

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

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

30 conforming provisions to changes made by the act;

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

32 active pharmaceutical ingredient in bulk form and does not

33 bear a label containing certain information; amending ss.

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

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

36 providing that the section relates only to permits;

37 providing requirements for obtaining a permit to operate

38 in certain capacities; deleting certain permit

39 requirements; amending and redesignating provisions of ss.

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

41 functions as provisions of that section; conforming

42 provisions and cross-references to changes made by the

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

44 relates to permit application requirements; amending the

45 provisions to conform; amending and redesignating

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

47 as provisions of that section; conforming provisions and

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

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

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

51 and handling of prescription drugs and recordkeeping;

52 directing the department to adopt rules requiring a

53 wholesale distributor to maintain pedigree papers separate

54 and distinct from other required records; deleting a

55 requirement that a person who is engaged in the wholesale

56 distribution of a prescription drug and who is not the

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

HB 7049

2008

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

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

107  
108 Section 1. Section 499.002, Florida Statutes, is amended;  
109 section 499.004, Florida Statutes, is redesignated as subsection  
110 (2) of that section and amended; section 499.0053, Florida  
111 Statutes, is redesignated as subsection (3) of that section and  
112 amended; section 499.07, Florida Statutes, is redesignated as

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

390

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HB 7049

2008

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HB 7049

2008

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

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

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

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

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

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

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



HB 7049

2008

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

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

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

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

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

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

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

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

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

952 (12) 499.0691 ADULTERATED AND MISBRANDED DRUGS; FALSE  
 953 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS  
 954 ~~Criminal punishment for violations related to drugs;~~  
 955 ~~dissemination of false advertisement.~~ --(1) Any person who  
 956 violates any of the following provisions commits a misdemeanor  
 957 of the second degree, punishable as provided in s. 775.082 or s.  
 958 775.083; but, if the violation is committed after a conviction  
 959 of such person under this subsection ~~section~~ has become final,  
 960 such person commits a misdemeanor of the first degree,  
 961 punishable as provided in s. 775.082 or s. 775.083, or as  
 962 otherwise provided in this part ~~ss. 499.001-499.081~~:

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

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

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

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

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

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

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

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

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

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

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

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

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

1002 2. Inspection of any record of that establishment;

HB 7049

2008

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

- 1117     ~~1.(a)~~ The packaging of the product.
- 1118     ~~2.(b)~~ The name and labeling of the product.
- 1119     ~~3.(c)~~ The manner of distribution, advertising, and  
 1120 promotion of the product, including verbal representations at  
 1121 the point of sale.
- 1122     ~~4.(d)~~ The duration, scope, and significance of abuse of  
 1123 the particular product.
- 1124     ~~(g)-(7)~~ The advertising of any drug or device represented  
 1125 to have any effect in any of the following conditions,  
 1126 disorders, diseases, or processes:
  - 1127         ~~1.(a)~~ Blood disorders.
  - 1128         ~~2.(b)~~ Bone or joint diseases.
  - 1129         ~~3.(c)~~ Kidney diseases or disorders.
  - 1130         ~~4.(d)~~ Cancer.
  - 1131         ~~5.(e)~~ Diabetes.
  - 1132         ~~6.(f)~~ Gall bladder diseases or disorders.
  - 1133         ~~7.(g)~~ Heart and vascular diseases.
  - 1134         ~~8.(h)~~ High blood pressure.
  - 1135         ~~9.(i)~~ Diseases or disorders of the ear or auditory  
 1136 apparatus, including hearing loss or deafness.
  - 1137         ~~10.(j)~~ Mental disease or mental retardation.
  - 1138         ~~11.(k)~~ Paralysis.
  - 1139         ~~12.(l)~~ Prostate gland disorders.
  - 1140         ~~13.(m)~~ Conditions of the scalp affecting hair loss.
  - 1141         ~~14.(n)~~ Baldness.

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

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

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

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

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

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

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

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

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

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

HB 7049

2008

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1250 (a) Adequate directions for use; and

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

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

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

1271           (9)~~(8)~~ If it is:

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

1274           (b) An imitation of another drug; or

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

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

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

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

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

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

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

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

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

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

HB 7049

2008

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

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

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

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

1323 (b) "Rx Only";

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

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

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

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



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

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

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

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

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

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

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

1371  
 1372 ~~For the purposes of this subsection and subsection (4), the term~~  
 1373 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HB 7049

2008

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HB 7049

2008

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

HB 7049

2008

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2085 3. If a corporation:

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

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

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

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

2096 5. If a limited liability company:

2097 a. The name and address of each member.

2098 b. The name and address of each manager.

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

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

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

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

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

2126 (h) The tax year of the applicant.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HB 7049

2008

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

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

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

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

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

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

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

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

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



HB 7049

2008

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



2435 (c) The department shall require information from each  
 2436 wholesale distributor as part of the permit and renewal of such  
 2437 permit, as required under ~~s. 499.01~~ or this section.

2438 ~~(14)~~(9) Personnel employed in wholesale distribution must  
 2439 have appropriate education and experience to enable them to  
 2440 perform their duties in compliance with state permitting  
 2441 requirements.

2442 ~~(15)~~(10) The name of a permittee or establishment on a  
 2443 prescription drug wholesale distributor ~~wholesaler~~ permit or an  
 2444 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
 2445 permit may not include any indicia of attainment of any  
 2446 educational degree, any indicia that the permittee or  
 2447 establishment possesses a professional license, or any name or  
 2448 abbreviation that the department determines is likely to cause  
 2449 confusion or mistake or that the department determines is  
 2450 deceptive, including that of any other entity authorized to  
 2451 purchase prescription drugs.

2452 ~~(16)~~(11)(a) Each establishment that is issued an initial  
 2453 or renewal permit as a prescription drug wholesale distributor  
 2454 ~~wholesaler~~ or an out-of-state prescription drug wholesale  
 2455 distributor ~~wholesaler~~ must designate in writing to the  
 2456 department at least one natural person to serve as the  
 2457 designated representative of the wholesale distributor  
 2458 ~~wholesaler~~. Such person must have an active certification as a  
 2459 designated representative from the department.

2460 (b) To be certified as a designated representative, a  
 2461 natural person must:

- 2462           1. Submit an application on a form furnished by the  
 2463 department and pay the appropriate fees;
- 2464           2. Be at least 18 years of age;
- 2465           3. Have not less than 2 years of verifiable full-time work  
 2466 experience in a pharmacy licensed in this state or another  
 2467 state, where the person's responsibilities included, but were  
 2468 not limited to, recordkeeping for prescription drugs, or have  
 2469 not less than 2 years of verifiable full-time managerial  
 2470 experience with a prescription drug wholesale distributor  
 2471 ~~wholesaler~~ licensed in this state or in another state;
- 2472           4. Receive a passing score of at least 75 percent on an  
 2473 examination given by the department regarding federal laws  
 2474 governing distribution of prescription drugs and this part ss.  
 2475 ~~499.001-499.081~~ and the rules adopted by the department  
 2476 governing the wholesale distribution of prescription drugs. This  
 2477 requirement shall be effective 1 year after the results of the  
 2478 initial examination are mailed to the persons that took the  
 2479 examination. The department shall offer such examinations at  
 2480 least four times each calendar year; and
- 2481           5. Provide the department with a personal information  
 2482 statement and fingerprints pursuant to subsection (9)~~(4)~~.
- 2483           (c) The department may deny an application for  
 2484 certification as a designated representative or may suspend or  
 2485 revoke a certification of a designated representative pursuant  
 2486 to s. 499.067.
- 2487           (d) A designated representative:
- 2488           1. Must be actively involved in and aware of the actual  
 2489 daily operation of the wholesale distributor.

2490           2. Must be employed full time in a managerial position by  
2491 the wholesale distributor.

2492           3. Must be physically present at the establishment during  
2493 normal business hours, except for time periods when absent due  
2494 to illness, family illness or death, scheduled vacation, or  
2495 other authorized absence.

2496           4. May serve as a designated representative for only one  
2497 wholesale distributor at any one time.

2498           (e) A wholesale distributor must notify the department  
2499 when a designated representative leaves the employ of the  
2500 wholesale distributor. Such notice must be provided to the  
2501 department within 10 business days after the last day of  
2502 designated representative's employment with the wholesale  
2503 distributor.

2504           (f) A wholesale distributor may not operate under a  
2505 prescription drug wholesale distributor ~~wholesaler~~ permit or an  
2506 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2507 permit for more than 10 business days after the designated  
2508 representative leaves the employ of the wholesale distributor,  
2509 unless the wholesale distributor employs another designated  
2510 representative and notifies the department within 10 business  
2511 days of the identity of the new designated representative.

2512           Section 12. Section 499.01201, Florida Statutes, is  
2513 amended to read:

2514           499.01201 Agency for Health Care Administration review and  
2515 use of statute and rule violation or compliance  
2516 data.--Notwithstanding any other provisions of law to the  
2517 contrary, the Agency for Health Care Administration may not:

HB 7049

2008

2518 (1) Review or use any violation or alleged violation of s.  
 2519 499.0121(6) or s. 499.01212, or any rules adopted under those  
 2520 sections ~~that section~~, as a ground for denying or withholding  
 2521 any payment of a Medicaid reimbursement to a pharmacy licensed  
 2522 under chapter 465; or

2523 (2) Review or use compliance with s. 499.0121(6) or s.  
 2524 499.01212, or any rules adopted under those sections ~~that~~  
 2525 ~~section~~, as the subject of any audit of Medicaid-related records  
 2526 held by a pharmacy licensed under chapter 465.

2527 Section 13. Section 499.0121, Florida Statutes, is  
 2528 amended, and subsection (4) of section 499.013, Florida  
 2529 Statutes, is redesignated as paragraph (d) of subsection (6) of  
 2530 that section and amended, to read:

2531 499.0121 Storage and handling of prescription drugs;  
 2532 recordkeeping.--The department shall adopt rules to implement  
 2533 this section as necessary to protect the public health, safety,  
 2534 and welfare. Such rules shall include, but not be limited to,  
 2535 requirements for the storage and handling of prescription drugs  
 2536 and for the establishment and maintenance of prescription drug  
 2537 distribution records.

2538 (1) ESTABLISHMENTS.--An establishment at which  
 2539 prescription drugs are stored, warehoused, handled, held,  
 2540 offered, marketed, or displayed must:

2541 (a) Be of suitable size and construction to facilitate  
 2542 cleaning, maintenance, and proper operations;

2543 (b) Have storage areas designed to provide adequate  
 2544 lighting, ventilation, temperature, sanitation, humidity, space,  
 2545 equipment, and security conditions;

HB 7049

2008

2546 (c) Have a quarantine area for storage of prescription  
 2547 drugs that are outdated, damaged, deteriorated, misbranded, or  
 2548 adulterated, or that are in immediate or sealed, secondary  
 2549 containers that have been opened;

2550 (d) Be maintained in a clean and orderly condition; and

2551 (e) Be free from infestation by insects, rodents, birds,  
 2552 or vermin of any kind.

2553 (2) SECURITY.--

2554 (a) An establishment that is used for wholesale drug  
 2555 distribution must be secure from unauthorized entry.

2556 1. Access from outside the premises must be kept to a  
 2557 minimum and be well-controlled.

2558 2. The outside perimeter of the premises must be well-  
 2559 lighted.

2560 3. Entry into areas where prescription drugs are held must  
 2561 be limited to authorized personnel.

2562 (b) An establishment that is used for wholesale drug  
 2563 distribution must be equipped with:

2564 1. An alarm system to detect entry after hours; however,  
 2565 the department may exempt by rule establishments that only hold  
 2566 a permit as prescription drug wholesale distributor-brokers  
 2567 ~~wholesaler brokers~~ and establishments that only handle medical  
 2568 oxygen; and

2569 2. A security system that will provide suitable protection  
 2570 against theft and diversion. When appropriate, the security  
 2571 system must provide protection against theft or diversion that  
 2572 is facilitated or hidden by tampering with computers or  
 2573 electronic records.

2574 (c) Any vehicle that contains prescription drugs must be  
 2575 secure from unauthorized access to the prescription drugs in the  
 2576 vehicle.

2577 (3) STORAGE.--All prescription drugs shall be stored at  
 2578 appropriate temperatures and under appropriate conditions in  
 2579 accordance with requirements, if any, in the labeling of such  
 2580 drugs, or with requirements in the official compendium.

2581 (a) If no storage requirements are established for a  
 2582 prescription drug, the drug may be held at "controlled" room  
 2583 temperature, as defined in the official compendium, to help  
 2584 ensure that its identity, strength, quality, and purity are not  
 2585 adversely affected.

2586 (b) Appropriate manual, electromechanical, or electronic  
 2587 temperature and humidity recording equipment, devices, or logs  
 2588 must be used to document proper storage of prescription drugs.

2589 (c) The recordkeeping requirements in subsection (6) must  
 2590 be followed for all stored prescription drugs.

2591 (4) EXAMINATION OF MATERIALS AND RECORDS.--

2592 (a) Upon receipt, each outside shipping container must be  
 2593 visually examined for identity and to prevent the acceptance of  
 2594 contaminated prescription drugs that are otherwise unfit for  
 2595 distribution. This examination must be adequate to reveal  
 2596 container damage that would suggest possible contamination or  
 2597 other damage to the contents.

2598 (b) Each outgoing shipment must be carefully inspected for  
 2599 identity of the prescription drug products and to ensure that  
 2600 there is no delivery of prescription drugs that have expired or  
 2601 been damaged in storage or held under improper conditions.

2602 (c) The recordkeeping requirements in subsection (6) must  
 2603 be followed for all incoming and outgoing prescription drugs.

2604 (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must  
 2605 review records required under this section for the acquisition  
 2606 of prescription drugs for accuracy and completeness, considering  
 2607 the total facts and circumstances surrounding the transactions  
 2608 and the wholesale distributors involved. This includes  
 2609 authenticating each transaction listed on a pedigree paper, as  
 2610 defined in s. 499.003(37) ~~s. 499.001(31)~~.

2611 (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

2612 (a)1. Prescription drugs that are outdated, damaged,  
 2613 deteriorated, misbranded, or adulterated must be quarantined and  
 2614 physically separated from other prescription drugs until they  
 2615 are destroyed or returned to their supplier. A quarantine  
 2616 section must be separate and apart from other sections where  
 2617 prescription drugs are stored so that prescription drugs in this  
 2618 section are not confused with usable prescription drugs.

2619 2. Prescription drugs must be examined at least every 12  
 2620 months, and drugs for which the expiration date has passed must  
 2621 be removed and quarantined.

2622 (b) Any prescription drugs of which the immediate or  
 2623 sealed outer containers or sealed secondary containers have been  
 2624 opened or used must be identified as such and must be  
 2625 quarantined and physically separated from other prescription  
 2626 drugs until they are either destroyed or returned to the  
 2627 supplier.

2628 (c) If the conditions under which a prescription drug has  
 2629 been returned cast doubt on the drug's safety, identity,

2630 strength, quality, or purity, the drug must be destroyed or  
 2631 returned to the supplier, unless examination, testing, or other  
 2632 investigation proves that the drug meets appropriate standards  
 2633 of safety, identity, strength, quality, and purity. In  
 2634 determining whether the conditions under which a drug has been  
 2635 returned cast doubt on the drug's safety, identity, strength,  
 2636 quality, or purity, the wholesale ~~drug~~ distributor must  
 2637 consider, among other things, the conditions under which the  
 2638 drug has been held, stored, or shipped before or during its  
 2639 return and the conditions of the drug and its container, carton,  
 2640 or labeling, as a result of storage or shipping.

2641 (d) The recordkeeping requirements in subsection (6) must  
 2642 be followed for all outdated, damaged, deteriorated, misbranded,  
 2643 or adulterated prescription drugs.

2644 (6) RECORDKEEPING.--The department shall adopt rules that  
 2645 require keeping such records of prescription drugs as are  
 2646 necessary for the protection of the public health.

2647 (a) Wholesale ~~drug~~ distributors must establish and  
 2648 maintain inventories and records of all transactions regarding  
 2649 the receipt and distribution or other disposition of  
 2650 prescription drugs. These records must provide a complete audit  
 2651 trail from receipt to sale or other disposition, be readily  
 2652 retrievable for inspection, and include, at a minimum, the  
 2653 following information:

2654 1. The source of the drugs, including the name and  
 2655 principal address of the seller or transferor, and the address  
 2656 of the location from which the drugs were shipped;



2657           2. The name, principal address, and state license permit  
 2658 or registration number of the person authorized to purchase  
 2659 prescription drugs;

2660           3. The name, strength, dosage form, and quantity of the  
 2661 drugs received and distributed or disposed of;

2662           4. The dates of receipt and distribution or other  
 2663 disposition of the drugs; and

2664           5. Any financial documentation supporting the transaction.

2665           (b) Inventories and records must be made available for  
 2666 inspection and photocopying by authorized federal, state, or  
 2667 local officials for a period of 2 years following disposition of  
 2668 the drugs or 3 years after the creation of the records,  
 2669 whichever period is longer.

2670           (c) Records described in this section that are kept at the  
 2671 inspection site or that can be immediately retrieved by computer  
 2672 or other electronic means must be readily available for  
 2673 authorized inspection during the retention period. Records that  
 2674 are kept at a central location outside of this state and that  
 2675 are not electronically retrievable must be made available for  
 2676 inspection within 2 working days after a request by an  
 2677 authorized official of a federal, state, or local law  
 2678 enforcement agency. Records that are maintained at a central  
 2679 location within this state must be maintained at an  
 2680 establishment that is permitted pursuant to this part ss.  
 2681 ~~499.001-499.081~~ and must be readily available.

2682           (d) ~~(4)~~ Each manufacturer or repackager of medical devices,  
 2683 over-the-counter drugs, or cosmetics must maintain records that  
 2684 include the name and principal address of the seller or

HB 7049

2008

2685 transferor of the product, the address of the location from  
2686 which the product was shipped, the date of the transaction, the  
2687 name and quantity of the product involved, and the name and  
2688 principal address of the person who purchased the product.

2689 (e) A wholesale distributor must maintain pedigree papers  
2690 separate and distinct from other records required under this  
2691 chapter.

2692 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~  
2693 ~~the wholesale distribution of a prescription drug and who is not~~  
2694 ~~the manufacturer of that drug must, before each wholesale~~  
2695 ~~distribution of such drug, provide to the person who receives~~  
2696 ~~the drug a pedigree paper as defined in s. 499.003(31).~~

2697 ~~2. A repackager must comply with this paragraph.~~

2698 ~~3. The pedigree paper requirements in this paragraph do~~  
2699 ~~not apply to compressed medical gases or veterinary legend~~  
2700 ~~drugs.~~

2701 ~~4. Each wholesale distributor of prescription drugs must~~  
2702 ~~maintain separate and distinct from other required records all~~  
2703 ~~statements that are required under subparagraph 1.~~

2704 ~~5. Subparagraph 1. is satisfied when a wholesale~~  
2705 ~~distributor takes title to, but not possession of, a~~  
2706 ~~prescription drug and the prescription drug's manufacturer ships~~  
2707 ~~the prescription drug directly to a person authorized by law to~~  
2708 ~~purchase prescription drugs for the purpose of administering or~~  
2709 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~  
2710 ~~affiliated group, as described in paragraph (f), with the~~  
2711 ~~exception of a repackager.~~

2712           ~~a. The wholesale distributor must deliver to the recipient~~  
 2713 ~~of the prescription drug, within 14 days after the shipment~~  
 2714 ~~notification from the manufacturer, an invoice and the following~~  
 2715 ~~sworn statement: "This wholesale distributor purchased the~~  
 2716 ~~specific unit of the prescription drug listed on the invoice~~  
 2717 ~~directly from the manufacturer, and the specific unit of~~  
 2718 ~~prescription drug was shipped by the manufacturer directly to a~~  
 2719 ~~person authorized by law to administer or dispense the legend~~  
 2720 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~  
 2721 ~~an affiliated group, as described in s. 499.0121(6)(f), Florida~~  
 2722 ~~Statutes, with the exception of a repackager." The invoice must~~  
 2723 ~~contain a unique cross reference to the shipping document sent~~  
 2724 ~~by the manufacturer to the recipient of the prescription drug.~~

2725           ~~b. The manufacturer of the prescription drug shipped~~  
 2726 ~~directly to the recipient under this section must provide and~~  
 2727 ~~the recipient of the prescription drug must acquire, within 14~~  
 2728 ~~days after receipt of the prescription drug, a shipping document~~  
 2729 ~~from the manufacturer that contains, at a minimum:~~

2730           ~~(I) The name and address of the manufacturer, including~~  
 2731 ~~the point of origin of the shipment, and the names and addresses~~  
 2732 ~~of the wholesaler and the purchaser.~~

2733           ~~(II) The name of the prescription drug as it appears on~~  
 2734 ~~the label.~~

2735           ~~(III) The quantity, dosage form, and strength of the~~  
 2736 ~~prescription drug.~~

2737           ~~(IV) The date of the shipment from the manufacturer.~~

2738           ~~e. The wholesale distributor must also maintain and make~~  
 2739 ~~available to the department, upon request, the lot number of~~

2740 ~~such drug if not contained in the shipping document acquired by~~  
 2741 ~~the recipient.~~

2742 ~~6. Failure of the manufacturer to provide, the recipient~~  
 2743 ~~to acquire, or the wholesale distributor to deliver, the~~  
 2744 ~~documentation required under subparagraph 5. shall constitute~~  
 2745 ~~failure to acquire or deliver a pedigree paper under s.~~  
 2746 ~~499.0051. Forgery by the manufacturer, the recipient, or the~~  
 2747 ~~wholesale distributor of the documentation required to be~~  
 2748 ~~acquired or delivered under subparagraph 5. shall constitute~~  
 2749 ~~forgery of a pedigree paper under s. 499.0051.~~

2750 ~~7. The department may, by rule, specify alternatives to~~  
 2751 ~~compliance with subparagraph 1. for a prescription drug in the~~  
 2752 ~~inventory of a permitted prescription drug wholesaler as of June~~  
 2753 ~~30, 2006, and the return of a prescription drug purchased prior~~  
 2754 ~~to July 1, 2006. The department may specify time limits for such~~  
 2755 ~~alternatives.~~

2756 (7)(e) PRESCRIPTION DRUG PURCHASE LIST.--Each wholesale  
 2757 distributor, except for a manufacturer, shall annually provide  
 2758 the department with a written list of all wholesale distributors  
 2759 and manufacturers from whom the wholesale distributor purchases  
 2760 prescription drugs. A wholesale distributor, except a  
 2761 manufacturer, shall notify the department not later than 10 days  
 2762 after any change to either list. Such portions of the  
 2763 information required pursuant to this subsection ~~paragraph~~ which  
 2764 are a trade secret, as defined in s. 812.081, shall be  
 2765 maintained by the department as trade secret information is  
 2766 required to be maintained under s. 499.051.

2767 ~~(f)1. This paragraph applies only to an affiliated group,~~  
2768 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~  
2769 ~~amended, which is composed of chain drug entities, including at~~  
2770 ~~least 50 retail pharmacies, warehouses, or repackagers, which~~  
2771 ~~are members of the same affiliated group, if the affiliated~~  
2772 ~~group:~~

2773 ~~a. Discloses to the department the names of all its~~  
2774 ~~members; and~~

2775 ~~b. Agrees in writing to provide records on prescription~~  
2776 ~~drug purchases by members of the affiliated group not later than~~  
2777 ~~48 hours after the department requests such records, regardless~~  
2778 ~~of the location where the records are stored.~~

2779 ~~2. Each warehouse within the affiliated group must comply~~  
2780 ~~with all applicable federal and state drug wholesale permit~~  
2781 ~~requirements and must purchase, receive, hold, and distribute~~  
2782 ~~prescription drugs only to a retail pharmacy or warehouse within~~  
2783 ~~the affiliated group. Such a warehouse is exempt from providing~~  
2784 ~~a pedigree paper in accordance with paragraph (d) to its~~  
2785 ~~affiliated group member warehouse or retail pharmacy, provided~~  
2786 ~~that:~~

2787 ~~a. Any affiliated group member that purchases or receives~~  
2788 ~~a prescription drug from outside the affiliated group must~~  
2789 ~~receive a pedigree paper if the prescription drug is distributed~~  
2790 ~~in or into this state and a pedigree paper is required under~~  
2791 ~~this section and must authenticate the documentation as required~~  
2792 ~~in subsection (4), regardless of whether the affiliated group~~  
2793 ~~member is directly subject to regulation under this chapter; and~~

2794 ~~b. The affiliated group makes available to the department~~  
 2795 ~~on request all records related to the purchase or acquisition of~~  
 2796 ~~prescription drugs by members of the affiliated group,~~  
 2797 ~~regardless of the location where the records are stored, if the~~  
 2798 ~~prescription drugs were distributed in or into this state.~~

2799 ~~3. If a repackager repackages prescription drugs solely~~  
 2800 ~~for distribution to its affiliated group members for the~~  
 2801 ~~exclusive distribution to and among retail pharmacies that are~~  
 2802 ~~members of the affiliated group to which the repackager is a~~  
 2803 ~~member.~~

2804 ~~a. The repackager must:~~

2805 ~~(I) In lieu of the written statement required by paragraph~~  
 2806 ~~(d), for all repackaged prescription drugs distributed in or~~  
 2807 ~~into this state, state in writing under oath with each~~  
 2808 ~~distribution of a repackaged prescription drug to an affiliated~~  
 2809 ~~group member warehouse or repackager: "All repackaged~~  
 2810 ~~prescription drugs are purchased by the affiliated group~~  
 2811 ~~directly from the manufacturer or from a prescription drug~~  
 2812 ~~wholesaler that purchased the prescription drugs directly from~~  
 2813 ~~the manufacturer.";~~

2814 ~~(II) Purchase all prescription drugs it repackages:~~

2815 ~~(A) Directly from the manufacturer; or~~

2816 ~~(B) From a prescription drug wholesaler that purchased the~~  
 2817 ~~prescription drugs directly from the manufacturer; and~~

2818 ~~(III) Maintain records in accordance with this section to~~  
 2819 ~~document that it purchased the prescription drugs directly from~~  
 2820 ~~the manufacturer or that its prescription drug wholesale~~

HB 7049

2008

2821 ~~supplier purchased the prescription drugs directly from the~~  
2822 ~~manufacturer.~~

2823 ~~b. All members of the affiliated group must provide to~~  
2824 ~~agents of the department on request records of purchases by all~~  
2825 ~~members of the affiliated group of prescription drugs that have~~  
2826 ~~been repackaged, regardless of the location where the records~~  
2827 ~~are stored or where the repackager is located.~~

2828 (8)~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale ~~drug~~  
2829 distributors must establish, maintain, and adhere to written  
2830 policies and procedures, which must be followed for the receipt,  
2831 security, storage, inventory, and distribution of prescription  
2832 drugs, including policies and procedures for identifying,  
2833 recording, and reporting losses or thefts, and for correcting  
2834 all errors and inaccuracies in inventories. Wholesale ~~drug~~  
2835 distributors must include in their written policies and  
2836 procedures:

2837 (a) A procedure whereby the oldest approved stock of a  
2838 prescription drug product is distributed first. The procedure  
2839 may permit deviation from this requirement, if the deviation is  
2840 temporary and appropriate.

2841 (b) A procedure to be followed for handling recalls and  
2842 withdrawals of prescription drugs. Such procedure must be  
2843 adequate to deal with recalls and withdrawals due to:

2844 1. Any action initiated at the request of the Food and  
2845 Drug Administration or any other federal, state, or local law  
2846 enforcement or other government agency, including the  
2847 department.

HB 7049

2008

2848           2. Any voluntary action by the manufacturer or repackager  
 2849 to remove defective or potentially defective drugs from the  
 2850 market; or

2851           3. Any action undertaken to promote public health and  
 2852 safety by replacing existing merchandise with an improved  
 2853 product or new package design.

2854           (c) A procedure to ensure that wholesale ~~drug~~ distributors  
 2855 prepare for, protect against, and handle any crisis that affects  
 2856 security or operation of any facility if a strike, fire, flood,  
 2857 or other natural disaster, or a local, state, or national  
 2858 emergency, occurs.

2859           (d) A procedure to ensure that any outdated prescription  
 2860 drugs are segregated from other drugs and either returned to the  
 2861 manufacturer or repackager or destroyed. This procedure must  
 2862 provide for written documentation of the disposition of outdated  
 2863 prescription drugs. This documentation must be maintained for 2  
 2864 years after disposition of the outdated drugs.

2865           (9)~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors  
 2866 must establish and maintain lists of officers, directors,  
 2867 managers, designated representatives, and other persons in  
 2868 charge of wholesale drug distribution, storage, and handling,  
 2869 including a description of their duties and a summary of their  
 2870 qualifications.

2871           (10)~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A  
 2872 wholesale ~~drug~~ distributor must operate in compliance with  
 2873 applicable federal, state, and local laws and regulations.

2874           (a) A wholesale ~~drug~~ distributor must allow the department  
 2875 and authorized federal, state, and local officials to enter and



2876 inspect its premises and delivery vehicles, and to audit its  
 2877 records and written operating procedures, at reasonable times  
 2878 and in a reasonable manner, to the extent authorized by law.

2879 (b) A wholesale ~~drug~~ distributor that deals in controlled  
 2880 substances must register with the Drug Enforcement  
 2881 Administration and must comply with all applicable state, local,  
 2882 and federal laws. A wholesale ~~drug~~ distributor that distributes  
 2883 any substance controlled under chapter 893 must notify the  
 2884 department when registering with the Drug Enforcement  
 2885 Administration pursuant to that chapter and must provide the  
 2886 department with its DEA number.

2887 (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~  
 2888 distributor is subject to any applicable federal, state, or  
 2889 local laws or regulations that relate to prescription drug  
 2890 product salvaging or reprocessing.

2891 (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person  
 2892 responsible for shipment and transportation of a prescription  
 2893 drug in a wholesale distribution may use a common carrier; its  
 2894 own vehicle or employee acting within the scope of employment if  
 2895 authorized under s. 499.03 for the possession of prescription  
 2896 drugs in this state; or, in the case of a prescription drug  
 2897 intended for domestic distribution, an independent contractor  
 2898 who must be the agent of the authorized seller or recipient  
 2899 responsible for shipping and transportation as set forth in a  
 2900 written contract between the parties. A person selling a  
 2901 prescription drug for export must obtain documentation, such as  
 2902 a validated airway bill, bill of lading, or other appropriate  
 2903 documentation that the prescription drug was exported. A person

2904 responsible for shipping or transporting prescription drugs is  
 2905 not required to maintain documentation from a common carrier  
 2906 that the designated recipient received the prescription drugs;  
 2907 however, the person must obtain such documentation from the  
 2908 common carrier and make it available to the department upon  
 2909 request of the department.

2910 (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing  
 2911 any prescription drugs from another wholesale ~~drug~~ distributor,  
 2912 a prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
 2913 state prescription drug wholesale distributor ~~wholesaler~~, or a  
 2914 prescription drug repackager must:

2915 (a) Enter an agreement with the selling wholesale ~~drug~~  
 2916 distributor by which the selling wholesale ~~drug~~ distributor will  
 2917 indemnify the purchasing wholesale ~~drug~~ distributor for any loss  
 2918 caused to the purchasing wholesale ~~drug~~ distributor related to  
 2919 the purchase of drugs from the selling wholesale ~~drug~~  
 2920 distributor which are determined to be counterfeit or to have  
 2921 been distributed in violation of any federal or state law  
 2922 governing the distribution of drugs.

2923 (b) Determine that the selling wholesale ~~drug~~ distributor  
 2924 has insurance coverage of not less than the greater of 1 percent  
 2925 of the amount of total dollar volume of the prescription drug  
 2926 sales reported to the department under s. 499.012(8)(g) ~~s.~~  
 2927 ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed  
 2928 \$2 million.

2929 (c) Obtain information from the selling wholesale ~~drug~~  
 2930 distributor, including the length of time the selling wholesale  
 2931 ~~drug~~ distributor has been licensed in this state, a copy of the

HB 7049

2008

2932 selling wholesale ~~drug~~ distributor's licenses or permits, and  
 2933 background information concerning the ownership of the selling  
 2934 wholesale ~~drug~~ distributor, including the experience of the  
 2935 wholesale distributor in the wholesale distribution of  
 2936 prescription drugs.

2937 (d) Verify that the selling wholesale ~~drug~~ distributor's  
 2938 Florida permit is valid.

2939 (e) Inspect the selling wholesale ~~drug~~ distributor's  
 2940 licensed establishment to document that it has a policies and  
 2941 procedures manual relating to the distribution of drugs, the  
 2942 appropriate temperature controlled environment for drugs  
 2943 requiring temperature control, an alarm system, appropriate  
 2944 access restrictions, and procedures to ensure that records  
 2945 related to the wholesale distribution of prescription drugs are  
 2946 maintained as required by law:

2947 1. Before purchasing any drug from the wholesale ~~drug~~  
 2948 distributor, and at least once each subsequent year; or

2949 2. Before purchasing any drug from the wholesale ~~drug~~  
 2950 distributor, and each subsequent year obtain a complete copy of  
 2951 the most recent inspection report for the establishment which  
 2952 was prepared by the department or the regulatory authority  
 2953 responsible for wholesale ~~drug~~ distributors in the state in  
 2954 which the establishment is located.

2955 Section 14. Section 499.01211, Florida Statutes, is  
 2956 amended to read:

2957 499.01211 Drug Wholesale Distributor ~~Wholesaler~~ Advisory  
 2958 Council.--

2959 (1) There is created the Drug Wholesale Distributor  
 2960 ~~Wholesaler~~ Advisory Council within the department. The council  
 2961 shall meet at least once each calendar quarter. Staff for the  
 2962 council shall be provided by the department. The council shall  
 2963 consist of 11 members who shall serve without compensation. The  
 2964 council shall elect a chairperson and a vice chairperson  
 2965 annually.

2966 (2) The State Surgeon General, or his or her designee, and  
 2967 the Secretary of Health Care Administration, or her or his  
 2968 designee, shall be members of the council. The State Surgeon  
 2969 General shall appoint nine additional members to the council who  
 2970 shall be appointed to a term of 4 years each, as follows:

2971 (a) Three different persons each of whom is employed by a  
 2972 different prescription drug wholesale distributor ~~wholesaler~~  
 2973 licensed under this part ~~chapter~~ which operates nationally and  
 2974 is a primary wholesale distributor ~~wholesaler~~, as defined in s.  
 2975 499.003 (48) ~~s. 499.012(1)(d)~~.

2976 (b) One person employed by a prescription drug wholesale  
 2977 distributor ~~wholesaler~~ licensed under this part ~~chapter~~ which is  
 2978 a secondary wholesale distributor ~~wholesaler~~, as defined in s.  
 2979 499.003 (53) ~~s. 499.012(1)(f)~~.

2980 (c) One person employed by a retail pharmacy chain located  
 2981 in this state.

2982 (d) One person who is a member of the Board of Pharmacy  
 2983 and is a pharmacist licensed under chapter 465.

2984 (e) One person who is a physician licensed pursuant to  
 2985 chapter 458 or chapter 459.

HB 7049

2008

2986 (f) One person who is an employee of a hospital licensed  
 2987 pursuant to chapter 395 and is a pharmacist licensed pursuant to  
 2988 chapter 465.

2989 (g) One person who is an employee of a pharmaceutical  
 2990 manufacturer.

2991 (3) The council shall review this part ~~ss. 499.001-499.081~~  
 2992 and the rules adopted to administer this part ~~ss. 499.001-~~  
 2993 ~~499.081~~ annually, provide input to the department regarding all  
 2994 proposed rules to administer this part ~~ss. 499.001-499.081~~, make  
 2995 recommendations to the department to improve the protection of  
 2996 the prescription drugs and public health, make recommendations  
 2997 to improve coordination with other states' regulatory agencies  
 2998 and the federal government concerning the wholesale distribution  
 2999 of drugs, and make recommendations to minimize the impact of  
 3000 regulation of the wholesale distribution industry while ensuring  
 3001 protection of the public health.

3002 Section 15. Section 499.01212, Florida Statutes, is  
 3003 created to read:

3004 499.01212 Pedigree paper.--

3005 (1) APPLICATION.--Each person who is engaged in the  
 3006 wholesale distribution of a prescription drug must, prior to or  
 3007 simultaneous with each wholesale distribution, provide a  
 3008 pedigree paper to the person who receives the drug.

3009 (2) FORMAT.--A pedigree paper must contain the following  
 3010 information:

3011 (a) For the wholesale distribution of a prescription drug  
 3012 within the normal distribution chain:

HB 7049

2008

3013           1. The following statement: "This wholesale distributor  
 3014 purchased the specific unit of the prescription drug directly  
 3015 from the manufacturer."

3016           2. The name of the prescription drug as it appears on the  
 3017 label.

3018           3. The quantity, dosage form, and strength of the  
 3019 prescription drug.

3020  
 3021 The wholesale distributor must also maintain and make available  
 3022 to the department, upon request, the point of origin of the  
 3023 prescription drugs, including intracompany transfers, the date  
 3024 of the shipment from the manufacturer to the wholesale  
 3025 distributor, the lot numbers of such drugs, and the invoice  
 3026 numbers from the manufacturer.

3027           (b) For all other wholesale distributions of prescription  
 3028 drugs:

3029           1. The quantity, dosage form, and strength of the  
 3030 prescription drugs.

3031           2. The lot numbers of the prescription drugs.

3032           3. The name and address of each owner of the prescription  
 3033 drug and his or her signature.

3034           4. Shipping information, including the name and address of  
 3035 each person certifying delivery or receipt of the prescription  
 3036 drug.

3037           5. An invoice number, a shipping document number, or  
 3038 another number uniquely identifying the transaction.

3039           6. A certification that the recipient wholesale  
 3040 distributor has authenticated the pedigree papers.

3041           7. The unique serialization of the prescription drug, if  
 3042 the manufacturer or repackager has uniquely serialized the  
 3043 individual prescription drug unit.

3044           8. The name, address, telephone number, and, if available,  
 3045 e-mail contact information of each wholesale distributor  
 3046 involved in the chain of the prescription drug's custody.

3047           (3) EXCEPTIONS.--A pedigree paper is not required for:

3048           (a) The wholesale distribution of a prescription drug by  
 3049 the manufacturer.

3050           (b) The wholesale distribution of a compressed medical  
 3051 gas.

3052           (c) The wholesale distribution of a veterinary  
 3053 prescription drug.

3054           (d) A drop shipment, provided:

3055           1. The wholesale distributor delivers to the recipient of  
 3056 the prescription drug, within 14 days after the shipment  
 3057 notification from the manufacturer, an invoice and the following  
 3058 sworn statement: "This wholesale distributor purchased the  
 3059 specific unit of the prescription drug listed on the invoice  
 3060 directly from the manufacturer, and the specific unit of  
 3061 prescription drug was shipped by the manufacturer directly to a  
 3062 person authorized by law to administer or dispense the legend  
 3063 drug, as defined in s. 465.003, Florida Statutes, or a member of  
 3064 an affiliated group, with the exception of a repackager." The  
 3065 invoice must contain a unique cross-reference to the shipping  
 3066 document sent by the manufacturer to the recipient of the  
 3067 prescription drug.

3068           2. The manufacturer of the prescription drug shipped  
 3069 directly to the recipient provides and the recipient of the  
 3070 prescription drug acquires, within 14 days after receipt of the  
 3071 prescription drug, a shipping document from the manufacturer  
 3072 that contains, at a minimum:

3073           a. The name and address of the manufacturer, including the  
 3074 point of origin of the shipment, and the names and addresses of  
 3075 the wholesale distributor and the purchaser.

3076           b. The name of the prescription drug as it appears on the  
 3077 label.

3078           c. The quantity, dosage form, and strength of the  
 3079 prescription drug.

3080           d. The date of the shipment from the manufacturer.

3081           3. The wholesale distributor maintains and makes available  
 3082 to the department, upon request, the lot number of such drug if  
 3083 not contained in the shipping document acquired by the  
 3084 recipient.

3085  
 3086 Failure of the manufacturer to provide, the recipient to  
 3087 acquire, or the wholesale distributor to deliver the  
 3088 documentation required under this paragraph shall constitute  
 3089 failure to acquire or deliver a pedigree paper under ss.  
 3090 499.005(28) and 499.0051. Forgery by the manufacturer, the  
 3091 recipient, or the wholesale distributor of the documentation  
 3092 required to be acquired or delivered under this paragraph shall  
 3093 constitute forgery of a pedigree paper under s. 499.0051.

3094           4. The wholesale distributor that takes title to, but not  
 3095 possession of, the prescription drug is not a member of the



3096 affiliated group that receives the prescription drug directly  
 3097 from the manufacturer.

3098 (e) The wholesale distribution of a prescription drug by a  
 3099 warehouse within an affiliated group to a warehouse or retail  
 3100 pharmacy within its affiliated group, provided:

3101 1. Any affiliated group member that purchases or receives  
 3102 a prescription drug from outside the affiliated group must  
 3103 receive a pedigree paper if the prescription drug is distributed  
 3104 in or into this state and a pedigree paper is required under  
 3105 this section and must authenticate the documentation as required  
 3106 in s. 499.0121(4), regardless of whether the affiliated group  
 3107 member is directly subject to regulation under this part; and

3108 2. The affiliated group makes available, within 48 hours,  
 3109 to the department on request to one or more of its members all  
 3110 records related to the purchase or acquisition of prescription  
 3111 drugs by members of the affiliated group, regardless of the  
 3112 location where the records are stored, if the prescription drugs  
 3113 were distributed in or into this state.

3114 (f) The repackaging of prescription drugs by a repackager  
 3115 solely for distribution to its affiliated group members for the  
 3116 exclusive distribution to and among retail pharmacies that are  
 3117 members of the affiliated group to which the repackager is a  
 3118 member.

3119 1. The repackager must:

3120 a. For all repackaged prescription drugs distributed in or  
 3121 into this state, state in writing under oath with each  
 3122 distribution of a repackaged prescription drug to an affiliated  
 3123 group member warehouse or repackager: "All repackaged

3124 prescription drugs are purchased by the affiliated group  
 3125 directly from the manufacturer or from a prescription drug  
 3126 wholesale distributor that purchased the prescription drugs  
 3127 directly from the manufacturer."

3128 b. Purchase all prescription drugs it repackages:  
 3129 (I) Directly from the manufacturer; or  
 3130 (II) From a prescription drug wholesale distributor that  
 3131 purchased the prescription drugs directly from the manufacturer.

3132 c. Maintain records in accordance with this section to  
 3133 document that it purchased the prescription drugs directly from  
 3134 the manufacturer or that its prescription drug wholesale  
 3135 supplier purchased the prescription drugs directly from the  
 3136 manufacturer.

3137 2. All members of the affiliated group must provide,  
 3138 within 48 hours, to agents of the department on request to one  
 3139 or more of its members records of purchases by all members of  
 3140 the affiliated group of prescription drugs that have been  
 3141 repackaged, regardless of the location at which the records are  
 3142 stored or at which the repackager is located.

3143 Section 16. Section 499.0122, Florida Statutes, is  
 3144 repealed.

3145 Section 17. Section 499.013, Florida Statutes, is  
 3146 repealed.

3147 Section 18. Subsections (1), (3), (4), (6), (8), and (9)  
 3148 of section 499.015, Florida Statutes, are amended to read:

3149 499.015 Registration of drugs, devices, and cosmetics;  
 3150 issuance of certificates of free sale.--

3151 (1) (a) Except for those persons exempted from the  
 3152 definition of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, any  
 3153 person who manufactures, packages, repackages, labels, or  
 3154 relabels a drug, device, or cosmetic in this state must register  
 3155 such drug, device, or cosmetic biennially with the department;  
 3156 pay a fee in accordance with the fee schedule provided by s.  
 3157 499.041; and comply with this section. The registrant must list  
 3158 each separate and distinct drug, device, or cosmetic at the time  
 3159 of registration.

3160 (b) The department may not register any product that does  
 3161 not comply with the Federal Food, Drug, and Cosmetic Act, as  
 3162 amended, or Title 21 C.F.R. Registration of a product by the  
 3163 department does not mean that the product does in fact comply  
 3164 with all provisions of the Federal Food, Drug, and Cosmetic Act,  
 3165 as amended.

3166 (3) Except for those persons exempted from the definition  
 3167 of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, a person may  
 3168 not sell any product that he or she has failed to register in  
 3169 conformity with this section. Such failure to register subjects  
 3170 such drug, device, or cosmetic product to seizure and  
 3171 condemnation as provided in s. 499.062 ~~ss. 499.062-499.064~~, and  
 3172 subjects such person to the penalties and remedies provided in  
 3173 this part ~~ss. 499.001-499.081~~.

3174 (4) Unless a registration is renewed, it expires 2 years  
 3175 after the last day of the month in which it was issued. The  
 3176 department may issue a stop-sale notice or order against a  
 3177 person that is subject to the requirements of this section and  
 3178 that fails to comply with this section within 31 days after the

3179 date the registration expires. The notice or order shall  
 3180 prohibit such person from selling or causing to be sold any  
 3181 drugs, devices, or cosmetics covered by this part ~~ss. 499.001-~~  
 3182 ~~499.081~~ until he or she complies with the requirements of this  
 3183 section.

3184 (6) The department may issue a certificate of free sale  
 3185 for any product that is required to be registered under this  
 3186 part ~~ss. 499.001-499.081~~.

3187 (8) Notwithstanding any requirements set forth in this  
 3188 part ~~ss. 499.001-499.081~~, a manufacturer of medical devices that  
 3189 is registered with the federal Food and Drug Administration is  
 3190 exempt from this section and s. 499.041(6) if:

3191 (a) The manufacturer's medical devices are approved for  
 3192 marketing by, or listed with the federal Food and Drug  
 3193 Administration in accordance with federal law for commercial  
 3194 distribution; or

3195 (b) The manufacturer subcontracts with a manufacturer of  
 3196 medical devices to manufacture components of such devices.

3197 (9) However, the manufacturer must submit evidence of such  
 3198 registration, listing, or approval with its initial application  
 3199 for a permit to do business in this state, as required in s.  
 3200 499.01 ~~s. 499.013~~ and any changes to such information previously  
 3201 submitted at the time of renewal of the permit. Evidence of  
 3202 approval, listing, and registration by the federal Food and Drug  
 3203 Administration must include:

3204 (a) For Class II devices, a copy of the pre-market  
 3205 notification letter (510K);

3206 (b) For Class III devices, a Federal Drug Administration  
 3207 pre-market approval number;

3208 (c) For a manufacturer who subcontracts with a  
 3209 manufacturer of medical devices to manufacture components of  
 3210 such devices, a Federal Drug Administration registration number;  
 3211 or

3212 (d) For a manufacturer of medical devices whose devices  
 3213 are exempt from pre-market approval by the Federal Drug  
 3214 Administration, a Federal Drug Administration registration  
 3215 number.

3216 Section 19. Subsections (3), (5), and (6) of section  
 3217 499.024, Florida Statutes, are amended to read:

3218 499.024 Drug product classification.--The State Surgeon  
 3219 General shall adopt rules to classify drug products intended for  
 3220 use by humans which the United States Food and Drug  
 3221 Administration has not classified in the federal act or the Code  
 3222 of Federal Regulations.

3223 (3) Any product that falls under the definition of drug in  
 3224 s. 499.003(19) definition, s. 499.003(17), may be classified  
 3225 under the authority of this section. This section does not  
 3226 subject portable emergency oxygen inhalators to classification;  
 3227 however, this section does not exempt any person from ss. 499.01  
 3228 and 499.015.

3229 (5) The department may by rule reclassify drugs subject to  
 3230 this part ~~ss. 499.001-499.081~~ when such classification action is  
 3231 necessary to protect the public health.

3232 (6) The department may adopt rules that exempt from any  
 3233 labeling or packaging requirements of this part ~~ss. 499.001-~~

3234 ~~499.081~~ drugs classified under this section if those  
 3235 requirements are not necessary to protect the public health.

3236 Section 20. Subsections (7), (12), and (15) of section  
 3237 499.028, Florida Statutes, are amended to read:

3238 499.028 Drug samples or complimentary drugs; starter  
 3239 packs; permits to distribute.--

3240 (7) A drug manufacturer or distributor must report to the  
 3241 department any conviction of itself or of its assigns, agents,  
 3242 employees, or representatives for a violation of s. 503(c)(1) of  
 3243 the federal act or of this part ~~ss. 499.001-499.081~~ because of  
 3244 the sale, purchase, or trade of a drug sample or the offer to  
 3245 sell, purchase, or trade a drug sample.

3246 (12) The department may suspend or revoke a permit issued  
 3247 under this section, after giving notice and an opportunity to be  
 3248 heard pursuant to chapter 120, when:

3249 (a) Such permit was obtained by misrepresentation or fraud  
 3250 or through a mistake of the department.

3251 (b) The holder of the permit has distributed or disposed  
 3252 of any prescription legend ~~legend~~ drug, directly or through its agents,  
 3253 employees, or independent contractors, to any person not  
 3254 authorized to possess such drug.

3255 (c) The holder of the permit, or its agents, employees, or  
 3256 independent contractors, has distributed or possessed any  
 3257 prescription legend ~~legend~~ drug except in the usual course of its  
 3258 business.

3259 (d) The holder of the permit, or its agents, employees, or  
 3260 independent contractors, has distributed any prescription legend

3261 drug that is misbranded or adulterated under this part ~~ss.~~  
 3262 ~~499.001-499.081~~.

3263 (e) The holder of the permit, or its agents, employees, or  
 3264 independent contractors, has distributed any prescription ~~legend~~  
 3265 drug without written request, when a written request is required  
 3266 by this section.

3267 (f) The holder of the permit has in its employ, or uses as  
 3268 agent or independent contractor for the purpose of distributing  
 3269 or disposing of drugs, any person who has:

3270 1. Violated the requirements of this section or any rule  
 3271 adopted under this section.

3272 2. Been convicted in any of the courts of this state, the  
 3273 United States, or any other state of a felony or any other crime  
 3274 involving moral turpitude or involving those drugs named or  
 3275 described in chapter 893.

3276 (15) A person may not possess a prescription drug sample  
 3277 unless:

3278 (a) The drug sample was prescribed to her or him as  
 3279 evidenced by the label required in s. 465.0276(5).

3280 (b) She or he is the employee of a complimentary drug  
 3281 distributor that holds a permit issued under this part ~~ss.~~  
 3282 ~~499.001-499.081~~.

3283 (c) She or he is a person to whom prescription drug  
 3284 samples may be distributed pursuant to this section.

3285 (d) He or she is an officer or employee of a federal,  
 3286 state, or local government acting within the scope of his or her  
 3287 employment.

3288 Section 21. Subsections (2) and (3) of section 499.029,  
 3289 Florida Statutes, are amended to read:

3290 499.029 Cancer Drug Donation Program.--

3291 (2) There is created a Cancer Drug Donation Program within  
 3292 the department ~~of Health~~ for the purpose of authorizing and  
 3293 facilitating the donation of cancer drugs and supplies to  
 3294 eligible patients.

3295 (3) As used in this section:

3296 (a) "Cancer drug" means a prescription drug that has been  
 3297 approved under s. 505 of the federal Food, Drug, and Cosmetic  
 3298 Act and is used to treat cancer or its side effects or is used  
 3299 to treat the side effects of a prescription drug used to treat  
 3300 cancer or its side effects. "Cancer drug" does not include a  
 3301 substance listed in Schedule II, Schedule III, Schedule IV, or  
 3302 Schedule V of s. 893.03.

3303 (b) "Closed drug delivery system" means a system in which  
 3304 the actual control of the unit-dose medication package is  
 3305 maintained by the facility rather than by the individual  
 3306 patient.

3307 ~~(c) "Department" means the Department of Health.~~

3308 (c) ~~(d)~~ "Donor" means a patient or patient representative  
 3309 who donates cancer drugs or supplies needed to administer cancer  
 3310 drugs that have been maintained within a closed drug delivery  
 3311 system; health care facilities, nursing homes, hospices, or  
 3312 hospitals with closed drug delivery systems; or pharmacies, drug  
 3313 manufacturers, medical device manufacturers or suppliers, or  
 3314 wholesalers of drugs or supplies, in accordance with this  
 3315 section. "Donor" includes a physician licensed under chapter 458



3316 or chapter 459 who receives cancer drugs or supplies directly  
 3317 from a drug manufacturer, wholesale distributor ~~drug wholesaler,~~  
 3318 or pharmacy.

3319 (d) ~~(e)~~ "Eligible patient" means a person who the  
 3320 department determines is eligible to receive cancer drugs from  
 3321 the program.

3322 (e) ~~(k)~~ "Participant facility" means a class II hospital  
 3323 pharmacy that has elected to participate in the program and that  
 3324 accepts donated cancer drugs and supplies under the rules  
 3325 adopted by the department for the program.

3326 ~~(e) "Prescription drug" means a drug as defined in s.~~  
 3327 ~~465.003(8).~~

3328 (f) ~~(p)~~ "Program" means the Cancer Drug Donation Program  
 3329 created by this section.

3330 (g) ~~(q)~~ "Supplies" means any supplies used in the  
 3331 administration of a cancer drug.

3332 Section 22. Subsection (1) of section 499.03, Florida  
 3333 Statutes, is amended to read:

3334 499.03 Possession of certain drugs without prescriptions  
 3335 unlawful; exemptions and exceptions.--

3336 (1) A person may not possess, or possess with intent to  
 3337 sell, dispense, or deliver, any habit-forming, toxic, harmful,  
 3338 or new drug subject to s. 499.003(33) ~~s. 499.003(29)~~, or  
 3339 prescription legend ~~legend~~ drug as defined in s. 499.003(44) ~~s.~~  
 3340 ~~499.003(25)~~, unless the possession of the drug has been obtained  
 3341 by a valid prescription of a practitioner licensed by law to  
 3342 prescribe the drug. However, this section does not apply to the  
 3343 delivery of such drugs to persons included in any of the classes

3344 | named in this subsection, or to the agents or employees of such  
 3345 | persons, for use in the usual course of their businesses or  
 3346 | practices or in the performance of their official duties, as the  
 3347 | case may be; nor does this section apply to the possession of  
 3348 | such drugs by those persons or their agents or employees for  
 3349 | such use:

3350 |       (a) A licensed pharmacist or any person under the licensed  
 3351 | pharmacist's supervision while acting within the scope of the  
 3352 | licensed pharmacist's practice;

3353 |       (b) A licensed practitioner authorized by law to prescribe  
 3354 | prescription ~~legend~~ drugs or any person under the licensed  
 3355 | practitioner's supervision while acting within the scope of the  
 3356 | licensed practitioner's practice;

3357 |       (c) A qualified person who uses prescription ~~legend~~ drugs  
 3358 | for lawful research, teaching, or testing, and not for resale;

3359 |       (d) A licensed hospital or other institution that procures  
 3360 | such drugs for lawful administration or dispensing by  
 3361 | practitioners;

3362 |       (e) An officer or employee of a federal, state, or local  
 3363 | government; or

3364 |       (f) A person that holds a valid permit issued by the  
 3365 | department pursuant to this part ~~ss. 499.001-499.081~~ which  
 3366 | authorizes that person to possess prescription drugs.

3367 |       Section 23. Section 499.032, Florida Statutes, is amended  
 3368 | to read:

3369 |       499.032 Phenylalanine; prescription  
 3370 | required.--Phenylalanine restricted formula is declared to be a  
 3371 | prescription ~~legend~~ drug and may be dispensed only upon the

3372 prescription of a practitioner authorized by law to prescribe  
 3373 prescription ~~medicinal~~ drugs.

3374 Section 24. Subsection (1) of section 499.033, Florida  
 3375 Statutes, is amended to read:

3376 499.033 Ephedrine; prescription required.--Ephedrine is  
 3377 declared to be a prescription drug.

3378 (1) Except as provided in subsection (2), any product that  
 3379 contains any quantity of ephedrine, a salt of ephedrine, an  
 3380 optical isomer of ephedrine, or a salt of an optical isomer of  
 3381 ephedrine may be dispensed only upon the prescription of a duly  
 3382 licensed practitioner authorized by the laws of the state to  
 3383 prescribe prescription ~~medicinal~~ drugs.

3384 Section 25. Subsections (1) and (3) of section 499.039,  
 3385 Florida Statutes, are amended to read:

3386 499.039 Sale, distribution, or transfer of harmful  
 3387 chemical substances; penalties; authority for enforcement.--It  
 3388 is unlawful for a person to sell, deliver, or give to a person  
 3389 under the age of 18 years any compound, liquid, or chemical  
 3390 containing toluol, hexane, trichloroethylene, acetone, toluene,  
 3391 ethyl acetate, methyl ethyl ketone, trichloroethane,  
 3392 isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl  
 3393 ether acetate, cyclohexanone, nitrous oxide, diethyl ether,  
 3394 alkyl nitrites (butyl nitrite), or any similar substance for the  
 3395 purpose of inducing by breathing, inhaling, or ingesting a  
 3396 condition of intoxication or which is intended to distort or  
 3397 disturb the auditory, visual, or other physical or mental  
 3398 processes.

3399 (1) On the first violation of this section, the department  
 3400 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if  
 3401 the violation has not caused temporary or permanent physical or  
 3402 mental injury to the user.

3403 (3) The department ~~of Health~~ shall adopt rules to  
 3404 implement this section.

3405 Section 26. Section 499.04, Florida Statutes, is amended  
 3406 to read:

3407 499.04 Fee authority.--The department may collect fees for  
 3408 all drug, device, and cosmetic applications, permits, product  
 3409 registrations, and free-sale certificates. The total amount of  
 3410 fees collected from all permits, applications, product  
 3411 registrations, and free-sale certificates must be adequate to  
 3412 fund the expenses incurred by the department in carrying out  
 3413 this part ~~ss. 499.001-499.081~~. The department shall, by rule,  
 3414 establish a schedule of fees that are within the ranges provided  
 3415 in this section and shall adjust those fees from time to time  
 3416 based on the costs associated with administering this part ~~ss.~~  
 3417 ~~499.001-499.081~~. The fees are payable to the department to be  
 3418 deposited into the Florida Drug, Device, and Cosmetic Trust Fund  
 3419 for the sole purpose of carrying out the provisions of this part  
 3420 ~~ss. 499.001-499.081~~.

3421 Section 27. Subsections (1) through (5), (8), and (10) of  
 3422 section 499.041, Florida Statutes, are amended to read:

3423 499.041 Schedule of fees for drug, device, and cosmetic  
 3424 applications and permits, product registrations, and free-sale  
 3425 certificates.--

3426 (1) The department shall assess applicants requiring a  
 3427 manufacturing permit an annual fee within the ranges established  
 3428 in this section for the specific type of manufacturer.

3429 (a) The fee for a prescription drug manufacturer  
 3430 ~~manufacturer's~~ permit may not be less than \$500 or more than  
 3431 \$750 annually.

3432 (b) The fee for a device manufacturer ~~manufacturer's~~  
 3433 permit may not be less than \$500 or more than \$600 annually.

3434 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~  
 3435 permit may not be less than \$250 or more than \$400 annually.

3436 (d) The fee for an over-the-counter drug manufacturer  
 3437 ~~manufacturer's~~ permit may not be less than \$300 or more than  
 3438 \$400 annually.

3439 (e) The fee for a compressed medical gas manufacturer  
 3440 ~~manufacturer's~~ permit may not be less than \$400 or more than  
 3441 \$500 annually.

3442 (f) The fee for a prescription drug repackager  
 3443 ~~repackager's~~ permit may not be less than \$500 or more than \$750  
 3444 annually.

3445 (g) A manufacturer may not be required to pay more than  
 3446 one fee per establishment to obtain an additional manufacturing  
 3447 permit, but each manufacturer must pay the highest fee  
 3448 applicable to his or her operation in each establishment.

3449 (2) The department shall assess an applicant that is  
 3450 required to have a wholesaling permit an annual fee within the  
 3451 ranges established in this section for the specific type of  
 3452 wholesaling.

3453 (a) The fee for a prescription drug wholesale distributor  
 3454 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800  
 3455 annually.

3456 (b) The fee for a compressed medical gas wholesale  
 3457 distributor ~~wholesaler's~~ permit may not be less than \$200 or  
 3458 more than \$300 annually.

3459 (c) The fee for an out-of-state prescription drug  
 3460 wholesale distributor ~~wholesaler's~~ permit may not be less than  
 3461 \$300 or more than \$800 annually.

3462 (d) The fee for a nonresident prescription drug  
 3463 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or  
 3464 more than \$500 annually.

3465 (e) The fee for a retail pharmacy drug wholesale  
 3466 distributor ~~wholesaler's~~ permit may not be less than \$35 or more  
 3467 than \$50 annually.

3468 (f) The fee for a freight forwarder ~~forwarder's~~ permit may  
 3469 not be less than \$200 or more than \$300 annually.

3470 (g) The fee for a veterinary prescription drug wholesale  
 3471 distributor ~~wholesaler's~~ permit may not be less than \$300 or  
 3472 more than \$500 annually.

3473 (h) The fee for a limited prescription drug veterinary  
 3474 wholesale distributor ~~wholesaler's~~ permit may not be less than  
 3475 \$300 or more than \$500 annually.

3476 (3) The department shall assess an applicant that is  
 3477 required to have a retail establishment permit an annual fee  
 3478 within the ranges established in this section for the specific  
 3479 type of retail establishment.

3480 (a) The fee for a veterinary prescription ~~legend~~ drug  
 3481 retail establishment permit may not be less than \$200 or more  
 3482 than \$300 annually.

3483 (b) The fee for a medical oxygen retail establishment  
 3484 permit may not be less than \$200 or more than \$300 annually.

3485 (4) The department shall assess an applicant that is  
 3486 required to have a restricted prescription drug distributor  
 3487 ~~distributor's~~ permit an annual fee of not less than \$200 or more  
 3488 than \$300.

3489 (5) In addition to the fee charged for a permit required  
 3490 by this part ~~ss. 499.001-499.081~~, the department shall assess  
 3491 applicants an initial application fee of \$150 for each new  
 3492 permit issued by the department which requires an onsite  
 3493 inspection.

3494 (8) The department shall assess an out-of-state  
 3495 prescription drug wholesale distributor ~~wholesaler~~ applicant or  
 3496 permittee an onsite inspection fee of not less than \$1,000 or  
 3497 more than \$3,000 annually, to be based on the actual cost of the  
 3498 inspection if an onsite inspection is performed by agents of the  
 3499 department.

3500 (10) The department shall assess other fees as provided in  
 3501 this part ~~ss. 499.001-499.081~~.

3502 Section 28. Section 499.05, Florida Statutes, is amended;  
 3503 subsection (3) of section 499.013, Florida Statutes, is  
 3504 redesignated as paragraph (k) of subsection (1) of that section  
 3505 and amended; paragraph (b) of subsection (2) of section  
 3506 499.0122, Florida Statutes, is redesignated as paragraph (1) of  
 3507 subsection (1) of that section and amended; and subsection (12)

3508 of section 499.012, Florida Statutes, is redesignated as  
 3509 paragraph (m) of subsection (1) of that section and amended, to  
 3510 read:

3511 499.05 Rules.--

3512 (1) The department shall adopt rules to implement and  
 3513 enforce this part ~~ss. 499.001-499.081~~ with respect to:

3514 (a) The definition of terms used in this part ~~ss. 499.001-~~  
 3515 ~~499.081~~, and used in the rules adopted under this part ~~ss.-~~  
 3516 ~~499.001-499.081~~, when the use of the term is not its usual and  
 3517 ordinary meaning.

3518 (b) Labeling requirements for drugs, devices, and  
 3519 cosmetics.

3520 (c) The establishment of fees authorized in this part ~~ss.-~~  
 3521 ~~499.001-499.081~~.

3522 (d) The identification of permits that require an initial  
 3523 application and onsite inspection or other prerequisites for  
 3524 permitting which demonstrate that the establishment and person  
 3525 are in compliance with the requirements of this part ~~ss.-~~  
 3526 ~~499.001-499.081~~.

3527 (e) The application processes and forms for product  
 3528 registration.

3529 (f) Procedures for requesting and issuing certificates of  
 3530 free sale.

3531 (g) Inspections and investigations conducted under s.  
 3532 499.051, and the identification of information claimed to be a  
 3533 trade secret and exempt from the public records law as provided  
 3534 in s. 499.051(7).



HB 7049

2008

3535 (h) The establishment of a range of penalties, as provided  
3536 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of  
3537 the potential impact of a violation of this part ~~ss. 499.001-~~  
3538 ~~499.081~~; and a process for the uncontested settlement of alleged  
3539 violations.

3540 (i) Additional conditions that qualify as an emergency  
3541 medical reason under s. 499.003(55)(b)2. ~~s. 499.012(1)(a)2.b.~~

3542 (j) Procedures and forms relating to the pedigree paper  
3543 requirement of s. 499.01212.

3544 ~~(k)(3) The department may adopt such rules as are~~  
3545 ~~necessary for~~ The protection of the public health, safety, and  
3546 welfare regarding good manufacturing practices that  
3547 manufacturers and repackagers must follow to ensure the safety  
3548 of the products.

3549 ~~(l)(b) The department shall adopt rules relating to~~  
3550 Information required from each retail establishment pursuant to  
3551 s. 499.012(3) ~~s. 499.01(4)~~, including requirements for  
3552 prescriptions or orders.

3553 ~~(m)(12) The department may adopt rules governing~~ The  
3554 recordkeeping, storage, and handling with respect to each of the  
3555 distributions of prescription drugs specified in s.  
3556 499.003(55)(a)-(d) subparagraphs (1)(a)1-4.

3557 (n) Alternatives to compliance with s. 499.01212 for a  
3558 prescription drug in the inventory of a permitted prescription  
3559 drug wholesale distributor as of June 30, 2006, and the return  
3560 of a prescription drug purchased prior to July 1, 2006. The  
3561 department may specify time limits for such alternatives.

HB 7049

2008

3562 (2) With respect to products in interstate commerce, those  
 3563 rules must not be inconsistent with rules and regulations of  
 3564 federal agencies unless specifically otherwise directed by the  
 3565 Legislature.

3566 (3) The department shall adopt rules regulating  
 3567 recordkeeping for and the storage, handling, and distribution of  
 3568 medical devices and over-the-counter drugs to protect the public  
 3569 from adulterated products.

3570 Section 29. Section 499.051, Florida Statutes, is amended  
 3571 to read:

3572 499.051 Inspections and investigations.--

3573 (1) The agents of the department ~~of Health~~ and of the  
 3574 Department of Law Enforcement, after they present proper  
 3575 identification, may inspect, monitor, and investigate any  
 3576 establishment permitted pursuant to this part ~~ss. 499.001-~~  
 3577 ~~499.081~~ during business hours for the purpose of enforcing this  
 3578 part ~~ss. 499.001-499.081~~, chapters 465, 501, and 893, and the  
 3579 rules of the department that protect the public health, safety,  
 3580 and welfare.

3581 (2) In addition to the authority set forth in subsection  
 3582 (1), the department and any duly designated officer or employee  
 3583 of the department may enter and inspect any other establishment  
 3584 for the purpose of determining compliance with this part ~~ss.~~  
 3585 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~  
 3586 regarding any drug, device, or cosmetic product.

3587 (3) Any application for a permit or product registration  
 3588 or for renewal of such permit or registration made pursuant to  
 3589 this part ~~ss. 499.001-499.081~~ and rules adopted under this part

3590 ~~these sections~~ constitutes permission for any entry or  
 3591 inspection of the premises in order to verify compliance with  
 3592 this part ~~these sections~~ and rules; to discover, investigate,  
 3593 and determine the existence of compliance; or to elicit,  
 3594 receive, respond to, and resolve complaints and violations.

3595 (4) Any application for a permit made pursuant to s.  
 3596 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that  
 3597 section ~~these sections~~ constitutes permission for agents of the  
 3598 department ~~of Health~~ and the Department of Law Enforcement,  
 3599 after presenting proper identification, to inspect, review, and  
 3600 copy any financial document or record related to the  
 3601 manufacture, repackaging, or distribution of a drug as is  
 3602 necessary to verify compliance with this part ~~ss. 499.001-~~  
 3603 ~~499.081~~ and the rules adopted by the department to administer  
 3604 this part ~~these sections~~, in order to discover, investigate, and  
 3605 determine the existence of compliance, or to elicit, receive,  
 3606 respond to, and resolve complaints and violations.

3607 (5) The authority to inspect under this section includes  
 3608 the authority to access, review, and copy any and all financial  
 3609 documents related to the activity of manufacturing, repackaging,  
 3610 or distributing prescription drugs.

3611 (6) The authority to inspect under this section includes  
 3612 the authority to secure:

3613 (a) Samples or specimens of any drug, device, or cosmetic;  
 3614 or

3615 (b) Such other evidence as is needed for any action to  
 3616 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted  
 3617 under this part ~~these sections~~.

3618 (7) The complaint and all information obtained pursuant to  
 3619 the investigation by the department are confidential and exempt  
 3620 from the provisions of s. 119.07(1) and s. 24(a), Art. I of the  
 3621 State Constitution until the investigation and the enforcement  
 3622 action are completed. However, trade secret information  
 3623 contained therein as defined by s. 812.081(1)(c) shall remain  
 3624 confidential and exempt from the provisions of s. 119.07(1) and  
 3625 s. 24(a), Art. I of the State Constitution, as long as the  
 3626 information is retained by the department. This subsection does  
 3627 not prohibit the department from using such information for  
 3628 regulatory or enforcement proceedings under this chapter or from  
 3629 providing such information to any law enforcement agency or any  
 3630 other regulatory agency. However, the receiving agency shall  
 3631 keep such records confidential and exempt as provided in this  
 3632 subsection. In addition, this subsection is not intended to  
 3633 prevent compliance with the provisions of s. 499.01212 ~~s.~~  
 3634 ~~499.0121(6)(d)~~, and the pedigree papers required in that section  
 3635 ~~subsection~~ shall not be deemed a trade secret.

3636 Section 30. Section 499.052, Florida Statutes, is amended  
 3637 to read:

3638 499.052 Records of interstate shipment.--For the purpose  
 3639 of enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in  
 3640 interstate commerce and persons receiving drugs, devices, or  
 3641 cosmetics in interstate commerce must, upon the request, in the  
 3642 manner set out below, by an officer or employee duly designated  
 3643 by the department, permit the officer or employee to have access  
 3644 to and to copy all records showing the movement in interstate

HB 7049

2008

3645 commerce of any drug, device, or cosmetic, and the quantity,  
 3646 shipper, and consignee thereof.

3647 Section 31. Subsection (4) of section 499.055, Florida  
 3648 Statutes, is amended to read:

3649 499.055 Reports and dissemination of information by  
 3650 department.--

3651 (4) The department shall publish on the department's  
 3652 website and update at least monthly:

3653 (a) A list of the prescription drug wholesale distributors  
 3654 ~~wholesalers~~, out-of-state prescription drug wholesale  
 3655 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
 3656 distributors ~~wholesalers~~ against whom the department has  
 3657 initiated enforcement action pursuant to this part ~~ss. 499.001-~~  
 3658 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or  
 3659 otherwise file an administrative complaint and the permit number  
 3660 of each such wholesale distributor ~~wholesaler~~.

3661 (b) A list of the prescription drug wholesale distributors  
 3662 ~~wholesalers~~, out-of-state prescription drug wholesale  
 3663 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
 3664 distributors ~~wholesalers~~ to which the department has issued a  
 3665 permit, including the date on which each permit will expire.

3666 (c) A list of the prescription drug wholesale distributor  
 3667 ~~wholesalers~~, out-of-state prescription drug wholesale  
 3668 distributor ~~wholesalers~~, and retail pharmacy drug wholesale  
 3669 distributor ~~wholesalers~~ permits that have been returned to the  
 3670 department, were suspended, were revoked, have expired, or were  
 3671 not renewed in the previous year.

3672 Section 32. Subsections (1) and (3) of section 499.06,  
 3673 Florida Statutes, are amended to read:

3674 499.06 Embargoing, detaining, or destroying article or  
 3675 processing equipment which is in violation of law or rule.--

3676 (1) When a duly authorized agent of the department finds,  
 3677 or has probable cause to believe, that any drug, device, or  
 3678 cosmetic is in violation of any provision of this part ~~ss.~~  
 3679 ~~499.001-499.081~~ or any rule adopted under this part ~~such~~  
 3680 ~~sections~~ so as to be dangerous, unwholesome, or fraudulent  
 3681 within the meaning of this part ~~ss. 499.001-499.081~~, she or he  
 3682 may issue and enforce a stop-sale, stop-use, removal, or hold  
 3683 order, which order gives notice that such article or processing  
 3684 equipment is, or is suspected of being, in violation and has  
 3685 been detained or embargoed, and which order warns all persons  
 3686 not to remove, use, or dispose of such article or processing  
 3687 equipment by sale or otherwise until permission for removal,  
 3688 use, or disposal is given by such agent or the court. It is  
 3689 unlawful for any person to remove, use, or dispose of such  
 3690 detained or embargoed article or processing equipment by sale or  
 3691 otherwise without such permission; and such act is a felony of  
 3692 the second degree, punishable as provided in s. 775.082, s.  
 3693 775.083, or s. 775.084.

3694 (3) If the court finds that the detained or embargoed  
 3695 article or processing equipment is in violation, such article or  
 3696 processing equipment shall, after entry of the court order, be  
 3697 destroyed or made sanitary at the expense of the claimant  
 3698 thereof, under the supervision of such agent; and all court  
 3699 costs, fees, and storage and other proper expenses shall be

3700 | taxed against the claimant of such article or processing  
 3701 | equipment or her or his agent. However, when the violation can  
 3702 | be corrected by proper labeling of the article or sanitizing of  
 3703 | the processing equipment, and after such costs, fees, and  
 3704 | expenses have been paid and a good and sufficient bond,  
 3705 | conditioned that such article be so labeled or processed or such  
 3706 | processing equipment be so sanitized, has been executed, the  
 3707 | court may by order direct that such article or processing  
 3708 | equipment be delivered to the claimant thereof for such  
 3709 | labeling, processing, or sanitizing, under the supervision of an  
 3710 | agent of the department. The expense of such supervision shall  
 3711 | be paid by the claimant. Such bond shall be returned to the  
 3712 | claimant of the article or processing equipment upon  
 3713 | representation to the court by the department that the article  
 3714 | or processing equipment is no longer in violation of this part  
 3715 | ~~ss. 499.001-499.081~~ and that the expenses of such supervision  
 3716 | have been paid.

3717 |         Section 33. Section 499.062, Florida Statutes, is amended;  
 3718 | section 499.063, Florida Statutes, is redesignated as section  
 3719 | (2) of that section and amended; and section 499.064, Florida  
 3720 | Statutes, is redesignated as paragraphs (a) and (b) of  
 3721 | subsection (2) of that section and amended, to read:

3722 |             499.062 ~~Cause for~~ Seizure and condemnation of drugs,  
 3723 | devices, or cosmetics.--

3724 |             (1) Any article of any drug, device, or cosmetic that is  
 3725 | adulterated or misbranded under this part ~~ss. 499.001-499.081~~ is  
 3726 | subject to seizure and condemnation by the department or by its

3727 | duly authorized agents designated for that purpose in regard to  
 3728 | drugs, devices, or cosmetics.

3729 |        ~~(2) 499.063 Seizure; procedure; prohibition on sale or~~  
 3730 | ~~disposal of article; penalty.~~ Whenever a duly authorized  
 3731 | officer or employee of the department finds cause, or has  
 3732 | probable cause to believe that cause exists, for the seizure of  
 3733 | any drug, device, or cosmetic, as set out in this part ss.  
 3734 | ~~499.001-499.081~~, he or she shall affix to the article a tag,  
 3735 | stamp, or other appropriate marking, giving notice that the  
 3736 | article is, or is suspected of being, subject to seizure under  
 3737 | this part ss. ~~499.001-499.081~~ and that the article has been  
 3738 | detained and seized by the department. Such officer or employee  
 3739 | shall also warn all persons not to remove or dispose of the  
 3740 | article, by sale or otherwise, until permission is given by the  
 3741 | department or the court. Any person who violates this subsection  
 3742 | ~~section~~ is guilty of a felony of the second degree, punishable  
 3743 | as provided in s. 775.082, s. 775.083, or s. 775.084.

3744 |        ~~(a) 499.064 Condemnation and sale; release of seized~~  
 3745 | ~~article.~~ ~~(1)~~ When any article detained or seized under this  
 3746 | subsection ~~s.~~ ~~499.063~~ has been found by the department to be  
 3747 | subject to seizure and condemnation ~~under s.~~ ~~499.063~~, the  
 3748 | department shall petition the court for an order of condemnation  
 3749 | or sale, as the court directs. The proceeds of the sale of  
 3750 | drugs, devices, and cosmetics, less the legal costs and charges,  
 3751 | shall be deposited into the Florida Drug, Device, and Cosmetic  
 3752 | Trust Fund.

3753 |        ~~(b) (2)~~ If the department finds that any article seized  
 3754 | under this subsection ~~s.~~ ~~499.063~~ was not subject to seizure



HB 7049

2008

3755 ~~under that section~~, the department or the designated officer or  
 3756 employee shall remove the tag or marking.

3757 Section 34. Section 499.065, Florida Statutes, is amended  
 3758 to read:

3759 499.065 Inspections; imminent danger.--

3760 (1) Notwithstanding s. 499.051, the department shall  
 3761 inspect each prescription drug wholesale distributor  
 3762 establishment, prescription drug repackager establishment,  
 3763 veterinary prescription drug wholesale distributor  
 3764 establishment, limited prescription drug veterinary wholesale  
 3765 distributor ~~wholesaler~~ establishment, and retail pharmacy drug  
 3766 wholesale distributor ~~wholesaler~~ establishment that is required  
 3767 to be permitted under this part ~~chapter~~ as often as necessary to  
 3768 ensure compliance with applicable laws and rules. The department  
 3769 shall have the right of entry and access to these facilities at  
 3770 any reasonable time.

3771 (2) To protect the public from prescription drugs that are  
 3772 adulterated or otherwise unfit for human or animal consumption,  
 3773 the department may examine, sample, seize, and stop the sale or  
 3774 use of prescription drugs to determine the condition of those  
 3775 drugs. The department may immediately seize and remove any  
 3776 prescription drugs if the State Surgeon General or his or her  
 3777 designee determines that the prescription drugs represent a  
 3778 threat to the public health. The owner of any property seized  
 3779 under this section may, within 10 days after the seizure, apply  
 3780 to a court of competent jurisdiction for whatever relief is  
 3781 appropriate. At any time after 10 days, the department may  
 3782 destroy the drugs as contraband.

3783           (3) The department may determine that a prescription drug  
 3784 wholesale distributor establishment, prescription drug  
 3785 repackager establishment, veterinary prescription drug wholesale  
 3786 distributor establishment, limited prescription drug veterinary  
 3787 wholesale distributor ~~wholesaler~~ establishment, or retail  
 3788 pharmacy drug wholesale distributor ~~wholesaler~~ establishment  
 3789 that is required to be permitted under this part ~~chapter~~ is an  
 3790 imminent danger to the public health and shall require its  
 3791 immediate closure if the establishment fails to comply with  
 3792 applicable laws and rules and, because of the failure, presents  
 3793 an imminent threat to the public's health, safety, or welfare.  
 3794 Any establishment so deemed and closed shall remain closed until  
 3795 allowed by the department or by judicial order to reopen.

3796           (4) For purposes of this section, a refusal to allow entry  
 3797 to the department for inspection at reasonable times, or a  
 3798 failure or refusal to provide the department with required  
 3799 documentation for purposes of inspection, constitutes an  
 3800 imminent danger to the public health.

3801           Section 35. Subsections (1) through (4) of section  
 3802 499.066, Florida Statutes, are amended to read:

3803           499.066 Penalties; remedies.--In addition to other  
 3804 penalties and other enforcement provisions:

3805           (1) The department may institute such suits or other legal  
 3806 proceedings as are required to enforce any provision of this  
 3807 part ~~ss. 499.001-499.081~~. If it appears that a person has  
 3808 violated any provision of this part ~~ss. 499.001-499.081~~ for  
 3809 which criminal prosecution is provided, the department may  
 3810 provide the appropriate state attorney or other prosecuting

3811 agency having jurisdiction with respect to such prosecution with  
 3812 the relevant information in the department's possession.

3813 (2) If any person engaged in any activity covered by this  
 3814 part ss. 499.001-499.081 violates any provision of this part  
 3815 ~~those sections~~, any rule adopted under this part ~~those sections~~,  
 3816 or a cease and desist order as provided by this part ~~those~~  
 3817 ~~sections~~, the department may obtain an injunction in the circuit  
 3818 court of the county in which the violation occurred or in which  
 3819 the person resides or has its principal place of business, and  
 3820 may apply in that court for such temporary and permanent orders  
 3821 as the department considers necessary to restrain the person  
 3822 from engaging in any such activities until the person complies  
 3823 with this part ss. 499.001-499.081, the rules adopted under this  
 3824 part ~~those sections~~, and the orders of the department authorized  
 3825 by this part ~~those sections~~ or to mandate compliance with this  
 3826 part ss. 499.001-499.081, the rules adopted under this part  
 3827 ~~those sections~~, and any order or permit issued by the department  
 3828 under this part ~~those sections~~.

3829 (3) The department may impose an administrative fine, not  
 3830 to exceed \$5,000 per violation per day, for the violation of any  
 3831 provision of this part ss. 499.001-499.081 or rules adopted  
 3832 under this part ~~those sections~~. Each day a violation continues  
 3833 constitutes a separate violation, and each separate violation is  
 3834 subject to a separate fine. All amounts collected pursuant to  
 3835 this section shall be deposited into the Florida Drug, Device,  
 3836 and Cosmetic Trust Fund and are appropriated for the use of the  
 3837 department in administering this part ss. 499.001-499.081. In

HB 7049

2008

3838 determining the amount of the fine to be levied for a violation,  
 3839 the department shall consider:

3840 (a) The severity of the violation;

3841 (b) Any actions taken by the person to correct the  
 3842 violation or to remedy complaints; and

3843 (c) Any previous violations.

3844 (4) The department shall deposit any rewards, fines, or  
 3845 collections that are due the department and which derive from  
 3846 joint enforcement activities with other state and federal  
 3847 agencies which relate to this part ss. 499.001-499.081, chapter  
 3848 893, or the federal act, into the Florida Drug, Device, and  
 3849 Cosmetic Trust Fund. The proceeds of those rewards, fines, and  
 3850 collections are appropriated for the use of the department in  
 3851 administering this part ss. 499.001-499.081.

3852 Section 36. Section 499.0661, Florida Statutes, is amended  
 3853 to read:

3854 499.0661 Cease and desist orders; removal of certain  
 3855 persons.--

3856 (1)~~(2)~~ CEASE AND DESIST ORDERS.--

3857 (a) In addition to any authority otherwise provided in  
 3858 this chapter, the department may issue and serve a complaint  
 3859 stating charges upon any permittee or upon any affiliated party,  
 3860 whenever the department has reasonable cause to believe that the  
 3861 person or individual named therein is engaging in or has engaged  
 3862 in conduct that is:

3863 1. An act that demonstrates a lack of fitness or  
 3864 trustworthiness to engage in the business authorized under the  
 3865 permit issued pursuant to this part ss. 499.001-499.081, is

3866 hazardous to the public health, or constitutes business  
 3867 operations that are a detriment to the public health;

3868 2. A violation of any provision of this part ~~ss. 499.001-~~  
 3869 ~~499.081~~;

3870 3. A violation of any rule of the department;

3871 4. A violation of any order of the department; or

3872 5. A breach of any written agreement with the department.

3873 (b) The complaint must contain a statement of facts and  
 3874 notice of opportunity for a hearing pursuant to ss. 120.569 and  
 3875 120.57.

3876 (c) If a hearing is not requested within the time allowed  
 3877 by ss. 120.569 and 120.57, or if a hearing is held and the  
 3878 department finds that any of the charges are proven, the  
 3879 department may enter an order directing the permittee or the  
 3880 affiliated party named in the complaint to cease and desist from  
 3881 engaging in the conduct complained of and take corrective action  
 3882 to remedy the effects of past improper conduct and assure future  
 3883 compliance.

3884 (d) A contested or default cease and desist order is  
 3885 effective when reduced to writing and served upon the permittee  
 3886 or affiliated party named therein. An uncontested cease and  
 3887 desist order is effective as agreed.

3888 (e) Whenever the department finds that conduct described  
 3889 in paragraph (a) is likely to cause an immediate threat to the  
 3890 public health, it may issue an emergency cease and desist order  
 3891 requiring the permittee or any affiliated party to immediately  
 3892 cease and desist from engaging in the conduct complained of and  
 3893 to take corrective and remedial action. The emergency order is

3894 effective immediately upon service of a copy of the order upon  
 3895 the permittee or affiliated party named therein and remains  
 3896 effective for 90 days. If the department begins nonemergency  
 3897 cease and desist proceedings under this subsection, the  
 3898 emergency order remains effective until the conclusion of the  
 3899 proceedings under ss. 120.569 and 120.57.

3900 (2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

3901 (a) The department may issue and serve a complaint stating  
 3902 charges upon any affiliated party and upon the permittee  
 3903 involved whenever the department has reason to believe that an  
 3904 affiliated party is engaging in or has engaged in conduct that  
 3905 constitutes:

3906 1. An act that demonstrates a lack of fitness or  
 3907 trustworthiness to engage in the business authorized under the  
 3908 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
 3909 hazardous to the public health, or constitutes business  
 3910 operations that are a detriment to the public health;

3911 2. A willful violation of this part ~~ss. 499.001-499.081~~;  
 3912 however, if the violation constitutes a misdemeanor, a complaint  
 3913 may not be served as provided in this section until the  
 3914 affiliated party is notified in writing of the matter of the  
 3915 violation and has been afforded a reasonable period of time, as  
 3916 set forth in the notice, to correct the violation and has failed  
 3917 to do so;

3918 3. A violation of any other law involving fraud or moral  
 3919 turpitude which constitutes a felony;

3920 4. A willful violation of any rule of the department;

3921 5. A willful violation of any order of the department; or

3922           6. A material misrepresentation of fact, made knowingly  
 3923 and willfully or made with reckless disregard for the truth of  
 3924 the matter.

3925           (b) The complaint must contain a statement of facts and  
 3926 notice of opportunity for a hearing pursuant to ss. 120.569 and  
 3927 120.57.

3928           (c) If a hearing is not requested within the time allotted  
 3929 by ss. 120.569 and 120.57, or if a hearing is held and the  
 3930 department finds that any of the charges in the complaint are  
 3931 proven true, the department may enter an order removing the  
 3932 affiliated party or restricting or prohibiting participation by  
 3933 the person in the affairs of that permittee or of any other  
 3934 permittee.

3935           (d) A contested or default order of removal, restriction,  
 3936 or prohibition is effective when reduced to writing and served  
 3937 on the permittee and the affiliated party. An uncontested order  
 3938 of removal, restriction, or prohibition is effective as agreed.

3939           (e)1. The chief executive officer, designated  
 3940 representative, or the person holding the equivalent office, of  
 3941 a permittee shall promptly notify the department if she or he  
 3942 has actual knowledge that any affiliated party is charged with a  
 3943 felony in a state or federal court.

3944           2. Whenever any affiliated party is charged with a felony  
 3945 in a state or federal court or with the equivalent of a felony  
 3946 in the courts of any foreign country with which the United  
 3947 States maintains diplomatic relations, and the charge alleges  
 3948 violation of any law involving prescription drugs,  
 3949 pharmaceuticals, fraud, theft, or moral turpitude, the

HB 7049

2008

3950 department may enter an emergency order suspending the  
3951 affiliated party or restricting or prohibiting participation by  
3952 the affiliated party in the affairs of the particular permittee  
3953 or of any other permittee upon service of the order upon the  
3954 permittee and the affiliated party charged. The order must  
3955 contain notice of opportunity for a hearing pursuant to ss.  
3956 120.569 and 120.57, where the affiliated party may request a  
3957 postsuspension hearing to show that continued service to or  
3958 participation in the affairs of the permittee does not pose a  
3959 threat to the public health or the interests of the permittee  
3960 and does not threaten to impair public confidence in the  
3961 permittee. In accordance with applicable departmental rules, the  
3962 department shall notify the affiliated party whether the order  
3963 suspending or prohibiting the person from participation in the  
3964 affairs of a permittee will be rescinded or otherwise modified.  
3965 The emergency order remains in effect, unless otherwise modified  
3966 by the department, until the criminal charge is disposed of. The  
3967 acquittal of the person charged, or the final, unappealed  
3968 dismissal of all charges against the person, dissolves the  
3969 emergency order but does not prohibit the department from  
3970 instituting proceedings under paragraph (a). If the person  
3971 charged is convicted or pleads guilty or nolo contendere,  
3972 whether or not an adjudication of guilt is entered by the court,  
3973 the emergency order shall become final.

3974 (f) Any affiliated party removed pursuant to this section  
3975 is not eligible for reemployment by the permittee or to be an  
3976 affiliated party of any permittee except upon the written  
3977 consent of the department. Any affiliated party who is removed,



HB 7049

2008

3978 restricted, or prohibited from participating in the affairs of a  
 3979 permittee pursuant to this section may petition the department  
 3980 for modification or termination of the removal, restriction, or  
 3981 prohibition.

3982 Section 37. Section 499.067, Florida Statutes, is amended  
 3983 to read:

3984 499.067 Denial, suspension, or revocation of permit,  
 3985 certification, or registration.--

3986 (1)(a) The department may deny, suspend, or revoke a  
 3987 permit if it finds that there has been a substantial failure to  
 3988 comply with this part ~~ss. 499.001-499.081~~ or chapter 465,  
 3989 chapter 501, or chapter 893, the rules adopted under this part  
 3990 ~~any of those sections~~ or those chapters, any final order of the  
 3991 department, or applicable federal laws or regulations or other  
 3992 state laws or rules governing drugs, devices, or cosmetics.

3993 (b) The department may deny an application for a permit or  
 3994 certification, or suspend or revoke a permit or certification,  
 3995 if the department finds that:

3996 1. The applicant is not of good moral character or that it  
 3997 would be a danger or not in the best interest of the public  
 3998 health, safety, and welfare if the applicant were issued a  
 3999 permit or certification.

4000 2. The applicant has not met the requirements for the  
 4001 permit or certification.

4002 3. The applicant is not eligible for a permit or  
 4003 certification for any of the reasons enumerated in s. 499.012 ~~s.~~  
 4004 ~~499.01~~ or ~~s. 499.012(5)~~.

4005           4. The applicant, permittee, or person certified under s.  
 4006 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions  
 4007 enumerated in s. 499.012 ~~s. 499.01~~ ~~or s. 499.012(5)~~.

4008           5. The applicant, permittee, or person certified under s.  
 4009 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.  
 4010 499.005-499.0054.

4011           (2) The department may deny, suspend, or revoke any  
 4012 registration required by the provisions of this part ~~ss.~~  
 4013 ~~499.001-499.081~~ for the violation of any provision of this part  
 4014 ~~ss. 499.001-499.081~~ or of any rules adopted under this part  
 4015 ~~those sections.~~

4016           (3) The department may revoke or suspend a permit:

4017           (a) If the permit was obtained by misrepresentation or  
 4018 fraud or through a mistake of the department;

4019           (b) If the permit was procured, or attempted to be  
 4020 procured, for any other person by making or causing to be made  
 4021 any false representation; or

4022           (c) If the permittee has violated any provision of this  
 4023 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~  
 4024 ~~sections.~~

4025           (4) If any permit issued under this part ~~ss. 499.001-~~  
 4026 ~~499.081~~ is revoked or suspended, the owner, manager, operator,  
 4027 or proprietor of the establishment shall cease to operate as the  
 4028 permit authorized, from the effective date of the suspension or  
 4029 revocation until the person is again registered with the  
 4030 department and possesses the required permit. If a permit is  
 4031 revoked or suspended, the owner, manager, or proprietor shall  
 4032 remove all signs and symbols that identify the operation as

HB 7049

2008

4033 premises permitted as a drug wholesaling establishment; drug,  
4034 device, or cosmetic manufacturing establishment; or retail  
4035 establishment. The department shall determine the length of time  
4036 for which the permit is to be suspended. If a permit is revoked,  
4037 the person that owns or operates the establishment may not apply  
4038 for any permit under this part ~~ss. 499.001-499.081~~ for a period  
4039 of 1 year after the date of the revocation. A revocation of a  
4040 permit may be permanent if the department considers that to be  
4041 in the best interest of the public health.

4042 (5) The department may deny, suspend, or revoke a permit  
4043 issued under this part ~~ss. 499.001-499.081~~ which authorizes the  
4044 permittee to purchase prescription drugs, if any owner, officer,  
4045 employee, or other person who participates in administering or  
4046 operating the establishment has been found guilty of any  
4047 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,  
4048 chapter 501, or chapter 893, any rules adopted under this part  
4049 ~~any of those sections~~ or those chapters, or any federal or state  
4050 drug law, regardless of whether the person has been pardoned,  
4051 had her or his civil rights restored, or had adjudication  
4052 withheld.

4053 (6) The department shall deny, suspend, or revoke the  
4054 permit of any person or establishment if the assignment, sale,  
4055 transfer, or lease of an establishment permitted under this part  
4056 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil  
4057 action, or criminal prosecution.

4058 (7) Notwithstanding s. 120.60(5), if a permittee fails to  
4059 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may  
4060 revoke the permit of the permittee and shall provide notice of

HB 7049

2008

4061 the intended agency action by posting a notice at the  
 4062 department's headquarters and by mailing a copy of the notice of  
 4063 intended agency action by certified mail to the most recent  
 4064 mailing address on record with the department and, if the  
 4065 permittee is not a natural person, to the permittee's registered  
 4066 agent on file with the Department of State.

4067 Section 38. Paragraph (a) of subsection (1) of section  
 4068 409.9201, Florida Statutes, is amended to read:

4069 409.9201 Medicaid fraud.--

4070 (1) As used in this section, the term:

4071 (a) "Legend drug" means any drug, including, but not  
 4072 limited to, finished dosage forms or active ingredients that are  
 4073 subject to, defined by, or described by s. 503(b) of the Federal  
 4074 Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.007(13)  
 4075 ~~s. 499.007(12)~~, or s. 499.003(47) or (54) ~~s. 499.0122(1)(b) or~~  
 4076 ~~(e)~~.

4077  
 4078 The value of individual items of the legend drugs or goods or  
 4079 services involved in distinct transactions committed during a  
 4080 single scheme or course of conduct, whether involving a single  
 4081 person or several persons, may be aggregated when determining  
 4082 the punishment for the offense.

4083 Section 39. Paragraph (c) of subsection (9) of section  
 4084 460.403, Florida Statutes, is amended to read:

4085 460.403 Definitions.--As used in this chapter, the term:

4086 (9)

4087 (c)1. Chiropractic physicians may adjust, manipulate, or  
 4088 treat the human body by manual, mechanical, electrical, or

4089 natural methods; by the use of physical means or physiotherapy,  
 4090 including light, heat, water, or exercise; by the use of  
 4091 acupuncture; or by the administration of foods, food  
 4092 concentrates, food extracts, and items for which a prescription  
 4093 is not required and may apply first aid and hygiene, but  
 4094 chiropractic physicians are expressly prohibited from  
 4095 prescribing or administering to any person any legend drug  
 4096 except as authorized under subparagraph 2., from performing any  
 4097 surgery except as stated herein, or from practicing obstetrics.

4098 2. Notwithstanding the prohibition against prescribing and  
 4099 administering legend drugs under subparagraph 1. or s.  
 4100 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic  
 4101 physicians may order, store, and administer, for emergency  
 4102 purposes only at the chiropractic physician's office or place of  
 4103 business, prescription medical oxygen and may also order, store,  
 4104 and administer the following topical anesthetics in aerosol  
 4105 form:

4106 a. Any solution consisting of 25 percent ethylchloride and  
 4107 75 percent dichlorodifluoromethane.

4108 b. Any solution consisting of 15 percent  
 4109 dichlorodifluoromethane and 85 percent  
 4110 trichloromonofluoromethane.

4111  
 4112 However, this paragraph does not authorize a chiropractic  
 4113 physician to prescribe medical oxygen as defined in chapter 499.

4114 Section 40. Subsection (3) of section 465.0265, Florida  
 4115 Statutes, is amended to read:

4116 465.0265 Centralized prescription filling.--

HB 7049

2008

4117 (3) The filling, delivery, and return of a prescription by  
 4118 one pharmacy for another pursuant to this section shall not be  
 4119 construed as the filling of a transferred prescription as set  
 4120 forth in s. 465.026 or as a wholesale distribution as set forth  
 4121 in s. 499.003(55) ~~s. 499.012(1)(a)~~.

4122 Section 41. Section 794.075, Florida Statutes, is amended  
 4123 to read:

4124 794.075 Sexual predators; erectile dysfunction drugs.--

4125 (1) A person may not possess a prescription drug, as  
 4126 defined in s. 499.003(44) ~~s. 499.003(25)~~, for the purpose of  
 4127 treating erectile dysfunction if the person is designated as a  
 4128 sexual predator under s. 775.21.

4129 (2) A person who violates a provision of this section for  
 4130 the first time commits a misdemeanor of the second degree,  
 4131 punishable as provided in s. 775.082 or s. 775.083. A person who  
 4132 violates a provision of this section a second or subsequent time  
 4133 commits a misdemeanor of the first degree, punishable as  
 4134 provided in s. 775.082 or s. 775.083.

4135 Section 42. Paragraph (a) of subsection (1) of section  
 4136 895.02, Florida Statutes, is amended to read:

4137 895.02 Definitions.--As used in ss. 895.01-895.08, the  
 4138 term:

4139 (1) "Racketeering activity" means to commit, to attempt to  
 4140 commit, to conspire to commit, or to solicit, coerce, or  
 4141 intimidate another person to commit:

4142 (a) Any crime that is chargeable by indictment or  
 4143 information under the following provisions of the Florida  
 4144 Statutes:

- 4145 |           1. Section 210.18, relating to evasion of payment of
- 4146 | cigarette taxes.
- 4147 |           2. Section 403.727(3)(b), relating to environmental
- 4148 | control.
- 4149 |           3. Section 409.920 or s. 409.9201, relating to Medicaid
- 4150 | fraud.
- 4151 |           4. Section 414.39, relating to public assistance fraud.
- 4152 |           5. Section 440.105 or s. 440.106, relating to workers'
- 4153 | compensation.
- 4154 |           6. Section 443.071(4), relating to creation of a
- 4155 | fictitious employer scheme to commit unemployment compensation
- 4156 | fraud.
- 4157 |           7. Section 465.0161, relating to distribution of medicinal
- 4158 | drugs without a permit as an Internet pharmacy.
- 4159 |           8. Section 499.0051 ~~Sections 499.0051, 499.0052,~~
- 4160 | ~~499.00535, 499.00545, and 499.0691,~~ relating to crimes involving
- 4161 | contraband and adulterated drugs.
- 4162 |           9. Part IV of chapter 501, relating to telemarketing.
- 4163 |           10. Chapter 517, relating to sale of securities and
- 4164 | investor protection.
- 4165 |           11. Section 550.235, s. 550.3551, or s. 550.3605, relating
- 4166 | to dogracing and horseracing.
- 4167 |           12. Chapter 550, relating to jai alai frontons.
- 4168 |           13. Section 551.109, relating to slot machine gaming.
- 4169 |           14. Chapter 552, relating to the manufacture,
- 4170 | distribution, and use of explosives.
- 4171 |           15. Chapter 560, relating to money transmitters, if the
- 4172 | violation is punishable as a felony.

- 4173 |           16. Chapter 562, relating to beverage law enforcement.
- 4174 |           17. Section 624.401, relating to transacting insurance
- 4175 | without a certificate of authority, s. 624.437(4)(c)1., relating
- 4176 | to operating an unauthorized multiple-employer welfare
- 4177 | arrangement, or s. 626.902(1)(b), relating to representing or
- 4178 | aiding an unauthorized insurer.
- 4179 |           18. Section 655.50, relating to reports of currency
- 4180 | transactions, when such violation is punishable as a felony.
- 4181 |           19. Chapter 687, relating to interest and usurious
- 4182 | practices.
- 4183 |           20. Section 721.08, s. 721.09, or s. 721.13, relating to
- 4184 | real estate timeshare plans.
- 4185 |           21. Chapter 782, relating to homicide.
- 4186 |           22. Chapter 784, relating to assault and battery.
- 4187 |           23. Chapter 787, relating to kidnapping or human
- 4188 | trafficking.
- 4189 |           24. Chapter 790, relating to weapons and firearms.
- 4190 |           25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.
- 4191 | 796.05, or s. 796.07, relating to prostitution and sex
- 4192 | trafficking.
- 4193 |           26. Chapter 806, relating to arson.
- 4194 |           27. Section 810.02(2)(c), relating to specified burglary
- 4195 | of a dwelling or structure.
- 4196 |           28. Chapter 812, relating to theft, robbery, and related
- 4197 | crimes.
- 4198 |           29. Chapter 815, relating to computer-related crimes.
- 4199 |           30. Chapter 817, relating to fraudulent practices, false
- 4200 | pretenses, fraud generally, and credit card crimes.



- 4201           31. Chapter 825, relating to abuse, neglect, or
- 4202 exploitation of an elderly person or disabled adult.
- 4203           32. Section 827.071, relating to commercial sexual
- 4204 exploitation of children.
- 4205           33. Chapter 831, relating to forgery and counterfeiting.
- 4206           34. Chapter 832, relating to issuance of worthless checks
- 4207 and drafts.
- 4208           35. Section 836.05, relating to extortion.
- 4209           36. Chapter 837, relating to perjury.
- 4210           37. Chapter 838, relating to bribery and misuse of public
- 4211 office.
- 4212           38. Chapter 843, relating to obstruction of justice.
- 4213           39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or
- 4214 s. 847.07, relating to obscene literature and profanity.
- 4215           40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.
- 4216 849.25, relating to gambling.
- 4217           41. Chapter 874, relating to criminal street gangs.
- 4218           42. Chapter 893, relating to drug abuse prevention and
- 4219 control.
- 4220           43. Chapter 896, relating to offenses related to financial
- 4221 transactions.
- 4222           44. Sections 914.22 and 914.23, relating to tampering with
- 4223 a witness, victim, or informant, and retaliation against a
- 4224 witness, victim, or informant.
- 4225           45. Sections 918.12 and 918.13, relating to tampering with
- 4226 jurors and evidence.

HB 7049

2008

4227 Section 43. Paragraphs (d), (f), (h), (i), and (j) of  
 4228 subsection (3) of section 921.0022, Florida Statutes, are  
 4229 amended to read:

4230 921.0022 Criminal Punishment Code; offense severity  
 4231 ranking chart.--

4232 (3) OFFENSE SEVERITY RANKING CHART

4233 (d) LEVEL 4

4234

Florida	Felony	Description
Statute	Degree	

4235

316.1935(3)(a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
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4236

499.0051(1)	3rd	Failure to maintain or deliver pedigree papers.
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4237

499.0051(2)	3rd	Failure to authenticate pedigree papers.
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4238

499.0051(6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband <u>prescription</u> <del>legend</del> drugs.
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4239

HB 7049

2008

4240	784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4241	784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
4242	784.075	3rd	Battery on detention or commitment facility staff.
4243	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
4244	784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
4245	784.081(3)	3rd	Battery on specified official or employee.
4246	784.082(3)	3rd	Battery by detained person on visitor or other detainee.
4247	784.083(3)	3rd	Battery on code inspector.
4248	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.

HB 7049

2008

4249	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
4250	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
4251	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4252	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4253	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
4254	790.115 (2) (c)	3rd	Possessing firearm on school property.
4255	800.04 (7) (d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4256	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.

HB 7049

2008

4257	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
4258	810.06	3rd	Burglary; possession of tools.
4259	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
4260	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4261	812.014 (2) (c) 4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4262	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4263	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
4264	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
	817.625 (2) (a)	3rd	Fraudulent use of scanning device or

HB 7049

2008

			reencoder.
4265	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
4266	837.02 (1)	3rd	Perjury in official proceedings.
4267	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4268	838.022	3rd	Official misconduct.
4269	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4270	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4271	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4272	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
4273	843.15 (1) (a)	3rd	Failure to appear while on bail for

HB 7049

2008

			felony (bond estreature or bond jumping).
4274	874.05(1)	3rd	Encouraging or recruiting another to join a criminal street gang.
4275	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).
4276	914.14(2)	3rd	Witnesses accepting bribes.
4277	914.22(1)	3rd	Force, threaten, etc., witness, victim, or informant.
4278	914.23(2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4279	918.12	3rd	Tampering with jurors.
4280	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
4281			
4282	(f)	LEVEL 6	
4283			
	Florida	Felony	Description
	Statute	Degree	
4284			

HB 7049

2008

4285	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
4286	499.0051 (3)	2nd	<u>Knowing</u> forgery of pedigree papers.
4287	499.0051 (4)	2nd	<u>Knowing</u> purchase or receipt of <u>prescription</u> <del>legend</del> drug from unauthorized person.
4288	499.0051 (5)	2nd	<u>Knowing</u> sale <u>or transfer</u> of <u>prescription</u> <del>legend</del> drug to unauthorized person.
4289	775.0875 (1)	3rd	Taking firearm from law enforcement officer.
4290	784.021 (1) (a)	3rd	Aggravated assault; deadly weapon without intent to kill.
4291	784.021 (1) (b)	3rd	Aggravated assault; intent to commit felony.
4292	784.041	3rd	Felony battery; domestic battery by strangulation.
4293	784.048 (3)	3rd	Aggravated stalking; credible threat.
4294	784.048 (5)	3rd	Aggravated stalking of person under 16.



HB 7049

2008

4295	784.07(2)(c)	2nd	Aggravated assault on law enforcement officer.
4296	784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.
4297	784.08(2)(b)	2nd	Aggravated assault on a person 65 years of age or older.
4298	784.081(2)	2nd	Aggravated assault on specified official or employee.
4299	784.082(2)	2nd	Aggravated assault by detained person on visitor or other detainee.
4300	784.083(2)	2nd	Aggravated assault on code inspector.
4301	787.02(2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4302	790.115(2)(d)	2nd	Discharging firearm or weapon on school property.
4303	790.161(2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.

HB 7049

2008

4304	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
4305	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
4306	794.011 (8) (a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
4307	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
4308	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.
4309	800.04 (6) (b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
4310	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
4311	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but

HB 7049

2008

less than \$100,000, grand theft in 2nd degree.

4312

812.014 (6) 2nd Theft; property stolen \$3,000 or more; coordination of others.

4313

812.015 (9) (a) 2nd Retail theft; property stolen \$300 or more; second or subsequent conviction.

4314

812.015 (9) (b) 2nd Retail theft; property stolen \$3,000 or more; coordination of others.

4315

812.13 (2) (c) 2nd Robbery, no firearm or other weapon (strong-arm robbery).

4316

817.034 (4) (a) 1. 1st Communications fraud, value greater than \$50,000.

4317

817.4821 (5) 2nd Possess cloning paraphernalia with intent to create cloned cellular telephones.

4318

825.102 (1) 3rd Abuse of an elderly person or disabled adult.

4319

825.102 (3) (c) 3rd Neglect of an elderly person or disabled adult.

4320

HB 7049

2008

4321	825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
4322	825.103(2)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4323	827.03(1)	3rd	Abuse of a child.
4324	827.03(3)(c)	3rd	Neglect of a child.
4325	827.071(2)&(3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
4326	836.05	2nd	Threats; extortion.
4327	836.10	2nd	Written threats to kill or do bodily injury.
4328	843.12	3rd	Aids or assists person to escape.
4329	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
	914.23	2nd	Retaliation against a witness, victim,

HB 7049

2008

or informant, with bodily injury.

4330

944.35(3)(a)2. 3rd Committing malicious battery upon or inflicting cruel or inhuman treatment on an inmate or offender on community supervision, resulting in great bodily harm.

4331

944.40 2nd Escapes.

4332

944.46 3rd Harboring, concealing, aiding escaped prisoners.

4333

944.47(1)(a)5. 2nd Introduction of contraband (firearm, weapon, or explosive) into correctional facility.

4334

951.22(1) 3rd Intoxicating drug, firearm, or weapon introduced into county facility.

4335

4336 (h) LEVEL 8

4337

Florida	Felony	Description
Statute	Degree	

4338

316.193(3)(c)3.a. 2nd DUI manslaughter.

4339

HB 7049

2008

4340	316.1935 (4) (b)	1st	Aggravated fleeing or attempted eluding with serious bodily injury or death.
4341	327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
4342	<u>499.0051 (8)</u>	1st	<u>Knowing</u> forgery of prescription labels or <u>prescription legend</u> drug labels.
	<del>499.0051 (7)</del>		
4343	<u>499.0051 (7)</u>	1st	<u>Knowing</u> trafficking in contraband <u>prescription legend</u> drugs.
	<del>499.0052</del>		
4344	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.
4345	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.
	655.50 (10) (b) 2.	2nd	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by

HB 7049

2008

4346			financial institutions.
	777.03 (2) (a)	1st	Accessory after the fact, capital felony.
4347			
	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.
4348			
	782.051 (2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04 (3).
4349			
	782.071 (1) (b)	1st	Committing vehicular homicide and failing to render aid or give information.
4350			
	782.072 (2)	1st	Committing vessel homicide and failing to render aid or give information.
4351			
	790.161 (3)	1st	Discharging a destructive device which results in bodily harm or

HB 7049

2008

4352			property damage.
	794.011 (5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.
4353			
	794.08 (3)	2nd	Female genital mutilation, removal of a victim younger than 18 years of age from this state.
4354			
	800.04 (4)	2nd	Lewd or lascivious battery.
4355			
	806.01 (1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4356			
	810.02 (2) (a)	1st, PBL	Burglary with assault or battery.
4357			
	810.02 (2) (b)	1st, PBL	Burglary; armed with explosives or dangerous weapon.
4358			
	810.02 (2) (c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
4359			
	812.014 (2) (a) 2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st



HB 7049

2008

			degree.
4360	812.13 (2) (b)	1st	Robbery with a weapon.
4361	812.135 (2) (c)	1st	Home-invasion robbery, no firearm, deadly weapon, or other weapon.
4362	817.568 (6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4363	825.102 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4364	825.1025 (2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4365	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4366	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4367	837.021 (2)	2nd	Making contradictory statements in official proceedings relating to

HB 7049

2008

4368			prosecution of a capital felony.
	860.121(2)(c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
4369			
	860.16	1st	Aircraft piracy.
4370			
	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).
4371			
	893.13(2)(b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4372			
	893.13(6)(c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4373			
	893.135(1)(a)2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
4374			
	893.135(1)(b)1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
4375			
	893.135(1)(c)1.b.	1st	Trafficking in illegal drugs, more

HB 7049

2008

4376	893.135(1)(d)1.b. 1st	than 14 grams, less than 28 grams.
4377	893.135(1)(d)1.b. 1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
4378	893.135(1)(e)1.b. 1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
4379	893.135(1)(f)1.b. 1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4380	893.135(1)(g)1.b. 1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4381	893.135(1)(h)1.b. 1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4382	893.135(1)(j)1.b. 1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4383	893.135(1)(k)2.b. 1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4383	895.03(1) 1st	Use or invest proceeds derived from

HB 7049

2008

4384			pattern of racketeering activity.
	895.03 (2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
4385			
	895.03 (3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.
4386			
	896.101 (5) (b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
4387			
	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.
4388			
4389	(i)	LEVEL 9	
4390			
	Florida Statute	Felony Degree	Description
4391			
	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render

HB 7049

2008

4392			aid or give information.
	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
4393	<u>499.0051 (9)</u>	1st	<u>Knowing</u> sale or purchase of
	<del>499.00535</del>		contraband <u>prescription</u> <del>legend</del> drugs resulting in great bodily harm.
4394	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
4395	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
4396	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4397	775.0844	1st	Aggravated white collar crime.
4398	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
4399			

HB 7049

2008

4400	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4401	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3).
4402	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
4403	787.01 (1) (a) 1.	1st, PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
4404	787.01 (1) (a) 2.	1st, PBL	Kidnapping with intent to commit or facilitate commission of any felony.
4405	787.01 (1) (a) 4.	1st, PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
	787.02 (3) (a)	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious

HB 7049

2008

			battery, molestation, conduct, or exhibition.
4406	790.161	1st	Attempted capital destructive device offense.
4407	790.166 (2)	1st, PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
4408	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
4409	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
4410	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4411	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
4412	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4413			

HB 7049

2008

4414	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4415	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4416	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
4417	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4418	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.
4419	827.03 (2)	1st	Aggravated child abuse.
4420	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
4421	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.



HB 7049

2008

4422	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.
4423	893.135	1st	Attempted capital trafficking offense.
4424	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
4425	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4426	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4427	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
4428	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4429	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more than 200 grams.

HB 7049

2008

4430	893.135 (1) (h) 1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
4431	893.135 (1) (j) 1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
4432	893.135 (1) (k) 2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
4433	896.101 (5) (c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
4434	896.104 (4) (a) 3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.
4435	(j)	LEVEL 10	
4436			
4437	Florida Statute	Felony Degree	Description
4438	<u>499.0051(10)</u> <del>499.00545</del>	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> <del>legend</del> drugs resulting in death.

HB 7049

2008

4439 782.04(2) 1st,PBL Unlawful killing of human; act is  
homicide, unpremeditated.

4440 787.01(1)(a)3. 1st,PBL Kidnapping; inflict bodily harm upon or  
terrorize victim.

4441 787.01(3)(a) Life Kidnapping; child under age 13,  
perpetrator also commits aggravated  
child abuse, sexual battery, or lewd or  
lascivious battery, molestation,  
conduct, or exhibition.

4442 782.07(3) 1st Aggravated manslaughter of a child.

4443 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.

4444 812.135(2)(a) 1st,PBL Home-invasion robbery with firearm or  
other deadly weapon.

4445 876.32 1st Treason against the state.

4446 Section 44. This act shall take effect July 1, 2008.