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HB 7049, Engrossed 2

2008 Legislature

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

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

30 | conforming provisions to changes made by the act;

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

32 | active pharmaceutical ingredient in bulk form and does not

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

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

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

36 | providing that the section relates only to permits;

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

38 | provider and a health care clinic establishment; providing

39 | requirements for obtaining a permit to operate in certain

40 | capacities; deleting certain permit requirements;

41 | providing an exemption for a nonresident prescription drug

42 | manufacturer permit; providing requirements for such

43 | exemption; providing requirements for a third party

44 | logistics provider permit and a health care clinic

45 | establishment permit; amending and redesignating

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

47 | such functions as provisions of that section; conforming

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

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

50 | relates to permit application requirements; providing that

51 | a separate establishment permit is not required when a

52 | permitted prescription drug wholesale distributor operates

53 | temporary transit storage facilities for the sole purpose

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

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

56 | to such functions as provisions of that section;

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

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

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

120

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

122

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

257 (b) When added or applied to a drug or cosmetic or to the
 258 human body, or any part thereof, is capable alone, or through
 259 reaction with other substances, of imparting color thereto;
 260
 261 ~~except that the term does not include any material which has~~
 262 ~~been or hereafter is exempt under the federal act.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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335 (c) Intended to affect the structure or any function of
 336 the body of humans or other animals; or
 337 (d) Intended for use as a component of any article
 338 specified in paragraph (a), paragraph (b), or paragraph (c), but
 339 does not include devices or their components, parts, or
 340 accessories.
 341 (20)~~(18)~~ "Establishment" means a place of business at one
 342 general physical location.
 343 (21)~~(19)~~ "Federal act" means the Federal Food, Drug, and
 344 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.
 345 (22)~~(20)~~ "Freight forwarder" means a person who receives
 346 prescription legend ~~legend~~ drugs which are owned by another person and
 347 designated by that person for export, and exports those
 348 prescription legend ~~legend~~ drugs.
 349 (23)~~(21)~~ "Health care entity" means a closed pharmacy or
 350 any person, organization, or business entity that provides
 351 diagnostic, medical, surgical, or dental treatment or care, or
 352 chronic or rehabilitative care, but does not include any
 353 wholesale distributor or retail pharmacy licensed under state
 354 law to deal in prescription drugs.
 355 (24)~~(f)~~ "Health care facility" means a health care
 356 facility licensed under chapter 395.
 357 (25)~~(h)~~ "Hospice" means a corporation licensed under part
 358 IV of chapter 400.
 359 (26)~~(i)~~ "Hospital" means a facility as defined in s.
 360 395.002 and licensed under chapter 395.
 361 (27)~~(22)~~ "Immediate container" does not include package
 362 liners.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1012 (a) The refusal or constructive refusal to allow:

1013 1. The department to enter or inspect an establishment in
 1014 which drugs are manufactured, processed, repackaged, sold,
 1015 brokered, or held;

1016 2. Inspection of any record of that establishment;

1017 3. The department to enter and inspect any vehicle that is
 1018 being used to transport drugs; or

1019 4. The department to take samples of any drug.

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

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

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

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

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

- 1037 1. Purchased by a public or private hospital or other
- 1038 health care entity; or
- 1039 2. Donated or supplied at a reduced price to a charitable
- 1040 organization.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 1131 1.~~(a)~~ The packaging of the product.
- 1132 2.~~(b)~~ The name and labeling of the product.

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

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

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

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

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

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

1144 4.~~(d)~~ Cancer.

1145 5.~~(e)~~ Diabetes.

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

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

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

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

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

1152 11.~~(k)~~ Paralysis.

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

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

1155 14.~~(n)~~ Baldness.

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

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

1158 17.~~(q)~~ Tumors.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1264 (a) Adequate directions for use; and

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

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

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

1285 (9)~~(8)~~ If it is:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1337 (b) "Rx Only";

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

1339 or

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

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

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

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

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

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

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

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

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

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1381 for dyeing the eyelashes or eyebrows; to do so may cause
 1382 blindness"; and
 1383 (b) The labeling of which bears adequate directions for
 1384 such preliminary testing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1863

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

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

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

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

1876

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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2047 5. The names of the owner and the operator of the
 2048 establishment, including:
 2049 a. If an individual, the name of the individual;
 2050 b. If a partnership, the name of each partner and the name
 2051 of the partnership;
 2052 c. If a corporation, the name and title of each corporate
 2053 officer and director, the corporate names, and the name of the
 2054 state of incorporation;
 2055 d. If a sole proprietorship, the full name of the sole
 2056 proprietor and the name of the business entity;
 2057 e. If a limited liability company, the name of each
 2058 member, the name of each manager, the name of the limited
 2059 liability company, and the name of the state in which the
 2060 limited liability company was organized; and
 2061 f. Any other relevant information that the department
 2062 requires.
 2063 (b) Upon approval of the application by the department and
 2064 payment of the required fee, the department shall issue a permit
 2065 to the applicant, if the applicant meets the requirements of
 2066 this part ~~ss. 499.001-499.081~~ and rules adopted under this part
 2067 ~~those sections~~.
 2068 (c) Any change in information required under paragraph (a)
 2069 must be submitted to the department before the change occurs.
 2070 (d) The department shall consider, at a minimum, the
 2071 following factors in reviewing the qualifications of persons to
 2072 be permitted under this part ~~ss. 499.001-499.081~~:
 2073 1. The applicant's having been found guilty, regardless of
 2074 adjudication, in a court of this state or other jurisdiction, of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2155 1. Return the permit to the department;

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

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

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

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

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

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

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

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

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

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

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

2186 3. If a corporation:

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

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

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

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

2197 5. If a limited liability company:

2198 a. The name and address of each member.

2199 b. The name and address of each manager.

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

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

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

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

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

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

2227 (h) The tax year of the applicant.

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

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

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

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

2244 (1) The name of each of the applicant's designated
 2245 representatives as required by subsection (16) ~~(11)~~, together
 2246 with the personal information statement and fingerprints
 2247 required pursuant to subsection (9) ~~(4)~~ for each such person.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2660 (2) SECURITY.--

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2771 5. Any financial documentation supporting the transaction.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2911 ~~a. The repackager must:~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3111 499.01212 Pedigree paper.--

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

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

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

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

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

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

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

3130
 3131 The wholesale distributor must also maintain and make available
 3132 to the department, upon request, the point of origin of the
 3133 prescription drugs, including intracompany transfers, the date
 3134 of the shipment from the manufacturer to the wholesale
 3135 distributor, the lot numbers of such drugs, and the invoice
 3136 numbers from the manufacturer.

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

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

3141 2. The lot numbers of the prescription drugs.

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

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

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- 3147 5. An invoice number, a shipping document number, or
 3148 another number uniquely identifying the transaction.
- 3149 6. A certification that the recipient wholesale
 3150 distributor has authenticated the pedigree papers.
- 3151 7. The unique serialization of the prescription drug, if
 3152 the manufacturer or repackager has uniquely serialized the
 3153 individual prescription drug unit.
- 3154 8. The name, address, telephone number, and, if available,
 3155 e-mail contact information of each wholesale distributor
 3156 involved in the chain of the prescription drug's custody.
- 3157 (3) EXCEPTIONS.--A pedigree paper is not required for:
- 3158 (a) The wholesale distribution of a prescription drug by
 3159 the manufacturer or by a third party logistics provider
 3160 performing a wholesale distribution of a prescription drug for a
 3161 manufacturer.
- 3162 (b) The wholesale distribution of a prescription drug by a
 3163 freight forwarder within the authority of a freight forwarder
 3164 permit.
- 3165 (c) The wholesale distribution of a prescription drug by a
 3166 limited prescription drug veterinary wholesale distributor to a
 3167 veterinarian.
- 3168 (d) The wholesale distribution of a compressed medical
 3169 gas.
- 3170 (e) The wholesale distribution of a veterinary
 3171 prescription drug.
- 3172 (f) A drop shipment, provided:
- 3173 1. The wholesale distributor delivers to the recipient of
 3174 the prescription drug, within 14 days after the shipment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3237 1. The repackager must:

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

3246 b. Purchase all prescription drugs it repackages:

3247 (I) Directly from the manufacturer; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3408 499.029 Cancer Drug Donation Program.--

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

3413 (3) As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3506 Section 25. Subsections (1) and (3) of section 499.039,
 3507 Florida Statutes, are amended to read:

3508 499.039 Sale, distribution, or transfer of harmful
 3509 chemical substances; penalties; authority for enforcement.--It
 3510 is unlawful for a person to sell, deliver, or give to a person
 3511 under the age of 18 years any compound, liquid, or chemical
 3512 containing toluol, hexane, trichloroethylene, acetone, toluene,
 3513 ethyl acetate, methyl ethyl ketone, trichloroethane,
 3514 isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl
 3515 ether acetate, cyclohexanone, nitrous oxide, diethyl ether,
 3516 alkyl nitrites (butyl nitrite), or any similar substance for the
 3517 purpose of inducing by breathing, inhaling, or ingesting a
 3518 condition of intoxication or which is intended to distort or
 3519 disturb the auditory, visual, or other physical or mental
 3520 processes.

3521 (1) On the first violation of this section, the department
 3522 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if
 3523 the violation has not caused temporary or permanent physical or
 3524 mental injury to the user.

3525 (3) The department ~~of Health~~ shall adopt rules to
 3526 implement this section.

3527 Section 26. Section 499.04, Florida Statutes, is amended
 3528 to read:

3529 499.04 Fee authority.--The department may collect fees for
 3530 all drug, device, and cosmetic applications, permits, product
 3531 registrations, and free-sale certificates. The total amount of

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3532 fees collected from all permits, applications, product
 3533 registrations, and free-sale certificates must be adequate to
 3534 fund the expenses incurred by the department in carrying out
 3535 this part ~~ss. 499.001-499.081~~. The department shall, by rule,
 3536 establish a schedule of fees that are within the ranges provided
 3537 in this section and shall adjust those fees from time to time
 3538 based on the costs associated with administering this part ~~ss.~~
 3539 ~~499.001-499.081~~. The fees are payable to the department to be
 3540 deposited into the Florida Drug, Device, and Cosmetic Trust Fund
 3541 for the sole purpose of carrying out the provisions of this part
 3542 ~~ss. 499.001-499.081~~.

3543 Section 27. Subsections (1) through (5), (8), and (10) of
 3544 section 499.041, Florida Statutes, are amended to read:

3545 499.041 Schedule of fees for drug, device, and cosmetic
 3546 applications and permits, product registrations, and free-sale
 3547 certificates.--

3548 (1) The department shall assess applicants requiring a
 3549 manufacturing permit an annual fee within the ranges established
 3550 in this section for the specific type of manufacturer.

3551 (a) The fee for a prescription drug manufacturer
 3552 ~~manufacturer's~~ permit may not be less than \$500 or more than
 3553 \$750 annually.

3554 (b) The fee for a device manufacturer ~~manufacturer's~~
 3555 permit may not be less than \$500 or more than \$600 annually.

3556 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~
 3557 permit may not be less than \$250 or more than \$400 annually.

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3558 (d) The fee for an over-the-counter drug manufacturer
 3559 ~~manufacturer's~~ permit may not be less than \$300 or more than
 3560 \$400 annually.

3561 (e) The fee for a compressed medical gas manufacturer
 3562 ~~manufacturer's~~ permit may not be less than \$400 or more than
 3563 \$500 annually.

3564 (f) The fee for a prescription drug repackager
 3565 ~~repackager's~~ permit may not be less than \$500 or more than \$750
 3566 annually.

3567 (g) A manufacturer may not be required to pay more than
 3568 one fee per establishment to obtain an additional manufacturing
 3569 permit, but each manufacturer must pay the highest fee
 3570 applicable to his or her operation in each establishment.

3571 (2) The department shall assess an applicant that is
 3572 required to have a wholesaling permit an annual fee within the
 3573 ranges established in this section for the specific type of
 3574 wholesaling.

3575 (a) The fee for a prescription drug wholesale distributor
 3576 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800
 3577 annually.

3578 (b) The fee for a compressed medical gas wholesale
 3579 distributor ~~wholesaler's~~ permit may not be less than \$200 or
 3580 more than \$300 annually.

3581 (c) The fee for an out-of-state prescription drug
 3582 wholesale distributor ~~wholesaler's~~ permit may not be less than
 3583 \$300 or more than \$800 annually.

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3584 (d) The fee for a nonresident prescription drug
 3585 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or
 3586 more than \$500 annually.

3587 (e) The fee for a retail pharmacy drug wholesale
 3588 distributor ~~wholesaler's~~ permit may not be less than \$35 or more
 3589 than \$50 annually.

3590 (f) The fee for a freight forwarder ~~forwarder's~~ permit may
 3591 not be less than \$200 or more than \$300 annually.

3592 (g) The fee for a veterinary prescription drug wholesale
 3593 distributor ~~wholesaler's~~ permit may not be less than \$300 or
 3594 more than \$500 annually.

3595 (h) The fee for a limited prescription drug veterinary
 3596 wholesale distributor ~~wholesaler's~~ permit may not be less than
 3597 \$300 or more than \$500 annually.

3598 (i) The fee for a third part logistics provider permit may
 3599 not be less than \$200 or more than \$300 annually.

3600 (3) The department shall assess an applicant that is
 3601 required to have a retail establishment permit an annual fee
 3602 within the ranges established in this section for the specific
 3603 type of retail establishment.

3604 (a) The fee for a veterinary prescription ~~legend~~ drug
 3605 retail establishment permit may not be less than \$200 or more
 3606 than \$300 annually.

3607 (b) The fee for a medical oxygen retail establishment
 3608 permit may not be less than \$200 or more than \$300 annually.

3609 (c) The fee for a health care clinic establishment permit
 3610 may not be less than \$125 or more than \$250 annually.

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3611 (4) The department shall assess an applicant that is
 3612 required to have a restricted prescription drug distributor
 3613 ~~distributor's~~ permit an annual fee of not less than \$200 or more
 3614 than \$300.

3615 (5) In addition to the fee charged for a permit required
 3616 by this part ~~ss. 499.001-499.081~~, the department shall assess
 3617 applicants an initial application fee of \$150 for each new
 3618 permit issued by the department which requires an onsite
 3619 inspection.

3620 (8) The department shall assess an out-of-state
 3621 prescription drug wholesale distributor ~~wholesaler~~ applicant or
 3622 permittee an onsite inspection fee of not less than \$1,000 or
 3623 more than \$3,000 annually, to be based on the actual cost of the
 3624 inspection if an onsite inspection is performed by agents of the
 3625 department.

3626 (10) The department shall assess other fees as provided in
 3627 this part ~~ss. 499.001-499.081~~.

3628 Section 28. Section 499.05, Florida Statutes, is amended;
 3629 subsection (3) of section 499.013, Florida Statutes, is
 3630 redesignated as paragraph (k) of subsection (1) of that section
 3631 and amended; paragraph (b) of subsection (2) of section
 3632 499.0122, Florida Statutes, is redesignated as paragraph (1) of
 3633 subsection (1) of that section and amended; and subsection (12)
 3634 of section 499.012, Florida Statutes, is redesignated as
 3635 paragraph (m) of subsection (1) of that section and amended, to
 3636 read:

3637 499.05 Rules.--

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3638 (1) The department shall adopt rules to implement and
 3639 enforce this part ~~ss. 499.001-499.081~~ with respect to:

3640 (a) The definition of terms used in this part ~~ss. 499.001-~~
 3641 ~~499.081~~, and used in the rules adopted under this part ~~ss.~~
 3642 ~~499.001-499.081~~, when the use of the term is not its usual and
 3643 ordinary meaning.

3644 (b) Labeling requirements for drugs, devices, and
 3645 cosmetics.

3646 (c) The establishment of fees authorized in this part ~~ss.~~
 3647 ~~499.001-499.081~~.

3648 (d) The identification of permits that require an initial
 3649 application and onsite inspection or other prerequisites for
 3650 permitting which demonstrate that the establishment and person
 3651 are in compliance with the requirements of this part ~~ss.~~
 3652 ~~499.001-499.081~~.

3653 (e) The application processes and forms for product
 3654 registration.

3655 (f) Procedures for requesting and issuing certificates of
 3656 free sale.

3657 (g) Inspections and investigations conducted under s.
 3658 499.051, and the identification of information claimed to be a
 3659 trade secret and exempt from the public records law as provided
 3660 in s. 499.051(7).

3661 (h) The establishment of a range of penalties, as provided
 3662 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of
 3663 the potential impact of a violation of this part ~~ss. 499.001-~~
 3664 ~~499.081~~; and a process for the uncontested settlement of alleged
 3665 violations.

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3666 (i) Additional conditions that qualify as an emergency
 3667 medical reason under s. 499.003(53)(b)2. ~~s. 499.012(1)(a)2.b.~~

3668 (j) Procedures and forms relating to the pedigree paper
 3669 requirement of s. 499.01212.

3670 ~~(k)(3) The department may adopt such rules as are~~
 3671 ~~necessary for~~ The protection of the public health, safety, and
 3672 welfare regarding good manufacturing practices that
 3673 manufacturers and repackagers must follow to ensure the safety
 3674 of the products.

3675 ~~(l)(b) The department shall adopt rules relating to~~
 3676 Information required from each retail establishment pursuant to
 3677 s. 499.012(3) ~~s. 499.01(4)~~, including requirements for
 3678 prescriptions or orders.

3679 ~~(m)(12) The department may adopt rules governing~~ The
 3680 recordkeeping, storage, and handling with respect to each of the
 3681 distributions of prescription drugs specified in s.
 3682 499.003(53)(a)-(d) subparagraphs (1)(a)1-4.

3683 (n) Alternatives to compliance with s. 499.01212 for a
 3684 prescription drug in the inventory of a permitted prescription
 3685 drug wholesale distributor as of June 30, 2006, and the return
 3686 of a prescription drug purchased prior to July 1, 2006. The
 3687 department may specify time limits for such alternatives.

3688 (2) With respect to products in interstate commerce, those
 3689 rules must not be inconsistent with rules and regulations of
 3690 federal agencies unless specifically otherwise directed by the
 3691 Legislature.

3692 (3) The department shall adopt rules regulating
 3693 recordkeeping for and the storage, handling, and distribution of

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3694 medical devices and over-the-counter drugs to protect the public
 3695 from adulterated products.

3696 Section 29. Section 499.051, Florida Statutes, is amended
 3697 to read:

3698 499.051 Inspections and investigations.--

3699 (1) The agents of the department ~~of Health~~ and of the
 3700 Department of Law Enforcement, after they present proper
 3701 identification, may inspect, monitor, and investigate any
 3702 establishment permitted pursuant to this part ~~ss. 499.001-~~
 3703 ~~499.081~~ during business hours for the purpose of enforcing this
 3704 part ~~ss. 499.001-499.081~~, chapters 465, 501, and 893, and the
 3705 rules of the department that protect the public health, safety,
 3706 and welfare.

3707 (2) In addition to the authority set forth in subsection
 3708 (1), the department and any duly designated officer or employee
 3709 of the department may enter and inspect any other establishment
 3710 for the purpose of determining compliance with this part ~~ss.~~
 3711 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~
 3712 regarding any drug, device, or cosmetic product.

3713 (3) Any application for a permit or product registration
 3714 or for renewal of such permit or registration made pursuant to
 3715 this part ~~ss. 499.001-499.081~~ and rules adopted under this part
 3716 ~~those sections~~ constitutes permission for any entry or
 3717 inspection of the premises in order to verify compliance with
 3718 this part ~~those sections~~ and rules; to discover, investigate,
 3719 and determine the existence of compliance; or to elicit,
 3720 receive, respond to, and resolve complaints and violations.

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3721 (4) Any application for a permit made pursuant to s.
 3722 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that
 3723 section ~~those sections~~ constitutes permission for agents of the
 3724 department ~~of Health~~ and the Department of Law Enforcement,
 3725 after presenting proper identification, to inspect, review, and
 3726 copy any financial document or record related to the
 3727 manufacture, repackaging, or distribution of a drug as is
 3728 necessary to verify compliance with this part ~~ss. 499.001-~~
 3729 ~~499.081~~ and the rules adopted by the department to administer
 3730 this part ~~those sections~~, in order to discover, investigate, and
 3731 determine the existence of compliance, or to elicit, receive,
 3732 respond to, and resolve complaints and violations.

3733 (5) The authority to inspect under this section includes
 3734 the authority to access, review, and copy any and all financial
 3735 documents related to the activity of manufacturing, repackaging,
 3736 or distributing prescription drugs.

3737 (6) The authority to inspect under this section includes
 3738 the authority to secure:

3739 (a) Samples or specimens of any drug, device, or cosmetic;
 3740 or

3741 (b) Such other evidence as is needed for any action to
 3742 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted
 3743 under this part ~~those sections~~.

3744 (7) The complaint and all information obtained pursuant to
 3745 the investigation by the department are confidential and exempt
 3746 from ~~the provisions of~~ s. 119.07(1) and s. 24(a), Art. I of the
 3747 State Constitution until the investigation and the enforcement
 3748 action are completed. However, trade secret information

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3749 contained therein as defined by s. 812.081(1)(c) shall remain
 3750 confidential and exempt from the provisions of s. 119.07(1) and
 3751 s. 24(a), Art. I of the State Constitution, as long as the
 3752 information is retained by the department. This subsection does
 3753 not prohibit the department from using such information for
 3754 regulatory or enforcement proceedings under this chapter or from
 3755 providing such information to any law enforcement agency or any
 3756 other regulatory agency. However, the receiving agency shall
 3757 keep such records confidential and exempt as provided in this
 3758 subsection. In addition, this subsection is not intended to
 3759 prevent compliance with the provisions of s. 499.01212 ~~s.~~
 3760 ~~499.0121(6)(d)~~, and the pedigree papers required in that section
 3761 ~~subsection~~ shall not be deemed a trade secret.

3762 Section 30. Section 499.052, Florida Statutes, is amended
 3763 to read:

3764 499.052 Records of interstate shipment.--For the purpose
 3765 of enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in
 3766 interstate commerce and persons receiving drugs, devices, or
 3767 cosmetics in interstate commerce must, upon the request, in the
 3768 manner set out below, by an officer or employee duly designated
 3769 by the department, permit the officer or employee to have access
 3770 to and to copy all records showing the movement in interstate
 3771 commerce of any drug, device, or cosmetic, and the quantity,
 3772 shipper, and consignee thereof.

3773 Section 31. Subsection (4) of section 499.055, Florida
 3774 Statutes, is amended to read:

3775 499.055 Reports and dissemination of information by
 3776 department.--

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3777 (4) The department shall publish on the department's
 3778 website and update at least monthly:

3779 (a) A list of the prescription drug wholesale distributors
 3780 ~~wholesalers~~, out-of-state prescription drug wholesale
 3781 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
 3782 distributors ~~wholesalers~~ against whom the department has
 3783 initiated enforcement action pursuant to this part ~~ss. 499.001-~~
 3784 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or
 3785 otherwise file an administrative complaint and the permit number
 3786 of each such wholesale distributor ~~wholesaler~~.

3787 (b) A list of the prescription drug wholesale distributors
 3788 ~~wholesalers~~, out-of-state prescription drug wholesale
 3789 distributors ~~wholesalers~~, and retail pharmacy drug wholesale
 3790 distributors ~~wholesalers~~ to which the department has issued a
 3791 permit, including the date on which each permit will expire.

3792 (c) A list of the prescription drug wholesale distributor
 3793 ~~wholesalers~~, out-of-state prescription drug wholesale
 3794 distributor ~~wholesalers~~, and retail pharmacy drug wholesale
 3795 distributor ~~wholesalers~~ permits that have been returned to the
 3796 department, were suspended, were revoked, have expired, or were
 3797 not renewed in the previous year.

3798 Section 32. Subsections (1) and (3) of section 499.06,
 3799 Florida Statutes, are amended to read:

3800 499.06 Embargoing, detaining, or destroying article or
 3801 processing equipment which is in violation of law or rule.--

3802 (1) When a duly authorized agent of the department finds,
 3803 or has probable cause to believe, that any drug, device, or
 3804 cosmetic is in violation of any provision of this part ~~ss-~~

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3805 ~~499.001-499.081~~ or any rule adopted under this part ~~such~~
 3806 ~~sections~~ so as to be dangerous, unwholesome, or fraudulent
 3807 within the meaning of this part ~~ss. 499.001-499.081~~, she or he
 3808 may issue and enforce a stop-sale, stop-use, removal, or hold
 3809 order, which order gives notice that such article or processing
 3810 equipment is, or is suspected of being, in violation and has
 3811 been detained or embargoed, and which order warns all persons
 3812 not to remove, use, or dispose of such article or processing
 3813 equipment by sale or otherwise until permission for removal,
 3814 use, or disposal is given by such agent or the court. It is
 3815 unlawful for any person to remove, use, or dispose of such
 3816 detained or embargoed article or processing equipment by sale or
 3817 otherwise without such permission; and such act is a felony of
 3818 the second degree, punishable as provided in s. 775.082, s.
 3819 775.083, or s. 775.084.

3820 (3) If the court finds that the detained or embargoed
 3821 article or processing equipment is in violation, such article or
 3822 processing equipment shall, after entry of the court order, be
 3823 destroyed or made sanitary at the expense of the claimant
 3824 thereof, under the supervision of such agent; and all court
 3825 costs, fees, and storage and other proper expenses shall be
 3826 taxed against the claimant of such article or processing
 3827 equipment or her or his agent. However, when the violation can
 3828 be corrected by proper labeling of the article or sanitizing of
 3829 the processing equipment, and after such costs, fees, and
 3830 expenses have been paid and a good and sufficient bond,
 3831 conditioned that such article be so labeled or processed or such
 3832 processing equipment be so sanitized, has been executed, the

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3833 court may by order direct that such article or processing
 3834 equipment be delivered to the claimant thereof for such
 3835 labeling, processing, or sanitizing, under the supervision of an
 3836 agent of the department. The expense of such supervision shall
 3837 be paid by the claimant. Such bond shall be returned to the
 3838 claimant of the article or processing equipment upon
 3839 representation to the court by the department that the article
 3840 or processing equipment is no longer in violation of this part
 3841 ~~ss. 499.001-499.081~~ and that the expenses of such supervision
 3842 have been paid.

3843 Section 33. Section 499.062, Florida Statutes, is amended;
 3844 section 499.063, Florida Statutes, is redesignated as section
 3845 (2) of that section and amended; and section 499.064, Florida
 3846 Statutes, is redesignated as paragraphs (a) and (b) of
 3847 subsection (2) of that section and amended, to read:

3848 499.062 ~~Cause for~~ Seizure and condemnation of drugs,
 3849 devices, or cosmetics.--

3850 (1) Any article of any drug, device, or cosmetic that is
 3851 adulterated or misbranded under this part ~~ss. 499.001-499.081~~ is
 3852 subject to seizure and condemnation by the department or by its
 3853 duly authorized agents designated for that purpose in regard to
 3854 drugs, devices, or cosmetics.

3855 (2) ~~499.063 Seizure; procedure; prohibition on sale or~~
 3856 ~~disposal of article; penalty.~~ Whenever a duly authorized
 3857 officer or employee of the department finds cause, or has
 3858 probable cause to believe that cause exists, for the seizure of
 3859 any drug, device, or cosmetic, as set out in this part ~~ss.~~
 3860 ~~499.001-499.081~~, he or she shall affix to the article a tag,

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3861 stamp, or other appropriate marking, giving notice that the
 3862 article is, or is suspected of being, subject to seizure under
 3863 this part ss. ~~499.001-499.081~~ and that the article has been
 3864 detained and seized by the department. Such officer or employee
 3865 shall also warn all persons not to remove or dispose of the
 3866 article, by sale or otherwise, until permission is given by the
 3867 department or the court. Any person who violates this subsection
 3868 ~~section~~ is guilty of a felony of the second degree, punishable
 3869 as provided in s. 775.082, s. 775.083, or s. 775.084.

3870 (a) ~~499.064~~ Condemnation and sale; release of seized
 3871 article. ~~(1)~~ When any article detained or seized under this
 3872 subsection s. ~~499.063~~ has been found by the department to be
 3873 subject to seizure and condemnation ~~under s. ~~499.063~~~~, the
 3874 department shall petition the court for an order of condemnation
 3875 or sale, as the court directs. The proceeds of the sale of
 3876 drugs, devices, and cosmetics, less the legal costs and charges,
 3877 shall be deposited into the Florida Drug, Device, and Cosmetic
 3878 Trust Fund.

3879 (b) ~~(2)~~ If the department finds that any article seized
 3880 under this subsection s. ~~499.063~~ was not subject to seizure
 3881 ~~under that section~~, the department or the designated officer or
 3882 employee shall remove the tag or marking.

3883 Section 34. Section 499.065, Florida Statutes, is amended
 3884 to read:

3885 499.065 Inspections; imminent danger.--

3886 (1) Notwithstanding s. 499.051, the department shall
 3887 inspect each prescription drug wholesale distributor
 3888 establishment, prescription drug repackager establishment,

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3889 | veterinary prescription drug wholesale distributor
 3890 | establishment, limited prescription drug veterinary wholesale
 3891 | distributor ~~wholesaler~~ establishment, and retail pharmacy drug
 3892 | wholesale distributor ~~wholesaler~~ establishment that is required
 3893 | to be permitted under this part ~~chapter~~ as often as necessary to
 3894 | ensure compliance with applicable laws and rules. The department
 3895 | shall have the right of entry and access to these facilities at
 3896 | any reasonable time.

3897 | (2) To protect the public from prescription drugs that are
 3898 | adulterated or otherwise unfit for human or animal consumption,
 3899 | the department may examine, sample, seize, and stop the sale or
 3900 | use of prescription drugs to determine the condition of those
 3901 | drugs. The department may immediately seize and remove any
 3902 | prescription drugs if the State Surgeon General or his or her
 3903 | designee determines that the prescription drugs represent a
 3904 | threat to the public health. The owner of any property seized
 3905 | under this section may, within 10 days after the seizure, apply
 3906 | to a court of competent jurisdiction for whatever relief is
 3907 | appropriate. At any time after 10 days, the department may
 3908 | destroy the drugs as contraband.

3909 | (3) The department may determine that a prescription drug
 3910 | wholesale distributor establishment, prescription drug
 3911 | repackager establishment, veterinary prescription drug wholesale
 3912 | distributor establishment, limited prescription drug veterinary
 3913 | wholesale distributor ~~wholesaler~~ establishment, or retail
 3914 | pharmacy drug wholesale distributor ~~wholesaler~~ establishment
 3915 | that is required to be permitted under this part ~~chapter~~ is an
 3916 | imminent danger to the public health and shall require its

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3917 immediate closure if the establishment fails to comply with
 3918 applicable laws and rules and, because of the failure, presents
 3919 an imminent threat to the public's health, safety, or welfare.
 3920 Any establishment so deemed and closed shall remain closed until
 3921 allowed by the department or by judicial order to reopen.

3922 (4) For purposes of this section, a refusal to allow entry
 3923 to the department for inspection at reasonable times, or a
 3924 failure or refusal to provide the department with required
 3925 documentation for purposes of inspection, constitutes an
 3926 imminent danger to the public health.

3927 Section 35. Subsections (1) through (4) of section
 3928 499.066, Florida Statutes, are amended to read:

3929 499.066 Penalties; remedies.--In addition to other
 3930 penalties and other enforcement provisions:

3931 (1) The department may institute such suits or other legal
 3932 proceedings as are required to enforce any provision of this
 3933 part ss. 499.001-499.081. If it appears that a person has
 3934 violated any provision of this part ss. 499.001-499.081 for
 3935 which criminal prosecution is provided, the department may
 3936 provide the appropriate state attorney or other prosecuting
 3937 agency having jurisdiction with respect to such prosecution with
 3938 the relevant information in the department's possession.

3939 (2) If any person engaged in any activity covered by this
 3940 part ss. 499.001-499.081 violates any provision of this part
 3941 ~~those sections~~, any rule adopted under this part ~~those sections~~,
 3942 or a cease and desist order as provided by this part ~~those~~
 3943 ~~sections~~, the department may obtain an injunction in the circuit
 3944 court of the county in which the violation occurred or in which

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3945 | the person resides or has its principal place of business, and
 3946 | may apply in that court for such temporary and permanent orders
 3947 | as the department considers necessary to restrain the person
 3948 | from engaging in any such activities until the person complies
 3949 | with this part ~~ss. 499.001-499.081~~, the rules adopted under this
 3950 | part ~~those sections~~, and the orders of the department authorized
 3951 | by this part ~~those sections~~ or to mandate compliance with this
 3952 | part ~~ss. 499.001-499.081~~, the rules adopted under this part
 3953 | ~~those sections~~, and any order or permit issued by the department
 3954 | under this part ~~those sections~~.

3955 | (3) The department may impose an administrative fine, not
 3956 | to exceed \$5,000 per violation per day, for the violation of any
 3957 | provision of this part ~~ss. 499.001-499.081~~ or rules adopted
 3958 | under this part ~~those sections~~. Each day a violation continues
 3959 | constitutes a separate violation, and each separate violation is
 3960 | subject to a separate fine. All amounts collected pursuant to
 3961 | this section shall be deposited into the Florida Drug, Device,
 3962 | and Cosmetic Trust Fund and are appropriated for the use of the
 3963 | department in administering this part ~~ss. 499.001-499.081~~. In
 3964 | determining the amount of the fine to be levied for a violation,
 3965 | the department shall consider:

- 3966 | (a) The severity of the violation;
- 3967 | (b) Any actions taken by the person to correct the
 3968 | violation or to remedy complaints; and
- 3969 | (c) Any previous violations.
- 3970 | (4) The department shall deposit any rewards, fines, or
 3971 | collections that are due the department and which derive from
 3972 | joint enforcement activities with other state and federal

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3973 agencies which relate to this part ~~ss. 499.001-499.081~~, chapter
 3974 893, or the federal act, into the Florida Drug, Device, and
 3975 Cosmetic Trust Fund. The proceeds of those rewards, fines, and
 3976 collections are appropriated for the use of the department in
 3977 administering this part ~~ss. 499.001-499.081~~.

3978 Section 36. Section 499.0661, Florida Statutes, is amended
 3979 to read:

3980 499.0661 Cease and desist orders; removal of certain
 3981 persons.--

3982 (1)~~(2)~~ CEASE AND DESIST ORDERS.--

3983 (a) In addition to any authority otherwise provided in
 3984 this chapter, the department may issue and serve a complaint
 3985 stating charges upon any permittee or upon any affiliated party,
 3986 whenever the department has reasonable cause to believe that the
 3987 person or individual named therein is engaging in or has engaged
 3988 in conduct that is:

3989 1. An act that demonstrates a lack of fitness or
 3990 trustworthiness to engage in the business authorized under the
 3991 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
 3992 hazardous to the public health, or constitutes business
 3993 operations that are a detriment to the public health;

3994 2. A violation of any provision of this part ~~ss. 499.001-~~
 3995 ~~499.081~~;

3996 3. A violation of any rule of the department;

3997 4. A violation of any order of the department; or

3998 5. A breach of any written agreement with the department.

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3999 (b) The complaint must contain a statement of facts and
 4000 notice of opportunity for a hearing pursuant to ss. 120.569 and
 4001 120.57.

4002 (c) If a hearing is not requested within the time allowed
 4003 by ss. 120.569 and 120.57, or if a hearing is held and the
 4004 department finds that any of the charges are proven, the
 4005 department may enter an order directing the permittee or the
 4006 affiliated party named in the complaint to cease and desist from
 4007 engaging in the conduct complained of and take corrective action
 4008 to remedy the effects of past improper conduct and assure future
 4009 compliance.

4010 (d) A contested or default cease and desist order is
 4011 effective when reduced to writing and served upon the permittee
 4012 or affiliated party named therein. An uncontested cease and
 4013 desist order is effective as agreed.

4014 (e) Whenever the department finds that conduct described
 4015 in paragraph (a) is likely to cause an immediate threat to the
 4016 public health, it may issue an emergency cease and desist order
 4017 requiring the permittee or any affiliated party to immediately
 4018 cease and desist from engaging in the conduct complained of and
 4019 to take corrective and remedial action. The emergency order is
 4020 effective immediately upon service of a copy of the order upon
 4021 the permittee or affiliated party named therein and remains
 4022 effective for 90 days. If the department begins nonemergency
 4023 cease and desist proceedings under this subsection, the
 4024 emergency order remains effective until the conclusion of the
 4025 proceedings under ss. 120.569 and 120.57.

4026 (2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

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4027 (a) The department may issue and serve a complaint stating
4028 charges upon any affiliated party and upon the permittee
4029 involved whenever the department has reason to believe that an
4030 affiliated party is engaging in or has engaged in conduct that
4031 constitutes:

4032 1. An act that demonstrates a lack of fitness or
4033 trustworthiness to engage in the business authorized under the
4034 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is
4035 hazardous to the public health, or constitutes business
4036 operations that are a detriment to the public health;

4037 2. A willful violation of this part ~~ss. 499.001-499.081~~;
4038 however, if the violation constitutes a misdemeanor, a complaint
4039 may not be served as provided in this section until the
4040 affiliated party is notified in writing of the matter of the
4041 violation and has been afforded a reasonable period of time, as
4042 set forth in the notice, to correct the violation and has failed
4043 to do so;

4044 3. A violation of any other law involving fraud or moral
4045 turpitude which constitutes a felony;

4046 4. A willful violation of any rule of the department;

4047 5. A willful violation of any order of the department; or

4048 6. A material misrepresentation of fact, made knowingly
4049 and willfully or made with reckless disregard for the truth of
4050 the matter.

4051 (b) The complaint must contain a statement of facts and
4052 notice of opportunity for a hearing pursuant to ss. 120.569 and
4053 120.57.

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4054 (c) If a hearing is not requested within the time allotted
4055 by ss. 120.569 and 120.57, or if a hearing is held and the
4056 department finds that any of the charges in the complaint are
4057 proven true, the department may enter an order removing the
4058 affiliated party or restricting or prohibiting participation by
4059 the person in the affairs of that permittee or of any other
4060 permittee.

4061 (d) A contested or default order of removal, restriction,
4062 or prohibition is effective when reduced to writing and served
4063 on the permittee and the affiliated party. An uncontested order
4064 of removal, restriction, or prohibition is effective as agreed.

4065 (e)1. The chief executive officer, designated
4066 representative, or the person holding the equivalent office, of
4067 a permittee shall promptly notify the department if she or he
4068 has actual knowledge that any affiliated party is charged with a
4069 felony in a state or federal court.

4070 2. Whenever any affiliated party is charged with a felony
4071 in a state or federal court or with the equivalent of a felony
4072 in the courts of any foreign country with which the United
4073 States maintains diplomatic relations, and the charge alleges
4074 violation of any law involving prescription drugs,
4075 pharmaceuticals, fraud, theft, or moral turpitude, the
4076 department may enter an emergency order suspending the
4077 affiliated party or restricting or prohibiting participation by
4078 the affiliated party in the affairs of the particular permittee
4079 or of any other permittee upon service of the order upon the
4080 permittee and the affiliated party charged. The order must
4081 contain notice of opportunity for a hearing pursuant to ss.

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4082 120.569 and 120.57, where the affiliated party may request a
4083 postsuspension hearing to show that continued service to or
4084 participation in the affairs of the permittee does not pose a
4085 threat to the public health or the interests of the permittee
4086 and does not threaten to impair public confidence in the
4087 permittee. In accordance with applicable departmental rules, the
4088 department shall notify the affiliated party whether the order
4089 suspending or prohibiting the person from participation in the
4090 affairs of a permittee will be rescinded or otherwise modified.
4091 The emergency order remains in effect, unless otherwise modified
4092 by the department, until the criminal charge is disposed of. The
4093 acquittal of the person charged, or the final, unappealed
4094 dismissal of all charges against the person, dissolves the
4095 emergency order but does not prohibit the department from
4096 instituting proceedings under paragraph (a). If the person
4097 charged is convicted or pleads guilty or nolo contendere,
4098 whether or not an adjudication of guilt is entered by the court,
4099 the emergency order shall become final.

4100 (f) Any affiliated party removed pursuant to this section
4101 is not eligible for reemployment by the permittee or to be an
4102 affiliated party of any permittee except upon the written
4103 consent of the department. Any affiliated party who is removed,
4104 restricted, or prohibited from participating in the affairs of a
4105 permittee pursuant to this section may petition the department
4106 for modification or termination of the removal, restriction, or
4107 prohibition.

4108 Section 37. Section 499.067, Florida Statutes, is amended
4109 to read:

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4110 499.067 Denial, suspension, or revocation of permit,
 4111 certification, or registration.--

4112 (1) (a) The department may deny, suspend, or revoke a
 4113 permit if it finds that there has been a substantial failure to
 4114 comply with this part ~~ss. 499.001-499.081~~ or chapter 465,
 4115 chapter 501, or chapter 893, the rules adopted under this part
 4116 ~~any of those sections~~ or those chapters, any final order of the
 4117 department, or applicable federal laws or regulations or other
 4118 state laws or rules governing drugs, devices, or cosmetics.

4119 (b) The department may deny an application for a permit or
 4120 certification, or suspend or revoke a permit or certification,
 4121 if the department finds that:

4122 1. The applicant is not of good moral character or that it
 4123 would be a danger or not in the best interest of the public
 4124 health, safety, and welfare if the applicant were issued a
 4125 permit or certification.

4126 2. The applicant has not met the requirements for the
 4127 permit or certification.

4128 3. The applicant is not eligible for a permit or
 4129 certification for any of the reasons enumerated in s. 499.012 ~~s.~~
 4130 ~~499.01 or s. 499.012(5)~~.

4131 4. The applicant, permittee, or person certified under s.
 4132 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions
 4133 enumerated in s. 499.012 ~~s. 499.01 or s. 499.012(5)~~.

4134 5. The applicant, permittee, or person certified under s.
 4135 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.
 4136 499.005-499.0054.

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4137 (2) The department may deny, suspend, or revoke any
 4138 registration required by the provisions of this part ~~ss.~~
 4139 ~~499.001-499.081~~ for the violation of any provision of this part
 4140 ~~ss. 499.001-499.081~~ or of any rules adopted under this part
 4141 ~~those sections.~~

4142 (3) The department may revoke or suspend a permit:

4143 (a) If the permit was obtained by misrepresentation or
 4144 fraud or through a mistake of the department;

4145 (b) If the permit was procured, or attempted to be
 4146 procured, for any other person by making or causing to be made
 4147 any false representation; or

4148 (c) If the permittee has violated any provision of this
 4149 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~those~~
 4150 ~~sections.~~

4151 (4) If any permit issued under this part ~~ss. 499.001-~~
 4152 ~~499.081~~ is revoked or suspended, the owner, manager, operator,
 4153 or proprietor of the establishment shall cease to operate as the
 4154 permit authorized, from the effective date of the suspension or
 4155 revocation until the person is again registered with the
 4156 department and possesses the required permit. If a permit is
 4157 revoked or suspended, the owner, manager, or proprietor shall
 4158 remove all signs and symbols that identify the operation as
 4159 premises permitted as a drug wholesaling establishment; drug,
 4160 device, or cosmetic manufacturing establishment; or retail
 4161 establishment. The department shall determine the length of time
 4162 for which the permit is to be suspended. If a permit is revoked,
 4163 the person that owns or operates the establishment may not apply
 4164 for any permit under this part ~~ss. 499.001-499.081~~ for a period

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4165 of 1 year after the date of the revocation. A revocation of a
 4166 permit may be permanent if the department considers that to be
 4167 in the best interest of the public health.

4168 (5) The department may deny, suspend, or revoke a permit
 4169 issued under this part ~~ss. 499.001-499.081~~ which authorizes the
 4170 permittee to purchase prescription drugs, if any owner, officer,
 4171 employee, or other person who participates in administering or
 4172 operating the establishment has been found guilty of any
 4173 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,
 4174 chapter 501, or chapter 893, any rules adopted under this part
 4175 ~~any of those sections~~ or those chapters, or any federal or state
 4176 drug law, regardless of whether the person has been pardoned,
 4177 had her or his civil rights restored, or had adjudication
 4178 withheld.

4179 (6) The department shall deny, suspend, or revoke the
 4180 permit of any person or establishment if the assignment, sale,
 4181 transfer, or lease of an establishment permitted under this part
 4182 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil
 4183 action, or criminal prosecution.

4184 (7) Notwithstanding s. 120.60(5), if a permittee fails to
 4185 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may
 4186 revoke the permit of the permittee and shall provide notice of
 4187 the intended agency action by posting a notice at the
 4188 department's headquarters and by mailing a copy of the notice of
 4189 intended agency action by certified mail to the most recent
 4190 mailing address on record with the department and, if the
 4191 permittee is not a natural person, to the permittee's registered
 4192 agent on file with the Department of State.

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4193 Section 38. Paragraph (a) of subsection (1) of section
 4194 409.9201, Florida Statutes, is amended to read:

4195 409.9201 Medicaid fraud.--

4196 (1) As used in this section, the term:

4197 (a) "Prescription Legend drug" means any drug, including,
 4198 but not limited to, finished dosage forms or active ingredients
 4199 that are subject to, defined by, or described by s. 503(b) of
 4200 the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s.
 4201 499.007(13) ~~s. 499.007(12)~~, or s. 499.003(45) or (52) ~~s.~~
 4202 ~~499.0122(1)(b) or (c)~~.

4203
 4204 The value of individual items of the legend drugs or goods or
 4205 services involved in distinct transactions committed during a
 4206 single scheme or course of conduct, whether involving a single
 4207 person or several persons, may be aggregated when determining
 4208 the punishment for the offense.

4209 Section 39. Paragraph (c) of subsection (9) of section
 4210 460.403, Florida Statutes, is amended to read:

4211 460.403 Definitions.--As used in this chapter, the term:

4212 (9)

4213 (c)1. Chiropractic physicians may adjust, manipulate, or
 4214 treat the human body by manual, mechanical, electrical, or
 4215 natural methods; by the use of physical means or physiotherapy,
 4216 including light, heat, water, or exercise; by the use of
 4217 acupuncture; or by the administration of foods, food
 4218 concentrates, food extracts, and items for which a prescription
 4219 is not required and may apply first aid and hygiene, but
 4220 chiropractic physicians are expressly prohibited from

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4221 prescribing or administering to any person any legend drug
 4222 except as authorized under subparagraph 2., from performing any
 4223 surgery except as stated herein, or from practicing obstetrics.

4224 2. Notwithstanding the prohibition against prescribing and
 4225 administering legend drugs under subparagraph 1.7 or s.
 4226 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic
 4227 physicians may order, store, and administer, for emergency
 4228 purposes only at the chiropractic physician's office or place of
 4229 business, prescription medical oxygen and may also order, store,
 4230 and administer the following topical anesthetics in aerosol
 4231 form:

4232 a. Any solution consisting of 25 percent ethylchloride and
 4233 75 percent dichlorodifluoromethane.

4234 b. Any solution consisting of 15 percent
 4235 dichlorodifluoromethane and 85 percent
 4236 trichloromonofluoromethane.

4237
 4238 However, this paragraph does not authorize a chiropractic
 4239 physician to prescribe medical oxygen as defined in chapter 499.

4240 Section 40. Subsection (3) of section 465.0265, Florida
 4241 Statutes, is amended to read:

4242 465.0265 Centralized prescription filling.--

4243 (3) The filling, delivery, and return of a prescription by
 4244 one pharmacy for another pursuant to this section shall not be
 4245 construed as the filling of a transferred prescription as set
 4246 forth in s. 465.026 or as a wholesale distribution as set forth
 4247 in s. 499.003(53) ~~s. 499.012(1)(a)~~.

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4248 Section 41. Section 794.075, Florida Statutes, is amended
 4249 to read:

4250 794.075 Sexual predators; erectile dysfunction drugs.--

4251 (1) A person may not possess a prescription drug, as
 4252 defined in s. 499.003(42) ~~s. 499.003(25)~~, for the purpose of
 4253 treating erectile dysfunction if the person is designated as a
 4254 sexual predator under s. 775.21.

4255 (2) A person who violates a provision of this section for
 4256 the first time commits a misdemeanor of the second degree,
 4257 punishable as provided in s. 775.082 or s. 775.083. A person who
 4258 violates a provision of this section a second or subsequent time
 4259 commits a misdemeanor of the first degree, punishable as
 4260 provided in s. 775.082 or s. 775.083.

4261 Section 42. Paragraph (a) of subsection (1) of section
 4262 895.02, Florida Statutes, is amended to read:

4263 895.02 Definitions.--As used in ss. 895.01-895.08, the
 4264 term:

4265 (1) "Racketeering activity" means to commit, to attempt to
 4266 commit, to conspire to commit, or to solicit, coerce, or
 4267 intimidate another person to commit:

4268 (a) Any crime that is chargeable by indictment or
 4269 information under the following provisions of the Florida
 4270 Statutes:

4271 1. Section 210.18, relating to evasion of payment of
 4272 cigarette taxes.

4273 2. Section 403.727(3)(b), relating to environmental
 4274 control.

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- 4275 | 3. Section 409.920 or s. 409.9201, relating to Medicaid
- 4276 | fraud.
- 4277 | 4. Section 414.39, relating to public assistance fraud.
- 4278 | 5. Section 440.105 or s. 440.106, relating to workers'
- 4279 | compensation.
- 4280 | 6. Section 443.071(4), relating to creation of a
- 4281 | fictitious employer scheme to commit unemployment compensation
- 4282 | fraud.
- 4283 | 7. Section 465.0161, relating to distribution of medicinal
- 4284 | drugs without a permit as an Internet pharmacy.
- 4285 | 8. Section 499.0051 ~~Sections 499.0051, 499.0052,~~
- 4286 | ~~499.00535, 499.00545, and 499.0691,~~ relating to crimes involving
- 4287 | contraband and adulterated drugs.
- 4288 | 9. Part IV of chapter 501, relating to telemarketing.
- 4289 | 10. Chapter 517, relating to sale of securities and
- 4290 | investor protection.
- 4291 | 11. Section 550.235, s. 550.3551, or s. 550.3605, relating
- 4292 | to dogracing and horseracing.
- 4293 | 12. Chapter 550, relating to jai alai frontons.
- 4294 | 13. Section 551.109, relating to slot machine gaming.
- 4295 | 14. Chapter 552, relating to the manufacture,
- 4296 | distribution, and use of explosives.
- 4297 | 15. Chapter 560, relating to money transmitters, if the
- 4298 | violation is punishable as a felony.
- 4299 | 16. Chapter 562, relating to beverage law enforcement.
- 4300 | 17. Section 624.401, relating to transacting insurance
- 4301 | without a certificate of authority, s. 624.437(4)(c)1., relating
- 4302 | to operating an unauthorized multiple-employer welfare

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4303 arrangement, or s. 626.902(1)(b), relating to representing or
 4304 aiding an unauthorized insurer.

4305 18. Section 655.50, relating to reports of currency
 4306 transactions, when such violation is punishable as a felony.

4307 19. Chapter 687, relating to interest and usurious
 4308 practices.

4309 20. Section 721.08, s. 721.09, or s. 721.13, relating to
 4310 real estate timeshare plans.

4311 21. Chapter 782, relating to homicide.

4312 22. Chapter 784, relating to assault and battery.

4313 23. Chapter 787, relating to kidnapping or human
 4314 trafficking.

4315 24. Chapter 790, relating to weapons and firearms.

4316 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.
 4317 796.05, or s. 796.07, relating to prostitution and sex
 4318 trafficking.

4319 26. Chapter 806, relating to arson.

4320 27. Section 810.02(2)(c), relating to specified burglary
 4321 of a dwelling or structure.

4322 28. Chapter 812, relating to theft, robbery, and related
 4323 crimes.

4324 29. Chapter 815, relating to computer-related crimes.

4325 30. Chapter 817, relating to fraudulent practices, false
 4326 pretenses, fraud generally, and credit card crimes.

4327 31. Chapter 825, relating to abuse, neglect, or
 4328 exploitation of an elderly person or disabled adult.

4329 32. Section 827.071, relating to commercial sexual
 4330 exploitation of children.

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- 4331 | 33. Chapter 831, relating to forgery and counterfeiting.
- 4332 | 34. Chapter 832, relating to issuance of worthless checks
- 4333 | and drafts.
- 4334 | 35. Section 836.05, relating to extortion.
- 4335 | 36. Chapter 837, relating to perjury.
- 4336 | 37. Chapter 838, relating to bribery and misuse of public
- 4337 | office.
- 4338 | 38. Chapter 843, relating to obstruction of justice.
- 4339 | 39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or
- 4340 | s. 847.07, relating to obscene literature and profanity.
- 4341 | 40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.
- 4342 | 849.25, relating to gambling.
- 4343 | 41. Chapter 874, relating to criminal street gangs.
- 4344 | 42. Chapter 893, relating to drug abuse prevention and
- 4345 | control.
- 4346 | 43. Chapter 896, relating to offenses related to financial
- 4347 | transactions.
- 4348 | 44. Sections 914.22 and 914.23, relating to tampering with
- 4349 | a witness, victim, or informant, and retaliation against a
- 4350 | witness, victim, or informant.
- 4351 | 45. Sections 918.12 and 918.13, relating to tampering with
- 4352 | jurors and evidence.
- 4353 | Section 43. Paragraphs (d), (f), (h), (i), and (j) of
- 4354 | subsection (3) of section 921.0022, Florida Statutes, are
- 4355 | amended to read:
- 4356 | 921.0022 Criminal Punishment Code; offense severity
- 4357 | ranking chart.--
- 4358 | (3) OFFENSE SEVERITY RANKING CHART

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4359	(d)	LEVEL 4	
4360			
	Florida	Felony	Description
	Statute	Degree	
4361	316.1935 (3) (a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
4362	499.0051 (1)	3rd	Failure to maintain or deliver pedigree papers.
4363	499.0051 (2)	3rd	Failure to authenticate pedigree papers.
4364	499.0051 (6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband <u>prescription</u> legend drugs.
4365	784.07 (2) (b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4366	784.074 (1) (c)	3rd	Battery of sexually violent predators facility staff.
4367			

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4368	784.075	3rd	Battery on detention or commitment facility staff.
4369	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
4370	784.08 (2) (c)	3rd	Battery on a person 65 years of age or older.
4371	784.081 (3)	3rd	Battery on specified official or employee.
4372	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
4373	784.083 (3)	3rd	Battery on code inspector.
4374	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
4375	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent

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4376			pending custody proceedings.
	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4377			
	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4378			
	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
4379			
	790.115 (2) (c)	3rd	Possessing firearm on school property.
4380			
	800.04 (7) (d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4381			
	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
4382			
	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
4383			

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4384	810.06	3rd	Burglary; possession of tools.
4385	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
4386	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4387	812.014 (2) (c) 4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4388	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4389	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
4390	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
4391	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any

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4392			registered horse or cattle.
4393	837.02 (1)	3rd	Perjury in official proceedings.
4394	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4395	838.022	3rd	Official misconduct.
4396	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4397	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4398	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4399	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
4400	843.15 (1) (a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
	874.05 (1)	3rd	Encouraging or recruiting another to

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4401			join a criminal street gang.
	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).
4402			
	914.14 (2)	3rd	Witnesses accepting bribes.
4403			
	914.22 (1)	3rd	Force, threaten, etc., witness, victim, or informant.
4404			
	914.23 (2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4405			
	918.12	3rd	Tampering with jurors.
4406			
	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
4407			
4408	(f)	LEVEL 6	
4409			
	Florida	Felony	Description
	Statute	Degree	
4410			
	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
4411			

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4412	499.0051 (3)	2nd	<u>Knowing</u> forgery of pedigree papers.
4413	499.0051 (4)	2nd	<u>Knowing</u> purchase or receipt of <u>prescription</u> legend drug from unauthorized person.
4414	499.0051 (5)	2nd	<u>Knowing</u> sale <u>or transfer</u> of <u>prescription</u> legend drug to unauthorized person.
4415	775.0875 (1)	3rd	Taking firearm from law enforcement officer.
4416	784.021 (1) (a)	3rd	Aggravated assault; deadly weapon without intent to kill.
4417	784.021 (1) (b)	3rd	Aggravated assault; intent to commit felony.
4418	784.041	3rd	Felony battery; domestic battery by strangulation.
4419	784.048 (3)	3rd	Aggravated stalking; credible threat.
4420	784.048 (5)	3rd	Aggravated stalking of person under 16.
4421	784.07 (2) (c)	2nd	Aggravated assault on law enforcement officer.

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4422	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
4423	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
4424	784.081 (2)	2nd	Aggravated assault on specified official or employee.
4425	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
4426	784.083 (2)	2nd	Aggravated assault on code inspector.
4427	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4428	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
4429	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
4430	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.

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4431	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
4432	794.011(8)(a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
4433	794.05(1)	2nd	Unlawful sexual activity with specified minor.
4434	800.04(5)(d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than 16 years; offender less than 18 years.
4435	800.04(6)(b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
4436	806.031(2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
4437	810.02(3)(c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
4438	812.014(2)(b)1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
	812.014(6)	2nd	Theft; property stolen \$3,000 or more;

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coordination of others.

4439

812.015 (9) (a) 2nd Retail theft; property stolen \$300 or more; second or subsequent conviction.

4440

812.015 (9) (b) 2nd Retail theft; property stolen \$3,000 or more; coordination of others.

4441

812.13 (2) (c) 2nd Robbery, no firearm or other weapon (strong-arm robbery).

4442

817.034 (4) (a) 1. 1st Communications fraud, value greater than \$50,000.

4443

817.4821 (5) 2nd Possess cloning paraphernalia with intent to create cloned cellular telephones.

4444

825.102 (1) 3rd Abuse of an elderly person or disabled adult.

4445

825.102 (3) (c) 3rd Neglect of an elderly person or disabled adult.

4446

825.1025 (3) 3rd Lewd or lascivious molestation of an elderly person or disabled adult.

4447

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4448	825.103 (2) (c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4449	827.03 (1)	3rd	Abuse of a child.
4450	827.03 (3) (c)	3rd	Neglect of a child.
4451	827.071 (2) & (3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
4452	836.05	2nd	Threats; extortion.
4453	836.10	2nd	Written threats to kill or do bodily injury.
4454	843.12	3rd	Aids or assists person to escape.
4455	847.0135 (2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
4456	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
	944.35 (3) (a) 2.	3rd	Committing malicious battery upon or

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inflicting cruel or inhuman treatment on
 an inmate or offender on community
 supervision, resulting in great bodily
 harm.

4457

944.40 2nd Escapes.

4458

944.46 3rd Harboring, concealing, aiding escaped
 prisoners.

4459

944.47(1)(a)5. 2nd Introduction of contraband (firearm,
 weapon, or explosive) into correctional
 facility.

4460

951.22(1) 3rd Intoxicating drug, firearm, or weapon
 introduced into county facility.

4461

4462 (h) LEVEL 8

4463

Florida	Felony	Description
Statute	Degree	

4464

316.193(3)(c)3.a. 2nd DUI manslaughter.

4465

316.1935(4)(b) 1st Aggravated fleeing or attempted
 eluding with serious bodily injury or
 death.

4466

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4467	327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
4468	<u>499.0051 (8)</u> 499.0051 (7)	1st	<u>Knowing</u> forgery of prescription labels or <u>prescription</u> legend drug labels.
4469	<u>499.0051 (7)</u> 499.0052	1st	<u>Knowing</u> trafficking in contraband <u>prescription</u> legend drugs.
4470	560.123 (8) (b) 2.	2nd	Failure to report currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000 by money transmitter.
4471	560.125 (5) (b)	2nd	Money transmitter business by unauthorized person, currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000.
4472	655.50 (10) (b) 2.	2nd	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by financial institutions.
4473	777.03 (2) (a)	1st	Accessory after the fact, capital felony.

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4474	782.04 (4)	2nd	Killing of human without design when engaged in act or attempt of any felony other than arson, sexual battery, robbery, burglary, kidnapping, aircraft piracy, or unlawfully discharging bomb.
4475	782.051 (2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04 (3).
4476	782.071 (1) (b)	1st	Committing vehicular homicide and failing to render aid or give information.
4477	782.072 (2)	1st	Committing vessel homicide and failing to render aid or give information.
4478	790.161 (3)	1st	Discharging a destructive device which results in bodily harm or property damage.
4479	794.011 (5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.

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4480	794.08 (3)	2nd	Female genital mutilation, removal of a victim younger than 18 years of age from this state.
4481	800.04 (4)	2nd	Lewd or lascivious battery.
4482	806.01 (1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4483	810.02 (2) (a)	1st, PBL	Burglary with assault or battery.
4484	810.02 (2) (b)	1st, PBL	Burglary; armed with explosives or dangerous weapon.
4485	810.02 (2) (c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
4486	812.014 (2) (a) 2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st degree.
4487	812.13 (2) (b)	1st	Robbery with a weapon.
4488	812.135 (2) (c)	1st	Home-invasion robbery, no firearm, deadly weapon, or other weapon.

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4489	817.568 (6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4490	825.102 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4491	825.1025 (2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4492	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4493	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4494	837.021 (2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.
4495	860.121 (2) (c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
4496	860.16	1st	Aircraft piracy.

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4497	893.13 (1) (b)	1st	Sell or deliver in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4498	893.13 (2) (b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4499	893.13 (6) (c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4500	893.135 (1) (a) 2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
4501	893.135 (1) (b) 1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
4502	893.135 (1) (c) 1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.
4503	893.135 (1) (d) 1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
4504	893.135 (1) (e) 1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.

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4505	893.135 (1) (f) 1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4506	893.135 (1) (g) 1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4507	893.135 (1) (h) 1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4508	893.135 (1) (j) 1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4509	893.135 (1) (k) 2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4510	895.03 (1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
4511	895.03 (2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
	895.03 (3)	1st	Conduct or participate in any enterprise through pattern of

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4512			racketeering activity.
	896.101 (5) (b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
4513			
	896.104 (4) (a) 2.	2nd	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$20,000 but less than \$100,000.
4514			
4515	(i) LEVEL 9		
4516			
	Florida Statute	Felony Degree	Description
4517			
	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
4518			
	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
4519			
	<u>499.0051 (9)</u> 499.00535	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> legend drugs resulting in great bodily harm.
4520			

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4521	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
4522	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
4523	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4524	775.0844	1st	Aggravated white collar crime.
4525	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
4526	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4527	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3) .

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4528	782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
4529	787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
4530	787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
4531	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
4532	787.02(3)(a)	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
4533	790.161	1st	Attempted capital destructive device offense.
4534	790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.

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4535	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
4536	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
4537	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4538	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
4539	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4540	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4541	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4542	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.

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4543	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4544	817.568 (7)	2nd, PBL	Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.
4545	827.03 (2)	1st	Aggravated child abuse.
4546	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
4547	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
4548	859.01	1st	Poisoning or introducing bacteria, radioactive materials, viruses, or chemical compounds into food, drink, medicine, or water with intent to kill or injure another person.
4549	893.135	1st	Attempted capital trafficking offense.
	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than

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4550			10,000 lbs.
	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4551			
	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4552			
	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
4553			
	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4554			
	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more than 200 grams.
4555			
	893.135 (1) (h) 1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
4556			
	893.135 (1) (j) 1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
4557			
	893.135 (1) (k) 2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
4558			

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4559	896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
4560	896.104(4)(a)3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
4561	(j) LEVEL 10		
4562			
4563	Florida Statute	Felony Degree	Description
4564	<u>499.0051(10)</u> 499.00545	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> legend drugs resulting in death.
4565	782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.
4566	787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
	787.01(3)(a)	Life	Kidnapping; child under age 13, perpetrator also commits aggravated child abuse, sexual battery, or lewd or

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lascivious battery, molestation,
 conduct, or exhibition.

4567

782.07(3) 1st Aggravated manslaughter of a child.

4568

794.011(3) Life Sexual battery; victim 12 years or
 older, offender uses or threatens to use
 deadly weapon or physical force to cause
 serious injury.

4569

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

4570

876.32 1st Treason against the state.

4571

4572 Section 44. This act shall take effect July 1, 2008.