with
 1393 such conspicuousness as compared with other words, statements,
 1394 designs, or devices in the labeling, and in such terms, as to
 1395 render the word, statement, or other information likely to be
 1396 read and understood by an individual under customary conditions
 1397 of purchase and use.

1398 (5) ~~Unless,~~ If it is a color additive, its packaging and
 1399 labeling are not in conformity with the packaging and labeling
 1400 requirements applicable to that color additive prescribed under
 1401 the federal act. This subsection does not apply to packages of
 1402 color additives that, with respect to their use for cosmetics,
 1403 are marketed and intended for use only in or on hair dyes.

1404 Section 10. Section 499.01, Florida Statutes, is amended;
 1405 the introductory paragraph and paragraphs (a) through (h) of
 1406 subsection (2) of section 499.012, Florida Statutes, are
 1407 redesignated as the introductory paragraph and paragraphs (d),
 1408 (n), (e), (f), (c), (i), (k), and (l), respectively, of
 1409 subsection (2) of that section and amended; paragraphs (b)
 1410 through (e) of subsection (2) of section 499.013, Florida
 1411 Statutes, are redesignated as paragraphs (p), (o), (q), and (r),
 1412 respectively, of subsection (2) of that section and amended; and
 1413 section 499.014, Florida Statutes, is redesignated as paragraph
 1414 (g) of subsection (2) of that section and amended, to read:

1415 499.01 ~~Permits, applications, renewal, general~~
 1416 ~~requirements.~~ --

- 1417 (1) Prior to operating, a permit is required for each
 1418 person and establishment that intends to operate as:
- 1419 (a) A prescription drug manufacturer;
 - 1420 (b) A prescription drug repackager;
 - 1421 (c) A nonresident prescription drug manufacturer;
 - 1422 (d) A prescription drug wholesale distributor;
 - 1423 (e) An out-of-state prescription drug wholesale
 1424 distributor;
 - 1425 (f) A retail pharmacy drug wholesale distributor;
 - 1426 (g) A restricted prescription drug distributor;
 - 1427 (h) A complimentary drug distributor;
 - 1428 (i) A freight forwarder;
 - 1429 (j) A veterinary prescription drug retail establishment;
 - 1430 (k) A veterinary prescription drug wholesale distributor;
 - 1431 (l) A limited prescription drug veterinary wholesale
 1432 distributor;
 - 1433 (m) A medical oxygen retail establishment;
 - 1434 (n) A compressed medical gas wholesale distributor;
 - 1435 (o) A compressed medical gas manufacturer;
 - 1436 (p)(e) An over-the-counter drug manufacturer;
 - 1437 ~~(d) A compressed medical gas manufacturer;~~
 - 1438 (q)(e) A device manufacturer; or
 - 1439 (r)(f) A cosmetic manufacturer.
 - 1440 ~~(g) A prescription drug wholesaler;~~
 - 1441 ~~(h) A veterinary prescription drug wholesaler;~~
 - 1442 ~~(i) A compressed medical gas wholesaler;~~
 - 1443 ~~(j) An out-of-state prescription drug wholesaler;~~
 - 1444 ~~(k) A nonresident prescription drug manufacturer;~~

- 1445 ~~(l) A freight forwarder;~~
- 1446 ~~(m) A retail pharmacy drug wholesaler;~~
- 1447 ~~(n) A veterinary legend drug retail establishment;~~
- 1448 ~~(o) A medical oxygen retail establishment;~~
- 1449 ~~(p) A complimentary drug distributor;~~
- 1450 ~~(q) A restricted prescription drug distributor; or~~
- 1451 ~~(r) A limited prescription drug veterinary wholesaler.~~

1452 (2) The following ~~types of wholesaler~~ permits are
 1453 established:

1454 (a) Prescription drug manufacturer permit.--A prescription
 1455 drug manufacturer permit is required for any person that
 1456 manufactures a prescription drug in this state.

1457 1. A person that operates an establishment permitted as a
 1458 prescription drug manufacturer may engage in wholesale
 1459 distribution of prescription drugs manufactured at that
 1460 establishment and must comply with all the provisions of this
 1461 part and the rules adopted under this part that apply to a
 1462 wholesale distributor.

1463 2. A prescription drug manufacturer must comply with all
 1464 appropriate state and federal good manufacturing practices.

1465 (b) Prescription drug repackager permit.--A prescription
 1466 drug repackager permit is required for any person that
 1467 repackages a prescription drug in this state.

1468 1. A person that operates an establishment permitted as a
 1469 prescription drug repackager may engage in wholesale
 1470 distribution of prescription drugs repackaged at that
 1471 establishment and must comply with all the provisions of this

1472 part and the rules adopted under this part that apply to a
 1473 wholesale distributor.

1474 2. A prescription drug repackager must comply with all
 1475 appropriate state and federal good manufacturing practices.

1476 (c)(e) Nonresident prescription drug manufacturer
 1477 permit.--A nonresident prescription drug manufacturer permit is
 1478 required for any person that is a manufacturer of prescription
 1479 drugs, or the distribution point for a manufacturer of
 1480 prescription drugs, and located outside of this state, or that
 1481 is an entity to whom an approved new drug application has been
 1482 issued by the United States Food and Drug Administration, or the
 1483 contracted manufacturer of the approved new drug application
 1484 holder, and located outside the United States, which engages in
 1485 the wholesale distribution in this state of the prescription
 1486 drugs it manufactures or is responsible for manufacturing. Each
 1487 such manufacturer or entity must be permitted by the department
 1488 and comply with all the provisions required of a wholesale
 1489 distributor under this part ~~ss. 499.001-499.081~~, except s.
 1490 499.01212 ~~s. 499.0121(6)(d)~~.

1491 1. A person that distributes prescription drugs that it
 1492 did not manufacture must also obtain an out-of-state
 1493 prescription drug wholesale distributor ~~wholesaler~~ permit
 1494 pursuant to this section to engage in the wholesale distribution
 1495 of the prescription drugs manufactured by another person and
 1496 comply with the requirements of an out-of-state prescription
 1497 drug wholesale distributor ~~wholesaler~~.

1498 2. Any such person must comply with the licensing or
 1499 permitting requirements of the jurisdiction in which the

1500 establishment is located and the federal act, and any product
 1501 wholesaled into this state must comply with this part ~~ss.~~
 1502 ~~499.001-499.081~~. If a person intends to import prescription
 1503 drugs from a foreign country into this state, the nonresident
 1504 prescription drug manufacturer must provide to the department a
 1505 list identifying each prescription drug it intends to import and
 1506 document approval by the United States Food and Drug
 1507 Administration for such importation.

1508 (d)(a) A Prescription drug wholesale distributor
 1509 ~~wholesaler's~~ permit.--A prescription drug wholesale distributor
 1510 ~~wholesaler~~ is a wholesale distributor that may engage in the
 1511 wholesale distribution of prescription drugs. A prescription
 1512 drug wholesale distributor ~~wholesaler~~ that applies to the
 1513 department for a new permit or the renewal of a permit must
 1514 submit a bond of \$100,000, or other equivalent means of security
 1515 acceptable to the department, such as an irrevocable letter of
 1516 credit or a deposit in a trust account or financial institution,
 1517 payable to the Florida Drug, Device, and Cosmetic Trust Fund.
 1518 The purpose of the bond is to secure payment of any
 1519 administrative penalties imposed by the department and any fees
 1520 and costs incurred by the department regarding that permit which
 1521 are authorized under state law and which the permittee fails to
 1522 pay 30 days after the fine or costs become final. The department
 1523 may make a claim against such bond or security until 1 year
 1524 after the permittee's license ceases to be valid or until 60
 1525 days after any administrative or legal proceeding authorized in
 1526 this part ~~ss. 499.001-499.081~~ which involves the permittee is
 1527 concluded, including any appeal, whichever occurs later. The

1528 department may adopt rules for issuing a prescription drug
 1529 wholesale distributor-broker ~~wholesaler-broker~~ permit to a
 1530 person who engages in the wholesale distribution of prescription
 1531 drugs and does not take physical possession of any prescription
 1532 drugs.

1533 (e) ~~(e)~~ ~~An~~ Out-of-state prescription drug wholesale
 1534 distributor ~~wholesaler's~~ permit.--An out-of-state prescription
 1535 drug wholesale distributor ~~wholesaler~~ is a wholesale distributor
 1536 located outside this state which engages in the wholesale
 1537 distribution of prescription drugs into this state and which
 1538 must be permitted by the department and comply with all the
 1539 provisions required of a wholesale distributor under this part
 1540 ~~ss. 499.001-499.081~~. An out-of-state prescription drug wholesale
 1541 distributor ~~wholesaler~~ that applies to the department for a new
 1542 permit or the renewal of a permit must submit a bond of
 1543 \$100,000, or other equivalent means of security acceptable to
 1544 the department, such as an irrevocable letter of credit or a
 1545 deposit in a trust account or financial institution, payable to
 1546 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose
 1547 of the bond is to secure payment of any administrative penalties
 1548 imposed by the department and any fees and costs incurred by the
 1549 department regarding that permit which are authorized under
 1550 state law and which the permittee fails to pay 30 days after the
 1551 fine or costs become final. The department may make a claim
 1552 against such bond or security until 1 year after the permittee's
 1553 license ceases to be valid or until 60 days after any
 1554 administrative or legal proceeding authorized in this part ~~ss.~~

1555 ~~499.001-499.081~~ which involves the permittee is concluded,
 1556 including any appeal, whichever occurs later.

1557 1. The out-of-state prescription drug wholesale
 1558 distributor ~~wholesaler~~ must maintain at all times a license or
 1559 permit to engage in the wholesale distribution of prescription
 1560 drugs in compliance with laws of the state in which it is a
 1561 resident.

1562 2. An out-of-state prescription drug wholesale distributor
 1563 ~~wholesaler's~~ permit is not required for an intracompany sale or
 1564 transfer of a prescription drug from an out-of-state
 1565 establishment that is duly licensed as a prescription drug
 1566 wholesale distributor ~~wholesaler~~, in its state of residence, to
 1567 a licensed prescription drug wholesale distributor ~~wholesaler~~ in
 1568 this state, if both wholesale distributors ~~wholesalers~~ conduct
 1569 wholesale distributions of prescription drugs under the same
 1570 business name. The recordkeeping requirements of ~~ss. 499.0121(6)~~
 1571 499.0121(6) and 499.01212 must be followed for this transaction.

1572 (f)~~(d)~~ A Retail pharmacy drug wholesale distributor
 1573 ~~wholesaler's~~ permit.--A retail pharmacy drug wholesale
 1574 distributor ~~wholesaler~~ is a retail pharmacy engaged in wholesale
 1575 distribution of prescription drugs within this state under the
 1576 following conditions:

1577 1. The pharmacy must obtain a retail pharmacy drug
 1578 wholesale distributor ~~wholesaler's~~ permit pursuant to this part
 1579 ~~ss. 499.001-499.081~~ and the rules adopted under this part ~~these~~
 1580 ~~sections~~.

1581 2. The wholesale distribution activity does not exceed 30
 1582 percent of the total annual purchases of prescription drugs. If

1583 the wholesale distribution activity exceeds the 30-percent
 1584 maximum, the pharmacy must obtain a prescription drug wholesale
 1585 distributor ~~wholesaler's~~ permit.

1586 3. The transfer of prescription drugs that appear in any
 1587 schedule contained in chapter 893 is subject to chapter 893 and
 1588 the federal Comprehensive Drug Abuse Prevention and Control Act
 1589 of 1970.

1590 4. The transfer is between a retail pharmacy and another
 1591 retail pharmacy, or a Modified Class II institutional pharmacy,
 1592 or a health care practitioner licensed in this state and
 1593 authorized by law to dispense or prescribe prescription drugs.

1594 5. All records of sales of prescription drugs subject to
 1595 this section must be maintained separate and distinct from other
 1596 records and comply with the recordkeeping requirements of this
 1597 part ~~ss. 499.001-499.081~~.

1598 (g) 499.014 Restricted prescription drug distributor permit
 1599 ~~Distribution of legend drugs by hospitals, health care entities,~~
 1600 ~~charitable organizations, and return or destruction companies;~~
 1601 ~~permits, general requirements.--~~

1602 ~~(1)~~ A restricted prescription drug distributor permit is
 1603 required for any person that engages in the distribution of a
 1604 prescription legend drug, which distribution is not considered
 1605 "wholesale distribution" under s. 499.003(55)(a) ~~s.~~
 1606 ~~499.012(1)(a)1~~.

1607 1.(2) A person who engages in the receipt or distribution
 1608 of a prescription legend drug in this state for the purpose of
 1609 processing its return or its destruction must obtain a permit as
 1610 a restricted prescription drug distributor if such person is not

1611 the person initiating the return, the prescription drug
 1612 wholesale supplier of the person initiating the return, or the
 1613 manufacturer of the drug.

1614 2.~~(3)~~ Storage, handling, and recordkeeping of these
 1615 distributions must comply with the requirements for wholesale
 1616 distributors under s. 499.0121, but not ~~except~~ those set forth
 1617 in s. 499.01212 ~~s. 499.0121(6)(d)~~.

1618 3.~~(4)~~ A person who applies for a permit as a restricted
 1619 prescription drug distributor, or for the renewal of such a
 1620 permit, must provide to the department the information required
 1621 under s. 499.012 ~~s. 499.01~~.

1622 4.~~(5)~~ The department may ~~issue permits to restricted~~
 1623 ~~prescription drug distributors and may~~ adopt rules regarding the
 1624 distribution of prescription drugs by hospitals, health care
 1625 entities, charitable organizations, or other persons not
 1626 involved in wholesale distribution, which rules are necessary
 1627 for the protection of the public health, safety, and welfare.

1628 (h) Complimentary drug distributor permit.--A
 1629 complimentary drug distributor permit is required for any person
 1630 that engages in the distribution of a complimentary drug,
 1631 subject to the requirements of s. 499.028.

1632 (i)~~(f)~~ Freight forwarder permit.--A freight forwarder
 1633 permit is required for any person that engages in the
 1634 distribution of a prescription ~~legend~~ drug as a freight
 1635 forwarder unless the person is a common carrier. The storage,
 1636 handling, and recordkeeping of such distributions must comply
 1637 with the requirements for wholesale distributors under s.
 1638 499.0121, but not ~~except~~ those set forth in s. 499.01212 ~~s.~~

1639 ~~499.0121(6)(d)~~. A freight forwarder must provide the source of
1640 the prescription legend drugs with a validated airway bill, bill
1641 of lading, or other appropriate documentation to evidence the
1642 exportation of the product.

1643 (j) Veterinary prescription drug retail establishment
1644 permit.--A veterinary prescription drug retail establishment
1645 permit is required for any person that sells veterinary
1646 prescription drugs to the public but does not include a pharmacy
1647 licensed under chapter 465.

1648 1. The sale to the public must be based on a valid written
1649 order from a veterinarian licensed in this state who has a valid
1650 client-veterinarian relationship with the purchaser's animal.

1651 2. Veterinary prescription drugs may not be sold in excess
1652 of the amount clearly indicated on the order or beyond the date
1653 indicated on the order.

1654 3. An order may not be valid for more than 1 year.

1655 4. A veterinary prescription drug retail establishment may
1656 not purchase, sell, trade, or possess human prescription drugs
1657 or any controlled substance as defined in chapter 893.

1658 5. A veterinary prescription drug retail establishment
1659 must sell a veterinary prescription drug in the original, sealed
1660 manufacturer's container with all labeling intact and legible.
1661 The department may adopt by rule additional labeling
1662 requirements for the sale of a veterinary prescription drug.

1663 6. A veterinary prescription drug retail establishment
1664 must comply with all of the wholesale distribution requirements
1665 of s. 499.0121.

1666 7. Prescription drugs sold by a veterinary prescription
 1667 drug retail establishment pursuant to a practitioner's order may
 1668 not be returned into the retail establishment's inventory.

1669 (k)~~(g)~~ A veterinary prescription drug wholesale
 1670 distributor ~~wholesaler~~ permit.--A veterinary prescription drug
 1671 wholesale distributor ~~wholesaler~~ permit is required for any
 1672 person that engages in the distribution of veterinary
 1673 prescription drugs in or into this state. A veterinary
 1674 prescription drug wholesale distributor ~~wholesaler~~ that also
 1675 distributes prescription drugs subject to, defined by, or
 1676 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
 1677 Act which it did not manufacture must obtain a permit as a
 1678 prescription drug wholesale distributor ~~wholesaler~~, an out-of-
 1679 state prescription drug wholesale distributor ~~wholesaler~~, or a
 1680 limited prescription drug veterinary wholesale distributor
 1681 ~~wholesaler~~ in lieu of the veterinary prescription drug wholesale
 1682 distributor ~~wholesaler~~ permit. A veterinary prescription drug
 1683 wholesale distributor ~~wholesaler~~ must comply with the
 1684 requirements for wholesale distributors under s. 499.0121, but
 1685 not except those set forth in s. 499.01212 ~~s. 499.0121(6)(d)~~.

1686 (l)~~(h)~~ Limited prescription drug veterinary wholesale
 1687 distributor ~~wholesaler~~ permit.--Unless engaging in the
 1688 activities of and permitted as a prescription drug manufacturer,
 1689 nonresident prescription drug manufacturer, prescription drug
 1690 wholesale distributor ~~wholesaler~~, or out-of-state prescription
 1691 drug wholesale distributor ~~wholesaler~~, a limited prescription
 1692 drug veterinary wholesale distributor ~~wholesaler~~ permit is
 1693 required for any person that engages in the distribution in or

1694 into this state of veterinary prescription drugs and
 1695 prescription drugs subject to, defined by, or described by s.
 1696 503(b) of the Federal Food, Drug, and Cosmetic Act under the
 1697 following conditions:

1698 1. The person is engaged in the business of wholesaling
 1699 prescription and veterinary prescription ~~legend~~ drugs to
 1700 persons:

1701 a. Licensed as veterinarians practicing on a full-time
 1702 basis;

1703 b. Regularly and lawfully engaged in instruction in
 1704 veterinary medicine;

1705 c. Regularly and lawfully engaged in law enforcement
 1706 activities;

1707 d. For use in research not involving clinical use; or

1708 e. For use in chemical analysis or physical testing or for
 1709 purposes of instruction in law enforcement activities, research,
 1710 or testing.

1711 2. No more than 30 percent of total annual prescription
 1712 drug sales may be prescription drugs approved for human use
 1713 which are subject to, defined by, or described by s. 503(b) of
 1714 the Federal Food, Drug, and Cosmetic Act.

1715 3. The person does not distribute ~~is not permitted,~~
 1716 ~~licensed, or otherwise authorized in any jurisdiction state to~~
 1717 ~~wholesale~~ prescription drugs subject to, defined by, or
 1718 described by s. 503(b) of the Federal Food, Drug, and Cosmetic
 1719 Act to any person who is authorized to sell, distribute,
 1720 purchase, trade, or use these drugs on or for humans.

1721 4. A limited prescription drug veterinary wholesale
 1722 distributor ~~wholesaler~~ that applies to the department for a new
 1723 permit or the renewal of a permit must submit a bond of \$20,000,
 1724 or other equivalent means of security acceptable to the
 1725 department, such as an irrevocable letter of credit or a deposit
 1726 in a trust account or financial institution, payable to the
 1727 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of
 1728 the bond is to secure payment of any administrative penalties
 1729 imposed by the department and any fees and costs incurred by the
 1730 department regarding that permit which are authorized under
 1731 state law and which the permittee fails to pay 30 days after the
 1732 fine or costs become final. The department may make a claim
 1733 against such bond or security until 1 year after the permittee's
 1734 license ceases to be valid or until 60 days after any
 1735 administrative or legal proceeding authorized in this part ~~ss.~~
 1736 ~~499.001-499.081~~ which involves the permittee is concluded,
 1737 including any appeal, whichever occurs later.

1738 5. A limited prescription drug veterinary wholesale
 1739 distributor ~~wholesaler~~ must maintain at all times a license or
 1740 permit to engage in the wholesale distribution of prescription
 1741 drugs in compliance with laws of the state in which it is a
 1742 resident.

1743 6. A limited prescription drug veterinary wholesale
 1744 distributor ~~wholesaler~~ must comply with the requirements for
 1745 wholesale distributors under ss. s. ~~499.0121~~ and 499.01212,
 1746 except that a limited prescription drug veterinary wholesale
 1747 distributor ~~wholesaler~~ is not required to provide a pedigree

1748 paper as required by s. 499.01212 ~~s. 499.0121(6)(d)~~ upon the
 1749 wholesale distribution of a prescription drug to a veterinarian.

1750 7. A limited prescription drug veterinary wholesale
 1751 distributor ~~wholesaler~~ may not return to inventory for
 1752 subsequent wholesale distribution any prescription drug subject
 1753 to, defined by, or described by s. 503(b) of the Federal Food,
 1754 Drug, and Cosmetic Act which has been returned by a
 1755 veterinarian.

1756 8. ~~An out of state prescription drug wholesaler's permit~~
 1757 ~~or~~ A limited prescription drug veterinary wholesale distributor
 1758 ~~wholesaler~~ permit is not required for an intracompany sale or
 1759 transfer of a prescription drug from an out-of-state
 1760 establishment that is duly licensed to engage in the wholesale
 1761 distribution of prescription drugs in its state of residence to
 1762 a licensed limited prescription drug veterinary wholesale
 1763 distributor ~~wholesaler~~ in this state if both wholesale
 1764 distributors ~~wholesalers~~ conduct wholesale distributions of
 1765 prescription drugs under the same business name. The
 1766 recordkeeping requirements of ss. s. 499.0121(6) and 499.01212
 1767 must be followed for this transaction.

1768 (m) Medical oxygen retail establishment permit.--A medical
 1769 oxygen retail establishment permit is required for any person
 1770 that sells medical oxygen to patients only. The sale must be
 1771 based on an order from a practitioner authorized by law to
 1772 prescribe. The term does not include a pharmacy licensed under
 1773 chapter 465.

1774 1. A medical oxygen retail establishment may not possess,
 1775 purchase, sell, or trade any prescription drug other than
 1776 medical oxygen.

1777 2. A medical oxygen retail establishment may refill
 1778 medical oxygen for an individual patient based on an order from
 1779 a practitioner authorized by law to prescribe. A medical oxygen
 1780 retail establishment that refills medical oxygen must comply
 1781 with all appropriate state and federal good manufacturing
 1782 practices.

1783 3. A medical oxygen retail establishment must comply with
 1784 all of the wholesale distribution requirements of s. 499.0121.

1785 4. Prescription medical oxygen sold by a medical oxygen
 1786 retail establishment pursuant to a practitioner's order may not
 1787 be returned into the retail establishment's inventory.

1788 (n) ~~(b)~~ A compressed medical gas wholesale distributor
 1789 ~~wholesaler's~~ permit.--A compressed medical gas wholesale
 1790 distributor ~~wholesaler~~ is a wholesale distributor that is
 1791 limited to the wholesale distribution of compressed medical
 1792 gases to other than the consumer or patient. The compressed
 1793 medical gas must be in the original sealed container that was
 1794 purchased by that wholesale distributor ~~wholesaler~~. A compressed
 1795 medical gas wholesale distributor ~~wholesaler~~ may not possess or
 1796 engage in the wholesale distribution of any prescription drug
 1797 other than compressed medical gases. The department shall adopt
 1798 rules that govern the wholesale distribution of prescription
 1799 medical oxygen for emergency use. With respect to the emergency
 1800 use of prescription medical oxygen, those rules may not be

1801 inconsistent with rules and regulations of federal agencies
 1802 unless the Legislature specifically directs otherwise.

1803 (o)-(e) Compressed medical gas manufacturer permit.--A
 1804 compressed medical gas manufacturer ~~manufacturer's~~ permit is
 1805 required for any person that engages in the manufacture of
 1806 compressed medical gases or repackages compressed medical gases
 1807 from one container to another.

1808 1. A compressed medical gas manufacturer ~~permittee~~ may not
 1809 manufacture or possess any prescription drug other than
 1810 compressed medical gases.

1811 2. A compressed medical gas manufacturer ~~permittee~~ may
 1812 engage in wholesale distribution of compressed medical gases
 1813 manufactured at that establishment and must comply with all the
 1814 provisions of this part ~~ss. 499.001-499.081~~ and the rules
 1815 adopted under this part ~~those sections~~ that apply to a wholesale
 1816 distributor.

1817 3. A compressed medical gas manufacturer ~~permittee~~ must
 1818 comply with all appropriate state and federal good manufacturing
 1819 practices.

1820 (p)-(b) Over-the-counter drug manufacturer permit.--An
 1821 over-the-counter drug manufacturer ~~manufacturer's~~ permit is
 1822 required for any person that engages in the manufacture or
 1823 repackaging of an over-the-counter drug.

1824 1. An over-the-counter drug manufacturer ~~permittee~~ may not
 1825 possess or purchase prescription drugs.

1826 2. A pharmacy is exempt from obtaining an over-the-counter
 1827 drug manufacturer ~~manufacturer's~~ permit if it is operating in

1828 compliance with pharmacy practice standards as defined in
 1829 chapter 465 and the rules adopted under that chapter.

1830 3. An over-the-counter drug manufacturer ~~permittee~~ must
 1831 comply with all appropriate state and federal good manufacturing
 1832 practices.

1833 (g)-(d) Device manufacturer permit.--A device manufacturer
 1834 ~~manufacturer's~~ permit is required for any person that engages in
 1835 the manufacture, repackaging, or assembly of medical devices for
 1836 human use in this state, except that a permit is not required if
 1837 the person is engaged only in manufacturing, repackaging, or
 1838 assembling a medical device pursuant to a practitioner's order
 1839 for a specific patient.

1840 1. A manufacturer or repackager of medical devices in this
 1841 state must comply with all appropriate state and federal good
 1842 manufacturing practices and quality system rules.

1843 2. The department shall adopt rules related to storage,
 1844 handling, and recordkeeping requirements for manufacturers of
 1845 medical devices for human use.

1846 (r)-(e) Cosmetic manufacturer permit.--A cosmetic
 1847 manufacturer ~~manufacturer's~~ permit is required for any person
 1848 that manufactures or repackages cosmetics in this state. A
 1849 person that only labels or changes the labeling of a cosmetic
 1850 but does not open the container sealed by the manufacturer of
 1851 the product is exempt from obtaining a permit under this
 1852 paragraph.

1853 Section 11. Section 499.012, Florida Statutes, is amended
 1854 and subsections (2) through (8) of section 499.01, Florida

1855 States, are redesignated as subsections (1) through (7) of that
 1856 section and amended, to read:

1857 499.012 Permit application ~~Wholesale distribution,~~
 1858 ~~definitions, permits, applications, general~~ requirements.--

1859 (1) ~~As used in this section, the term:~~

1860 ~~(2)~~(a) A permit issued pursuant to this part ~~ss. 499.001-~~
 1861 ~~499.081~~ may be issued only to a natural person who is at least
 1862 18 years of age or to an applicant that is not a natural person
 1863 if each person who, directly or indirectly, manages, controls,
 1864 or oversees the operation of that applicant is at least 18 years
 1865 of age.

1866 (b) An establishment that is a place of residence may not
 1867 receive a permit and may not operate under this part ~~ss.~~
 1868 ~~499.001-499.081.~~

1869 (c) A person that applies for or renews a permit to
 1870 manufacture or distribute prescription ~~legend~~ drugs may not use
 1871 a name identical to the name used by any other establishment or
 1872 licensed person authorized to purchase prescription drugs in
 1873 this state, except that a restricted drug distributor permit
 1874 issued to a health care entity will be issued in the name in
 1875 which the institutional pharmacy permit is issued and a retail
 1876 pharmacy drug wholesale distributor ~~wholesaler~~ will be issued a
 1877 permit in the name of its retail pharmacy permit.

1878 (d) A permit for a prescription drug manufacturer,
 1879 prescription drug repackager, prescription drug wholesale
 1880 distributor ~~wholesaler~~, limited prescription drug veterinary
 1881 wholesale distributor ~~wholesaler~~, or retail pharmacy drug
 1882 wholesale distributor ~~wholesaler~~ may not be issued to the

1883 address of a health care entity or to a pharmacy licensed under
 1884 chapter 465, except as provided in this paragraph. The
 1885 department may issue a prescription drug manufacturer permit to
 1886 an applicant at the same address as a licensed nuclear pharmacy,
 1887 which is a health care entity, for the purpose of manufacturing
 1888 prescription drugs used in positron emission tomography or other
 1889 radiopharmaceuticals, as listed in a rule adopted by the
 1890 department pursuant to this paragraph. The purpose of this
 1891 exemption is to assure availability of state-of-the-art
 1892 pharmaceuticals that would pose a significant danger to the
 1893 public health if manufactured at a separate establishment
 1894 address from the nuclear pharmacy from which the prescription
 1895 drugs are dispensed. The department may also issue a retail
 1896 pharmacy drug wholesale distributor ~~wholesaler~~ permit to the
 1897 address of a community pharmacy licensed under chapter 465 which
 1898 does not meet the definition of a closed pharmacy in s. 499.003.

1899 (e) A county or municipality may not issue an occupational
 1900 license for any licensing period beginning on or after October
 1901 1, 2003, for any establishment that requires a permit pursuant
 1902 to this part ~~ss. 499.001-499.081~~, unless the establishment
 1903 exhibits a current permit issued by the department for the
 1904 establishment. Upon presentation of the requisite permit issued
 1905 by the department, an occupational license may be issued by the
 1906 municipality or county in which application is made. The
 1907 department shall furnish to local agencies responsible for
 1908 issuing occupational licenses a current list of all
 1909 establishments licensed pursuant to this part ~~ss. 499.001-~~
 1910 ~~499.081~~.

1911 (2)~~(3)~~ Notwithstanding subsection (6) ~~(7)~~, a permitted
 1912 person in good standing may change the type of permit issued to
 1913 that person by completing a new application for the requested
 1914 permit, paying the amount of the difference in the permit fees
 1915 if the fee for the new permit is more than the fee for the
 1916 original permit, and meeting the applicable permitting
 1917 conditions for the new permit type. The new permit expires on
 1918 the expiration date of the original permit being changed;
 1919 however, a new permit for a prescription drug wholesale
 1920 distributor ~~wholesaler~~, an out-of-state prescription drug
 1921 wholesale distributor ~~wholesaler~~, or a retail pharmacy drug
 1922 wholesale distributor ~~wholesaler~~ shall expire on the expiration
 1923 date of the original permit or 1 year after the date of issuance
 1924 of the new permit, whichever is earlier. A refund may not be
 1925 issued if the fee for the new permit is less than the fee that
 1926 was paid for the original permit.

1927 (3)~~(4)~~ A written application for a permit or to renew a
 1928 permit must be filed with the department on forms furnished by
 1929 the department. The department shall establish, by rule, the
 1930 form and content of the application to obtain or renew a permit.
 1931 The applicant must submit to the department with the application
 1932 a statement that swears or affirms that the information is true
 1933 and correct.

1934 (4)~~(5)~~(a) Except for a permit for a prescription drug
 1935 wholesale distributor ~~wholesaler~~ or an out-of-state prescription
 1936 drug wholesale distributor ~~wholesaler~~, an application for a
 1937 permit must include:

- 1938 1. The name, full business address, and telephone number
 1939 of the applicant;
- 1940 2. All trade or business names used by the applicant;
- 1941 3. The address, telephone numbers, and the names of
 1942 contact persons for each facility used by the applicant for the
 1943 storage, handling, and distribution of prescription drugs;
- 1944 4. The type of ownership or operation, such as a
 1945 partnership, corporation, or sole proprietorship; and
- 1946 5. The names of the owner and the operator of the
 1947 establishment, including:
- 1948 a. If an individual, the name of the individual;
- 1949 b. If a partnership, the name of each partner and the name
 1950 of the partnership;
- 1951 c. If a corporation, the name and title of each corporate
 1952 officer and director, the corporate names, and the name of the
 1953 state of incorporation;
- 1954 d. If a sole proprietorship, the full name of the sole
 1955 proprietor and the name of the business entity;
- 1956 e. If a limited liability company, the name of each
 1957 member, the name of each manager, the name of the limited
 1958 liability company, and the name of the state in which the
 1959 limited liability company was organized; and
- 1960 f. Any other relevant information that the department
 1961 requires.
- 1962 (b) Upon approval of the application by the department and
 1963 payment of the required fee, the department shall issue a permit
 1964 to the applicant, if the applicant meets the requirements of

1965 this part ~~ss. 499.001-499.081~~ and rules adopted under this part
 1966 ~~those sections.~~

1967 (c) Any change in information required under paragraph (a)
 1968 must be submitted to the department before the change occurs.

1969 (d) The department shall consider, at a minimum, the
 1970 following factors in reviewing the qualifications of persons to
 1971 be permitted under this part ~~ss. 499.001-499.081~~:

1972 1. The applicant's having been found guilty, regardless of
 1973 adjudication, in a court of this state or other jurisdiction, of
 1974 a violation of a law that directly relates to a drug, device, or
 1975 cosmetic. A plea of nolo contendere constitutes a finding of
 1976 guilt for purposes of this subparagraph.

1977 2. The applicant's having been disciplined by a regulatory
 1978 agency in any state for any offense that would constitute a
 1979 violation of this part ~~ss. 499.001-499.081~~.

1980 3. Any felony conviction of the applicant under a federal,
 1981 state, or local law;

1982 4. The applicant's past experience in manufacturing or
 1983 distributing drugs, devices, or cosmetics;

1984 5. The furnishing by the applicant of false or fraudulent
 1985 material in any application made in connection with
 1986 manufacturing or distributing drugs, devices, or cosmetics;

1987 6. Suspension or revocation by a federal, state, or local
 1988 government of any permit currently or previously held by the
 1989 applicant for the manufacture or distribution of any drugs,
 1990 devices, or cosmetics;

1991 7. Compliance with permitting requirements under any
 1992 previously granted permits;

1993 8. Compliance with requirements to maintain or make
 1994 available to the state permitting authority or to federal,
 1995 state, or local law enforcement officials those records required
 1996 under this section; and

1997 9. Any other factors or qualifications the department
 1998 considers relevant to and consistent with the public health and
 1999 safety.

2000 ~~(5)-(6)~~ Except for a permit ~~permits~~ for a prescription drug
 2001 wholesale distributor ~~wholesalers~~ or an out-of-state
 2002 prescription drug wholesale distributor ~~wholesalers~~:

2003 (a) The department shall adopt rules for the biennial
 2004 renewal of permits.

2005 (b) The department shall renew a permit upon receipt of
 2006 the renewal application and renewal fee if the applicant meets
 2007 the requirements established under this part ~~ss. 499.001-499.081~~
 2008 and the rules adopted under this part ~~those sections~~.

2009 (c) A permit, unless sooner suspended or revoked,
 2010 automatically expires 2 years after the last day of the
 2011 anniversary month in which the permit was originally issued. A
 2012 permit issued under this part ~~ss. 499.001-499.081~~ may be renewed
 2013 by making application for renewal on forms furnished by the
 2014 department and paying the appropriate fees. If a renewal
 2015 application and fee are submitted and postmarked after the
 2016 expiration date of the permit, the permit may be renewed only
 2017 upon payment of a late renewal delinquent fee of \$100, plus the
 2018 required renewal fee, not later than 60 days after the
 2019 expiration date.

2020 (d) Failure to renew a permit in accordance with this
 2021 section precludes any future renewal of that permit. If a permit
 2022 issued pursuant to this part ~~section~~ has expired and cannot be
 2023 renewed, before an establishment may engage in activities that
 2024 require a permit under this part ~~ss. 499.001-499.081~~, the
 2025 establishment must submit an application for a new permit, pay
 2026 the applicable application fee, the initial permit fee, and all
 2027 applicable penalties, and be issued a new permit by the
 2028 department.

2029 ~~(6)(7)~~ A permit issued by the department is
 2030 nontransferable. Each permit is valid only for the person or
 2031 governmental unit to which it is issued and is not subject to
 2032 sale, assignment, or other transfer, voluntarily or
 2033 involuntarily; nor is a permit valid for any establishment other
 2034 than the establishment for which it was originally issued.

2035 (a) A person permitted under this part ~~ss. 499.001-499.081~~
 2036 must notify the department before making a change of address.
 2037 The department shall set a change of location fee not to exceed
 2038 \$100.

2039 (b)1. An application for a new permit is required when a
 2040 majority of the ownership or controlling interest of a permitted
 2041 establishment is transferred or assigned or when a lessee agrees
 2042 to undertake or provide services to the extent that legal
 2043 liability for operation of the establishment will rest with the
 2044 lessee. The application for the new permit must be made before
 2045 the date of the sale, transfer, assignment, or lease.

2046 2. A permittee that is authorized to distribute
 2047 prescription legend ~~legend~~ drugs may transfer such drugs to the new

2048 owner or lessee under subparagraph 1. only after the new owner
 2049 or lessee has been approved for a permit to distribute
 2050 prescription legend drugs.

2051 (c) If an establishment permitted under this part ~~ss.~~
 2052 ~~499.001-499.081~~ closes, the owner must notify the department in
 2053 writing before the effective date of closure and must:

- 2054 1. Return the permit to the department;
- 2055 2. If the permittee is authorized to distribute
 2056 prescription legend drugs, indicate the disposition of such
 2057 drugs, including the name, address, and inventory, and provide
 2058 the name and address of a person to contact regarding access to
 2059 records that are required to be maintained under this part ~~ss.~~
 2060 ~~499.001-499.081~~. Transfer of ownership of prescription legend
 2061 drugs may be made only to persons authorized to possess
 2062 prescription legend drugs under this part ~~ss. 499.001-499.081~~.

2063
 2064 The department may revoke the permit of any person that fails to
 2065 comply with the requirements of this subsection.

2066 ~~(7)-(8)~~ A permit must be posted in a conspicuous place on
 2067 the licensed premises.

2068 ~~(8)-(3)~~ An application for a permit or to renew a permit
 2069 for a prescription drug wholesale distributor ~~wholesaler~~ or an
 2070 out-of-state prescription drug wholesale distributor ~~wholesaler~~
 2071 submitted to the department must include:

2072 (a) The name, full business address, and telephone number
 2073 of the applicant.

2074 (b) All trade or business names used by the applicant.

2075 (c) The address, telephone numbers, and the names of
 2076 contact persons for each facility used by the applicant for the
 2077 storage, handling, and distribution of prescription drugs.

2078 (d) The type of ownership or operation, such as a
 2079 partnership, corporation, or sole proprietorship.

2080 (e) The names of the owner and the operator of the
 2081 establishment, including:

2082 1. If an individual, the name of the individual.

2083 2. If a partnership, the name of each partner and the name
 2084 of the partnership.

2085 3. If a corporation:

2086 a. The name, address, and title of each corporate officer
 2087 and director.

2088 b. The name and address of the corporation, resident agent
 2089 of the corporation, the resident agent's address, and the
 2090 corporation's state of incorporation.

2091 c. The name and address of each shareholder of the
 2092 corporation that owns 5 percent or more of the outstanding stock
 2093 of the corporation.

2094 4. If a sole proprietorship, the full name of the sole
 2095 proprietor and the name of the business entity.

2096 5. If a limited liability company:

2097 a. The name and address of each member.

2098 b. The name and address of each manager.

2099 c. The name and address of the limited liability company,
 2100 the resident agent of the limited liability company, and the
 2101 name of the state in which the limited liability company was
 2102 organized.

2103 (f) If applicable, the name and address of each member of
 2104 the affiliated group of which the applicant is a member.

2105 (g)1. For an application for a new permit, the estimated
 2106 annual dollar volume of prescription drug sales of the
 2107 applicant, the estimated annual percentage of the applicant's
 2108 total company sales that are prescription drugs, the applicant's
 2109 estimated annual total dollar volume of purchases of
 2110 prescription drugs, and the applicant's estimated annual total
 2111 dollar volume of prescription drug purchases directly from
 2112 manufacturers.

2113 2. For an application to renew a permit, the total dollar
 2114 volume of prescription drug sales in the previous year, the
 2115 total dollar volume of prescription drug sales made in the
 2116 previous 6 months, the percentage of total company sales that
 2117 were prescription drugs in the previous year, the total dollar
 2118 volume of purchases of prescription drugs in the previous year,
 2119 and the total dollar volume of prescription drug purchases
 2120 directly from manufacturers in the previous year.

2121
 2122 Such portions of the information required pursuant to this
 2123 paragraph which are a trade secret, as defined in s. 812.081,
 2124 shall be maintained by the department as trade secret
 2125 information is required to be maintained under s. 499.051.

2126 (h) The tax year of the applicant.

2127 (i) A copy of the deed for the property on which
 2128 applicant's establishment is located, if the establishment is
 2129 owned by the applicant, or a copy of the applicant's lease for
 2130 the property on which applicant's establishment is located that

2131 has an original term of not less than 1 calendar year, if the
 2132 establishment is not owned by the applicant.

2133 (j) A list of all licenses and permits issued to the
 2134 applicant by any other state which authorize the applicant to
 2135 purchase or possess prescription drugs.

2136 (k) The name of the manager of the establishment that is
 2137 applying for the permit or to renew the permit, the next four
 2138 highest ranking employees responsible for prescription drug
 2139 wholesale operations for the establishment, and the name of all
 2140 affiliated parties for the establishment, together with the
 2141 personal information statement and fingerprints required
 2142 pursuant to subsection (9) ~~(4)~~ for each of such persons.

2143 (l) The name of each of the applicant's designated
 2144 representatives as required by subsection (16) ~~(11)~~, together
 2145 with the personal information statement and fingerprints
 2146 required pursuant to subsection (9) ~~(4)~~ for each such person.

2147 (m) For an applicant that is a secondary wholesale
 2148 distributor ~~wholesaler~~, each of the following:

2149 1. A personal background information statement containing
 2150 the background information and fingerprints required pursuant to
 2151 subsection (9) ~~(4)~~ for each person named in the applicant's
 2152 response to paragraphs (k) and (l) and for each affiliated party
 2153 of the applicant.

2154 2. If any of the five largest shareholders of the
 2155 corporation seeking the permit is a corporation, the name,
 2156 address, and title of each corporate officer and director of
 2157 each such corporation; the name and address of such corporation;
 2158 the name of such corporation's resident agent, such

2159 corporation's resident agent's address, and such corporation's
 2160 state of its incorporation; and the name and address of each
 2161 shareholder of such corporation that owns 5 percent or more of
 2162 the stock of such corporation.

2163 3. The name and address of all financial institutions in
 2164 which the applicant has an account which is used to pay for the
 2165 operation of the establishment or to pay for drugs purchased for
 2166 the establishment, together with the names of all persons that
 2167 are authorized signatories on such accounts. The portions of the
 2168 information required pursuant to this subparagraph which are a
 2169 trade secret, as defined in s. 812.081, shall be maintained by
 2170 the department as trade secret information is required to be
 2171 maintained under s. 499.051.

2172 4. The sources of all funds and the amounts of such funds
 2173 used to purchase or finance purchases of prescription drugs or
 2174 to finance the premises on which the establishment is to be
 2175 located.

2176 5. If any of the funds identified in subparagraph 4. were
 2177 borrowed, copies of all promissory notes or loans used to obtain
 2178 such funds.

2179 (n) Any other relevant information that the department
 2180 requires, including, but not limited to, any information related
 2181 to whether the applicant satisfies the definition of a primary
 2182 wholesale distributor ~~wholesaler~~ or a secondary wholesale
 2183 distributor ~~wholesaler~~.

2184 (9) ~~(4)~~ (a) Each person required by subsection (8) ~~(3)~~ to
 2185 provide a personal information statement and fingerprints shall

2186 provide the following information to the department on forms
2187 prescribed by the department:

2188 1. The person's places of residence for the past 7 years.

2189 2. The person's date and place of birth.

2190 3. The person's occupations, positions of employment, and
2191 offices held during the past 7 years.

2192 4. The principal business and address of any business,
2193 corporation, or other organization in which each such office of
2194 the person was held or in which each such occupation or position
2195 of employment was carried on.

2196 5. Whether the person has been, during the past 7 years,
2197 the subject of any proceeding for the revocation of any license
2198 and, if so, the nature of the proceeding and the disposition of
2199 the proceeding.

2200 6. Whether, during the past 7 years, the person has been
2201 enjoined, either temporarily or permanently, by a court of
2202 competent jurisdiction from violating any federal or state law
2203 regulating the possession, control, or distribution of
2204 prescription drugs, together with details concerning any such
2205 event.

2206 7. A description of any involvement by the person with any
2207 business, including any investments, other than the ownership of
2208 stock in a publicly traded company or mutual fund, during the
2209 past 7 years, which manufactured, administered, prescribed,
2210 distributed, or stored pharmaceutical products and any lawsuits
2211 in which such businesses were named as a party.

2212 8. A description of any felony criminal offense of which
2213 the person, as an adult, was found guilty, regardless of whether

2214 adjudication of guilt was withheld or whether the person pled
 2215 guilty or nolo contendere. A criminal offense committed in
 2216 another jurisdiction which would have been a felony in this
 2217 state must be reported. If the person indicates that a criminal
 2218 conviction is under appeal and submits a copy of the notice of
 2219 appeal of that criminal offense, the applicant must, within 15
 2220 days after the disposition of the appeal, submit to the
 2221 department a copy of the final written order of disposition.

2222 9. A photograph of the person taken in the previous 30
 2223 days.

2224 10. A set of fingerprints for the person on a form and
 2225 under procedures specified by the department, together with
 2226 payment of an amount equal to the costs incurred by the
 2227 department for the criminal record check of the person.

2228 11. The name, address, occupation, and date and place of
 2229 birth for each member of the person's immediate family who is 18
 2230 years of age or older. As used in this subparagraph, the term
 2231 "member of the person's immediate family" includes the person's
 2232 spouse, children, parents, siblings, the spouses of the person's
 2233 children, and the spouses of the person's siblings.

2234 12. Any other relevant information that the department
 2235 requires.

2236 (b) The information required pursuant to paragraph (a)
 2237 shall be provided under oath.

2238 (c) The department shall submit the fingerprints provided
 2239 by a person for initial licensure to the Department of Law
 2240 Enforcement for a statewide criminal record check and for
 2241 forwarding to the Federal Bureau of Investigation for a national

2242 criminal record check of the person. The department shall submit
 2243 the fingerprints provided by a person as a part of a renewal
 2244 application to the Department of Law Enforcement for a statewide
 2245 criminal record check, and for forwarding to the Federal Bureau
 2246 of Investigation for a national criminal record check, for the
 2247 initial renewal of a permit after January 1, 2004; for any
 2248 subsequent renewal of a permit, the department shall submit the
 2249 required information for a statewide and national criminal
 2250 record check of the person. Any person who as a part of an
 2251 initial permit application or initial permit renewal after
 2252 January 1, 2004, submits to the department a set of fingerprints
 2253 required for the criminal record check required in this
 2254 paragraph shall not be required to provide a subsequent set of
 2255 fingerprints for a criminal record check to the department, if
 2256 the person has undergone a criminal record check as a condition
 2257 of the issuance of an initial permit or the initial renewal of a
 2258 permit of an applicant after January 1, 2004.

2259 (10)~~(5)~~ The department may deny an application for a
 2260 permit or refuse to renew a permit for a prescription drug
 2261 wholesale distributor ~~wholesaler~~ or an out-of-state prescription
 2262 drug wholesale distributor ~~wholesaler~~ if:

2263 (a) The applicant has not met the requirements for the
 2264 permit.

2265 (b) The management, officers, or directors of the
 2266 applicant or any affiliated party are found by the department to
 2267 be incompetent or untrustworthy.

2268 (c) The applicant is so lacking in experience in managing
2269 a wholesale distributor as to make the issuance of the proposed
2270 permit hazardous to the public health.

2271 (d) The applicant is so lacking in experience in managing
2272 a wholesale distributor as to jeopardize the reasonable promise
2273 of successful operation of the wholesale distributor.

2274 (e) The applicant is lacking in experience in the
2275 distribution of prescription drugs.

2276 (f) The applicant's past experience in manufacturing or
2277 distributing prescription drugs indicates that the applicant
2278 poses a public health risk.

2279 (g) The applicant is affiliated directly or indirectly
2280 through ownership, control, or other business relations, with
2281 any person or persons whose business operations are or have been
2282 detrimental to the public health.

2283 (h) The applicant, or any affiliated party, has been found
2284 guilty of or has pleaded guilty or nolo contendere to any felony
2285 or crime punishable by imprisonment for 1 year or more under the
2286 laws of the United States, any state, or any other country,
2287 regardless of whether adjudication of guilt was withheld.

2288 (i) The applicant or any affiliated party has been charged
2289 with a felony in a state or federal court and the disposition of
2290 that charge is pending during the application review or renewal
2291 review period.

2292 (j) The applicant has furnished false or fraudulent
2293 information or material in any application made in this state or
2294 any other state in connection with obtaining a permit or license
2295 to manufacture or distribute drugs, devices, or cosmetics.

2296 (k) That a federal, state, or local government permit
 2297 currently or previously held by the applicant, or any affiliated
 2298 party, for the manufacture or distribution of any drugs,
 2299 devices, or cosmetics has been disciplined, suspended, or
 2300 revoked and has not been reinstated.

2301 (l) The applicant does not possess the financial or
 2302 physical resources to operate in compliance with the permit
 2303 being sought, this chapter, and the rules adopted under this
 2304 chapter.

2305 (m) The applicant or any affiliated party receives,
 2306 directly or indirectly, financial support and assistance from a
 2307 person who was an affiliated party of a permittee whose permit
 2308 was subject to discipline or was suspended or revoked, other
 2309 than through the ownership of stock in a publicly traded company
 2310 or a mutual fund.

2311 (n) The applicant or any affiliated party receives,
 2312 directly or indirectly, financial support and assistance from a
 2313 person who has been found guilty of any violation of this part
 2314 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,
 2315 any rules adopted under any of this part ~~those sections~~ or those
 2316 chapters, any federal or state drug law, or any felony where the
 2317 underlying facts related to drugs, regardless of whether the
 2318 person has been pardoned, had her or his civil rights restored,
 2319 or had adjudication withheld, other than through the ownership
 2320 of stock in a publicly traded company or a mutual fund.

2321 (o) The applicant for renewal of a permit under s.
 2322 499.01(2)(d) ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph~~
 2323 ~~(2)(e)~~ has not actively engaged in the wholesale distribution

2324 of prescription drugs, as demonstrated by the regular and
 2325 systematic distribution of prescription drugs throughout the
 2326 year as evidenced by not fewer than 12 wholesale distributions
 2327 in the previous year and not fewer than three wholesale
 2328 distributions in the previous 6 months.

2329 (p) Information obtained in response to s. 499.01(2)(d)
 2330 ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~
 2331 demonstrates it would not be in the best interest of the public
 2332 health, safety, and welfare to issue a permit.

2333 (q) The applicant does not possess the financial standing
 2334 and business experience for the successful operation of the
 2335 applicant.

2336 (r) The applicant or any affiliated party has failed to
 2337 comply with the requirements for manufacturing or distributing
 2338 prescription drugs under this part ~~ss. 499.001-499.081~~, similar
 2339 federal laws, similar laws in other states, or the rules adopted
 2340 under such laws.

2341 ~~(11)(6)~~ Upon approval of the application by the department
 2342 and payment of the required fee, the department shall issue or
 2343 renew a prescription drug wholesale distributor ~~wholesaler~~ or an
 2344 out-of-state prescription drug wholesale distributor ~~wholesaler~~
 2345 permit to the applicant.

2346 ~~(12)(7)~~ For a permit ~~permits~~ for a prescription drug
 2347 wholesale distributor ~~wholesalers~~ or an out-of-state
 2348 prescription drug wholesale distributor ~~wholesalers~~:

2349 (a) The department shall adopt rules for the annual
 2350 renewal of permits. At least 90 days before the expiration of a
 2351 permit, the department shall forward a permit renewal

2352 notification and renewal application to the prescription drug
 2353 wholesale distributor ~~wholesaler~~ or out-of-state prescription
 2354 drug wholesale distributor ~~wholesaler~~ at the mailing address of
 2355 the permitted establishment on file with the department. The
 2356 permit renewal notification must state conspicuously the date on
 2357 which the permit for the establishment will expire and that the
 2358 establishment may not operate unless the permit for the
 2359 establishment is renewed timely.

2360 (b) A permit, unless sooner suspended or revoked,
 2361 automatically expires 1 year after the last day of the
 2362 anniversary month in which the permit was originally issued. A
 2363 permit may be renewed by making application for renewal on forms
 2364 furnished by the department and paying the appropriate fees. If
 2365 a renewal application and fee are submitted and postmarked after
 2366 45 days prior to the expiration date of the permit, the permit
 2367 may be renewed only upon payment of a late renewal fee of \$100,
 2368 plus the required renewal fee. A permittee that has submitted a
 2369 renewal application in accordance with this paragraph may
 2370 continue to operate under its permit, unless the permit is
 2371 suspended or revoked, until final disposition of the renewal
 2372 application.

2373 (c) Failure to renew a permit in accordance with this
 2374 section precludes any future renewal of that permit. If a permit
 2375 issued pursuant to this section has expired and cannot be
 2376 renewed, before an establishment may engage in activities that
 2377 require a permit under this part ~~ss. 499.001-499.081~~, the
 2378 establishment must submit an application for a new permit; pay
 2379 the applicable application fee, initial permit fee, and all

2380 applicable penalties; and be issued a new permit by the
 2381 department.

2382 (13)~~(8)~~ A person that engages in wholesale distribution of
 2383 prescription drugs in this state must have a wholesale
 2384 distributor's permit issued by the department, except as noted
 2385 in this section. Each establishment must be separately permitted
 2386 except as noted in this subsection.

2387 (a) A separate establishment permit is not required when a
 2388 permitted prescription drug wholesale distributor ~~wholesaler~~
 2389 consigns a prescription drug to a pharmacy that is permitted
 2390 under chapter 465 and located in this state, provided that:

2391 1. The consignor wholesale distributor ~~wholesaler~~ notifies
 2392 the department in writing of the contract to consign
 2393 prescription drugs to a pharmacy along with the identity and
 2394 location of each consignee pharmacy;

2395 2. The pharmacy maintains its permit under chapter 465;

2396 3. The consignor wholesale distributor ~~wholesaler~~, which
 2397 has no legal authority to dispense prescription drugs, complies
 2398 with all wholesale distribution requirements of ss. ~~§~~ 499.0121
 2399 and 499.01212 with respect to the consigned drugs and maintains
 2400 records documenting the transfer of title or other completion of
 2401 the wholesale distribution of the consigned prescription drugs;

2402 4. The distribution of the prescription drug is otherwise
 2403 lawful under this chapter and other applicable law;

2404 5. Open packages containing prescription drugs within a
 2405 pharmacy are the responsibility of the pharmacy, regardless of
 2406 how the drugs are titled; and

2407 6. The pharmacy dispenses the consigned prescription drug
 2408 in accordance with the limitations of its permit under chapter
 2409 465 or returns the consigned prescription drug to the consignor
 2410 wholesale distributor ~~wholesaler~~. In addition, a person who
 2411 holds title to prescription drugs may transfer the drugs to a
 2412 person permitted or licensed to handle the reverse distribution
 2413 or destruction of drugs. Any other distribution by and means of
 2414 the consigned prescription drug by any person, not limited to
 2415 the consignor wholesale distributor ~~wholesaler~~ or consignee
 2416 pharmacy, to any other person is prohibited.

2417 (b) A wholesale distributor's permit is not required for
 2418 the one-time transfer of title of a pharmacy's lawfully acquired
 2419 prescription drug inventory by a pharmacy with a valid permit
 2420 issued under chapter 465 to a consignor prescription drug
 2421 wholesale distributor ~~wholesaler~~, permitted under this chapter,
 2422 in accordance with a written consignment agreement between the
 2423 pharmacy and that wholesale distributor ~~wholesaler~~ if+ the
 2424 permitted pharmacy and the permitted prescription drug wholesale
 2425 distributor ~~wholesaler~~ comply with all of the provisions of
 2426 paragraph (a) and the prescription drugs continue to be within
 2427 the permitted pharmacy's inventory for dispensing in accordance
 2428 with the limitations of the pharmacy permit under chapter 465. A
 2429 consignor drug wholesale distributor ~~wholesaler~~ may not use the
 2430 pharmacy as a wholesale distributor through which it distributes
 2431 the prescription ~~legend~~ drugs to other pharmacies. Nothing in
 2432 this section is intended to prevent a wholesale ~~drug~~ distributor
 2433 from obtaining this inventory in the event of nonpayment by the
 2434 pharmacy.

2435 (c) A separate establishment permit is not required when a
 2436 permitted prescription drug wholesale distributor:

2437 1. Operates temporary transit storage facilities for the
 2438 sole purpose of storage, for a period not to exceed 12 hours, of
 2439 a delivery of prescription drugs when the wholesale distributor
 2440 was temporarily unable to complete the delivery to the
 2441 recipient; or

2442 2. Uses a post office box or other address for billing,
 2443 payment, or other administrative purposes.

2444 (d)-(e) The department shall require information from each
 2445 wholesale distributor as part of the permit and renewal of such
 2446 permit, as required under ~~s. 499.01~~ or this section.

2447 (14)-(9) Personnel employed in wholesale distribution must
 2448 have appropriate education and experience to enable them to
 2449 perform their duties in compliance with state permitting
 2450 requirements.

2451 (15)-(10) The name of a permittee or establishment on a
 2452 prescription drug wholesale distributor ~~wholesaler~~ permit or an
 2453 out-of-state prescription drug wholesale distributor ~~wholesaler~~
 2454 permit may not include any indicia of attainment of any
 2455 educational degree, any indicia that the permittee or
 2456 establishment possesses a professional license, or any name or
 2457 abbreviation that the department determines is likely to cause
 2458 confusion or mistake or that the department determines is
 2459 deceptive, including that of any other entity authorized to
 2460 purchase prescription drugs.

2461 (16)-(11)(a) Each establishment that is issued an initial
 2462 or renewal permit as a prescription drug wholesale distributor

2463 ~~wholesaler~~ or an out-of-state prescription drug wholesale
 2464 distributor ~~wholesaler~~ must designate in writing to the
 2465 department at least one natural person to serve as the
 2466 designated representative of the wholesale distributor
 2467 ~~wholesaler~~. Such person must have an active certification as a
 2468 designated representative from the department.

2469 (b) To be certified as a designated representative, a
 2470 natural person must:

- 2471 1. Submit an application on a form furnished by the
 2472 department and pay the appropriate fees;
- 2473 2. Be at least 18 years of age;
- 2474 3. Have not less than 2 years of verifiable full-time work
 2475 experience in a pharmacy licensed in this state or another
 2476 state, where the person's responsibilities included, but were
 2477 not limited to, recordkeeping for prescription drugs, or have
 2478 not less than 2 years of verifiable full-time managerial
 2479 experience with a prescription drug wholesale distributor
 2480 ~~wholesaler~~ licensed in this state or in another state;
- 2481 4. Receive a passing score of at least 75 percent on an
 2482 examination given by the department regarding federal laws
 2483 governing distribution of prescription drugs and this part ~~ss.~~
 2484 ~~499.001-499.081~~ and the rules adopted by the department
 2485 governing the wholesale distribution of prescription drugs. This
 2486 requirement shall be effective 1 year after the results of the
 2487 initial examination are mailed to the persons that took the
 2488 examination. The department shall offer such examinations at
 2489 least four times each calendar year; and

2490 5. Provide the department with a personal information
 2491 statement and fingerprints pursuant to subsection (9)~~(4)~~.

2492 (c) The department may deny an application for
 2493 certification as a designated representative or may suspend or
 2494 revoke a certification of a designated representative pursuant
 2495 to s. 499.067.

2496 (d) A designated representative:

2497 1. Must be actively involved in and aware of the actual
 2498 daily operation of the wholesale distributor.

2499 2. Must be employed full time in a managerial position by
 2500 the wholesale distributor.

2501 3. Must be physically present at the establishment during
 2502 normal business hours, except for time periods when absent due
 2503 to illness, family illness or death, scheduled vacation, or
 2504 other authorized absence.

2505 4. May serve as a designated representative for only one
 2506 wholesale distributor at any one time.

2507 (e) A wholesale distributor must notify the department
 2508 when a designated representative leaves the employ of the
 2509 wholesale distributor. Such notice must be provided to the
 2510 department within 10 business days after the last day of
 2511 designated representative's employment with the wholesale
 2512 distributor.

2513 (f) A wholesale distributor may not operate under a
 2514 prescription drug wholesale distributor ~~wholesaler~~ permit or an
 2515 out-of-state prescription drug wholesale distributor ~~wholesaler~~
 2516 permit for more than 10 business days after the designated
 2517 representative leaves the employ of the wholesale distributor,

2518 unless the wholesale distributor employs another designated
 2519 representative and notifies the department within 10 business
 2520 days of the identity of the new designated representative.

2521 Section 12. Section 499.01201, Florida Statutes, is
 2522 amended to read:

2523 499.01201 Agency for Health Care Administration review and
 2524 use of statute and rule violation or compliance
 2525 data.--Notwithstanding any other provisions of law to the
 2526 contrary, the Agency for Health Care Administration may not:

2527 (1) Review or use any violation or alleged violation of s.
 2528 499.0121(6) or s. 499.01212, or any rules adopted under those
 2529 sections ~~that section~~, as a ground for denying or withholding
 2530 any payment of a Medicaid reimbursement to a pharmacy licensed
 2531 under chapter 465; or

2532 (2) Review or use compliance with s. 499.0121(6) or s.
 2533 499.01212, or any rules adopted under those sections ~~that~~
 2534 ~~section~~, as the subject of any audit of Medicaid-related records
 2535 held by a pharmacy licensed under chapter 465.

2536 Section 13. Section 499.0121, Florida Statutes, is
 2537 amended, and subsection (4) of section 499.013, Florida
 2538 Statutes, is redesignated as paragraph (d) of subsection (6) of
 2539 that section and amended, to read:

2540 499.0121 Storage and handling of prescription drugs;
 2541 recordkeeping.--The department shall adopt rules to implement
 2542 this section as necessary to protect the public health, safety,
 2543 and welfare. Such rules shall include, but not be limited to,
 2544 requirements for the storage and handling of prescription drugs

2545 and for the establishment and maintenance of prescription drug
 2546 distribution records.

2547 (1) ESTABLISHMENTS.--An establishment at which
 2548 prescription drugs are stored, warehoused, handled, held,
 2549 offered, marketed, or displayed must:

2550 (a) Be of suitable size and construction to facilitate
 2551 cleaning, maintenance, and proper operations;

2552 (b) Have storage areas designed to provide adequate
 2553 lighting, ventilation, temperature, sanitation, humidity, space,
 2554 equipment, and security conditions;

2555 (c) Have a quarantine area for storage of prescription
 2556 drugs that are outdated, damaged, deteriorated, misbranded, or
 2557 adulterated, or that are in immediate or sealed, secondary
 2558 containers that have been opened;

2559 (d) Be maintained in a clean and orderly condition; and

2560 (e) Be free from infestation by insects, rodents, birds,
 2561 or vermin of any kind.

2562 (2) SECURITY.--

2563 (a) An establishment that is used for wholesale drug
 2564 distribution must be secure from unauthorized entry.

2565 1. Access from outside the premises must be kept to a
 2566 minimum and be well-controlled.

2567 2. The outside perimeter of the premises must be well-
 2568 lighted.

2569 3. Entry into areas where prescription drugs are held must
 2570 be limited to authorized personnel.

2571 (b) An establishment that is used for wholesale drug
 2572 distribution must be equipped with:

2573 1. An alarm system to detect entry after hours; however,
 2574 the department may exempt by rule establishments that only hold
 2575 a permit as prescription drug wholesale distributor-brokers
 2576 ~~wholesaler brokers~~ and establishments that only handle medical
 2577 oxygen; and

2578 2. A security system that will provide suitable protection
 2579 against theft and diversion. When appropriate, the security
 2580 system must provide protection against theft or diversion that
 2581 is facilitated or hidden by tampering with computers or
 2582 electronic records.

2583 (c) Any vehicle that contains prescription drugs must be
 2584 secure from unauthorized access to the prescription drugs in the
 2585 vehicle.

2586 (3) STORAGE.--All prescription drugs shall be stored at
 2587 appropriate temperatures and under appropriate conditions in
 2588 accordance with requirements, if any, in the labeling of such
 2589 drugs, or with requirements in the official compendium.

2590 (a) If no storage requirements are established for a
 2591 prescription drug, the drug may be held at "controlled" room
 2592 temperature, as defined in the official compendium, to help
 2593 ensure that its identity, strength, quality, and purity are not
 2594 adversely affected.

2595 (b) Appropriate manual, electromechanical, or electronic
 2596 temperature and humidity recording equipment, devices, or logs
 2597 must be used to document proper storage of prescription drugs.

2598 (c) The recordkeeping requirements in subsection (6) must
 2599 be followed for all stored prescription drugs.

2600 (4) EXAMINATION OF MATERIALS AND RECORDS.--

2601 (a) Upon receipt, each outside shipping container must be
 2602 visually examined for identity and to prevent the acceptance of
 2603 contaminated prescription drugs that are otherwise unfit for
 2604 distribution. This examination must be adequate to reveal
 2605 container damage that would suggest possible contamination or
 2606 other damage to the contents.

2607 (b) Each outgoing shipment must be carefully inspected for
 2608 identity of the prescription drug products and to ensure that
 2609 there is no delivery of prescription drugs that have expired or
 2610 been damaged in storage or held under improper conditions.

2611 (c) The recordkeeping requirements in subsection (6) must
 2612 be followed for all incoming and outgoing prescription drugs.

2613 (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must
 2614 review records required under this section for the acquisition
 2615 of prescription drugs for accuracy and completeness, considering
 2616 the total facts and circumstances surrounding the transactions
 2617 and the wholesale distributors involved. This includes
 2618 authenticating each transaction listed on a pedigree paper, as
 2619 defined in s. 499.003(37) ~~s. 499.001(31)~~.

2620 (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

2621 (a)1. Prescription drugs that are outdated, damaged,
 2622 deteriorated, misbranded, or adulterated must be quarantined and
 2623 physically separated from other prescription drugs until they
 2624 are destroyed or returned to their supplier. A quarantine
 2625 section must be separate and apart from other sections where
 2626 prescription drugs are stored so that prescription drugs in this
 2627 section are not confused with usable prescription drugs.

2628 2. Prescription drugs must be examined at least every 12
 2629 months, and drugs for which the expiration date has passed must
 2630 be removed and quarantined.

2631 (b) Any prescription drugs of which the immediate or
 2632 sealed outer containers or sealed secondary containers have been
 2633 opened or used must be identified as such and must be
 2634 quarantined and physically separated from other prescription
 2635 drugs until they are either destroyed or returned to the
 2636 supplier.

2637 (c) If the conditions under which a prescription drug has
 2638 been returned cast doubt on the drug's safety, identity,
 2639 strength, quality, or purity, the drug must be destroyed or
 2640 returned to the supplier, unless examination, testing, or other
 2641 investigation proves that the drug meets appropriate standards
 2642 of safety, identity, strength, quality, and purity. In
 2643 determining whether the conditions under which a drug has been
 2644 returned cast doubt on the drug's safety, identity, strength,
 2645 quality, or purity, the wholesale ~~drug~~ distributor must
 2646 consider, among other things, the conditions under which the
 2647 drug has been held, stored, or shipped before or during its
 2648 return and the conditions of the drug and its container, carton,
 2649 or labeling, as a result of storage or shipping.

2650 (d) The recordkeeping requirements in subsection (6) must
 2651 be followed for all outdated, damaged, deteriorated, misbranded,
 2652 or adulterated prescription drugs.

2653 (6) RECORDKEEPING.--The department shall adopt rules that
 2654 require keeping such records of prescription drugs as are
 2655 necessary for the protection of the public health.

2656 (a) Wholesale ~~drug~~ distributors must establish and
 2657 maintain inventories and records of all transactions regarding
 2658 the receipt and distribution or other disposition of
 2659 prescription drugs. These records must provide a complete audit
 2660 trail from receipt to sale or other disposition, be readily
 2661 retrievable for inspection, and include, at a minimum, the
 2662 following information:

2663 1. The source of the drugs, including the name and
 2664 principal address of the seller or transferor, and the address
 2665 of the location from which the drugs were shipped;

2666 2. The name, principal address, and state license permit
 2667 or registration number of the person authorized to purchase
 2668 prescription drugs;

2669 3. The name, strength, dosage form, and quantity of the
 2670 drugs received and distributed or disposed of;

2671 4. The dates of receipt and distribution or other
 2672 disposition of the drugs; and

2673 5. Any financial documentation supporting the transaction.

2674 (b) Inventories and records must be made available for
 2675 inspection and photocopying by authorized federal, state, or
 2676 local officials for a period of 2 years following disposition of
 2677 the drugs or 3 years after the creation of the records,
 2678 whichever period is longer.

2679 (c) Records described in this section that are kept at the
 2680 inspection site or that can be immediately retrieved by computer
 2681 or other electronic means must be readily available for
 2682 authorized inspection during the retention period. Records that
 2683 are kept at a central location outside of this state and that

2684 are not electronically retrievable must be made available for
 2685 inspection within 2 working days after a request by an
 2686 authorized official of a federal, state, or local law
 2687 enforcement agency. Records that are maintained at a central
 2688 location within this state must be maintained at an
 2689 establishment that is permitted pursuant to this part ~~ss.~~
 2690 ~~499.001-499.081~~ and must be readily available.

2691 (d)(4) Each manufacturer or repackager of medical devices,
 2692 over-the-counter drugs, or cosmetics must maintain records that
 2693 include the name and principal address of the seller or
 2694 transferor of the product, the address of the location from
 2695 which the product was shipped, the date of the transaction, the
 2696 name and quantity of the product involved, and the name and
 2697 principal address of the person who purchased the product.

2698 (e) A wholesale distributor must maintain pedigree papers
 2699 separate and distinct from other records required under this
 2700 chapter.

2701 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~
 2702 ~~the wholesale distribution of a prescription drug and who is not~~
 2703 ~~the manufacturer of that drug must, before each wholesale~~
 2704 ~~distribution of such drug, provide to the person who receives~~
 2705 ~~the drug a pedigree paper as defined in s. 499.003(31).~~

2706 ~~2. A repackager must comply with this paragraph.~~

2707 ~~3. The pedigree paper requirements in this paragraph do~~
 2708 ~~not apply to compressed medical gases or veterinary legend~~
 2709 ~~drugs.~~

2710 ~~4. Each wholesale distributor of prescription drugs must~~
2711 ~~maintain separate and distinct from other required records all~~
2712 ~~statements that are required under subparagraph 1.~~

2713 ~~5. Subparagraph 1. is satisfied when a wholesale~~
2714 ~~distributor takes title to, but not possession of, a~~
2715 ~~prescription drug and the prescription drug's manufacturer ships~~
2716 ~~the prescription drug directly to a person authorized by law to~~
2717 ~~purchase prescription drugs for the purpose of administering or~~
2718 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~
2719 ~~affiliated group, as described in paragraph (f), with the~~
2720 ~~exception of a repackager.~~

2721 ~~a. The wholesale distributor must deliver to the recipient~~
2722 ~~of the prescription drug, within 14 days after the shipment~~
2723 ~~notification from the manufacturer, an invoice and the following~~
2724 ~~sworn statement: "This wholesale distributor purchased the~~
2725 ~~specific unit of the prescription drug listed on the invoice~~
2726 ~~directly from the manufacturer, and the specific unit of~~
2727 ~~prescription drug was shipped by the manufacturer directly to a~~
2728 ~~person authorized by law to administer or dispense the legend~~
2729 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~
2730 ~~an affiliated group, as described in s. 499.0121(6)(f), Florida~~
2731 ~~Statutes, with the exception of a repackager." The invoice must~~
2732 ~~contain a unique cross reference to the shipping document sent~~
2733 ~~by the manufacturer to the recipient of the prescription drug.~~

2734 ~~b. The manufacturer of the prescription drug shipped~~
2735 ~~directly to the recipient under this section must provide and~~
2736 ~~the recipient of the prescription drug must acquire, within 14~~

2737 ~~days after receipt of the prescription drug, a shipping document~~
2738 ~~from the manufacturer that contains, at a minimum:~~

2739 ~~(I) The name and address of the manufacturer, including~~
2740 ~~the point of origin of the shipment, and the names and addresses~~
2741 ~~of the wholesaler and the purchaser.~~

2742 ~~(II) The name of the prescription drug as it appears on~~
2743 ~~the label.~~

2744 ~~(III) The quantity, dosage form, and strength of the~~
2745 ~~prescription drug.~~

2746 ~~(IV) The date of the shipment from the manufacturer.~~

2747 ~~e. The wholesale distributor must also maintain and make~~
2748 ~~available to the department, upon request, the lot number of~~
2749 ~~such drug if not contained in the shipping document acquired by~~
2750 ~~the recipient.~~

2751 ~~6. Failure of the manufacturer to provide, the recipient~~
2752 ~~to acquire, or the wholesale distributor to deliver, the~~
2753 ~~documentation required under subparagraph 5. shall constitute~~
2754 ~~failure to acquire or deliver a pedigree paper under s.~~
2755 ~~499.0051. Forgery by the manufacturer, the recipient, or the~~
2756 ~~wholesale distributor of the documentation required to be~~
2757 ~~acquired or delivered under subparagraph 5. shall constitute~~
2758 ~~forgery of a pedigree paper under s. 499.0051.~~

2759 ~~7. The department may, by rule, specify alternatives to~~
2760 ~~compliance with subparagraph 1. for a prescription drug in the~~
2761 ~~inventory of a permitted prescription drug wholesaler as of June~~
2762 ~~30, 2006, and the return of a prescription drug purchased prior~~
2763 ~~to July 1, 2006. The department may specify time limits for such~~
2764 ~~alternatives.~~

2765 (7)(e) PRESCRIPTION DRUG PURCHASE LIST.--Each wholesale
 2766 distributor, except for a manufacturer, shall annually provide
 2767 the department with a written list of all wholesale distributors
 2768 and manufacturers from whom the wholesale distributor purchases
 2769 prescription drugs. A wholesale distributor, except a
 2770 manufacturer, shall notify the department not later than 10 days
 2771 after any change to either list. Such portions of the
 2772 information required pursuant to this subsection ~~paragraph~~ which
 2773 are a trade secret, as defined in s. 812.081, shall be
 2774 maintained by the department as trade secret information is
 2775 required to be maintained under s. 499.051.

2776 ~~(f)1. This paragraph applies only to an affiliated group,~~
 2777 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~
 2778 ~~amended, which is composed of chain drug entities, including at~~
 2779 ~~least 50 retail pharmacies, warehouses, or repackagers, which~~
 2780 ~~are members of the same affiliated group, if the affiliated~~
 2781 ~~group:~~

2782 ~~a. Discloses to the department the names of all its~~
 2783 ~~members; and~~

2784 ~~b. Agrees in writing to provide records on prescription~~
 2785 ~~drug purchases by members of the affiliated group not later than~~
 2786 ~~48 hours after the department requests such records, regardless~~
 2787 ~~of the location where the records are stored.~~

2788 ~~2. Each warehouse within the affiliated group must comply~~
 2789 ~~with all applicable federal and state drug wholesale permit~~
 2790 ~~requirements and must purchase, receive, hold, and distribute~~
 2791 ~~prescription drugs only to a retail pharmacy or warehouse within~~
 2792 ~~the affiliated group. Such a warehouse is exempt from providing~~

2793 ~~a pedigree paper in accordance with paragraph (d) to its~~
 2794 ~~affiliated group member warehouse or retail pharmacy, provided~~
 2795 ~~that.~~

2796 ~~a. Any affiliated group member that purchases or receives~~
 2797 ~~a prescription drug from outside the affiliated group must~~
 2798 ~~receive a pedigree paper if the prescription drug is distributed~~
 2799 ~~in or into this state and a pedigree paper is required under~~
 2800 ~~this section and must authenticate the documentation as required~~
 2801 ~~in subsection (4), regardless of whether the affiliated group~~
 2802 ~~member is directly subject to regulation under this chapter; and~~

2803 ~~b. The affiliated group makes available to the department~~
 2804 ~~on request all records related to the purchase or acquisition of~~
 2805 ~~prescription drugs by members of the affiliated group,~~
 2806 ~~regardless of the location where the records are stored, if the~~
 2807 ~~prescription drugs were distributed in or into this state.~~

2808 ~~3. If a repackager repackages prescription drugs solely~~
 2809 ~~for distribution to its affiliated group members for the~~
 2810 ~~exclusive distribution to and among retail pharmacies that are~~
 2811 ~~members of the affiliated group to which the repackager is a~~
 2812 ~~member.~~

2813 ~~a. The repackager must.~~

2814 ~~(I) In lieu of the written statement required by paragraph~~
 2815 ~~(d), for all repackaged prescription drugs distributed in or~~
 2816 ~~into this state, state in writing under oath with each~~
 2817 ~~distribution of a repackaged prescription drug to an affiliated~~
 2818 ~~group member warehouse or repackager: "All repackaged~~
 2819 ~~prescription drugs are purchased by the affiliated group~~
 2820 ~~directly from the manufacturer or from a prescription drug~~

2821 ~~wholesaler that purchased the prescription drugs directly from~~
 2822 ~~the manufacturer.";~~

2823 ~~(II) Purchase all prescription drugs it repackages:~~

2824 ~~(A) Directly from the manufacturer; or~~

2825 ~~(B) From a prescription drug wholesaler that purchased the~~
 2826 ~~prescription drugs directly from the manufacturer; and~~

2827 ~~(III) Maintain records in accordance with this section to~~
 2828 ~~document that it purchased the prescription drugs directly from~~
 2829 ~~the manufacturer or that its prescription drug wholesale~~
 2830 ~~supplier purchased the prescription drugs directly from the~~
 2831 ~~manufacturer.~~

2832 ~~b. All members of the affiliated group must provide to~~
 2833 ~~agents of the department on request records of purchases by all~~
 2834 ~~members of the affiliated group of prescription drugs that have~~
 2835 ~~been repackaged, regardless of the location where the records~~
 2836 ~~are stored or where the repackager is located.~~

2837 (8) ~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale ~~drug~~
 2838 distributors must establish, maintain, and adhere to written
 2839 policies and procedures, which must be followed for the receipt,
 2840 security, storage, inventory, and distribution of prescription
 2841 drugs, including policies and procedures for identifying,
 2842 recording, and reporting losses or thefts, and for correcting
 2843 all errors and inaccuracies in inventories. Wholesale ~~drug~~
 2844 distributors must include in their written policies and
 2845 procedures:

2846 (a) A procedure whereby the oldest approved stock of a
 2847 prescription drug product is distributed first. The procedure

2848 | may permit deviation from this requirement, if the deviation is
 2849 | temporary and appropriate.

2850 | (b) A procedure to be followed for handling recalls and
 2851 | withdrawals of prescription drugs. Such procedure must be
 2852 | adequate to deal with recalls and withdrawals due to:

2853 | 1. Any action initiated at the request of the Food and
 2854 | Drug Administration or any other federal, state, or local law
 2855 | enforcement or other government agency, including the
 2856 | department.

2857 | 2. Any voluntary action by the manufacturer or repackager
 2858 | to remove defective or potentially defective drugs from the
 2859 | market; or

2860 | 3. Any action undertaken to promote public health and
 2861 | safety by replacing existing merchandise with an improved
 2862 | product or new package design.

2863 | (c) A procedure to ensure that wholesale ~~drug~~ distributors
 2864 | prepare for, protect against, and handle any crisis that affects
 2865 | security or operation of any facility if a strike, fire, flood,
 2866 | or other natural disaster, or a local, state, or national
 2867 | emergency, occurs.

2868 | (d) A procedure to ensure that any outdated prescription
 2869 | drugs are segregated from other drugs and either returned to the
 2870 | manufacturer or repackager or destroyed. This procedure must
 2871 | provide for written documentation of the disposition of outdated
 2872 | prescription drugs. This documentation must be maintained for 2
 2873 | years after disposition of the outdated drugs.

2874 | (9) ~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors
 2875 | must establish and maintain lists of officers, directors,

2876 managers, designated representatives, and other persons in
 2877 charge of wholesale drug distribution, storage, and handling,
 2878 including a description of their duties and a summary of their
 2879 qualifications.

2880 (10)~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A
 2881 wholesale ~~drug~~ distributor must operate in compliance with
 2882 applicable federal, state, and local laws and regulations.

2883 (a) A wholesale ~~drug~~ distributor must allow the department
 2884 and authorized federal, state, and local officials to enter and
 2885 inspect its premises and delivery vehicles, and to audit its
 2886 records and written operating procedures, at reasonable times
 2887 and in a reasonable manner, to the extent authorized by law.

2888 (b) A wholesale ~~drug~~ distributor that deals in controlled
 2889 substances must register with the Drug Enforcement
 2890 Administration and must comply with all applicable state, local,
 2891 and federal laws. A wholesale ~~drug~~ distributor that distributes
 2892 any substance controlled under chapter 893 must notify the
 2893 department when registering with the Drug Enforcement
 2894 Administration pursuant to that chapter and must provide the
 2895 department with its DEA number.

2896 (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~
 2897 distributor is subject to any applicable federal, state, or
 2898 local laws or regulations that relate to prescription drug
 2899 product salvaging or reprocessing.

2900 (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person
 2901 responsible for shipment and transportation of a prescription
 2902 drug in a wholesale distribution may use a common carrier; its
 2903 own vehicle or employee acting within the scope of employment if

2904 authorized under s. 499.03 for the possession of prescription
 2905 drugs in this state; or, in the case of a prescription drug
 2906 intended for domestic distribution, an independent contractor
 2907 who must be the agent of the authorized seller or recipient
 2908 responsible for shipping and transportation as set forth in a
 2909 written contract between the parties. A person selling a
 2910 prescription drug for export must obtain documentation, such as
 2911 a validated airway bill, bill of lading, or other appropriate
 2912 documentation that the prescription drug was exported. A person
 2913 responsible for shipping or transporting prescription drugs is
 2914 not required to maintain documentation from a common carrier
 2915 that the designated recipient received the prescription drugs;
 2916 however, the person must obtain such documentation from the
 2917 common carrier and make it available to the department upon
 2918 request of the department.

2919 (13) ~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing
 2920 any prescription drugs from another wholesale ~~drug~~ distributor,
 2921 a prescription drug wholesale distributor ~~wholesaler~~, an out-of-
 2922 state prescription drug wholesale distributor ~~wholesaler~~, or a
 2923 prescription drug repackager must:

2924 (a) Enter an agreement with the selling wholesale ~~drug~~
 2925 distributor by which the selling wholesale ~~drug~~ distributor will
 2926 indemnify the purchasing wholesale ~~drug~~ distributor for any loss
 2927 caused to the purchasing wholesale ~~drug~~ distributor related to
 2928 the purchase of drugs from the selling wholesale ~~drug~~
 2929 distributor which are determined to be counterfeit or to have
 2930 been distributed in violation of any federal or state law
 2931 governing the distribution of drugs.

2932 (b) Determine that the selling wholesale ~~drug~~ distributor
 2933 has insurance coverage of not less than the greater of 1 percent
 2934 of the amount of total dollar volume of the prescription drug
 2935 sales reported to the department under s. 499.012(8)(g) ~~s.~~
 2936 ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed
 2937 \$2 million.

2938 (c) Obtain information from the selling wholesale ~~drug~~
 2939 distributor, including the length of time the selling wholesale
 2940 ~~drug~~ distributor has been licensed in this state, a copy of the
 2941 selling wholesale ~~drug~~ distributor's licenses or permits, and
 2942 background information concerning the ownership of the selling
 2943 wholesale ~~drug~~ distributor, including the experience of the
 2944 wholesale distributor in the wholesale distribution of
 2945 prescription drugs.

2946 (d) Verify that the selling wholesale ~~drug~~ distributor's
 2947 Florida permit is valid.

2948 (e) Inspect the selling wholesale ~~drug~~ distributor's
 2949 licensed establishment to document that it has a policies and
 2950 procedures manual relating to the distribution of drugs, the
 2951 appropriate temperature controlled environment for drugs
 2952 requiring temperature control, an alarm system, appropriate
 2953 access restrictions, and procedures to ensure that records
 2954 related to the wholesale distribution of prescription drugs are
 2955 maintained as required by law:

2956 1. Before purchasing any drug from the wholesale ~~drug~~
 2957 distributor, and at least once each subsequent year; or

2958 2. Before purchasing any drug from the wholesale ~~drug~~
 2959 distributor, and each subsequent year obtain a complete copy of

2960 the most recent inspection report for the establishment which
 2961 was prepared by the department or the regulatory authority
 2962 responsible for wholesale ~~drug~~ distributors in the state in
 2963 which the establishment is located.

2964 Section 14. Section 499.01211, Florida Statutes, is
 2965 amended to read:

2966 499.01211 Drug Wholesale Distributor ~~Wholesaler~~ Advisory
 2967 Council.--

2968 (1) There is created the Drug Wholesale Distributor
 2969 ~~Wholesaler~~ Advisory Council within the department. The council
 2970 shall meet at least once each calendar quarter. Staff for the
 2971 council shall be provided by the department. The council shall
 2972 consist of 11 members who shall serve without compensation. The
 2973 council shall elect a chairperson and a vice chairperson
 2974 annually.

2975 (2) The State Surgeon General, or his or her designee, and
 2976 the Secretary of Health Care Administration, or her or his
 2977 designee, shall be members of the council. The State Surgeon
 2978 General shall appoint nine additional members to the council who
 2979 shall be appointed to a term of 4 years each, as follows:

2980 (a) Three different persons each of whom is employed by a
 2981 different prescription drug wholesale distributor ~~wholesaler~~
 2982 licensed under this part ~~chapter~~ which operates nationally and
 2983 is a primary wholesale distributor ~~wholesaler~~, as defined in s.
 2984 499.003(48) ~~s. 499.012(1)(d)~~.

2985 (b) One person employed by a prescription drug wholesale
 2986 distributor ~~wholesaler~~ licensed under this part ~~chapter~~ which is

2987 a secondary wholesale distributor ~~wholesaler~~, as defined in s.
 2988 499.003(53) ~~s. 499.012(1)(f)~~.

2989 (c) One person employed by a retail pharmacy chain located
 2990 in this state.

2991 (d) One person who is a member of the Board of Pharmacy
 2992 and is a pharmacist licensed under chapter 465.

2993 (e) One person who is a physician licensed pursuant to
 2994 chapter 458 or chapter 459.

2995 (f) One person who is an employee of a hospital licensed
 2996 pursuant to chapter 395 and is a pharmacist licensed pursuant to
 2997 chapter 465.

2998 (g) One person who is an employee of a pharmaceutical
 2999 manufacturer.

3000 (3) The council shall review this part ~~ss. 499.001-499.081~~
 3001 and the rules adopted to administer this part ~~ss. 499.001-~~
 3002 ~~499.081~~ annually, provide input to the department regarding all
 3003 proposed rules to administer this part ~~ss. 499.001-499.081~~, make
 3004 recommendations to the department to improve the protection of
 3005 the prescription drugs and public health, make recommendations
 3006 to improve coordination with other states' regulatory agencies
 3007 and the federal government concerning the wholesale distribution
 3008 of drugs, and make recommendations to minimize the impact of
 3009 regulation of the wholesale distribution industry while ensuring
 3010 protection of the public health.

3011 Section 15. Section 499.01212, Florida Statutes, is
 3012 created to read:

3013 499.01212 Pedigree paper.--

3014 (1) APPLICATION.--Each person who is engaged in the
 3015 wholesale distribution of a prescription drug must, prior to or
 3016 simultaneous with each wholesale distribution, provide a
 3017 pedigree paper to the person who receives the drug.

3018 (2) FORMAT.--A pedigree paper must contain the following
 3019 information:

3020 (a) For the wholesale distribution of a prescription drug
 3021 within the normal distribution chain:

3022 1. The following statement: "This wholesale distributor
 3023 purchased the specific unit of the prescription drug directly
 3024 from the manufacturer."

3025 2. The name of the prescription drug as it appears on the
 3026 label.

3027 3. The quantity, dosage form, and strength of the
 3028 prescription drug.

3029
 3030 The wholesale distributor must also maintain and make available
 3031 to the department, upon request, the point of origin of the
 3032 prescription drugs, including intracompany transfers, the date
 3033 of the shipment from the manufacturer to the wholesale
 3034 distributor, the lot numbers of such drugs, and the invoice
 3035 numbers from the manufacturer.

3036 (b) For all other wholesale distributions of prescription
 3037 drugs:

3038 1. The quantity, dosage form, and strength of the
 3039 prescription drugs.

3040 2. The lot numbers of the prescription drugs.

3041 3. The name and address of each owner of the prescription
 3042 drug and his or her signature.

3043 4. Shipping information, including the name and address of
 3044 each person certifying delivery or receipt of the prescription
 3045 drug.

3046 5. An invoice number, a shipping document number, or
 3047 another number uniquely identifying the transaction.

3048 6. A certification that the recipient wholesale
 3049 distributor has authenticated the pedigree papers.

3050 7. The unique serialization of the prescription drug, if
 3051 the manufacturer or repackager has uniquely serialized the
 3052 individual prescription drug unit.

3053 8. The name, address, telephone number, and, if available,
 3054 e-mail contact information of each wholesale distributor
 3055 involved in the chain of the prescription drug's custody.

3056 (3) EXCEPTIONS.--A pedigree paper is not required for:

3057 (a) The wholesale distribution of a prescription drug by
 3058 the manufacturer.

3059 (b) The wholesale distribution of a compressed medical
 3060 gas.

3061 (c) The wholesale distribution of a veterinary
 3062 prescription drug.

3063 (d) A drop shipment, provided:

3064 1. The wholesale distributor delivers to the recipient of
 3065 the prescription drug, within 14 days after the shipment
 3066 notification from the manufacturer, an invoice and the following
 3067 sworn statement: "This wholesale distributor purchased the
 3068 specific unit of the prescription drug listed on the invoice

3069 directly from the manufacturer, and the specific unit of
 3070 prescription drug was shipped by the manufacturer directly to a
 3071 person authorized by law to administer or dispense the legend
 3072 drug, as defined in s. 465.003, Florida Statutes, or a member of
 3073 an affiliated group, with the exception of a repackager." The
 3074 invoice must contain a unique cross-reference to the shipping
 3075 document sent by the manufacturer to the recipient of the
 3076 prescription drug.

3077 2. The manufacturer of the prescription drug shipped
 3078 directly to the recipient provides and the recipient of the
 3079 prescription drug acquires, within 14 days after receipt of the
 3080 prescription drug, a shipping document from the manufacturer
 3081 that contains, at a minimum:

3082 a. The name and address of the manufacturer, including the
 3083 point of origin of the shipment, and the names and addresses of
 3084 the wholesale distributor and the purchaser.

3085 b. The name of the prescription drug as it appears on the
 3086 label.

3087 c. The quantity, dosage form, and strength of the
 3088 prescription drug.

3089 d. The date of the shipment from the manufacturer.

3090 3. The wholesale distributor maintains and makes available
 3091 to the department, upon request, the lot number of such drug if
 3092 not contained in the shipping document acquired by the
 3093 recipient.

3094
 3095 Failure of the manufacturer to provide, the recipient to
 3096 acquire, or the wholesale distributor to deliver the

3097 documentation required under this paragraph shall constitute
 3098 failure to acquire or deliver a pedigree paper under ss.
 3099 499.005(28) and 499.0051. Forgery by the manufacturer, the
 3100 recipient, or the wholesale distributor of the documentation
 3101 required to be acquired or delivered under this paragraph shall
 3102 constitute forgery of a pedigree paper under s. 499.0051.

3103 4. The wholesale distributor that takes title to, but not
 3104 possession of, the prescription drug is not a member of the
 3105 affiliated group that receives the prescription drug directly
 3106 from the manufacturer.

3107 (e) The wholesale distribution of a prescription drug by a
 3108 warehouse within an affiliated group to a warehouse or retail
 3109 pharmacy within its affiliated group, provided:

3110 1. Any affiliated group member that purchases or receives
 3111 a prescription drug from outside the affiliated group must
 3112 receive a pedigree paper if the prescription drug is distributed
 3113 in or into this state and a pedigree paper is required under
 3114 this section and must authenticate the documentation as required
 3115 in s. 499.0121(4), regardless of whether the affiliated group
 3116 member is directly subject to regulation under this part; and

3117 2. The affiliated group makes available, within 48 hours,
 3118 to the department on request to one or more of its members all
 3119 records related to the purchase or acquisition of prescription
 3120 drugs by members of the affiliated group, regardless of the
 3121 location where the records are stored, if the prescription drugs
 3122 were distributed in or into this state.

3123 (f) The repackaging of prescription drugs by a repackager
 3124 solely for distribution to its affiliated group members for the

3125 exclusive distribution to and among retail pharmacies that are
 3126 members of the affiliated group to which the repackager is a
 3127 member.

3128 1. The repackager must:

3129 a. For all repackaged prescription drugs distributed in or
 3130 into this state, state in writing under oath with each
 3131 distribution of a repackaged prescription drug to an affiliated
 3132 group member warehouse or repackager: "All repackaged
 3133 prescription drugs are purchased by the affiliated group
 3134 directly from the manufacturer or from a prescription drug
 3135 wholesale distributor that purchased the prescription drugs
 3136 directly from the manufacturer."

3137 b. Purchase all prescription drugs it repackages:

3138 (I) Directly from the manufacturer; or

3139 (II) From a prescription drug wholesale distributor that
 3140 purchased the prescription drugs directly from the manufacturer.

3141 c. Maintain records in accordance with this section to
 3142 document that it purchased the prescription drugs directly from
 3143 the manufacturer or that its prescription drug wholesale
 3144 supplier purchased the prescription drugs directly from the
 3145 manufacturer.

3146 2. All members of the affiliated group must provide,
 3147 within 48 hours, to agents of the department on request to one
 3148 or more of its members records of purchases by all members of
 3149 the affiliated group of prescription drugs that have been
 3150 repackaged, regardless of the location at which the records are
 3151 stored or at which the repackager is located.

3152 Section 16. Section 499.0122, Florida Statutes, is
 3153 repealed.

3154 Section 17. Section 499.013, Florida Statutes, is
 3155 repealed.

3156 Section 18. Subsections (1), (3), (4), (6), (8), and (9)
 3157 of section 499.015, Florida Statutes, are amended to read:

3158 499.015 Registration of drugs, devices, and cosmetics;
 3159 issuance of certificates of free sale.--

3160 (1)(a) Except for those persons exempted from the
 3161 definition of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, any
 3162 person who manufactures, packages, repackages, labels, or
 3163 relabels a drug, device, or cosmetic in this state must register
 3164 such drug, device, or cosmetic biennially with the department;
 3165 pay a fee in accordance with the fee schedule provided by s.
 3166 499.041; and comply with this section. The registrant must list
 3167 each separate and distinct drug, device, or cosmetic at the time
 3168 of registration.

3169 (b) The department may not register any product that does
 3170 not comply with the Federal Food, Drug, and Cosmetic Act, as
 3171 amended, or Title 21 C.F.R. Registration of a product by the
 3172 department does not mean that the product does in fact comply
 3173 with all provisions of the Federal Food, Drug, and Cosmetic Act,
 3174 as amended.

3175 (3) Except for those persons exempted from the definition
 3176 of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, a person may
 3177 not sell any product that he or she has failed to register in
 3178 conformity with this section. Such failure to register subjects
 3179 such drug, device, or cosmetic product to seizure and

3180 condemnation as provided in s. 499.062 ~~ss. 499.062-499.064~~, and
 3181 subjects such person to the penalties and remedies provided in
 3182 this part ~~ss. 499.001-499.081~~.

3183 (4) Unless a registration is renewed, it expires 2 years
 3184 after the last day of the month in which it was issued. The
 3185 department may issue a stop-sale notice or order against a
 3186 person that is subject to the requirements of this section and
 3187 that fails to comply with this section within 31 days after the
 3188 date the registration expires. The notice or order shall
 3189 prohibit such person from selling or causing to be sold any
 3190 drugs, devices, or cosmetics covered by this part ~~ss. 499.001-~~
 3191 ~~499.081~~ until he or she complies with the requirements of this
 3192 section.

3193 (6) The department may issue a certificate of free sale
 3194 for any product that is required to be registered under this
 3195 part ~~ss. 499.001-499.081~~.

3196 (8) Notwithstanding any requirements set forth in this
 3197 part ~~ss. 499.001-499.081~~, a manufacturer of medical devices that
 3198 is registered with the federal Food and Drug Administration is
 3199 exempt from this section and s. 499.041(6) if:

3200 (a) The manufacturer's medical devices are approved for
 3201 marketing by, or listed with the federal Food and Drug
 3202 Administration in accordance with federal law for commercial
 3203 distribution; or

3204 (b) The manufacturer subcontracts with a manufacturer of
 3205 medical devices to manufacture components of such devices.

3206 (9) However, the manufacturer must submit evidence of such
 3207 registration, listing, or approval with its initial application

3208 for a permit to do business in this state, as required in s.
 3209 499.01 ~~s. 499.013~~ and any changes to such information previously
 3210 submitted at the time of renewal of the permit. Evidence of
 3211 approval, listing, and registration by the federal Food and Drug
 3212 Administration must include:

3213 (a) For Class II devices, a copy of the pre-market
 3214 notification letter (510K);

3215 (b) For Class III devices, a Federal Drug Administration
 3216 pre-market approval number;

3217 (c) For a manufacturer who subcontracts with a
 3218 manufacturer of medical devices to manufacture components of
 3219 such devices, a Federal Drug Administration registration number;
 3220 or

3221 (d) For a manufacturer of medical devices whose devices
 3222 are exempt from pre-market approval by the Federal Drug
 3223 Administration, a Federal Drug Administration registration
 3224 number.

3225 Section 19. Subsections (3), (5), and (6) of section
 3226 499.024, Florida Statutes, are amended to read:

3227 499.024 Drug product classification.--The State Surgeon
 3228 General shall adopt rules to classify drug products intended for
 3229 use by humans which the United States Food and Drug
 3230 Administration has not classified in the federal act or the Code
 3231 of Federal Regulations.

3232 (3) Any product that falls under the definition of drug in
 3233 s. 499.003(19) definition, s. 499.003(17), may be classified
 3234 under the authority of this section. This section does not
 3235 subject portable emergency oxygen inhalators to classification;

3236 however, this section does not exempt any person from ss. 499.01
 3237 and 499.015.

3238 (5) The department may by rule reclassify drugs subject to
 3239 this part ~~ss. 499.001-499.081~~ when such classification action is
 3240 necessary to protect the public health.

3241 (6) The department may adopt rules that exempt from any
 3242 labeling or packaging requirements of this part ~~ss. 499.001-~~
 3243 ~~499.081~~ drugs classified under this section if those
 3244 requirements are not necessary to protect the public health.

3245 Section 20. Subsections (7), (12), and (15) of section
 3246 499.028, Florida Statutes, are amended to read:

3247 499.028 Drug samples or complimentary drugs; starter
 3248 packs; permits to distribute.--

3249 (7) A drug manufacturer or distributor must report to the
 3250 department any conviction of itself or of its assigns, agents,
 3251 employees, or representatives for a violation of s. 503(c)(1) of
 3252 the federal act or of this part ~~ss. 499.001-499.081~~ because of
 3253 the sale, purchase, or trade of a drug sample or the offer to
 3254 sell, purchase, or trade a drug sample.

3255 (12) The department may suspend or revoke a permit issued
 3256 under this section, after giving notice and an opportunity to be
 3257 heard pursuant to chapter 120, when:

3258 (a) Such permit was obtained by misrepresentation or fraud
 3259 or through a mistake of the department.

3260 (b) The holder of the permit has distributed or disposed
 3261 of any prescription ~~legend~~ drug, directly or through its agents,
 3262 employees, or independent contractors, to any person not
 3263 authorized to possess such drug.

3264 (c) The holder of the permit, or its agents, employees, or
 3265 independent contractors, has distributed or possessed any
 3266 prescription legend ~~drug~~ drug except in the usual course of its
 3267 business.

3268 (d) The holder of the permit, or its agents, employees, or
 3269 independent contractors, has distributed any prescription legend
 3270 drug that is misbranded or adulterated under this part ~~ss.~~
 3271 ~~499.001-499.081.~~

3272 (e) The holder of the permit, or its agents, employees, or
 3273 independent contractors, has distributed any prescription legend
 3274 drug without written request, when a written request is required
 3275 by this section.

3276 (f) The holder of the permit has in its employ, or uses as
 3277 agent or independent contractor for the purpose of distributing
 3278 or disposing of drugs, any person who has:

3279 1. Violated the requirements of this section or any rule
 3280 adopted under this section.

3281 2. Been convicted in any of the courts of this state, the
 3282 United States, or any other state of a felony or any other crime
 3283 involving moral turpitude or involving those drugs named or
 3284 described in chapter 893.

3285 (15) A person may not possess a prescription drug sample
 3286 unless:

3287 (a) The drug sample was prescribed to her or him as
 3288 evidenced by the label required in s. 465.0276(5).

3289 (b) She or he is the employee of a complimentary drug
 3290 distributor that holds a permit issued under this part ~~ss.~~
 3291 ~~499.001-499.081.~~

3292 (c) She or he is a person to whom prescription drug
 3293 samples may be distributed pursuant to this section.

3294 (d) He or she is an officer or employee of a federal,
 3295 state, or local government acting within the scope of his or her
 3296 employment.

3297 Section 21. Subsections (2) and (3) of section 499.029,
 3298 Florida Statutes, are amended to read:

3299 499.029 Cancer Drug Donation Program.--

3300 (2) There is created a Cancer Drug Donation Program within
 3301 the department ~~of Health~~ for the purpose of authorizing and
 3302 facilitating the donation of cancer drugs and supplies to
 3303 eligible patients.

3304 (3) As used in this section:

3305 (a) "Cancer drug" means a prescription drug that has been
 3306 approved under s. 505 of the federal Food, Drug, and Cosmetic
 3307 Act and is used to treat cancer or its side effects or is used
 3308 to treat the side effects of a prescription drug used to treat
 3309 cancer or its side effects. "Cancer drug" does not include a
 3310 substance listed in Schedule II, Schedule III, Schedule IV, or
 3311 Schedule V of s. 893.03.

3312 (b) "Closed drug delivery system" means a system in which
 3313 the actual control of the unit-dose medication package is
 3314 maintained by the facility rather than by the individual
 3315 patient.

3316 ~~(c) "Department" means the Department of Health.~~

3317 (c) ~~(d)~~ "Donor" means a patient or patient representative
 3318 who donates cancer drugs or supplies needed to administer cancer
 3319 drugs that have been maintained within a closed drug delivery

3320 system; health care facilities, nursing homes, hospices, or
 3321 hospitals with closed drug delivery systems; or pharmacies, drug
 3322 manufacturers, medical device manufacturers or suppliers, or
 3323 wholesalers of drugs or supplies, in accordance with this
 3324 section. "Donor" includes a physician licensed under chapter 458
 3325 or chapter 459 who receives cancer drugs or supplies directly
 3326 from a drug manufacturer, wholesale distributor ~~drug wholesaler~~,
 3327 or pharmacy.

3328 (d)~~(e)~~ "Eligible patient" means a person who the
 3329 department determines is eligible to receive cancer drugs from
 3330 the program.

3331 (e)~~(k)~~ "Participant facility" means a class II hospital
 3332 pharmacy that has elected to participate in the program and that
 3333 accepts donated cancer drugs and supplies under the rules
 3334 adopted by the department for the program.

3335 ~~(o) "Prescription drug" means a drug as defined in s.~~
 3336 ~~465.003(8).~~

3337 (f)~~(p)~~ "Program" means the Cancer Drug Donation Program
 3338 created by this section.

3339 (g)~~(q)~~ "Supplies" means any supplies used in the
 3340 administration of a cancer drug.

3341 Section 22. Subsection (1) of section 499.03, Florida
 3342 Statutes, is amended to read:

3343 499.03 Possession of certain drugs without prescriptions
 3344 unlawful; exemptions and exceptions.--

3345 (1) A person may not possess, or possess with intent to
 3346 sell, dispense, or deliver, any habit-forming, toxic, harmful,
 3347 or new drug subject to s. 499.003(33) ~~s. 499.003(29)~~, or

3348 prescription ~~legend~~ drug as defined in s. 499.003(44) ~~s.~~
 3349 ~~499.003(25)~~, unless the possession of the drug has been obtained
 3350 by a valid prescription of a practitioner licensed by law to
 3351 prescribe the drug. However, this section does not apply to the
 3352 delivery of such drugs to persons included in any of the classes
 3353 named in this subsection, or to the agents or employees of such
 3354 persons, for use in the usual course of their businesses or
 3355 practices or in the performance of their official duties, as the
 3356 case may be; nor does this section apply to the possession of
 3357 such drugs by those persons or their agents or employees for
 3358 such use:

3359 (a) A licensed pharmacist or any person under the licensed
 3360 pharmacist's supervision while acting within the scope of the
 3361 licensed pharmacist's practice;

3362 (b) A licensed practitioner authorized by law to prescribe
 3363 prescription ~~legend~~ drugs or any person under the licensed
 3364 practitioner's supervision while acting within the scope of the
 3365 licensed practitioner's practice;

3366 (c) A qualified person who uses prescription ~~legend~~ drugs
 3367 for lawful research, teaching, or testing, and not for resale;

3368 (d) A licensed hospital or other institution that procures
 3369 such drugs for lawful administration or dispensing by
 3370 practitioners;

3371 (e) An officer or employee of a federal, state, or local
 3372 government; or

3373 (f) A person that holds a valid permit issued by the
 3374 department pursuant to this part ~~ss. 499.001-499.081~~ which
 3375 authorizes that person to possess prescription drugs.

3376 Section 23. Section 499.032, Florida Statutes, is amended
 3377 to read:

3378 499.032 Phenylalanine; prescription
 3379 required.--Phenylalanine restricted formula is declared to be a
 3380 prescription ~~legend~~ drug and may be dispensed only upon the
 3381 prescription of a practitioner authorized by law to prescribe
 3382 prescription ~~medicinal~~ drugs.

3383 Section 24. Subsection (1) of section 499.033, Florida
 3384 Statutes, is amended to read:

3385 499.033 Ephedrine; prescription required.--Ephedrine is
 3386 declared to be a prescription drug.

3387 (1) Except as provided in subsection (2), any product that
 3388 contains any quantity of ephedrine, a salt of ephedrine, an
 3389 optical isomer of ephedrine, or a salt of an optical isomer of
 3390 ephedrine may be dispensed only upon the prescription of a duly
 3391 licensed practitioner authorized by the laws of the state to
 3392 prescribe prescription ~~medicinal~~ drugs.

3393 Section 25. Subsections (1) and (3) of section 499.039,
 3394 Florida Statutes, are amended to read:

3395 499.039 Sale, distribution, or transfer of harmful
 3396 chemical substances; penalties; authority for enforcement.--It
 3397 is unlawful for a person to sell, deliver, or give to a person
 3398 under the age of 18 years any compound, liquid, or chemical
 3399 containing toluol, hexane, trichloroethylene, acetone, toluene,
 3400 ethyl acetate, methyl ethyl ketone, trichloroethane,
 3401 isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl
 3402 ether acetate, cyclohexanone, nitrous oxide, diethyl ether,
 3403 alkyl nitrites (butyl nitrite), or any similar substance for the

3404 purpose of inducing by breathing, inhaling, or ingesting a
 3405 condition of intoxication or which is intended to distort or
 3406 disturb the auditory, visual, or other physical or mental
 3407 processes.

3408 (1) On the first violation of this section, the department
 3409 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if
 3410 the violation has not caused temporary or permanent physical or
 3411 mental injury to the user.

3412 (3) The department ~~of Health~~ shall adopt rules to
 3413 implement this section.

3414 Section 26. Section 499.04, Florida Statutes, is amended
 3415 to read:

3416 499.04 Fee authority.--The department may collect fees for
 3417 all drug, device, and cosmetic applications, permits, product
 3418 registrations, and free-sale certificates. The total amount of
 3419 fees collected from all permits, applications, product
 3420 registrations, and free-sale certificates must be adequate to
 3421 fund the expenses incurred by the department in carrying out
 3422 this part ~~ss. 499.001-499.081~~. The department shall, by rule,
 3423 establish a schedule of fees that are within the ranges provided
 3424 in this section and shall adjust those fees from time to time
 3425 based on the costs associated with administering this part ~~ss.~~
 3426 ~~499.001-499.081~~. The fees are payable to the department to be
 3427 deposited into the Florida Drug, Device, and Cosmetic Trust Fund
 3428 for the sole purpose of carrying out the provisions of this part
 3429 ~~ss. 499.001-499.081~~.

3430 Section 27. Subsections (1) through (5), (8), and (10) of
 3431 section 499.041, Florida Statutes, are amended to read:

3432 499.041 Schedule of fees for drug, device, and cosmetic
 3433 applications and permits, product registrations, and free-sale
 3434 certificates.--

3435 (1) The department shall assess applicants requiring a
 3436 manufacturing permit an annual fee within the ranges established
 3437 in this section for the specific type of manufacturer.

3438 (a) The fee for a prescription drug manufacturer
 3439 ~~manufacturer's~~ permit may not be less than \$500 or more than
 3440 \$750 annually.

3441 (b) The fee for a device manufacturer ~~manufacturer's~~
 3442 permit may not be less than \$500 or more than \$600 annually.

3443 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~
 3444 permit may not be less than \$250 or more than \$400 annually.

3445 (d) The fee for an over-the-counter drug manufacturer
 3446 ~~manufacturer's~~ permit may not be less than \$300 or more than
 3447 \$400 annually.

3448 (e) The fee for a compressed medical gas manufacturer
 3449 ~~manufacturer's~~ permit may not be less than \$400 or more than
 3450 \$500 annually.

3451 (f) The fee for a prescription drug repackager
 3452 ~~repackager's~~ permit may not be less than \$500 or more than \$750
 3453 annually.

3454 (g) A manufacturer may not be required to pay more than
 3455 one fee per establishment to obtain an additional manufacturing
 3456 permit, but each manufacturer must pay the highest fee
 3457 applicable to his or her operation in each establishment.

3458 (2) The department shall assess an applicant that is
 3459 required to have a wholesaling permit an annual fee within the

3460 | ranges established in this section for the specific type of
 3461 | wholesaling.

3462 | (a) The fee for a prescription drug wholesale distributor
 3463 | ~~wholesaler's~~ permit may not be less than \$300 or more than \$800
 3464 | annually.

3465 | (b) The fee for a compressed medical gas wholesale
 3466 | distributor ~~wholesaler's~~ permit may not be less than \$200 or
 3467 | more than \$300 annually.

3468 | (c) The fee for an out-of-state prescription drug
 3469 | wholesale distributor ~~wholesaler's~~ permit may not be less than
 3470 | \$300 or more than \$800 annually.

3471 | (d) The fee for a nonresident prescription drug
 3472 | manufacturer ~~manufacturer's~~ permit may not be less than \$300 or
 3473 | more than \$500 annually.

3474 | (e) The fee for a retail pharmacy drug wholesale
 3475 | distributor ~~wholesaler's~~ permit may not be less than \$35 or more
 3476 | than \$50 annually.

3477 | (f) The fee for a freight forwarder ~~forwarder's~~ permit may
 3478 | not be less than \$200 or more than \$300 annually.

3479 | (g) The fee for a veterinary prescription drug wholesale
 3480 | distributor ~~wholesaler's~~ permit may not be less than \$300 or
 3481 | more than \$500 annually.

3482 | (h) The fee for a limited prescription drug veterinary
 3483 | wholesale distributor ~~wholesaler's~~ permit may not be less than
 3484 | \$300 or more than \$500 annually.

3485 | (3) The department shall assess an applicant that is
 3486 | required to have a retail establishment permit an annual fee

3487 within the ranges established in this section for the specific
 3488 type of retail establishment.

3489 (a) The fee for a veterinary prescription ~~legend~~ drug
 3490 retail establishment permit may not be less than \$200 or more
 3491 than \$300 annually.

3492 (b) The fee for a medical oxygen retail establishment
 3493 permit may not be less than \$200 or more than \$300 annually.

3494 (4) The department shall assess an applicant that is
 3495 required to have a restricted prescription drug distributor
 3496 ~~distributor's~~ permit an annual fee of not less than \$200 or more
 3497 than \$300.

3498 (5) In addition to the fee charged for a permit required
 3499 by this part ~~ss. 499.001-499.081~~, the department shall assess
 3500 applicants an initial application fee of \$150 for each new
 3501 permit issued by the department which requires an onsite
 3502 inspection.

3503 (8) The department shall assess an out-of-state
 3504 prescription drug wholesale distributor ~~wholesaler~~ applicant or
 3505 permittee an onsite inspection fee of not less than \$1,000 or
 3506 more than \$3,000 annually, to be based on the actual cost of the
 3507 inspection if an onsite inspection is performed by agents of the
 3508 department.

3509 (10) The department shall assess other fees as provided in
 3510 this part ~~ss. 499.001-499.081~~.

3511 Section 28. Section 499.05, Florida Statutes, is amended;
 3512 subsection (3) of section 499.013, Florida Statutes, is
 3513 redesignated as paragraph (k) of subsection (1) of that section
 3514 and amended; paragraph (b) of subsection (2) of section

3515 499.0122, Florida Statutes, is redesignated as paragraph (1) of
3516 subsection (1) of that section and amended; and subsection (12)
3517 of section 499.012, Florida Statutes, is redesignated as
3518 paragraph (m) of subsection (1) of that section and amended, to
3519 read:

3520 499.05 Rules.--

3521 (1) The department shall adopt rules to implement and
3522 enforce this part ~~ss. 499.001-499.081~~ with respect to:

3523 (a) The definition of terms used in this part ~~ss. 499.001-~~
3524 ~~499.081~~, and used in the rules adopted under this part ~~ss.~~
3525 ~~499.001-499.081~~, when the use of the term is not its usual and
3526 ordinary meaning.

3527 (b) Labeling requirements for drugs, devices, and
3528 cosmetics.

3529 (c) The establishment of fees authorized in this part ~~ss.~~
3530 ~~499.001-499.081~~.

3531 (d) The identification of permits that require an initial
3532 application and onsite inspection or other prerequisites for
3533 permitting which demonstrate that the establishment and person
3534 are in compliance with the requirements of this part ~~ss.~~
3535 ~~499.001-499.081~~.

3536 (e) The application processes and forms for product
3537 registration.

3538 (f) Procedures for requesting and issuing certificates of
3539 free sale.

3540 (g) Inspections and investigations conducted under s.
3541 499.051, and the identification of information claimed to be a

3542 trade secret and exempt from the public records law as provided
 3543 in s. 499.051(7).

3544 (h) The establishment of a range of penalties, as provided
 3545 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of
 3546 the potential impact of a violation of this part ~~ss. 499.001-~~
 3547 ~~499.081~~; and a process for the uncontested settlement of alleged
 3548 violations.

3549 (i) Additional conditions that qualify as an emergency
 3550 medical reason under s. 499.003(55)(b)2. ~~s. 499.012(1)(a)2.b.~~

3551 (j) Procedures and forms relating to the pedigree paper
 3552 requirement of s. 499.01212.

3553 ~~(k)(3) The department may adopt such rules as are~~
 3554 ~~necessary for~~ The protection of the public health, safety, and
 3555 welfare regarding good manufacturing practices that
 3556 manufacturers and repackagers must follow to ensure the safety
 3557 of the products.

3558 ~~(l)(b) The department shall adopt rules relating to~~
 3559 Information required from each retail establishment pursuant to
 3560 s. 499.012(3) ~~s. 499.01(4)~~, including requirements for
 3561 prescriptions or orders.

3562 ~~(m)(12) The department may adopt rules governing~~ The
 3563 recordkeeping, storage, and handling with respect to each of the
 3564 distributions of prescription drugs specified in s.
 3565 499.003(55)(a)-(d) subparagraphs (1)(a)1.-4.

3566 (n) Alternatives to compliance with s. 499.01212 for a
 3567 prescription drug in the inventory of a permitted prescription
 3568 drug wholesale distributor as of June 30, 2006, and the return

3569 of a prescription drug purchased prior to July 1, 2006. The
 3570 department may specify time limits for such alternatives.

3571 (2) With respect to products in interstate commerce, those
 3572 rules must not be inconsistent with rules and regulations of
 3573 federal agencies unless specifically otherwise directed by the
 3574 Legislature.

3575 (3) The department shall adopt rules regulating
 3576 recordkeeping for and the storage, handling, and distribution of
 3577 medical devices and over-the-counter drugs to protect the public
 3578 from adulterated products.

3579 Section 29. Section 499.051, Florida Statutes, is amended
 3580 to read:

3581 499.051 Inspections and investigations.--

3582 (1) The agents of the department ~~of Health~~ and of the
 3583 Department of Law Enforcement, after they present proper
 3584 identification, may inspect, monitor, and investigate any
 3585 establishment permitted pursuant to this part ~~ss. 499.001-~~
 3586 ~~499.081~~ during business hours for the purpose of enforcing this
 3587 part ~~ss. 499.001-499.081~~, chapters 465, 501, and 893, and the
 3588 rules of the department that protect the public health, safety,
 3589 and welfare.

3590 (2) In addition to the authority set forth in subsection
 3591 (1), the department and any duly designated officer or employee
 3592 of the department may enter and inspect any other establishment
 3593 for the purpose of determining compliance with this part ~~ss.~~
 3594 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~
 3595 regarding any drug, device, or cosmetic product.

3596 (3) Any application for a permit or product registration
 3597 or for renewal of such permit or registration made pursuant to
 3598 this part ss. 499.001-499.081 and rules adopted under this part
 3599 ~~those sections~~ constitutes permission for any entry or
 3600 inspection of the premises in order to verify compliance with
 3601 this part ~~those sections~~ and rules; to discover, investigate,
 3602 and determine the existence of compliance; or to elicit,
 3603 receive, respond to, and resolve complaints and violations.

3604 (4) Any application for a permit made pursuant to s.
 3605 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that
 3606 section ~~those sections~~ constitutes permission for agents of the
 3607 department ~~of Health~~ and the Department of Law Enforcement,
 3608 after presenting proper identification, to inspect, review, and
 3609 copy any financial document or record related to the
 3610 manufacture, repackaging, or distribution of a drug as is
 3611 necessary to verify compliance with this part ss. 499.001-
 3612 499.081 and the rules adopted by the department to administer
 3613 this part ~~those sections~~, in order to discover, investigate, and
 3614 determine the existence of compliance, or to elicit, receive,
 3615 respond to, and resolve complaints and violations.

3616 (5) The authority to inspect under this section includes
 3617 the authority to access, review, and copy any and all financial
 3618 documents related to the activity of manufacturing, repackaging,
 3619 or distributing prescription drugs.

3620 (6) The authority to inspect under this section includes
 3621 the authority to secure:

3622 (a) Samples or specimens of any drug, device, or cosmetic;
 3623 or

3624 (b) Such other evidence as is needed for any action to
 3625 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted
 3626 under this part ~~those sections~~.

3627 (7) The complaint and all information obtained pursuant to
 3628 the investigation by the department are confidential and exempt
 3629 from the provisions of s. 119.07(1) and s. 24(a), Art. I of the
 3630 State Constitution until the investigation and the enforcement
 3631 action are completed. However, trade secret information
 3632 contained therein as defined by s. 812.081(1)(c) shall remain
 3633 confidential and exempt from the provisions of s. 119.07(1) and
 3634 s. 24(a), Art. I of the State Constitution, as long as the
 3635 information is retained by the department. This subsection does
 3636 not prohibit the department from using such information for
 3637 regulatory or enforcement proceedings under this chapter or from
 3638 providing such information to any law enforcement agency or any
 3639 other regulatory agency. However, the receiving agency shall
 3640 keep such records confidential and exempt as provided in this
 3641 subsection. In addition, this subsection is not intended to
 3642 prevent compliance with the provisions of s. 499.01212 ~~s.~~
 3643 ~~499.0121(6)-(d)~~, and the pedigree papers required in that section
 3644 ~~subsection~~ shall not be deemed a trade secret.

3645 Section 30. Section 499.052, Florida Statutes, is amended
 3646 to read:

3647 499.052 Records of interstate shipment.--For the purpose
 3648 of enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in
 3649 interstate commerce and persons receiving drugs, devices, or
 3650 cosmetics in interstate commerce must, upon the request, in the
 3651 manner set out below, by an officer or employee duly designated

3652 by the department, permit the officer or employee to have access
 3653 to and to copy all records showing the movement in interstate
 3654 commerce of any drug, device, or cosmetic, and the quantity,
 3655 shipper, and consignee thereof.

3656 Section 31. Subsection (4) of section 499.055, Florida
 3657 Statutes, is amended to read:

3658 499.055 Reports and dissemination of information by
 3659 department.--

3660 (4) The department shall publish on the department's
 3661 website and update at least monthly:

3662 (a) A list of the prescription drug wholesale distributors
 3663 ~~wholesalers~~, out-of-state prescription drug wholesale
 3664 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
 3665 distributors ~~wholesalers~~ against whom the department has
 3666 initiated enforcement action pursuant to this part ~~ss. 499.001-~~
 3667 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or
 3668 otherwise file an administrative complaint and the permit number
 3669 of each such wholesale distributor ~~wholesaler~~.

3670 (b) A list of the prescription drug wholesale distributors
 3671 ~~wholesalers~~, out-of-state prescription drug wholesale
 3672 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
 3673 distributors ~~wholesalers~~ to which the department has issued a
 3674 permit, including the date on which each permit will expire.

3675 (c) A list of the prescription drug wholesale distributor
 3676 ~~wholesalers~~, out-of-state prescription drug wholesale
 3677 distributor ~~wholesalers~~, and retail pharmacy drug wholesale
 3678 distributor ~~wholesalers~~ permits that have been returned to the

3679 department, were suspended, were revoked, have expired, or were
 3680 not renewed in the previous year.

3681 Section 32. Subsections (1) and (3) of section 499.06,
 3682 Florida Statutes, are amended to read:

3683 499.06 Embargoing, detaining, or destroying article or
 3684 processing equipment which is in violation of law or rule.--

3685 (1) When a duly authorized agent of the department finds,
 3686 or has probable cause to believe, that any drug, device, or
 3687 cosmetic is in violation of any provision of this part ~~ss.~~
 3688 ~~499.001-499.081~~ or any rule adopted under this part ~~such~~
 3689 ~~sections~~ so as to be dangerous, unwholesome, or fraudulent
 3690 within the meaning of this part ~~ss. 499.001-499.081~~, she or he
 3691 may issue and enforce a stop-sale, stop-use, removal, or hold
 3692 order, which order gives notice that such article or processing
 3693 equipment is, or is suspected of being, in violation and has
 3694 been detained or embargoed, and which order warns all persons
 3695 not to remove, use, or dispose of such article or processing
 3696 equipment by sale or otherwise until permission for removal,
 3697 use, or disposal is given by such agent or the court. It is
 3698 unlawful for any person to remove, use, or dispose of such
 3699 detained or embargoed article or processing equipment by sale or
 3700 otherwise without such permission; and such act is a felony of
 3701 the second degree, punishable as provided in s. 775.082, s.
 3702 775.083, or s. 775.084.

3703 (3) If the court finds that the detained or embargoed
 3704 article or processing equipment is in violation, such article or
 3705 processing equipment shall, after entry of the court order, be
 3706 destroyed or made sanitary at the expense of the claimant

3707 | thereof, under the supervision of such agent; and all court
 3708 | costs, fees, and storage and other proper expenses shall be
 3709 | taxed against the claimant of such article or processing
 3710 | equipment or her or his agent. However, when the violation can
 3711 | be corrected by proper labeling of the article or sanitizing of
 3712 | the processing equipment, and after such costs, fees, and
 3713 | expenses have been paid and a good and sufficient bond,
 3714 | conditioned that such article be so labeled or processed or such
 3715 | processing equipment be so sanitized, has been executed, the
 3716 | court may by order direct that such article or processing
 3717 | equipment be delivered to the claimant thereof for such
 3718 | labeling, processing, or sanitizing, under the supervision of an
 3719 | agent of the department. The expense of such supervision shall
 3720 | be paid by the claimant. Such bond shall be returned to the
 3721 | claimant of the article or processing equipment upon
 3722 | representation to the court by the department that the article
 3723 | or processing equipment is no longer in violation of this part
 3724 | ~~ss. 499.001-499.081~~ and that the expenses of such supervision
 3725 | have been paid.

3726 | Section 33. Section 499.062, Florida Statutes, is amended;
 3727 | section 499.063, Florida Statutes, is redesignated as section
 3728 | (2) of that section and amended; and section 499.064, Florida
 3729 | Statutes, is redesignated as paragraphs (a) and (b) of
 3730 | subsection (2) of that section and amended, to read:

3731 | 499.062 ~~Cause for~~ Seizure and condemnation of drugs,
 3732 | devices, or cosmetics.--

3733 | (1) Any article of any drug, device, or cosmetic that is
 3734 | adulterated or misbranded under this part ~~ss. 499.001-499.081~~ is

3735 subject to seizure and condemnation by the department or by its
3736 duly authorized agents designated for that purpose in regard to
3737 drugs, devices, or cosmetics.

3738 (2) ~~499.063~~ ~~Seizure; procedure; prohibition on sale or~~
3739 ~~disposal of article; penalty.~~ Whenever a duly authorized
3740 officer or employee of the department finds cause, or has
3741 probable cause to believe that cause exists, for the seizure of
3742 any drug, device, or cosmetic, as set out in this part ~~ss.~~
3743 ~~499.001-499.081~~, he or she shall affix to the article a tag,
3744 stamp, or other appropriate marking, giving notice that the
3745 article is, or is suspected of being, subject to seizure under
3746 this part ~~ss. 499.001-499.081~~ and that the article has been
3747 detained and seized by the department. Such officer or employee
3748 shall also warn all persons not to remove or dispose of the
3749 article, by sale or otherwise, until permission is given by the
3750 department or the court. Any person who violates this subsection
3751 ~~section~~ is guilty of a felony of the second degree, punishable
3752 as provided in s. 775.082, s. 775.083, or s. 775.084.

3753 (a) ~~499.064~~ ~~Condemnation and sale; release of seized~~
3754 ~~article.~~ (1) When any article detained or seized under this
3755 subsection ~~s. 499.063~~ has been found by the department to be
3756 subject to seizure and condemnation ~~under s. 499.063~~, the
3757 department shall petition the court for an order of condemnation
3758 or sale, as the court directs. The proceeds of the sale of
3759 drugs, devices, and cosmetics, less the legal costs and charges,
3760 shall be deposited into the Florida Drug, Device, and Cosmetic
3761 Trust Fund.

3762 (b)~~(2)~~ If the department finds that any article seized
 3763 under this subsection ~~s. 499.063~~ was not subject to seizure
 3764 ~~under that section~~, the department or the designated officer or
 3765 employee shall remove the tag or marking.

3766 Section 34. Section 499.065, Florida Statutes, is amended
 3767 to read:

3768 499.065 Inspections; imminent danger.--

3769 (1) Notwithstanding s. 499.051, the department shall
 3770 inspect each prescription drug wholesale distributor
 3771 establishment, prescription drug repackager establishment,
 3772 veterinary prescription drug wholesale distributor
 3773 establishment, limited prescription drug veterinary wholesale
 3774 distributor ~~wholesaler~~ establishment, and retail pharmacy drug
 3775 wholesale distributor ~~wholesaler~~ establishment that is required
 3776 to be permitted under this part ~~chapter~~ as often as necessary to
 3777 ensure compliance with applicable laws and rules. The department
 3778 shall have the right of entry and access to these facilities at
 3779 any reasonable time.

3780 (2) To protect the public from prescription drugs that are
 3781 adulterated or otherwise unfit for human or animal consumption,
 3782 the department may examine, sample, seize, and stop the sale or
 3783 use of prescription drugs to determine the condition of those
 3784 drugs. The department may immediately seize and remove any
 3785 prescription drugs if the State Surgeon General or his or her
 3786 designee determines that the prescription drugs represent a
 3787 threat to the public health. The owner of any property seized
 3788 under this section may, within 10 days after the seizure, apply
 3789 to a court of competent jurisdiction for whatever relief is

3790 appropriate. At any time after 10 days, the department may
 3791 destroy the drugs as contraband.

3792 (3) The department may determine that a prescription drug
 3793 wholesale distributor establishment, prescription drug
 3794 repackager establishment, veterinary prescription drug wholesale
 3795 distributor establishment, limited prescription drug veterinary
 3796 wholesale distributor ~~wholesaler~~ establishment, or retail
 3797 pharmacy drug wholesale distributor ~~wholesaler~~ establishment
 3798 that is required to be permitted under this part ~~chapter~~ is an
 3799 imminent danger to the public health and shall require its
 3800 immediate closure if the establishment fails to comply with
 3801 applicable laws and rules and, because of the failure, presents
 3802 an imminent threat to the public's health, safety, or welfare.
 3803 Any establishment so deemed and closed shall remain closed until
 3804 allowed by the department or by judicial order to reopen.

3805 (4) For purposes of this section, a refusal to allow entry
 3806 to the department for inspection at reasonable times, or a
 3807 failure or refusal to provide the department with required
 3808 documentation for purposes of inspection, constitutes an
 3809 imminent danger to the public health.

3810 Section 35. Subsections (1) through (4) of section
 3811 499.066, Florida Statutes, are amended to read:

3812 499.066 Penalties; remedies.--In addition to other
 3813 penalties and other enforcement provisions:

3814 (1) The department may institute such suits or other legal
 3815 proceedings as are required to enforce any provision of this
 3816 part ~~ss. 499.001-499.081~~. If it appears that a person has
 3817 violated any provision of this part ~~ss. 499.001-499.081~~ for

3818 | which criminal prosecution is provided, the department may
 3819 | provide the appropriate state attorney or other prosecuting
 3820 | agency having jurisdiction with respect to such prosecution with
 3821 | the relevant information in the department's possession.

3822 | (2) If any person engaged in any activity covered by this
 3823 | part ss. 499.001-499.081 violates any provision of this part
 3824 | ~~those sections~~, any rule adopted under this part ~~those sections~~,
 3825 | or a cease and desist order as provided by this part ~~those~~
 3826 | ~~sections~~, the department may obtain an injunction in the circuit
 3827 | court of the county in which the violation occurred or in which
 3828 | the person resides or has its principal place of business, and
 3829 | may apply in that court for such temporary and permanent orders
 3830 | as the department considers necessary to restrain the person
 3831 | from engaging in any such activities until the person complies
 3832 | with this part ss. 499.001-499.081, the rules adopted under this
 3833 | part ~~those sections~~, and the orders of the department authorized
 3834 | by this part ~~those sections~~ or to mandate compliance with this
 3835 | part ss. 499.001-499.081, the rules adopted under this part
 3836 | ~~those sections~~, and any order or permit issued by the department
 3837 | under this part ~~those sections~~.

3838 | (3) The department may impose an administrative fine, not
 3839 | to exceed \$5,000 per violation per day, for the violation of any
 3840 | provision of this part ss. 499.001-499.081 or rules adopted
 3841 | under this part ~~those sections~~. Each day a violation continues
 3842 | constitutes a separate violation, and each separate violation is
 3843 | subject to a separate fine. All amounts collected pursuant to
 3844 | this section shall be deposited into the Florida Drug, Device,
 3845 | and Cosmetic Trust Fund and are appropriated for the use of the

3846 department in administering this part ~~ss. 499.001-499.081~~. In
 3847 determining the amount of the fine to be levied for a violation,
 3848 the department shall consider:

3849 (a) The severity of the violation;

3850 (b) Any actions taken by the person to correct the
 3851 violation or to remedy complaints; and

3852 (c) Any previous violations.

3853 (4) The department shall deposit any rewards, fines, or
 3854 collections that are due the department and which derive from
 3855 joint enforcement activities with other state and federal
 3856 agencies which relate to this part ~~ss. 499.001-499.081~~, chapter
 3857 893, or the federal act, into the Florida Drug, Device, and
 3858 Cosmetic Trust Fund. The proceeds of those rewards, fines, and
 3859 collections are appropriated for the use of the department in
 3860 administering this part ~~ss. 499.001-499.081~~.

3861 Section 36. Section 499.0661, Florida Statutes, is amended
 3862 to read:

3863 499.0661 Cease and desist orders; removal of certain
 3864 persons.--

3865 (1)~~(2)~~ CEASE AND DESIST ORDERS.--

3866 (a) In addition to any authority otherwise provided in
 3867 this chapter, the department may issue and serve a complaint
 3868 stating charges upon any permittee or upon any affiliated party,
 3869 whenever the department has reasonable cause to believe that the
 3870 person or individual named therein is engaging in or has engaged
 3871 in conduct that is:

3872 1. An act that demonstrates a lack of fitness or
 3873 trustworthiness to engage in the business authorized under the

3874 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
 3875 hazardous to the public health, or constitutes business
 3876 operations that are a detriment to the public health;

3877 2. A violation of any provision of this part ~~ss. 499.001-~~
 3878 ~~499.081~~;

3879 3. A violation of any rule of the department;

3880 4. A violation of any order of the department; or

3881 5. A breach of any written agreement with the department.

3882 (b) The complaint must contain a statement of facts and
 3883 notice of opportunity for a hearing pursuant to ss. 120.569 and
 3884 120.57.

3885 (c) If a hearing is not requested within the time allowed
 3886 by ss. 120.569 and 120.57, or if a hearing is held and the
 3887 department finds that any of the charges are proven, the
 3888 department may enter an order directing the permittee or the
 3889 affiliated party named in the complaint to cease and desist from
 3890 engaging in the conduct complained of and take corrective action
 3891 to remedy the effects of past improper conduct and assure future
 3892 compliance.

3893 (d) A contested or default cease and desist order is
 3894 effective when reduced to writing and served upon the permittee
 3895 or affiliated party named therein. An uncontested cease and
 3896 desist order is effective as agreed.

3897 (e) Whenever the department finds that conduct described
 3898 in paragraph (a) is likely to cause an immediate threat to the
 3899 public health, it may issue an emergency cease and desist order
 3900 requiring the permittee or any affiliated party to immediately
 3901 cease and desist from engaging in the conduct complained of and

3902 to take corrective and remedial action. The emergency order is
 3903 effective immediately upon service of a copy of the order upon
 3904 the permittee or affiliated party named therein and remains
 3905 effective for 90 days. If the department begins nonemergency
 3906 cease and desist proceedings under this subsection, the
 3907 emergency order remains effective until the conclusion of the
 3908 proceedings under ss. 120.569 and 120.57.

3909 (2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

3910 (a) The department may issue and serve a complaint stating
 3911 charges upon any affiliated party and upon the permittee
 3912 involved whenever the department has reason to believe that an
 3913 affiliated party is engaging in or has engaged in conduct that
 3914 constitutes:

3915 1. An act that demonstrates a lack of fitness or
 3916 trustworthiness to engage in the business authorized under the
 3917 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
 3918 hazardous to the public health, or constitutes business
 3919 operations that are a detriment to the public health;

3920 2. A willful violation of this part ~~ss. 499.001-499.081~~;
 3921 however, if the violation constitutes a misdemeanor, a complaint
 3922 may not be served as provided in this section until the
 3923 affiliated party is notified in writing of the matter of the
 3924 violation and has been afforded a reasonable period of time, as
 3925 set forth in the notice, to correct the violation and has failed
 3926 to do so;

3927 3. A violation of any other law involving fraud or moral
 3928 turpitude which constitutes a felony;

3929 4. A willful violation of any rule of the department;

3930 5. A willful violation of any order of the department; or
 3931 6. A material misrepresentation of fact, made knowingly
 3932 and willfully or made with reckless disregard for the truth of
 3933 the matter.

3934 (b) The complaint must contain a statement of facts and
 3935 notice of opportunity for a hearing pursuant to ss. 120.569 and
 3936 120.57.

3937 (c) If a hearing is not requested within the time allotted
 3938 by ss. 120.569 and 120.57, or if a hearing is held and the
 3939 department finds that any of the charges in the complaint are
 3940 proven true, the department may enter an order removing the
 3941 affiliated party or restricting or prohibiting participation by
 3942 the person in the affairs of that permittee or of any other
 3943 permittee.

3944 (d) A contested or default order of removal, restriction,
 3945 or prohibition is effective when reduced to writing and served
 3946 on the permittee and the affiliated party. An uncontested order
 3947 of removal, restriction, or prohibition is effective as agreed.

3948 (e)1. The chief executive officer, designated
 3949 representative, or the person holding the equivalent office, of
 3950 a permittee shall promptly notify the department if she or he
 3951 has actual knowledge that any affiliated party is charged with a
 3952 felony in a state or federal court.

3953 2. Whenever any affiliated party is charged with a felony
 3954 in a state or federal court or with the equivalent of a felony
 3955 in the courts of any foreign country with which the United
 3956 States maintains diplomatic relations, and the charge alleges
 3957 violation of any law involving prescription drugs,

3958 | pharmaceuticals, fraud, theft, or moral turpitude, the
 3959 | department may enter an emergency order suspending the
 3960 | affiliated party or restricting or prohibiting participation by
 3961 | the affiliated party in the affairs of the particular permittee
 3962 | or of any other permittee upon service of the order upon the
 3963 | permittee and the affiliated party charged. The order must
 3964 | contain notice of opportunity for a hearing pursuant to ss.
 3965 | 120.569 and 120.57, where the affiliated party may request a
 3966 | postsuspension hearing to show that continued service to or
 3967 | participation in the affairs of the permittee does not pose a
 3968 | threat to the public health or the interests of the permittee
 3969 | and does not threaten to impair public confidence in the
 3970 | permittee. In accordance with applicable departmental rules, the
 3971 | department shall notify the affiliated party whether the order
 3972 | suspending or prohibiting the person from participation in the
 3973 | affairs of a permittee will be rescinded or otherwise modified.
 3974 | The emergency order remains in effect, unless otherwise modified
 3975 | by the department, until the criminal charge is disposed of. The
 3976 | acquittal of the person charged, or the final, unappealed
 3977 | dismissal of all charges against the person, dissolves the
 3978 | emergency order but does not prohibit the department from
 3979 | instituting proceedings under paragraph (a). If the person
 3980 | charged is convicted or pleads guilty or nolo contendere,
 3981 | whether or not an adjudication of guilt is entered by the court,
 3982 | the emergency order shall become final.

3983 | (f) Any affiliated party removed pursuant to this section
 3984 | is not eligible for reemployment by the permittee or to be an
 3985 | affiliated party of any permittee except upon the written

3986 consent of the department. Any affiliated party who is removed,
 3987 restricted, or prohibited from participating in the affairs of a
 3988 permittee pursuant to this section may petition the department
 3989 for modification or termination of the removal, restriction, or
 3990 prohibition.

3991 Section 37. Section 499.067, Florida Statutes, is amended
 3992 to read:

3993 499.067 Denial, suspension, or revocation of permit,
 3994 certification, or registration.--

3995 (1) (a) The department may deny, suspend, or revoke a
 3996 permit if it finds that there has been a substantial failure to
 3997 comply with this part ~~ss. 499.001-499.081~~ or chapter 465,
 3998 chapter 501, or chapter 893, the rules adopted under this part
 3999 ~~any of those sections~~ or those chapters, any final order of the
 4000 department, or applicable federal laws or regulations or other
 4001 state laws or rules governing drugs, devices, or cosmetics.

4002 (b) The department may deny an application for a permit or
 4003 certification, or suspend or revoke a permit or certification,
 4004 if the department finds that:

4005 1. The applicant is not of good moral character or that it
 4006 would be a danger or not in the best interest of the public
 4007 health, safety, and welfare if the applicant were issued a
 4008 permit or certification.

4009 2. The applicant has not met the requirements for the
 4010 permit or certification.

4011 3. The applicant is not eligible for a permit or
 4012 certification for any of the reasons enumerated in s. 499.012 ~~s.~~
 4013 ~~499.01~~ ~~or s. 499.012(5)~~.

4014 4. The applicant, permittee, or person certified under s.
 4015 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions
 4016 enumerated in s. 499.012 ~~s. 499.01~~ ~~or s. 499.012(5)~~.

4017 5. The applicant, permittee, or person certified under s.
 4018 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.
 4019 499.005-499.0054.

4020 (2) The department may deny, suspend, or revoke any
 4021 registration required by the provisions of this part ~~ss.~~
 4022 ~~499.001-499.081~~ for the violation of any provision of this part
 4023 ~~ss. 499.001-499.081~~ or of any rules adopted under this part
 4024 ~~those sections.~~

4025 (3) The department may revoke or suspend a permit:

4026 (a) If the permit was obtained by misrepresentation or
 4027 fraud or through a mistake of the department;

4028 (b) If the permit was procured, or attempted to be
 4029 procured, for any other person by making or causing to be made
 4030 any false representation; or

4031 (c) If the permittee has violated any provision of this
 4032 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~
 4033 ~~sections.~~

4034 (4) If any permit issued under this part ~~ss. 499.001-~~
 4035 ~~499.081~~ is revoked or suspended, the owner, manager, operator,
 4036 or proprietor of the establishment shall cease to operate as the
 4037 permit authorized, from the effective date of the suspension or
 4038 revocation until the person is again registered with the
 4039 department and possesses the required permit. If a permit is
 4040 revoked or suspended, the owner, manager, or proprietor shall
 4041 remove all signs and symbols that identify the operation as

4042 premises permitted as a drug wholesaling establishment; drug,
 4043 device, or cosmetic manufacturing establishment; or retail
 4044 establishment. The department shall determine the length of time
 4045 for which the permit is to be suspended. If a permit is revoked,
 4046 the person that owns or operates the establishment may not apply
 4047 for any permit under this part ~~ss. 499.001-499.081~~ for a period
 4048 of 1 year after the date of the revocation. A revocation of a
 4049 permit may be permanent if the department considers that to be
 4050 in the best interest of the public health.

4051 (5) The department may deny, suspend, or revoke a permit
 4052 issued under this part ~~ss. 499.001-499.081~~ which authorizes the
 4053 permittee to purchase prescription drugs, if any owner, officer,
 4054 employee, or other person who participates in administering or
 4055 operating the establishment has been found guilty of any
 4056 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,
 4057 chapter 501, or chapter 893, any rules adopted under this part
 4058 ~~any of those sections~~ or those chapters, or any federal or state
 4059 drug law, regardless of whether the person has been pardoned,
 4060 had her or his civil rights restored, or had adjudication
 4061 withheld.

4062 (6) The department shall deny, suspend, or revoke the
 4063 permit of any person or establishment if the assignment, sale,
 4064 transfer, or lease of an establishment permitted under this part
 4065 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil
 4066 action, or criminal prosecution.

4067 (7) Notwithstanding s. 120.60(5), if a permittee fails to
 4068 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may
 4069 revoke the permit of the permittee and shall provide notice of

4070 the intended agency action by posting a notice at the
 4071 department's headquarters and by mailing a copy of the notice of
 4072 intended agency action by certified mail to the most recent
 4073 mailing address on record with the department and, if the
 4074 permittee is not a natural person, to the permittee's registered
 4075 agent on file with the Department of State.

4076 Section 38. Paragraph (a) of subsection (1) of section
 4077 409.9201, Florida Statutes, is amended to read:

4078 409.9201 Medicaid fraud.--

4079 (1) As used in this section, the term:

4080 (a) "Legend drug" means any drug, including, but not
 4081 limited to, finished dosage forms or active ingredients that are
 4082 subject to, defined by, or described by s. 503(b) of the Federal
 4083 Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.007(13)
 4084 ~~s. 499.007(12)~~, or s. 499.003(47) or (54) ~~s. 499.0122(1)(b) or~~
 4085 ~~(e)~~.

4086
 4087 The value of individual items of the legend drugs or goods or
 4088 services involved in distinct transactions committed during a
 4089 single scheme or course of conduct, whether involving a single
 4090 person or several persons, may be aggregated when determining
 4091 the punishment for the offense.

4092 Section 39. Paragraph (c) of subsection (9) of section
 4093 460.403, Florida Statutes, is amended to read:

4094 460.403 Definitions.--As used in this chapter, the term:

4095 (9)

4096 (c)1. Chiropractic physicians may adjust, manipulate, or
 4097 treat the human body by manual, mechanical, electrical, or

4098 natural methods; by the use of physical means or physiotherapy,
 4099 including light, heat, water, or exercise; by the use of
 4100 acupuncture; or by the administration of foods, food
 4101 concentrates, food extracts, and items for which a prescription
 4102 is not required and may apply first aid and hygiene, but
 4103 chiropractic physicians are expressly prohibited from
 4104 prescribing or administering to any person any legend drug
 4105 except as authorized under subparagraph 2., from performing any
 4106 surgery except as stated herein, or from practicing obstetrics.

4107 2. Notwithstanding the prohibition against prescribing and
 4108 administering legend drugs under subparagraph 1. or s.
 4109 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic
 4110 physicians may order, store, and administer, for emergency
 4111 purposes only at the chiropractic physician's office or place of
 4112 business, prescription medical oxygen and may also order, store,
 4113 and administer the following topical anesthetics in aerosol
 4114 form:

4115 a. Any solution consisting of 25 percent ethylchloride and
 4116 75 percent dichlorodifluoromethane.

4117 b. Any solution consisting of 15 percent
 4118 dichlorodifluoromethane and 85 percent
 4119 trichloromonofluoromethane.

4120
 4121 However, this paragraph does not authorize a chiropractic
 4122 physician to prescribe medical oxygen as defined in chapter 499.

4123 Section 40. Subsection (3) of section 465.0265, Florida
 4124 Statutes, is amended to read:

4125 465.0265 Centralized prescription filling.--

4126 (3) The filling, delivery, and return of a prescription by
 4127 one pharmacy for another pursuant to this section shall not be
 4128 construed as the filling of a transferred prescription as set
 4129 forth in s. 465.026 or as a wholesale distribution as set forth
 4130 in s. 499.003(55) ~~s. 499.012(1)(a)~~.

4131 Section 41. Section 794.075, Florida Statutes, is amended
 4132 to read:

4133 794.075 Sexual predators; erectile dysfunction drugs.--

4134 (1) A person may not possess a prescription drug, as
 4135 defined in s. 499.003(44) ~~s. 499.003(25)~~, for the purpose of
 4136 treating erectile dysfunction if the person is designated as a
 4137 sexual predator under s. 775.21.

4138 (2) A person who violates a provision of this section for
 4139 the first time commits a misdemeanor of the second degree,
 4140 punishable as provided in s. 775.082 or s. 775.083. A person who
 4141 violates a provision of this section a second or subsequent time
 4142 commits a misdemeanor of the first degree, punishable as
 4143 provided in s. 775.082 or s. 775.083.

4144 Section 42. Paragraph (a) of subsection (1) of section
 4145 895.02, Florida Statutes, is amended to read:

4146 895.02 Definitions.--As used in ss. 895.01-895.08, the
 4147 term:

4148 (1) "Racketeering activity" means to commit, to attempt to
 4149 commit, to conspire to commit, or to solicit, coerce, or
 4150 intimidate another person to commit:

4151 (a) Any crime that is chargeable by indictment or
 4152 information under the following provisions of the Florida
 4153 Statutes:

- 4154 1. Section 210.18, relating to evasion of payment of
4155 cigarette taxes.
- 4156 2. Section 403.727(3)(b), relating to environmental
4157 control.
- 4158 3. Section 409.920 or s. 409.9201, relating to Medicaid
4159 fraud.
- 4160 4. Section 414.39, relating to public assistance fraud.
- 4161 5. Section 440.105 or s. 440.106, relating to workers'
4162 compensation.
- 4163 6. Section 443.071(4), relating to creation of a
4164 fictitious employer scheme to commit unemployment compensation
4165 fraud.
- 4166 7. Section 465.0161, relating to distribution of medicinal
4167 drugs without a permit as an Internet pharmacy.
- 4168 8. Section 499.0051 ~~Sections 499.0051, 499.0052,~~
4169 ~~499.00535, 499.00545, and 499.0691,~~ relating to crimes involving
4170 contraband and adulterated drugs.
- 4171 9. Part IV of chapter 501, relating to telemarketing.
- 4172 10. Chapter 517, relating to sale of securities and
4173 investor protection.
- 4174 11. Section 550.235, s. 550.3551, or s. 550.3605, relating
4175 to dogracing and horseracing.
- 4176 12. Chapter 550, relating to jai alai frontons.
- 4177 13. Section 551.109, relating to slot machine gaming.
- 4178 14. Chapter 552, relating to the manufacture,
4179 distribution, and use of explosives.
- 4180 15. Chapter 560, relating to money transmitters, if the
4181 violation is punishable as a felony.

- 4182 16. Chapter 562, relating to beverage law enforcement.
- 4183 17. Section 624.401, relating to transacting insurance
- 4184 without a certificate of authority, s. 624.437(4)(c)1., relating
- 4185 to operating an unauthorized multiple-employer welfare
- 4186 arrangement, or s. 626.902(1)(b), relating to representing or
- 4187 aiding an unauthorized insurer.
- 4188 18. Section 655.50, relating to reports of currency
- 4189 transactions, when such violation is punishable as a felony.
- 4190 19. Chapter 687, relating to interest and usurious
- 4191 practices.
- 4192 20. Section 721.08, s. 721.09, or s. 721.13, relating to
- 4193 real estate timeshare plans.
- 4194 21. Chapter 782, relating to homicide.
- 4195 22. Chapter 784, relating to assault and battery.
- 4196 23. Chapter 787, relating to kidnapping or human
- 4197 trafficking.
- 4198 24. Chapter 790, relating to weapons and firearms.
- 4199 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.
- 4200 796.05, or s. 796.07, relating to prostitution and sex
- 4201 trafficking.
- 4202 26. Chapter 806, relating to arson.
- 4203 27. Section 810.02(2)(c), relating to specified burglary
- 4204 of a dwelling or structure.
- 4205 28. Chapter 812, relating to theft, robbery, and related
- 4206 crimes.
- 4207 29. Chapter 815, relating to computer-related crimes.
- 4208 30. Chapter 817, relating to fraudulent practices, false
- 4209 pretenses, fraud generally, and credit card crimes.

- 4210 31. Chapter 825, relating to abuse, neglect, or
 4211 exploitation of an elderly person or disabled adult.
- 4212 32. Section 827.071, relating to commercial sexual
 4213 exploitation of children.
- 4214 33. Chapter 831, relating to forgery and counterfeiting.
- 4215 34. Chapter 832, relating to issuance of worthless checks
 4216 and drafts.
- 4217 35. Section 836.05, relating to extortion.
- 4218 36. Chapter 837, relating to perjury.
- 4219 37. Chapter 838, relating to bribery and misuse of public
 4220 office.
- 4221 38. Chapter 843, relating to obstruction of justice.
- 4222 39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or
 4223 s. 847.07, relating to obscene literature and profanity.
- 4224 40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.
 4225 849.25, relating to gambling.
- 4226 41. Chapter 874, relating to criminal street gangs.
- 4227 42. Chapter 893, relating to drug abuse prevention and
 4228 control.
- 4229 43. Chapter 896, relating to offenses related to financial
 4230 transactions.
- 4231 44. Sections 914.22 and 914.23, relating to tampering with
 4232 a witness, victim, or informant, and retaliation against a
 4233 witness, victim, or informant.
- 4234 45. Sections 918.12 and 918.13, relating to tampering with
 4235 jurors and evidence.

4236 Section 43. Paragraphs (d), (f), (h), (i), and (j) of
 4237 subsection (3) of section 921.0022, Florida Statutes, are
 4238 amended to read:

4239 921.0022 Criminal Punishment Code; offense severity
 4240 ranking chart.--

4241 (3) OFFENSE SEVERITY RANKING CHART

4242 (d) LEVEL 4

4243

Florida	Felony	Description
Statute	Degree	

4244

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.
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4245

499.0051(1)	3rd	Failure to maintain or deliver pedigree papers.
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4246

499.0051(2)	3rd	Failure to authenticate pedigree papers.
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4247

499.0051(6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband <u>prescription</u> legend drugs.
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4248

HB 7049, Engrossed 1

2008

4249	784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4250	784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
4251	784.075	3rd	Battery on detention or commitment facility staff.
4252	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
4253	784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
4254	784.081(3)	3rd	Battery on specified official or employee.
4255	784.082(3)	3rd	Battery by detained person on visitor or other detainee.
4256	784.083(3)	3rd	Battery on code inspector.
4257	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.

4258	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
4259	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
4260	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4261	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4262	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
4263	790.115 (2) (c)	3rd	Possessing firearm on school property.
4264	800.04 (7) (d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4265	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.

4266	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
4267	810.06	3rd	Burglary; possession of tools.
4268	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
4269	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4270	812.014 (2) (c) 4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4271	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4272	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
4273	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
	817.625 (2) (a)	3rd	Fraudulent use of scanning device or

			reencoder.
4274	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
4275	837.02 (1)	3rd	Perjury in official proceedings.
4276	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4277	838.022	3rd	Official misconduct.
4278	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4279	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4280	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4281	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
4282	843.15 (1) (a)	3rd	Failure to appear while on bail for

4283			felony (bond estreature or bond jumping).
	874.05 (1)	3rd	Encouraging or recruiting another to join a criminal street gang.
4284			
	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).
4285			
	914.14 (2)	3rd	Witnesses accepting bribes.
4286			
	914.22 (1)	3rd	Force, threaten, etc., witness, victim, or informant.
4287			
	914.23 (2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4288			
	918.12	3rd	Tampering with jurors.
4289			
	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
4290			
4291	(f)	LEVEL 6	
4292			
	Florida	Felony	Description
	Statute	Degree	
4293			

HB 7049, Engrossed 1

2008

4294	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
4295	499.0051 (3)	2nd	<u>Knowing</u> forgery of pedigree papers.
4296	499.0051 (4)	2nd	<u>Knowing</u> purchase or receipt of <u>prescription</u> legend drug from unauthorized person.
4297	499.0051 (5)	2nd	<u>Knowing</u> sale <u>or transfer</u> of <u>prescription</u> legend drug to unauthorized person.
4298	775.0875 (1)	3rd	Taking firearm from law enforcement officer.
4299	784.021 (1) (a)	3rd	Aggravated assault; deadly weapon without intent to kill.
4300	784.021 (1) (b)	3rd	Aggravated assault; intent to commit felony.
4301	784.041	3rd	Felony battery; domestic battery by strangulation.
4302	784.048 (3)	3rd	Aggravated stalking; credible threat.
4303	784.048 (5)	3rd	Aggravated stalking of person under 16.

HB 7049, Engrossed 1

2008

4304	784.07(2)(c)	2nd	Aggravated assault on law enforcement officer.
4305	784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
4306	784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
4307	784.081(2)	2nd	Aggravated assault on specified official or employee.
4308	784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
4309	784.083(2)	2nd	Aggravated assault on code inspector.
4310	787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4311	790.115(2)(d)	2nd	Discharging firearm or weapon on school property.
4312	790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.

4313	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
4314	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
4315	794.011 (8) (a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
4316	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
4317	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.
4318	800.04 (6) (b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
4319	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
4320	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but

less than \$100,000, grand theft in 2nd degree.

4321

812.014 (6) 2nd Theft; property stolen \$3,000 or more; coordination of others.

4322

812.015 (9) (a) 2nd Retail theft; property stolen \$300 or more; second or subsequent conviction.

4323

812.015 (9) (b) 2nd Retail theft; property stolen \$3,000 or more; coordination of others.

4324

812.13 (2) (c) 2nd Robbery, no firearm or other weapon (strong-arm robbery).

4325

817.034 (4) (a) 1. 1st Communications fraud, value greater than \$50,000.

4326

817.4821 (5) 2nd Possess cloning paraphernalia with intent to create cloned cellular telephones.

4327

825.102 (1) 3rd Abuse of an elderly person or disabled adult.

4328

825.102 (3) (c) 3rd Neglect of an elderly person or disabled adult.

4329

HB 7049, Engrossed 1

2008

4330	825.1025 (3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
4331	825.103 (2) (c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4332	827.03 (1)	3rd	Abuse of a child.
4333	827.03 (3) (c)	3rd	Neglect of a child.
4334	827.071 (2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
4335	836.05	2nd	Threats; extortion.
4336	836.10	2nd	Written threats to kill or do bodily injury.
4337	843.12	3rd	Aids or assists person to escape.
4338	847.0135 (2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
	914.23	2nd	Retaliation against a witness, victim,

or informant, with bodily injury.

4339

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.

4340

944.40 2nd Escapes.

4341

944.46 3rd Harboring, concealing, aiding escaped prisoners.

4342

944.47(1)(a)5. 2nd Introduction of contraband (firearm, weapon, or explosive) into correctional facility.

4343

951.22(1) 3rd Intoxicating drug, firearm, or weapon introduced into county facility.

4344

4345 (h) LEVEL 8

4346

Florida	Felony	Description
Statute	Degree	

4347

316.193(3)(c)3.a. 2nd DUI manslaughter.

4348

HB 7049, Engrossed 1

2008

4349	316.1935 (4) (b)	1st	Aggravated fleeing or attempted eluding with serious bodily injury or death.
4350	327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
4351	<u>499.0051 (8)</u> 499.0051 (7)	1st	<u>Knowing</u> forgery of prescription labels or <u>prescription legend</u> drug labels.
4352	<u>499.0051 (7)</u> 499.0052	1st	<u>Knowing</u> trafficking in contraband <u>prescription legend</u> drugs.
4353	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.
4354	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.
4354	655.50 (10) (b) 2.	2nd	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by

			financial institutions.
4355	777.03 (2) (a)	1st	Accessory after the fact, capital felony.
4356	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.
4357	782.051 (2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04 (3).
4358	782.071 (1) (b)	1st	Committing vehicular homicide and failing to render aid or give information.
4359	782.072 (2)	1st	Committing vessel homicide and failing to render aid or give information.
4360	790.161 (3)	1st	Discharging a destructive device which results in bodily harm or

4361			property damage.
	794.011 (5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.
4362			
	794.08 (3)	2nd	Female genital mutilation, removal of a victim younger than 18 years of age from this state.
4363			
	800.04 (4)	2nd	Lewd or lascivious battery.
4364			
	806.01 (1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4365			
	810.02 (2) (a)	1st, PBL	Burglary with assault or battery.
4366			
	810.02 (2) (b)	1st, PBL	Burglary; armed with explosives or dangerous weapon.
4367			
	810.02 (2) (c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
4368			
	812.014 (2) (a) 2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st

			degree.
4369	812.13 (2) (b)	1st	Robbery with a weapon.
4370	812.135 (2) (c)	1st	Home-invasion robbery, no firearm, deadly weapon, or other weapon.
4371	817.568 (6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4372	825.102 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4373	825.1025 (2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4374	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4375	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4376	837.021 (2)	2nd	Making contradictory statements in official proceedings relating to

			prosecution of a capital felony.
4377	860.121(2)(c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
4378	860.16	1st	Aircraft piracy.
4379	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).
4380	893.13(2)(b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4381	893.13(6)(c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4382	893.135(1)(a)2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
4383	893.135(1)(b)1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
4384	893.135(1)(c)1.b.	1st	Trafficking in illegal drugs, more

4385	893.135 (1) (d) 1.b. 1st	than 14 grams, less than 28 grams.
4386	893.135 (1) (e) 1.b. 1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
4387	893.135 (1) (f) 1.b. 1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
4388	893.135 (1) (g) 1.b. 1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4389	893.135 (1) (h) 1.b. 1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4390	893.135 (1) (j) 1.b. 1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4391	893.135 (1) (k) 2.b. 1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4392	895.03 (1) 1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
	895.03 (1) 1st	Use or invest proceeds derived from

4393			pattern of racketeering activity.
	895.03 (2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
4394			
	895.03 (3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.
4395			
	896.101 (5) (b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
4396			
	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.
4397			
4398	(i)	LEVEL 9	
4399			
	Florida Statute	Felony Degree	Description
4400			
	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render

4401			aid or give information.
	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
4402	<u>499.0051 (9)</u>	1st	<u>Knowing</u> sale or purchase of
	499.00535		contraband <u>prescription</u> legend drugs resulting in great bodily harm.
4403	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
4404	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
4405	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4406	775.0844	1st	Aggravated white collar crime.
4407	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
4408			

4409	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4410	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3).
4411	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
4412	787.01 (1) (a) 1.	1st, PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
4413	787.01 (1) (a) 2.	1st, PBL	Kidnapping with intent to commit or facilitate commission of any felony.
4414	787.01 (1) (a) 4.	1st, PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
	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.
4415	790.161	1st	Attempted capital destructive device offense.
4416	790.166 (2)	1st, PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
4417	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
4418	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
4419	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4420	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
4421	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4422			

4423	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4424	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4425	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
4426	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4427	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.
4428	827.03 (2)	1st	Aggravated child abuse.
4429	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
4430	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.

4431	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.
	893.135	1st	Attempted capital trafficking offense.
4432	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
4433	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4434	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4435	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
4436	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4437	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more than 200 grams.
4438			

4439	893.135 (1) (h) 1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
4440	893.135 (1) (j) 1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
4441	893.135 (1) (k) 2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
4442	896.101 (5) (c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
4443	896.104 (4) (a) 3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
4444	(j)	LEVEL 10	
4445	Florida Statute	Felony Degree	Description
4446	<u>499.0051(10)</u>	1st	<u>Knowing</u> sale or purchase of contraband
4447	499.00545		<u>prescription</u> legend drugs resulting in death.

4448 782.04 (2) 1st,PBL Unlawful killing of human; act is
homicide, unpremeditated.

4449 787.01 (1) (a) 3. 1st,PBL Kidnapping; inflict bodily harm upon or
terrorize victim.

4450 787.01 (3) (a) Life Kidnapping; child under age 13,
perpetrator also commits aggravated
child abuse, sexual battery, or lewd or
lascivious battery, molestation,
conduct, or exhibition.

4451 782.07 (3) 1st Aggravated manslaughter of a child.

4452 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.

4453 812.135 (2) (a) 1st,PBL Home-invasion robbery with firearm or
other deadly weapon.

4454 876.32 1st Treason against the state.

4455 Section 44. This act shall take effect July 1, 2008.