

By the Committees on Judiciary; Health Regulation; and Senator  
Peaden

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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.;

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30 conforming provisions to changes made by the act;  
31 providing that a drug or device is misbranded if it is an  
32 active pharmaceutical ingredient in bulk form and does not  
33 bear a label containing certain information; amending ss.  
34 499.008 and 499.009, F.S.; conforming provisions to  
35 changes made by the act; amending s. 499.01, F.S.;  
36 providing that the section relates only to permits;  
37 requiring a permit to operate as a third party logistics  
38 provider and a health care clinic establishment; providing  
39 requirements for obtaining a permit to operate in certain  
40 capacities; deleting certain permit requirements;  
41 providing an exemption for a nonresident prescription drug  
42 manufacturer permit; providing requirements for such  
43 exemption; providing requirements for a third party  
44 logistics provider permit and a health care clinic  
45 establishment permit; amending and redesignating  
46 provisions of ss. 499.013, and 499.014, F.S., relating to  
47 such functions as provisions of that section; conforming  
48 provisions and cross-references to changes made by the  
49 act; amending s. 499.012, F.S.; providing that the section  
50 relates to permit application requirements; providing that  
51 a separate establishment permit is not required when a  
52 permitted prescription drug wholesale distributor operates  
53 temporary transit storage facilities for the sole purpose  
54 of storage; amending the provisions to conform; amending  
55 and redesignating provisions of s. 499.01, F.S., relating  
56 to such functions as provisions of that section;  
57 conforming provisions and cross-references to changes made  
58 by the act; amending s. 499.01201, F.S.; conforming

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59 | provisions to changes made by the act; amending s.  
60 | 499.0121, F.S., relating to storage and handling of  
61 | prescription drugs and recordkeeping; directing the  
62 | department to adopt rules requiring a wholesale  
63 | distributor to maintain pedigree papers separate and  
64 | distinct from other required records; deleting a  
65 | requirement that a person who is engaged in the wholesale  
66 | distribution of a prescription drug and who is not the  
67 | manufacturer of that drug provide a pedigree paper to the  
68 | person who receives the drug; deleting the department's  
69 | requirement to adopt rules with regard to recordkeeping by  
70 | affiliated groups; conforming provisions and cross-  
71 | references to changes made by the act; amending and  
72 | redesignating a provision of s. 499.013, F.S., relating to  
73 | such functions as a provision of that section; amending s.  
74 | 499.01211, F.S.; conforming provisions and cross-  
75 | references to changes made by the act; creating s.  
76 | 499.01212, F.S.; requiring a person who is engaged in the  
77 | wholesale distribution of a prescription drug to provide a  
78 | pedigree paper to the person who receives the drug;  
79 | requiring certain information in a pedigree paper;  
80 | requiring a wholesale distributor to maintain and make  
81 | available to the department certain information; providing  
82 | exceptions to the requirement of a pedigree paper;  
83 | repealing s. 499.0122, F.S., relating to medical oxygen  
84 | and veterinary legend drug retail establishments;  
85 | repealing s. 499.013, F.S., relating to manufacturers and  
86 | repackagers of drugs, devices, and cosmetics; amending ss.  
87 | 499.015, 499.024, 499.028, 499.029, and 499.03, F.S.;

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88 conforming provisions and cross-references to changes made  
89 by the act; amending ss. 499.032 and 499.033, F.S.;  
90 conforming terminology to changes made by the act;  
91 amending s. 499.039, F.S.; conforming a provision and  
92 cross-reference; amending ss. 499.04, F.S.; conforming  
93 provisions to changes made by the act; amending s.  
94 499.041, F.S.; conforming provisions to changes made by  
95 the act; requiring the department to assess an annual fee  
96 for a third part logistic provider permit and a health  
97 care clinic establishment permit; amending s. 499.05,  
98 F.S.; conforming provisions to changes made by the act;  
99 requiring the department to adopt rules with regard to  
100 procedures and forms relating to pedigree paper  
101 requirements, alternatives to compliance with the  
102 requirement of certain pedigree papers, and the return of  
103 prescription drugs purchased before a specified date;  
104 amending and redesignating provisions of ss. 499.013 and  
105 499.0122, F.S., as provisions relating to rulemaking  
106 functions of that section; amending ss. 499.051, 499.052,  
107 499.055, and 499.06, F.S.; conforming provisions to  
108 changes made by the act; amending s. 499.062, F.S.;  
109 providing that the section relates to seizure and  
110 condemnation of drugs, devices, or cosmetics; conforming a  
111 provision to changes made by the act; amending and  
112 redesignating ss. 499.063 and 499.064, F.S., as provisions  
113 relating to such functions in that section; amending ss.  
114 499.065, 499.066, 499.0661, and 499.067, F.S.; conforming  
115 provisions and cross-references to changes made by the  
116 act; amending ss. 409.9201, 460.403, 465.0265, 794.075,

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117 895.02, and 921.0022, F.S.; conforming provisions to  
118 changes made by the act; conforming cross-references to  
119 changes made by the act; providing an effective date.  
120

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

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

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

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

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

139 (b)(2) Provide uniform legislation to be administered so  
140 far as practicable in conformity with the provisions of, and  
141 regulations issued under the authority of, the Federal Food,  
142 Drug, and Cosmetic Act and that portion of the Federal Trade  
143 Commission Act which expressly prohibits the false advertisement  
144 of drugs, devices, and cosmetics.

145 (c)(3) Promote thereby uniformity of such state and federal

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146 laws, and their administration and enforcement, throughout the  
147 United States.

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

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

164 (4) ~~499.07 Duty of prosecuting officer.~~ Each state  
165 attorney, county attorney, or municipal attorney to whom the  
166 department or its designated agent reports any violation of this  
167 part ~~ss. 499.001-499.081~~ shall cause appropriate proceedings to  
168 be instituted in the proper courts without delay and to be  
169 prosecuted in the manner required by law.

170 (5) ~~499.071 Issuance of warnings for minor~~  
171 ~~violations.~~ This part ~~does Sections 499.001-499.081~~ do not  
172 require the department to report, for the institution of  
173 proceedings under this part ~~ss. 499.001-499.081~~, minor violations  
174 of this part ~~ss. 499.001-499.081~~ when it believes that the public

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175 interest will be adequately served in the circumstances by a  
176 suitable written notice or warning.

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

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

192 499.003 Definitions of terms used in this part ~~ss. 499.001-~~  
193 ~~499.081.~~ --As used in this part ~~ss. 499.001-499.081~~, the term:

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

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

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204 (3)~~(2)~~ "Affiliated party" means:

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

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

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

218 (d) The five largest natural shareholders that own at least  
219 5 percent of the permittee or applicant.

220 (4)~~(3)~~ "Applicant" means a person applying for a permit or  
221 certification under this part ~~ss. 499.001-499.081~~.

222 (5)~~(4)~~ "Authenticate" means to affirmatively verify upon  
223 receipt ~~before any distribution~~ of a prescription legend drug  
224 ~~occurs~~ that each transaction listed on the pedigree paper has  
225 occurred.

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

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

232 (6)~~(5)~~ "Certificate of free sale" means a document prepared



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233 | by the department which certifies a drug, device, or cosmetic,  
234 | that is registered with the department, as one that can be  
235 | legally sold in the state.

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

241 |       ~~(8)-(6)~~ "Closed pharmacy" means a pharmacy that is licensed  
242 | under chapter 465 and purchases prescription drugs for use by a  
243 | limited patient population and not for wholesale distribution or  
244 | sale to the public. The term does not include retail pharmacies.

245 |       ~~(9)-(7)~~ "Color" includes black, white, and intermediate  
246 | grays.

247 |       ~~(10)-(8)~~ "Color additive" means, with the exception of any  
248 | material that has been or hereafter is exempt under the federal  
249 | act, a material that:

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

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

258 |  
259 | ~~except that the term does not include any material which has been~~  
260 | ~~or hereafter is exempt under the federal act.~~

261 |       ~~(11)-(9)~~ "Compressed medical gas" means any liquefied or

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262 vaporized gas that is a prescription drug, whether it is alone or  
263 in combination with other gases.

264 (12)~~(10)~~ "Contraband prescription legend drug" means any  
265 adulterated drug, as defined in s. 499.006, any counterfeit drug,  
266 as defined in this section, and also means any prescription  
267 ~~legend~~ drug for which a pedigree paper does not exist, or for  
268 which the pedigree paper in existence has been forged,  
269 counterfeited, falsely created, or contains any altered, false,  
270 or misrepresented matter.

271 (13)~~(11)~~ "Cosmetic" means an article, with the exception of  
272 soap, that is:

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

277 (b) Intended for use as a component of any such article;  
278  
279 ~~except that the term does not include soap.~~

280 (14)~~(12)~~ "Counterfeit drug," "counterfeit device," or  
281 "counterfeit drug, counterfeit device, or counterfeit cosmetic"  
282 means a drug, device, or cosmetic which, or the container, seal,  
283 or labeling of which, without authorization, bears the trademark,  
284 trade name, or other identifying mark, imprint, or device, or any  
285 likeness thereof, of a drug, device, or cosmetic manufacturer,  
286 processor, packer, or distributor other than the person that in  
287 fact manufactured, processed, packed, or distributed that drug,  
288 device, or cosmetic and which thereby falsely purports or is  
289 represented to be the product of, or to have been packed or  
290 distributed by, that other drug, device, or cosmetic

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291 manufacturer, processor, packer, or distributor.

292 (15)~~(13)~~ "Department" means the Department of Health.

293 (16)~~(14)~~ "Device" means any instrument, apparatus,  
294 implement, machine, contrivance, implant, in vitro reagent, or  
295 other similar or related article, including its components,  
296 parts, or accessories, which is:

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

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

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

304

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

310 (17)~~(15)~~ "Distribute or distribution" or "distribution"  
311 means to sell; offer to sell; give away; transfer, whether by  
312 passage of title, physical movement, or both; deliver; or offer  
313 to deliver. The term does not mean to administer or dispense.

314 (18) "Drop shipment" means the sale of a prescription drug  
315 from a manufacturer to a wholesale distributor, where the  
316 wholesale distributor takes title to, but not possession of, the  
317 prescription drug and the manufacturer of the prescription drug  
318 ships the prescription drug directly to a chain pharmacy  
319 warehouse or a person authorized by law to purchase prescription

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320 drugs for the purpose of administering or dispensing the drug, as  
321 defined in s. 465.003.

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

325 (19)~~(17)~~ "Drug" means an article that is:

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

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

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

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

339 (20)~~(18)~~ "Establishment" means a place of business at one  
340 general physical location.

341 (21)~~(19)~~ "Federal act" means the Federal Food, Drug, and  
342 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

343 (22)~~(20)~~ "Freight forwarder" means a person who receives  
344 prescription ~~legend~~ drugs which are owned by another person and  
345 designated by that person for export, and exports those  
346 prescription ~~legend~~ drugs.

347 (23)~~(21)~~ "Health care entity" means a closed pharmacy or  
348 any person, organization, or business entity that provides

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349 diagnostic, medical, surgical, or dental treatment or care, or  
350 chronic or rehabilitative care, but does not include any  
351 wholesale distributor or retail pharmacy licensed under state law  
352 to deal in prescription drugs.

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

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

357 (26)~~(i)~~ "Hospital" means a facility as defined in s.  
358 395.002 and licensed under chapter 395.

359 (27)~~(22)~~ "Immediate container" does not include package  
360 liners.

361 (28)~~(23)~~ "Label" means a display of written, printed, or  
362 graphic matter upon the immediate container of any drug, device,  
363 or cosmetic. A requirement made by or under authority of this  
364 part ss. 499.001-499.081 or rules adopted under this part ~~these~~  
365 ~~sections~~ that any word, statement, or other information appear on  
366 the label is not complied with unless such word, statement, or  
367 other information also appears on the outside container or  
368 wrapper, if any, of the retail package of such drug, device, or  
369 cosmetic or is easily legible through the outside container or  
370 wrapper.

371 (29)~~(24)~~ "Labeling" means all labels and other written,  
372 printed, or graphic matters:

373 (a) Upon a drug, device, or cosmetic, or any of its  
374 containers or wrappers; or

375 (b) Accompanying or related to such drug, device, or  
376 cosmetic.

377 ~~(25) "Legend drug," "prescription drug," or "medicinal~~

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

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

388 ~~(30)(27)~~ "Manufacture" means the preparation, deriving,  
389 compounding, propagation, processing, producing, or fabrication  
390 of any drug, device, or cosmetic.

391 ~~(31)(28)~~ "Manufacturer" means:

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

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

405  
406 The term excludes pharmacies that are operating in compliance

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407 | with pharmacy practice standards as defined in chapter 465 and  
408 | rules adopted under that chapter.

409 |       ~~(32)-(29)~~ "New drug" means:

410 |           (a) Any drug the composition of which is such that the drug  
411 | is not generally recognized, among experts qualified by  
412 | scientific training and experience to evaluate the safety and  
413 | effectiveness of drugs, as safe and effective for use under the  
414 | conditions prescribed, recommended, or suggested in the labeling  
415 | of that drug; or

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

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

434 |       ~~(34)-(j)~~ "Nursing home" means a facility licensed under part  
435 | II of chapter 400.

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436        ~~(35)~~(30) "Official compendium" means the current edition of  
437 the official United States Pharmacopoeia and National Formulary,  
438 or any supplement thereto.

439        ~~(36)~~(31) "Pedigree paper" means:

440        ~~(a) Effective July 1, 2006, A document in written or~~  
441 ~~electronic form approved by the department which contains of~~  
442 ~~Health and containing information required by s. 499.01212~~  
443 ~~regarding the sale and that records each distribution of any~~  
444 ~~given prescription legend drug, from sale by a pharmaceutical~~  
445 ~~manufacturer, through acquisition and sale by any wholesaler or~~  
446 ~~repackager, until final sale to a pharmacy or other person~~  
447 ~~administering or dispensing the drug. The information required to~~  
448 ~~be included on the form approved by the department pursuant to~~  
449 ~~this paragraph must at least detail the amount of the legend~~  
450 ~~drug; its dosage form and strength; its lot numbers; the name and~~  
451 ~~address of each owner of the legend drug and his or her~~  
452 ~~signature; its shipping information, including the name and~~  
453 ~~address of each person certifying delivery or receipt of the~~  
454 ~~legend drug; an invoice number, a shipping document number, or~~  
455 ~~another number uniquely identifying the transaction; and a~~  
456 ~~certification that the recipient wholesaler has authenticated the~~  
457 ~~pedigree papers. If the manufacturer or repackager has uniquely~~  
458 ~~serialized the individual legend drug unit, that identifier must~~  
459 ~~also be included on the form approved pursuant to this paragraph.~~  
460 ~~It must also include the name, address, telephone number and, if~~  
461 ~~available, e-mail contact information of each wholesaler involved~~  
462 ~~in the chain of the legend drug's custody; or~~

463        ~~(b) A statement, under oath, in written or electronic form,~~  
464 ~~confirming that a wholesale distributor purchases and receives~~



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465 ~~the specific unit of the prescription drug directly from the~~  
466 ~~manufacturer of the prescription drug and distributes the~~  
467 ~~prescription drug directly, or through an intracompany transfer,~~  
468 ~~to a chain pharmacy warehouse or a person authorized by law to~~  
469 ~~purchase prescription drugs for the purpose of administering or~~  
470 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~  
471 ~~this subsection, the term "chain pharmacy warehouse" means a~~  
472 ~~wholesale distributor permitted pursuant to s. 499.01 that~~  
473 ~~maintains a physical location for prescription drugs that~~  
474 ~~functions solely as a central warehouse to perform intracompany~~  
475 ~~transfers of such drugs to a member of its affiliated group as~~  
476 ~~described in s. 499.0121(6)(f)1.~~

477 ~~1. The information required to be included pursuant to this~~  
478 ~~paragraph must include:~~

479 ~~a. The following statement: "This wholesale distributor~~  
480 ~~purchased the specific unit of the prescription drug directly~~  
481 ~~from the manufacturer."~~

482 ~~b. The manufacturer's national drug code identifier and the~~  
483 ~~name and address of the wholesaler and the purchaser of the~~  
484 ~~prescription drug.~~

485 ~~c. The name of the prescription drug as it appears on the~~  
486 ~~label.~~

487 ~~d. The quantity, dosage form, and strength of the~~  
488 ~~prescription drug.~~

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

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494 ~~numbers from the manufacturer.~~

495

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

498 ~~(37)(1) DEFINITION. As used in this section, the term~~  
499 ~~"Permittee" means any person holding a permit issued pursuant to~~  
500 ~~s. 499.012.~~

501 ~~(38)(32)~~ "Person" means any individual, child, joint  
502 venture, syndicate, fiduciary, partnership, corporation, division  
503 of a corporation, firm, trust, business trust, company, estate,  
504 public or private institution, association, organization, group,  
505 city, county, city and county, political subdivision of this  
506 state, other governmental agency within this state, and any  
507 representative, agent, or agency of any of the foregoing, or any  
508 other group or combination of the foregoing.

509 ~~(39)(1)~~ "Pharmacist" means a person licensed under chapter  
510 465.

511 ~~(40)(m)~~ "Pharmacy" means an entity licensed under chapter  
512 465.

513 ~~(41)(33)~~ "Prepackaged drug product" means a drug that  
514 originally was in finished packaged form sealed by a manufacturer  
515 and that is placed in a properly labeled container by a pharmacy  
516 or practitioner authorized to dispense pursuant to chapter 465  
517 for the purpose of dispensing in the establishment in which the  
518 prepackaging occurred.

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

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523 465.003(8), s. 499.007(13), or subsection (11), subsection (47),  
524 or subsection (54).

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

530 (44)~~(34)~~ "Prescription label" means any display of written,  
531 printed, or graphic matter upon the immediate container of any  
532 prescription ~~legend~~ drug dispensed pursuant to a prescription of  
533 a practitioner authorized by law to prescribe.

534 (45)~~(35)~~ "Prescription medical oxygen" means oxygen USP  
535 which is a drug that can only be sold on the order or  
536 prescription of a practitioner authorized by law to prescribe.  
537 The label of prescription medical oxygen must comply with current  
538 labeling requirements for oxygen under the Federal Food, Drug,  
539 and Cosmetic Act.

540 (46)~~(d)~~ "Primary wholesale distributor ~~wholesaler~~" means  
541 any wholesale distributor that:

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

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

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

551 (c)~~(e)~~ For purposes of this subsection, "directly from

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552 manufacturers ~~a manufacturer~~" means:

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

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

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

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

568 ~~(47)-(36)~~ "Proprietary drug," or "OTC drug," means a patent  
569 or over-the-counter drug in its unbroken, original package, which  
570 drug is sold to the public by, or under the authority of, the  
571 manufacturer or primary distributor thereof, is not misbranded  
572 under the provisions of this part ~~ss. 499.001-499.081~~, and can be  
573 purchased without a prescription.

574 ~~(48)-(37)~~ "Repackage" includes repacking or otherwise  
575 changing the container, wrapper, or labeling to further the  
576 distribution of the drug, device, or cosmetic.

577 ~~(49)-(38)~~ "Repackager" means a person who repackages. The  
578 term excludes pharmacies that are operating in compliance with  
579 pharmacy practice standards as defined in chapter 465 and rules  
580 adopted under that chapter.

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581        (50)~~(e)~~ "Retail pharmacy" means a community pharmacy  
582 licensed under chapter 465 that purchases prescription drugs at  
583 fair market prices and provides prescription services to the  
584 public.

585        (51)~~(f)~~ "Secondary wholesale distributor ~~wholesaler~~" means  
586 a wholesale distributor that is not a primary wholesale  
587 distributor ~~wholesaler~~.

588        (53)~~(39)~~ "Veterinary prescription drug" means a  
589 prescription ~~legend~~ drug intended solely for veterinary use. The  
590 label of the drug must bear the statement, "Caution: Federal law  
591 restricts this drug to sale by or on the order of a licensed  
592 veterinarian."

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

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

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

602        1.a. The purchase or other acquisition by a hospital or  
603 other health care entity that is a member of a group purchasing  
604 organization of a prescription drug for its own use from the  
605 group purchasing organization or from other hospitals or health  
606 care entities that are members of that organization.

607        2.b. The sale, purchase, or trade of a prescription drug or  
608 an offer to sell, purchase, or trade a prescription drug by a  
609 charitable organization described in s. 501(c)(3) of the Internal

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610 Revenue Code of 1986, as amended and revised, to a nonprofit  
611 affiliate of the organization to the extent otherwise permitted  
612 by law.

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

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

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

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

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

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

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

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

661        g.~~(VII)~~ In addition to the departmental inspection  
662 authority set forth in s. 499.051, the establishment of the  
663 contract provider and subcontractor and all records pertaining to  
664 prescription drugs subject to this subparagraph ~~sub-subparagraph~~  
665 shall be subject to inspection by the agency or entity. All  
666 records relating to prescription drugs of a manufacturer under  
667 this subparagraph ~~sub-subparagraph~~ shall be subject to audit by

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668 the manufacturer of those drugs, without identifying individual  
669 patient information.

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

673 1.a. The sale, purchase, or trade of a prescription drug  
674 among federal, state, or local government health care entities  
675 that are under common control and are authorized to purchase such  
676 prescription drug.

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

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

688 4.d. The revocation of a sale or the return of a  
689 prescription drug to the person's prescription drug wholesale  
690 supplier.

691 5.e. The donation of a prescription drug by a health care  
692 entity to a charitable organization that has been granted an  
693 exemption under s. 501(c)(3) of the Internal Revenue Code of  
694 1986, as amended, and that is authorized to possess prescription  
695 drugs.

696 6.f. The transfer of a prescription drug by a person



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697 authorized to purchase or receive prescription drugs to a person  
698 licensed or permitted to handle reverse distributions or  
699 destruction under the laws of the jurisdiction in which the  
700 person handling the reverse distribution or destruction receives  
701 the drug.

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

714 (c)3. The distribution of prescription drug samples by  
715 manufacturers' representatives or distributors' representatives  
716 conducted in accordance with s. 499.028.

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

723 (e)5. The lawful dispensing of a prescription drug in  
724 accordance with chapter 465.

725 (f)6. The sale, purchase, or trade of a prescription drug

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726 between pharmacies as a result of a sale, transfer, merger, or  
727 consolidation of all or part of the business of the pharmacies  
728 from or with another pharmacy, whether accomplished as a purchase  
729 and sale of stock or of business assets.

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

738 Section 3. Subsections (4), (10), (11), (12), (14), (15),  
739 (18), (19), (20), (22), (24), (28), and (29) of section 499.005,  
740 Florida Statutes, are amended to read:

741 499.005 Prohibited acts.--It is unlawful for a person to  
742 perform or cause the performance of any of the following acts in  
743 this state:

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

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

752 (11) The use, on the labeling of any drug or in any  
753 advertisement relating to such drug, of any representation or  
754 suggestion that an application of the drug is effective when it

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755 is not or that the drug complies with this part ~~ss. 499.001-~~  
756 ~~499.081~~ when it does not.

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

759 (14) The purchase or receipt of a prescription ~~legend~~ drug  
760 from a person that is not authorized under this chapter to  
761 distribute prescription ~~legend~~ drugs to that purchaser or  
762 recipient.

763 (15) The sale or transfer of a prescription ~~legend~~ drug to  
764 a person that is not authorized under the law of the jurisdiction  
765 in which the person receives the drug to purchase or possess  
766 prescription ~~legend~~ drugs from the person selling or transferring  
767 the prescription ~~legend~~ drug.

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

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

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

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

780 (24) The distribution of a prescription ~~legend~~ device to  
781 the patient or ultimate consumer without a prescription or order  
782 from a practitioner licensed by law to use or prescribe the  
783 device.

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

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

792 Section 4. Section 499.0051, Florida Statutes, is amended;  
793 section 499.0052, Florida Statutes, is redesignated as subsection  
794 (7) of that section and amended; section 499.00535, Florida  
795 Statutes, is redesignated as subsection (9) of that section and  
796 amended; section 499.00545, Florida Statutes, is redesignated as  
797 subsection (10) of that section and amended; section 499.069,  
798 Florida Statutes, is redesignated as subsection (11) of that  
799 section and amended; and section 499.0691, Florida Statutes, is  
800 redesignated as subsections (12) through (15) of that section and  
801 amended, to read:

802 499.0051 Criminal acts ~~involving contraband or adulterated~~  
803 ~~drugs~~.--

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

805 (a) A person, other than a manufacturer, engaged in the  
806 wholesale distribution of prescription ~~legend~~ drugs who fails to  
807 deliver to another person complete and accurate pedigree papers  
808 concerning a prescription ~~legend~~ drug or contraband prescription  
809 ~~legend~~ drug prior to, or simultaneous with, the transfer of  
810 ~~transferring~~ the prescription ~~legend~~ drug or contraband  
811 prescription ~~legend~~ drug to another person commits a felony of  
812 the third degree, punishable as provided in s. 775.082, s.

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813 775.083, or s. 775.084.

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

822 (c) Any person who knowingly destroys, alters, conceals, or  
823 fails to maintain complete and accurate pedigree papers  
824 concerning any prescription legend drug or contraband  
825 prescription legend drug in his or her possession commits a  
826 felony of the third degree, punishable as provided in s. 775.082,  
827 s. 775.083, or s. 775.084.

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

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

838 (b) A person in possession of pedigree papers concerning  
839 prescription legend drugs or contraband prescription legend drugs  
840 who falsely swears or certifies that he or she has authenticated  
841 the matters contained in the pedigree papers commits a felony of

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842 the third degree, punishable as provided in s. 775.082, s.  
843 775.083, or s. 775.084.

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

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

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

866 (6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO  
867 SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is  
868 knowingly in actual or constructive possession of any amount of  
869 contraband prescription ~~legend~~ drugs, who knowingly sells or  
870 delivers, or who possesses with intent to sell or deliver any

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871 amount of contraband prescription ~~legend~~ drugs, commits a felony  
872 of the second degree, punishable as provided in s. 775.082, s.  
873 775.083, or s. 775.084.

874 ~~(7) 499.0052~~ KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION  
875 ~~LEGEND~~ DRUGS.--A person who knowingly sells, purchases,  
876 manufactures, delivers, or brings into this state, or who is  
877 knowingly in actual or constructive possession of any amount of  
878 contraband prescription ~~legend~~ drugs valued at \$25,000 or more  
879 commits a felony of the first degree, punishable as provided in  
880 s. 775.082, s. 775.083, or s. 775.084.

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

883 1.~~(1)~~ If the value of contraband prescription ~~legend~~ drugs  
884 involved is \$25,000 or more, but less than \$100,000, the  
885 defendant shall pay a mandatory fine of \$25,000. If the defendant  
886 is a corporation or other person that is not a natural person, it  
887 shall pay a mandatory fine of \$75,000.

888 2.~~(2)~~ If the value of contraband prescription ~~legend~~ drugs  
889 involved is \$100,000 or more, but less than \$250,000, the  
890 defendant shall pay a mandatory fine of \$100,000. If the  
891 defendant is a corporation or other person that is not a natural  
892 person, it shall pay a mandatory fine of \$300,000.

893 3.~~(3)~~ If the value of contraband prescription ~~legend~~ drugs  
894 involved is \$250,000 or more, the defendant shall pay a mandatory  
895 fine of \$200,000. If the defendant is a corporation or other  
896 person that is not a natural person, it shall pay a mandatory  
897 fine of \$600,000.

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

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900 the offense or, if such cannot be satisfactorily ascertained, the  
901 cost of replacement of the property within a reasonable time  
902 after the offense. Amounts of value of separate contraband  
903 prescription legend drugs involved in distinct transactions for  
904 the distribution of the contraband prescription legend drugs  
905 committed pursuant to one scheme or course of conduct, whether  
906 involving the same person or several persons, may be aggregated  
907 in determining the punishment of the offense.

908 ~~(8)~~ (7) KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION  
909 ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges, counterfeits,  
910 or falsely creates any prescription label or prescription legend  
911 drug label, or who falsely represents any factual matter  
912 contained on any prescription label or prescription legend drug  
913 label, commits a felony of the first degree, punishable as  
914 provided in s. 775.082, s. 775.083, or s. 775.084.

915 ~~(9)~~ ~~499.00535~~ KNOWING Sale or purchase of contraband  
916 prescription legend drugs resulting in great bodily harm.--A  
917 person who knowingly sells, purchases, manufactures, delivers, or  
918 brings into this state, or who is knowingly in actual or  
919 constructive possession of any amount of contraband prescription  
920 ~~legend~~ drugs, and whose acts in violation of this subsection  
921 ~~section~~ result in great bodily harm to a person, commits a felony  
922 of the first degree, as provided in s. 775.082, s. 775.083, or s.  
923 775.084.

924 ~~(10)~~ ~~499.00545~~ Knowing Sale or purchase of contraband  
925 prescription legend drugs resulting in death.--A person who  
926 knowingly manufactures, sells, purchases, delivers, or brings  
927 into this state, or who is knowingly in actual or constructive  
928 possession of any amount of contraband prescription legend drugs,



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929 and whose acts in violation of this subsection ~~section~~ result in  
930 the death of a person, commits a felony of the first degree,  
931 punishable by a term of years not exceeding life, as provided in  
932 s. 775.082, s. 775.083, or s. 775.084.

933 (11)~~499.069~~ ~~Criminal punishment for~~ violations of s.  
934 499.005 related to devices and cosmetics; dissemination of false  
935 advertisement.--

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

949 (b)~~(2)~~ A publisher, radio broadcast licensee, or agency or  
950 medium for the dissemination of an advertisement, except the  
951 manufacturer, wholesaler, or seller of the article to which a  
952 false advertisement relates, is not liable under this subsection  
953 ~~section~~ by reason of the dissemination by him or her of such  
954 false advertisement, unless he or she has refused, on the request  
955 of the department, to furnish to the department the name and post  
956 office address of the manufacturer, wholesaler, seller, or  
957 advertising agency that asked him or her to disseminate such

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958 advertisement.

959 (12) 499.0691 ADULTERATED AND MISBRANDED DRUGS; FALSE  
960 ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS

961 ~~Criminal punishment for violations related to drugs;~~  
962 ~~dissemination of false advertisement.--(1)~~ Any person who  
963 violates any of the following provisions commits a misdemeanor of  
964 the second degree, punishable as provided in s. 775.082 or s.  
965 775.083; but, if the violation is committed after a conviction of  
966 such person under this subsection ~~section~~ has become final, such  
967 person commits a misdemeanor of the first degree, punishable as  
968 provided in s. 775.082 or s. 775.083, or as otherwise provided in  
969 this part ~~ss. 499.001-499.081~~:

970 (a) The manufacture, repackaging, sale, delivery, or  
971 holding or offering for sale of any drug that is adulterated or  
972 misbranded or has otherwise been rendered unfit for human or  
973 animal use.

974 (b) The adulteration or misbranding of any drug intended  
975 for further distribution.

976 (c) The receipt of any drug that is adulterated or  
977 misbranded, and the delivery or proffered delivery of such drug,  
978 for pay or otherwise.

979 (d) The dissemination of any false or misleading  
980 advertisement of a drug.

981 (e) The use, on the labeling of any drug or in any  
982 advertisement relating to such drug, of any representation or  
983 suggestion that an application of the drug is effective when it  
984 is not or that the drug complies with this part ~~ss. 499.001-~~  
985 ~~499.081~~ when it does not.

986 (f) The purchase or receipt of a compressed medical gas

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987 | from a person that is not authorized under this chapter to  
988 | distribute compressed medical gases.

989 | (g) Charging a dispensing fee for dispensing,  
990 | administering, or distributing a prescription drug sample.

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

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

998 | (13) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR  
999 | TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO  
1000 | PRESCRIPTION DRUGS.--(2) Any person who violates any of the  
1001 | following provisions commits a felony of the third degree,  
1002 | punishable as provided in s. 775.082, s. 775.083, or s. 775.084,  
1003 | or as otherwise provided in this part: ~~ss. 499.001-499.081~~.

1004 | (a) The refusal or constructive refusal to allow:

1005 | 1. The department to enter or inspect an establishment in  
1006 | which drugs are manufactured, processed, repackaged, sold,  
1007 | brokered, or held;

1008 | 2. Inspection of any record of that establishment;

1009 | 3. The department to enter and inspect any vehicle that is  
1010 | being used to transport drugs; or

1011 | 4. The department to take samples of any drug.

1012 | (b) The sale, purchase, or trade, or the offer to sell,  
1013 | purchase, or trade, a drug sample as defined in s. 499.028; the  
1014 | distribution of a drug sample in violation of s. 499.028; or the  
1015 | failure to otherwise comply with s. 499.028.

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1016 (c) Providing the department with false or fraudulent  
1017 records, or making false or fraudulent statements, regarding any  
1018 matter within the provisions of this part ~~chapter~~ related to a  
1019 drug.

1020 (d) The failure to receive, maintain, or provide invoices  
1021 and shipping documents, other than pedigree papers, if  
1022 applicable, related to the distribution of a prescription ~~legend~~  
1023 drug.

1024 (e) The importation of a prescription ~~legend~~ drug for  
1025 wholesale distribution, except as provided by s. 801(d) of the  
1026 Federal Food, Drug, and Cosmetic Act.

1027 (f) The wholesale distribution of a any prescription drug  
1028 that was:

1029 1. Purchased by a public or private hospital or other  
1030 health care entity; or

1031 2. Donated or supplied at a reduced price to a charitable  
1032 organization.

1033 (g) The failure to obtain a permit as a prescription drug  
1034 wholesale distributor ~~wholesaler~~ when a permit is required by  
1035 this part ~~ss. 499.001-499.081~~ for that activity.

1036 (h) Knowingly possessing any adulterated or misbranded  
1037 prescription ~~legend~~ drug outside of a designated quarantine area.

1038 (i) The purchase or sale of a prescription ~~drug~~ ~~drugs~~ for  
1039 wholesale distribution in exchange for currency, as defined in s.  
1040 560.103(6).

1041 (14) OTHER VIOLATIONS.--(3) Any person who violates any of  
1042 the following provisions commits a felony of the second degree,  
1043 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,  
1044 or as otherwise provided in this part: ~~ss. 499.001-499.081.~~

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1045 (a) Knowingly manufacturing, repackaging, selling,  
1046 delivering, or holding or offering for sale any drug that is  
1047 adulterated or misbranded or has otherwise been rendered unfit  
1048 for human or animal use.

1049 (b) Knowingly adulterating a drug that is intended for  
1050 further distribution.

1051 (c) Knowingly receiving a drug that is adulterated and  
1052 delivering or proffering delivery of such drug for pay or  
1053 otherwise.

1054 (d) Committing any act that causes a drug to be a  
1055 counterfeit drug, or selling, dispensing, or knowingly holding  
1056 for sale a counterfeit drug.

1057 (e) Forging, counterfeiting, simulating, or falsely  
1058 representing any drug, or, without the authority of the  
1059 manufacturer, using any mark, stamp, tag, label, or other  
1060 identification device authorized or required by rules adopted  
1061 under this part ~~ss. 499.001-499.081~~.

1062 (f) Knowingly obtaining or attempting to obtain a  
1063 prescription drug for wholesale distribution by fraud, deceit,  
1064 misrepresentation, or subterfuge, or engaging in  
1065 misrepresentation or fraud in the distribution of a drug.

1066 (g) Removing a pharmacy's dispensing label from a dispensed  
1067 prescription drug with the intent to further distribute the  
1068 prescription drug.

1069 (h) Knowingly distributing a prescription drug that was  
1070 previously dispensed by a licensed pharmacy, unless such  
1071 distribution was authorized in chapter 465 or the rules adopted  
1072 under chapter 465.

1073 (15) FALSE ADVERTISEMENT.--(4) A publisher, radio

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1074 broadcast licensee, or agency or medium for the dissemination of  
1075 an advertisement, except the manufacturer, repackager, wholesale  
1076 distributor ~~wholesaler~~, or seller of the article to which a false  
1077 advertisement relates, is not liable under subsection (12),  
1078 subsection (13), or subsection (14) ~~this section~~ by reason of the  
1079 dissemination by him or her of such false advertisement, unless  
1080 he or she has refused, on the request of the department, to  
1081 furnish to the department the name and post office address of the  
1082 manufacturer, repackager, wholesale distributor ~~wholesaler~~,  
1083 seller, or advertising agency that asked him or her to  
1084 disseminate such advertisement.

1085 Section 5. Section 499.0054, Florida Statutes, is amended;  
1086 section 499.0055, Florida Statutes, is redesignated as subsection  
1087 (2) of that section and amended; and section 499.0057, Florida  
1088 Statutes, is redesignated as subsection (3) of that section and  
1089 amended, to read:

1090 499.0054 Advertising and labeling of drugs, devices, and  
1091 cosmetics; exemptions.--

1092 (1) It is a violation of the Florida Drug and Cosmetic Act  
1093 to perform or cause the performance of any of the following acts:

1094 (a) ~~(1)~~ The dissemination of any false advertisement of any  
1095 drug, device, or cosmetic. An advertisement is false if it is  
1096 false or misleading in any way.

1097 (b) ~~(2)~~ The distribution in commerce of any drug, device, or  
1098 cosmetic, if its labeling or advertising is in violation of this  
1099 part ~~ss. 499.001-499.081~~.

1100 (c) ~~(3)~~ The manufacturing, repackaging, packaging, selling,  
1101 delivery, holding, or offering for sale of any drug, device, or  
1102 cosmetic for which the advertising or labeling is false or

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1103 | misleading.

1104 |       (d)~~(4)~~ The advertising of any drug, device, or cosmetic  
1105 | that is adulterated or misbranded.

1106 |       (e)~~(5)~~ The receiving in commerce of any drug, device, or  
1107 | cosmetic that is falsely advertised or labeled or the delivering  
1108 | or proffering for delivery of any such drug, device, or cosmetic.

1109 |       (f)~~(6)~~ The advertising or labeling of any product  
1110 | containing ephedrine, a salt of ephedrine, an isomer of  
1111 | ephedrine, or a salt of an isomer of ephedrine, for the  
1112 | indication of stimulation, mental alertness, weight loss,  
1113 | appetite control, energy, or other indications not approved by  
1114 | the pertinent United States Food and Drug Administration Over-  
1115 | the-Counter Final or Tentative Final Monograph or approved new  
1116 | drug application under the federal act. In determining compliance  
1117 | with this requirement, the department may consider the following  
1118 | factors:

1119 |       1.(a) The packaging of the product.

1120 |       2.(b) The name and labeling of the product.

1121 |       3.(c) The manner of distribution, advertising, and  
1122 | promotion of the product, including verbal representations at the  
1123 | point of sale.

1124 |       4.(d) The duration, scope, and significance of abuse of the  
1125 | particular product.

1126 |       (g)~~(7)~~ The advertising of any drug or device represented to  
1127 | have any effect in any of the following conditions, disorders,  
1128 | diseases, or processes:

1129 |       1.(a) Blood disorders.

1130 |       2.(b) Bone or joint diseases.

1131 |       3.(c) Kidney diseases or disorders.

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- 1132        4.~~(d)~~ Cancer.
- 1133        5.~~(e)~~ Diabetes.
- 1134        6.~~(f)~~ Gall bladder diseases or disorders.
- 1135        7.~~(g)~~ Heart and vascular diseases.
- 1136        8.~~(h)~~ High blood pressure.
- 1137        9.~~(i)~~ Diseases or disorders of the ear or auditory  
1138 apparatus, including hearing loss or deafness.
- 1139        10.~~(j)~~ Mental disease or mental retardation.
- 1140        11.~~(k)~~ Paralysis.
- 1141        12.~~(l)~~ Prostate gland disorders.
- 1142        13.~~(m)~~ Conditions of the scalp affecting hair loss.
- 1143        14.~~(n)~~ Baldness.
- 1144        15.~~(o)~~ Endocrine disorders.
- 1145        16.~~(p)~~ Sexual impotence.
- 1146        17.~~(q)~~ Tumors.
- 1147        18.~~(r)~~ Venereal diseases.
- 1148        19.~~(s)~~ Varicose ulcers.
- 1149        20.~~(t)~~ Breast enlargement.
- 1150        21.~~(u)~~ Purifying blood.
- 1151        22.~~(v)~~ Metabolic disorders.
- 1152        23.~~(w)~~ Immune system disorders or conditions affecting the  
1153 immune system.
- 1154        24.~~(x)~~ Extension of life expectancy.
- 1155        25.~~(y)~~ Stress and tension.
- 1156        26.~~(z)~~ Brain stimulation or performance.
- 1157        27.~~(aa)~~ The body's natural defense mechanisms.
- 1158        28.~~(bb)~~ Blood flow.
- 1159        29.~~(cc)~~ Depression.
- 1160        30.~~(dd)~~ Human immunodeficiency virus or acquired immune



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1161 deficiency syndrome or related disorders or conditions.

1162 (h)~~(8)~~ The representation or suggestion in labeling or  
1163 advertising that an article is approved under this part ~~ss.~~  
1164 ~~499.001-499.081~~, when such is not the case.

1165 (2)~~499.0055~~ ~~False or misleading advertisement.~~ In  
1166 determining whether an advertisement is false or misleading, the  
1167 department shall review the representations made or suggested by  
1168 statement, word, design, device, sound, or any combination  
1169 thereof within the advertisement and the extent to which the  
1170 advertisement fails to reveal material facts with respect to  
1171 consequences that can result from the use of the drug, device, or  
1172 cosmetic to which the advertisement relates under the conditions  
1173 of use prescribed in the labeling or advertisement.

1174 (3)~~499.0057~~ ~~Advertisement exemptions.~~

1175 (a)~~(1)~~ An advertisement that is not prohibited under  
1176 paragraph (1) (a) ~~s. 499.0054(1)~~ is not prohibited under paragraph  
1177 (1) (g) ~~s. 499.0054(7)~~ if it is disseminated:

1178 1. To the public solely to advertise the product for those  
1179 indications that are safe and effective indications and the  
1180 product is safe and effective for self-medication, as established  
1181 by the United States Food and Drug Administration; or

1182 2. ~~if it is disseminated~~ Only to members of the medical,  
1183 dental, pharmaceutical, or veterinary professions or appears only  
1184 in the scientific periodicals of these professions.

1185 (b)~~(2)~~ Compliance with this part ~~ss. 499.001-499.081~~ and  
1186 the rules adopted under this part ~~those sections~~ creates no legal  
1187 presumption that a drug or device is safe or effective.

1188 Section 6. Subsections (3), (10), and (11) of section  
1189 499.006, Florida Statutes, are amended to read:

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1190 499.006 Adulterated drug or device.--A drug or device is  
1191 adulterated:

1192 (3) If it is a drug and the methods used in, or the  
1193 facilities or controls used for, its manufacture, processing,  
1194 packing, or holding do not conform to, or are not operated or  
1195 administered in conformity with, current good manufacturing  
1196 practices to assure that the drug meets the requirements of this  
1197 part ss. ~~499.001-499.081~~ and that the drug has the identity and  
1198 strength, and meets the standard of quality and purity, which it  
1199 purports or is represented to possess;

1200 (10) If it is a prescription legend drug for which the  
1201 required pedigree paper is nonexistent, fraudulent, or incomplete  
1202 under the requirements of this part ss. ~~499.001-499.081~~ or  
1203 applicable rules, or that has been purchased, held, sold, or  
1204 distributed at any time by a person not authorized under federal  
1205 or state law to do so; or

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

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

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1219 drug. For the purpose of this paragraph, the finished dosage form  
1220 of a prescription medicinal drug is that form of the drug which  
1221 is, or is intended to be, dispensed or administered to the  
1222 patient and requires no further manufacturing or processing other  
1223 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 packages.

1228 (3) If it is an active pharmaceutical ingredient in bulk  
1229 form and does not bear a label containing:

1230 (a) The name and place of business of the manufacturer,  
1231 repackager, or distributor; and

1232 (b) An accurate statement of the quantity of the contents  
1233 in terms of weight, measure, or numerical count.

1234 (4)~~(3)~~ If any word, statement, or other information  
1235 required by or under this part ~~ss. 499.001-499.081~~ to appear on  
1236 the label or labeling is not prominently placed thereon with such  
1237 conspicuousness as compared with other words, statements,  
1238 designs, or devices in the labeling, and in such terms, as to  
1239 render the word, statement, or other information likely to be  
1240 read and understood under customary conditions of purchase and  
1241 use.

1242 (5)~~(4)~~ If it is a drug and is not designated solely by a  
1243 name recognized in an official compendium and,~~unless~~ its label  
1244 does not bear ~~bears~~:

1245 (a) The common or usual name of the drug, if any; and

1246 (b) In case it is fabricated from two or more ingredients,  
1247 the common or usual name and quantity of each active ingredient.

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- 1248        (6)~~(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:
- 1249            (a) Adequate directions for use; and
- 1250            (b) Adequate warnings against use in those pathological
- 1251 conditions in which its use may be dangerous to health or against
- 1252 use by children if its use may be dangerous to health, or against
- 1253 unsafe dosage or methods or duration of administration or
- 1254 application, in such manner and form as are necessary for the
- 1255 protection of users.
- 1256        (7)~~(6)~~ If it purports to be a drug the name of which is
- 1257 recognized in the official compendium and,~~unless~~ it is not
- 1258 packaged and labeled as prescribed therein.~~;~~ However, the method
- 1259 of packaging may be modified with the consent of the department.
- 1260        (8)~~(7)~~ If it has been found by the department to be a drug
- 1261 liable to deterioration and,~~unless~~ it is not packaged in such
- 1262 form and manner, and its label bears a statement of such
- 1263 precautions, as the department by rule requires as necessary to
- 1264 protect the public health. Such rule may not be established for
- 1265 any drug recognized in an official compendium until the
- 1266 department has informed the appropriate body charged with the
- 1267 revision of such compendium of the need for such packaging or
- 1268 labeling requirements and that body has failed within a
- 1269 reasonable time to prescribe such requirements.
- 1270        (9)~~(8)~~ If it is:
- 1271            (a) A drug and its container or finished dosage form is so
- 1272 made, formed, or filled as to be misleading;
- 1273            (b) An imitation of another drug; or
- 1274            (c) Offered for sale under the name of another drug.
- 1275        (10)~~(9)~~ If it is dangerous to health when used in the
- 1276 dosage or with the frequency or duration prescribed, recommended,

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1277 or suggested in the labeling of the drug.

1278 ~~(11)-(10)~~ If it is, purports to be, or is represented as a  
1279 drug composed wholly or partly of insulin and, ~~unless~~—  
1280 ~~(a)~~ it is not from a batch with respect to which a  
1281 certificate has been issued pursuant to s. 506 of the federal  
1282 act, which; ~~and~~

1283 ~~(b)~~—The certificate is in effect with respect to the drug.

1284 ~~(12)-(11)~~ If it is, purports to be, or is represented as a  
1285 drug composed wholly or partly of any kind of antibiotic  
1286 requiring certification under the federal act and ~~unless~~—  
1287 ~~(a)~~ it is not from a batch with respect to which a  
1288 certificate has been issued pursuant to s. 507 of the federal  
1289 act, which; ~~and~~

1290 ~~(b)~~ the certificate is in effect with respect to the drug.†

1291

1292 However, this subsection does not apply to any drug or class of  
1293 drugs exempted by regulations adopted under s. 507(c) or (d) of  
1294 the federal act.

1295 ~~(13)-(12)~~ If it is a drug intended for use by humans which  
1296 is a habit-forming drug or which, because of its toxicity or  
1297 other potentiality for harmful effect, or the method of its use,  
1298 or the collateral measures necessary to its use, is not safe for  
1299 use except under the supervision of a practitioner licensed by  
1300 law to administer such drugs,† or which is limited by an  
1301 effective application under s. 505 of the federal act to use  
1302 under the professional supervision of a practitioner licensed by  
1303 law to prescribe such drug, if ~~unless~~ it is not dispensed only:  
1304 (a) Upon the written prescription of a practitioner  
1305 licensed by law to prescribe such drug;

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

1312  
1313 This subsection does not relieve any person from any requirement  
1314 prescribed by law with respect to controlled substances as  
1315 defined in the applicable federal and state laws.

1316 ~~(14)-(13)~~ If it is a drug that is subject to paragraph  
1317 ~~(13)-(12)~~(a), and if, at any time before it is dispensed, its  
1318 label does not ~~fails to~~ bear the statement:

1319 (a) "Caution: Federal Law Prohibits Dispensing Without  
1320 Prescription";

1321 (b) "Rx Only";

1322 (c) The prescription symbol followed by the word "Only"; or

1323 (d) "Caution: State Law Prohibits Dispensing Without  
1324 Prescription."

1325 ~~(15)-(14)~~ If it is a drug that is not subject to paragraph  
1326 ~~(13)-(12)~~(a), if at any time before it is dispensed its label  
1327 bears the statement of caution required in subsection ~~(14)~~ ~~(13)~~.

1328 ~~(16)-(15)~~ If it is a color additive, the intended use of  
1329 which in or on drugs is for the purpose of coloring only and,  
1330 ~~unless~~ its packaging and labeling are not in conformity with the  
1331 packaging and labeling requirements that apply to such color  
1332 additive and are prescribed under the federal act.

1333 (17) A drug dispensed by filling or refilling a written or  
1334 oral prescription of a practitioner licensed by law to prescribe

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1335 such drug is exempt from the requirements of this section, except  
1336 subsections (1), (9) ~~(8)~~, (11) ~~(10)~~, and (12) ~~(11)~~ and the  
1337 packaging requirements of subsections (7) ~~(6)~~ and (8) ~~(7)~~, if the  
1338 drug bears a label that contains the name and address of the  
1339 dispenser or seller, the prescription number and the date the  
1340 prescription was written or filled, the name of the prescriber  
1341 and the name of the patient, and the directions for use and  
1342 cautionary statements. This exemption does not apply to any drug  
1343 dispensed in the course of the conduct of a business of  
1344 dispensing drugs pursuant to diagnosis by mail or to any drug  
1345 dispensed in violation of subsection (13) ~~(12)~~. The department  
1346 may, by rule, exempt drugs subject to s. 499.062 ~~ss. 499.062-~~  
1347 ~~499.064~~ from subsection (13) ~~(12)~~ if compliance with that  
1348 subsection is not necessary to protect the public health, safety,  
1349 and welfare.

1350 Section 8. Subsection (1) of section 499.008, Florida  
1351 Statutes, is amended and subsection (5) is added to that section  
1352 to read:

1353 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

1354 (1) If it bears or contains any poisonous or deleterious  
1355 substance that is injurious to users under the conditions of use  
1356 prescribed in the labeling or advertisement thereof or under such  
1357 conditions of use as are customary or usual; however, this  
1358 subsection does not apply to coal-tar hair dye:

1359 (a) The label of which bears the following legend  
1360 conspicuously displayed thereon: "Caution: This product contains  
1361 ingredients which may cause skin irritation on certain  
1362 individuals, and a preliminary test according to accompanying  
1363 directions should first be made. This product must not be used

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1364 for dyeing the eyelashes or eyebrows; to do so may cause  
1365 blindness"; and

1366 (b) The labeling of which bears adequate directions for  
1367 such preliminary testing.

1368  
1369 ~~For the purposes of this subsection and subsection (4), the term~~  
1370 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1371 (5) For the purposes of subsections (1) and (4), the term  
1372 "hair dye" does not include eyelash dyes or eyebrow dyes.

1373 Section 9. Subsections (2), (3), and (5) of section  
1374 499.009, Florida Statutes, are amended to read:

1375 499.009 Misbranded cosmetics.--A cosmetic is misbranded:

1376 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a  
1377 label containing:

1378 (a) The name and place of business of the manufacturer,  
1379 packer, or distributor;

1380 (b) An accurate statement of the quantity of the contents  
1381 in terms of weight, measure, or numerical count; however, under  
1382 this paragraph reasonable variations are permitted, and the  
1383 department shall establish by rule exemptions for small packages;  
1384 and

1385 (c) A declaration of ingredients in descending order of  
1386 predominance, or as otherwise required by federal law.

1387 (3) If any word, statement, or other information required  
1388 by or under authority of this part ~~ss. 499.001-499.081~~ to appear  
1389 on the label or labeling is not prominently placed thereon with  
1390 such conspicuousness as compared with other words, statements,  
1391 designs, or devices in the labeling, and in such terms, as to  
1392 render the word, statement, or other information likely to be



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1393 read and understood by an individual under customary conditions  
1394 of purchase and use.

1395 (5) ~~Unless,~~ If it is a color additive, its packaging and  
1396 labeling are not in conformity with the packaging and labeling  
1397 requirements applicable to that color additive prescribed under  
1398 the federal act. This subsection does not apply to packages of  
1399 color additives that, with respect to their use for cosmetics,  
1400 are marketed and intended for use only in or on hair dyes.

1401 Section 10. Section 499.01, Florida Statutes, is amended;  
1402 the introductory paragraph and paragraphs (a) through (h) of  
1403 subsection (2) of section 499.012, Florida Statutes, are  
1404 redesignated as the introductory paragraph and paragraphs (d),  
1405 (n), (e), (f), (c), (i), (k), and (l), respectively, of  
1406 subsection (2) of that section and amended; paragraphs (b)  
1407 through (e) of subsection (2) of section 499.013, Florida  
1408 Statutes, are redesignated as paragraphs (p), (o), (q), and (r),  
1409 respectively, of subsection (2) of that section and amended; and  
1410 section 499.014, Florida Statutes, is redesignated as paragraph  
1411 (g) of subsection (2) of that section and amended, to read:

1412 499.01 ~~Permits; applications; renewal; general~~  
1413 ~~requirements.--~~

1414 (1) Prior to operating, a permit is required for each  
1415 person and establishment that intends to operate as:

- 1416 (a) A prescription drug manufacturer;  
1417 (b) A prescription drug repackager;  
1418 (c) A nonresident prescription drug manufacturer;  
1419 (d) A prescription drug wholesale distributor;  
1420 (e) An out-of-state prescription drug wholesale  
1421 distributor;

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- 1422        (f) A retail pharmacy drug wholesale distributor;  
1423        (g) A restricted prescription drug distributor;  
1424        (h) A complimentary drug distributor;  
1425        (i) A freight forwarder;  
1426        (j) A veterinary prescription drug retail establishment;  
1427        (k) A veterinary prescription drug wholesale distributor;  
1428        (l) A limited prescription drug veterinary wholesale  
1429 distributor;  
1430        (m) A medical oxygen retail establishment;  
1431        (n) A compressed medical gas wholesale distributor;  
1432        (o) A compressed medical gas manufacturer;  
1433        (p)~~(e)~~ An over-the-counter drug manufacturer;  
1434        ~~(d) A compressed medical gas manufacturer;~~  
1435        (q)~~(e)~~ A device manufacturer;  
1436        (r)~~(f)~~ A cosmetic manufacturer;  
1437        (s) A third party logistic provider; or  
1438        (t) A health care clinic establishment.  
1439        ~~(g) A prescription drug wholesaler;~~  
1440        ~~(h) A veterinary prescription drug wholesaler;~~  
1441        ~~(i) A compressed medical gas wholesaler;~~  
1442        ~~(j) An out-of-state prescription drug wholesaler;~~  
1443        ~~(k) A nonresident prescription drug manufacturer;~~  
1444        ~~(l) A freight forwarder;~~  
1445        ~~(m) A retail pharmacy drug wholesaler;~~  
1446        ~~(n) A veterinary legend drug retail establishment;~~  
1447        ~~(o) A medical oxygen retail establishment;~~  
1448        ~~(p) A complimentary drug distributor;~~  
1449        ~~(q) A restricted prescription drug distributor; or~~  
1450        ~~(r) A limited prescription drug veterinary wholesaler.~~

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1451           (2) The following ~~types of wholesaler~~ permits are  
1452 established:

1453           (a) Prescription drug manufacturer permit.--A prescription  
1454 drug manufacturer permit is required for any person that  
1455 manufactures a prescription drug in this state.

1456           1. A person that operates an establishment permitted as a  
1457 prescription drug manufacturer may engage in wholesale  
1458 distribution of prescription drugs manufactured at that  
1459 establishment and must comply with all the provisions of this  
1460 part and the rules adopted under this part that apply to a  
1461 wholesale distributor.

1462           2. A prescription drug manufacturer must comply with all  
1463 appropriate state and federal good manufacturing practices.

1464           (b) Prescription drug repackager permit.--A prescription  
1465 drug repackager permit is required for any person that repackages  
1466 a prescription drug in this state.

1467           1. A person that operates an establishment permitted as a  
1468 prescription drug repackager may engage in wholesale distribution  
1469 of prescription drugs repackaged at that establishment and must  
1470 comply with all the provisions of this part and the rules adopted  
1471 under this part that apply to a wholesale distributor.

1472           2. A prescription drug repackager must comply with all  
1473 appropriate state and federal good manufacturing practices.

1474           (c) (e) Nonresident prescription drug manufacturer  
1475 permit.--A nonresident prescription drug manufacturer permit is  
1476 required for any person that is a manufacturer of prescription  
1477 drugs, or the distribution point for a manufacturer of  
1478 prescription drugs, and located outside of this state, or that is  
1479 an entity to whom an approved new drug application has been

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1480 issued by the United States Food and Drug Administration, or the  
1481 contracted manufacturer of the approved new drug application  
1482 holder, and located outside the United States, which engages in  
1483 the wholesale distribution in this state of the prescription  
1484 drugs it manufactures or is responsible for manufacturing. Each  
1485 such manufacturer or entity must be permitted by the department  
1486 and comply with all the provisions required of a wholesale  
1487 distributor under this part ~~ss. 499.001-499.081~~, except s.  
1488 499.01212 ~~s. 499.0121(6)(d)~~.

1489 1. A person that distributes prescription drugs that it did  
1490 not manufacture must also obtain an out-of-state prescription  
1491 drug wholesale distributor ~~wholesaler~~ permit pursuant to this  
1492 section to engage in the wholesale distribution of the  
1493 prescription drugs manufactured by another person and comply with  
1494 the requirements of an out-of-state prescription drug wholesale  
1495 distributor ~~wholesaler~~.

1496 2. Any such person must comply with the licensing or  
1497 permitting requirements of the jurisdiction in which the  
1498 establishment is located and the federal act, and any product  
1499 wholesaled into this state must comply with this part ~~ss.~~  
1500 ~~499.001-499.081~~. If a person intends to import prescription drugs  
1501 from a foreign country into this state, the nonresident  
1502 prescription drug manufacturer must provide to the department a  
1503 list identifying each prescription drug it intends to import and  
1504 document approval by the United States Food and Drug  
1505 Administration for such importation.

1506 3. A nonresident prescription drug manufacturer permit is  
1507 not required for a manufacturer to distribute a prescription drug  
1508 active pharmaceutical ingredient that it manufactures to a

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1509 prescription drug manufacturer permitted in this state in limited  
1510 quantities intended for research and development and not for  
1511 resale, or human use other than lawful clinical trials and  
1512 biostudies authorized and regulated by federal law. A  
1513 manufacturer claiming to be exempt from the permit requirements  
1514 of this subparagraph and the prescription drug manufacturer  
1515 purchasing and receiving the active pharmaceutical ingredient  
1516 shall comply with the recordkeeping requirements of s.  
1517 499.0121(6), but not the requirements of s. 499.01212. The  
1518 prescription drug manufacturer purchasing and receiving the  
1519 active pharmaceutical ingredient shall maintain on file a record  
1520 of the FDA registration number; the out-of-state license, permit,  
1521 or registration number; and, if available, a copy of the most  
1522 current FDA inspection report, for all manufacturers from whom  
1523 they purchase active pharmaceutical ingredients under this  
1524 section. The department shall specify by rule the allowable  
1525 number of transactions within a given period of time and the  
1526 amount of active pharmaceutical ingredients that qualify as  
1527 limited quantities for purposes of this exemption. The failure to  
1528 comply with the requirements of this subparagraph, or rules  
1529 adopted by the department to administer this subparagraph, for  
1530 the purchase of prescription drug active pharmaceutical  
1531 ingredients is a violation of s. 499.005(14).

1532 (d)(a) A Prescription drug wholesale distributor  
1533 ~~wholesaler's~~ permit.--A prescription drug wholesale distributor  
1534 ~~wholesaler~~ is a wholesale distributor that may engage in the  
1535 wholesale distribution of prescription drugs. A prescription drug  
1536 wholesale distributor ~~wholesaler~~ that applies to the department  
1537 for a new permit or the renewal of a permit must submit a bond of

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1538 \$100,000, or other equivalent means of security acceptable to the  
1539 department, such as an irrevocable letter of credit or a deposit  
1540 in a trust account or financial institution, payable to the  
1541 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the  
1542 bond is to secure payment of any administrative penalties imposed  
1543 by the department and any fees and costs incurred by the  
1544 department regarding that permit which are authorized under state  
1545 law and which the permittee fails to pay 30 days after the fine  
1546 or costs become final. The department may make a claim against  
1547 such bond or security until 1 year after the permittee's license  
1548 ceases to be valid or until 60 days after any administrative or  
1549 legal proceeding authorized in this part ~~ss. 499.001-499.081~~  
1550 which involves the permittee is concluded, including any appeal,  
1551 whichever occurs later. The department may adopt rules for  
1552 issuing a prescription drug wholesale distributor-broker  
1553 ~~wholesaler-broker~~ permit to a person who engages in the wholesale  
1554 distribution of prescription drugs and does not take physical  
1555 possession of any prescription drugs.

1556 (e) ~~(e)~~ An Out-of-state prescription drug wholesale  
1557 distributor ~~wholesaler's~~ permit.--An out-of-state prescription  
1558 drug wholesale distributor ~~wholesaler~~ is a wholesale distributor  
1559 located outside this state which engages in the wholesale  
1560 distribution of prescription drugs into this state and which must  
1561 be permitted by the department and comply with all the provisions  
1562 required of a wholesale distributor under this part ~~ss. 499.001-~~  
1563 ~~499.081~~. An out-of-state prescription drug wholesale distributor  
1564 ~~wholesaler~~ that applies to the department for a new permit or the  
1565 renewal of a permit must submit a bond of \$100,000, or other  
1566 equivalent means of security acceptable to the department, such

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1567 as an irrevocable letter of credit or a deposit in a trust  
1568 account or financial institution, payable to the Florida Drug,  
1569 Device, and Cosmetic Trust Fund. The purpose of the bond is to  
1570 secure payment of any administrative penalties imposed by the  
1571 department and any fees and costs incurred by the department  
1572 regarding that permit which are authorized under state law and  
1573 which the permittee fails to pay 30 days after the fine or costs  
1574 become final. The department may make a claim against such bond  
1575 or security until 1 year after the permittee's license ceases to  
1576 be valid or until 60 days after any administrative or legal  
1577 proceeding authorized in this part ss. 499.001-499.081 which  
1578 involves the permittee is concluded, including any appeal,  
1579 whichever occurs later.

1580 1. The out-of-state prescription drug wholesale distributor  
1581 ~~wholesaler~~ must maintain at all times a license or permit to  
1582 engage in the wholesale distribution of prescription drugs in  
1583 compliance with laws of the state in which it is a resident.

1584 2. An out-of-state prescription drug wholesale distributor  
1585 ~~wholesaler's~~ permit is not required for an intracompany sale or  
1586 transfer of a prescription drug from an out-of-state  
1587 establishment that is duly licensed as a prescription drug  
1588 wholesale distributor ~~wholesaler~~, in its state of residence, to a  
1589 licensed prescription drug wholesale distributor ~~wholesaler~~ in  
1590 this state, if both wholesale distributors ~~wholesalers~~ conduct  
1591 wholesale distributions of prescription drugs under the same  
1592 business name. The recordkeeping requirements of ss. s.  
1593 499.0121(6) and 499.01212 must be followed for this transaction.

1594 (f) ~~(d)~~ A Retail pharmacy drug wholesale distributor  
1595 ~~wholesaler's~~ permit.--A retail pharmacy drug wholesale

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1596 distributor ~~wholesaler~~ is a retail pharmacy engaged in wholesale  
1597 distribution of prescription drugs within this state under the  
1598 following conditions:

1599 1. The pharmacy must obtain a retail pharmacy drug  
1600 wholesale distributor ~~wholesaler's~~ permit pursuant to this part  
1601 ~~ss. 499.001-499.081~~ and the rules adopted under this part ~~these~~  
1602 ~~sections~~.

1603 2. The wholesale distribution activity does not exceed 30  
1604 percent of the total annual purchases of prescription drugs. If  
1605 the wholesale distribution activity exceeds the 30-percent  
1606 maximum, the pharmacy must obtain a prescription drug wholesale  
1607 distributor ~~wholesaler's~~ permit.

1608 3. The transfer of prescription drugs that appear in any  
1609 schedule contained in chapter 893 is subject to chapter 893 and  
1610 the federal Comprehensive Drug Abuse Prevention and Control Act  
1611 of 1970.

1612 4. The transfer is between a retail pharmacy and another  
1613 retail pharmacy, or a Modified Class II institutional pharmacy,  
1614 or a health care practitioner licensed in this state and  
1615 authorized by law to dispense or prescribe prescription drugs.

1616 5. All records of sales of prescription drugs subject to  
1617 this section must be maintained separate and distinct from other  
1618 records and comply with the recordkeeping requirements of this  
1619 part ~~ss. 499.001-499.081~~.

1620 (g) 499.014 Restricted prescription drug distributor permit  
1621 ~~Distribution of legend drugs by hospitals, health care entities,~~  
1622 ~~charitable organizations, and return or destruction companies;~~  
1623 ~~permits, general requirements.--~~

1624 ~~(1)~~ A restricted prescription drug distributor permit is



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1625 required for any person that engages in the distribution of a  
1626 prescription legend ~~legend~~ drug, which distribution is not considered  
1627 "wholesale distribution" under s. 499.003(53)(a) ~~s.~~  
1628 ~~499.012(1)(a)1.~~

1629 1.(2) A person who engages in the receipt or distribution  
1630 of a prescription legend ~~legend~~ drug in this state for the purpose of  
1631 processing its return or its destruction must obtain a permit as  
1632 a restricted prescription drug distributor if such person is not  
1633 the person initiating the return, the prescription drug wholesale  
1634 supplier of the person initiating the return, or the manufacturer  
1635 of the drug.

1636 2.(3) Storage, handling, and recordkeeping of these  
1637 distributions must comply with the requirements for wholesale  
1638 distributors under s. 499.0121, but not ~~except~~ those set forth in  
1639 s. 499.01212 ~~s. 499.0121(6)(d).~~

1640 3.(4) A person who applies for a permit as a restricted  
1641 prescription drug distributor, or for the renewal of such a  
1642 permit, must provide to the department the information required  
1643 under s. 499.012 ~~s. 499.01.~~

1644 4.(5) The department may ~~issue permits to restricted~~  
1645 ~~prescription drug distributors and may~~ adopt rules regarding the  
1646 distribution of prescription drugs by hospitals, health care  
1647 entities, charitable organizations, or other persons not involved  
1648 in wholesale distribution, which rules are necessary for the  
1649 protection of the public health, safety, and welfare.

1650 (h) Complimentary drug distributor permit.--A complimentary  
1651 drug distributor permit is required for any person that engages  
1652 in the distribution of a complimentary drug, subject to the  
1653 requirements of s. 499.028.

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1654        (i)~~(f)~~ Freight forwarder permit.--A freight forwarder  
1655 permit is required for any person that engages in the  
1656 distribution of a prescription legend drug as a freight forwarder  
1657 unless the person is a common carrier. The storage, handling, and  
1658 recordkeeping of such distributions must comply with the  
1659 requirements for wholesale distributors under s. 499.0121, but  
1660 not except those set forth in s. 499.01212 ~~s. 499.0121(6)(d)~~. A  
1661 freight forwarder must provide the source of the prescription  
1662 ~~legend~~ drugs with a validated airway bill, bill of lading, or  
1663 other appropriate documentation to evidence the exportation of  
1664 the product.

1665        (j) Veterinary prescription drug retail establishment  
1666 permit.--A veterinary prescription drug retail establishment  
1667 permit is required for any person that sells veterinary  
1668 prescription drugs to the public but does not include a pharmacy  
1669 licensed under chapter 465.

1670        1. The sale to the public must be based on a valid written  
1671 order from a veterinarian licensed in this state who has a valid  
1672 client-veterinarian relationship with the purchaser's animal.

1673        2. Veterinary prescription drugs may not be sold in excess  
1674 of the amount clearly indicated on the order or beyond the date  
1675 indicated on the order.

1676        3. An order may not be valid for more than 1 year.

1677        4. A veterinary prescription drug retail establishment may  
1678 not purchase, sell, trade, or possess human prescription drugs or  
1679 any controlled substance as defined in chapter 893.

1680        5. A veterinary prescription drug retail establishment must  
1681 sell a veterinary prescription drug in the original, sealed  
1682 manufacturer's container with all labeling intact and legible.

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1683 The department may adopt by rule additional labeling requirements  
1684 for the sale of a veterinary prescription drug.

1685 6. A veterinary prescription drug retail establishment must  
1686 comply with all of the wholesale distribution requirements of s.  
1687 499.0121.

1688 7. Prescription drugs sold by a veterinary prescription  
1689 drug retail establishment pursuant to a practitioner's order may  
1690 not be returned into the retail establishment's inventory.

1691 (k)(g) A veterinary prescription drug wholesale distributor  
1692 ~~wholesaler~~ permit.--A veterinary prescription drug wholesale  
1693 distributor ~~wholesaler~~ permit is required for any person that  
1694 engages in the distribution of veterinary prescription drugs in  
1695 or into this state. A veterinary prescription drug wholesale  
1696 distributor ~~wholesaler~~ that also distributes prescription drugs  
1697 subject to, defined by, or described by s. 503(b) of the Federal  
1698 Food, Drug, and Cosmetic Act which it did not manufacture must  
1699 obtain a permit as a prescription drug wholesale distributor  
1700 ~~wholesaler~~, an out-of-state prescription drug wholesale  
1701 distributor ~~wholesaler~~, or a limited prescription drug veterinary  
1702 wholesale distributor ~~wholesaler~~ in lieu of the veterinary  
1703 prescription drug wholesale distributor ~~wholesaler~~ permit. A  
1704 veterinary prescription drug wholesale distributor ~~wholesaler~~  
1705 must comply with the requirements for wholesale distributors  
1706 under s. 499.0121, but not except those set forth in s. 499.01212  
1707 ~~s. 499.0121(6)(d).~~

1708 (l)(h) Limited prescription drug veterinary wholesale  
1709 distributor ~~wholesaler~~ permit.--Unless engaging in the activities  
1710 of and permitted as a prescription drug manufacturer, nonresident  
1711 prescription drug manufacturer, prescription drug wholesale

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1712 distributor ~~wholesaler~~, or out-of-state prescription drug  
1713 wholesale distributor ~~wholesaler~~, a limited prescription drug  
1714 veterinary wholesale distributor ~~wholesaler~~ permit is required  
1715 for any person that engages in the distribution in or into this  
1716 state of veterinary prescription drugs and prescription drugs  
1717 subject to, defined by, or described by s. 503(b) of the Federal  
1718 Food, Drug, and Cosmetic Act under the following conditions:

- 1719 1. The person is engaged in the business of wholesaling  
1720 prescription and veterinary prescription ~~legend~~ drugs to persons:
  - 1721 a. Licensed as veterinarians practicing on a full-time  
1722 basis;
  - 1723 b. Regularly and lawfully engaged in instruction in  
1724 veterinary medicine;
  - 1725 c. Regularly and lawfully engaged in law enforcement  
1726 activities;
  - 1727 d. For use in research not involving clinical use; or
  - 1728 e. For use in chemical analysis or physical testing or for  
1729 purposes of instruction in law enforcement activities, research,  
1730 or testing.
- 1731 2. No more than 30 percent of total annual prescription  
1732 drug sales may be prescription drugs approved for human use which  
1733 are subject to, defined by, or described by s. 503(b) of the  
1734 Federal Food, Drug, and Cosmetic Act.
- 1735 3. The person does not distribute ~~is not permitted,~~  
1736 ~~licensed, or otherwise authorized~~ in any jurisdiction ~~state~~ to  
1737 ~~wholesale~~ prescription drugs subject to, defined by, or described  
1738 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any  
1739 person who is authorized to sell, distribute, purchase, trade, or  
1740 use these drugs on or for humans.

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1741           4. A limited prescription drug veterinary wholesale  
1742 distributor ~~wholesaler~~ that applies to the department for a new  
1743 permit or the renewal of a permit must submit a bond of \$20,000,  
1744 or other equivalent means of security acceptable to the  
1745 department, such as an irrevocable letter of credit or a deposit  
1746 in a trust account or financial institution, payable to the  
1747 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the  
1748 bond is to secure payment of any administrative penalties imposed  
1749 by the department and any fees and costs incurred by the  
1750 department regarding that permit which are authorized under state  
1751 law and which the permittee fails to pay 30 days after the fine  
1752 or costs become final. The department may make a claim against  
1753 such bond or security until 1 year after the permittee's license  
1754 ceases to be valid or until 60 days after any administrative or  
1755 legal proceeding authorized in this part ~~ss. 499.001-499.081~~  
1756 which involves the permittee is concluded, including any appeal,  
1757 whichever occurs later.

1758           5. A limited prescription drug veterinary wholesale  
1759 distributor ~~wholesaler~~ must maintain at all times a license or  
1760 permit to engage in the wholesale distribution of prescription  
1761 drugs in compliance with laws of the state in which it is a  
1762 resident.

1763           6. A limited prescription drug veterinary wholesale  
1764 distributor ~~wholesaler~~ must comply with the requirements for  
1765 wholesale distributors under ss. s. 499.0121 and 499.01212,  
1766 except that a limited prescription drug veterinary wholesale  
1767 distributor ~~wholesaler~~ is not required to provide a pedigree  
1768 paper as required by s. 499.01212 ~~s. 499.0121(6)(d)~~ upon the  
1769 wholesale distribution of a prescription drug to a veterinarian.

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1770 7. A limited prescription drug veterinary wholesale  
1771 distributor ~~wholesaler~~ may not return to inventory for subsequent  
1772 wholesale distribution any prescription drug subject to, defined  
1773 by, or described by s. 503(b) of the Federal Food, Drug, and  
1774 Cosmetic Act which has been returned by a veterinarian.

1775 8. ~~An out-of-state prescription drug wholesaler's permit or~~  
1776 A limited prescription drug veterinary wholesale distributor  
1777 ~~wholesaler~~ permit is not required for an intracompany sale or  
1778 transfer of a prescription drug from an out-of-state  
1779 establishment that is duly licensed to engage in the wholesale  
1780 distribution of prescription drugs in its state of residence to a  
1781 licensed limited prescription drug veterinary wholesale  
1782 distributor ~~wholesaler~~ in this state if both wholesale  
1783 distributors ~~wholesalers~~ conduct wholesale distributions of  
1784 prescription drugs under the same business name. The  
1785 recordkeeping requirements of ss. s. 499.0121(6) and 499.01212  
1786 must be followed for this transaction.

1787 (m) Medical oxygen retail establishment permit.--A medical  
1788 oxygen retail establishment permit is required for any person  
1789 that sells medical oxygen to patients only. The sale must be  
1790 based on an order from a practitioner authorized by law to  
1791 prescribe. The term does not include a pharmacy licensed under  
1792 chapter 465.

1793 1. A medical oxygen retail establishment may not possess,  
1794 purchase, sell, or trade any prescription drug other than medical  
1795 oxygen.

1796 2. A medical oxygen retail establishment may refill medical  
1797 oxygen for an individual patient based on an order from a  
1798 practitioner authorized by law to prescribe. A medical oxygen

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1799 retail establishment that refills medical oxygen must comply with  
1800 all appropriate state and federal good manufacturing practices.

1801 3. A medical oxygen retail establishment must comply with  
1802 all of the wholesale distribution requirements of s. 499.0121.

1803 4. Prescription medical oxygen sold by a medical oxygen  
1804 retail establishment pursuant to a practitioner's order may not  
1805 be returned into the retail establishment's inventory.

1806 (n) ~~(b)~~ A compressed medical gas wholesale distributor  
1807 wholesaler's permit.--A compressed medical gas wholesale  
1808 distributor wholesaler is a wholesale distributor that is limited  
1809 to the wholesale distribution of compressed medical gases to  
1810 other than the consumer or patient. The compressed medical gas  
1811 must be in the original sealed container that was purchased by  
1812 that wholesale distributor wholesaler. A compressed medical gas  
1813 wholesale distributor wholesaler may not possess or engage in the  
1814 wholesale distribution of any prescription drug other than  
1815 compressed medical gases. The department shall adopt rules that  
1816 govern the wholesale distribution of prescription medical oxygen  
1817 for emergency use. With respect to the emergency use of  
1818 prescription medical oxygen, those rules may not be inconsistent  
1819 with rules and regulations of federal agencies unless the  
1820 Legislature specifically directs otherwise.

1821 (o) ~~(e)~~ Compressed medical gas manufacturer permit.--A  
1822 compressed medical gas manufacturer manufacturer's permit is  
1823 required for any person that engages in the manufacture of  
1824 compressed medical gases or repackages compressed medical gases  
1825 from one container to another.

1826 1. A compressed medical gas manufacturer permittee may not  
1827 manufacture or possess any prescription drug other than

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1828 compressed medical gases.

1829       2. A compressed medical gas manufacturer ~~permittee~~ may  
1830 engage in wholesale distribution of compressed medical gases  
1831 manufactured at that establishment and must comply with all the  
1832 provisions of this part ss. 499.001-499.081 and the rules adopted  
1833 under this part ~~those sections~~ that apply to a wholesale  
1834 distributor.

1835       3. A compressed medical gas manufacturer ~~permittee~~ must  
1836 comply with all appropriate state and federal good manufacturing  
1837 practices.

1838       

~~(p)-(b)~~ Over-the-counter drug manufacturer permit.--An over-  
1839 the-counter drug manufacturer ~~manufacturer's~~ permit is required  
1840 for any person that engages in the manufacture or repackaging of  
1841 an over-the-counter drug.

1842       1. An over-the-counter drug manufacturer ~~permittee~~ may not  
1843 possess or purchase prescription drugs.

1844       2. A pharmacy is exempt from obtaining an over-the-counter  
1845 drug manufacturer ~~manufacturer's~~ permit if it is operating in  
1846 compliance with pharmacy practice standards as defined in chapter  
1847 465 and the rules adopted under that chapter.

1848       3. An over-the-counter drug manufacturer ~~permittee~~ must  
1849 comply with all appropriate state and federal good manufacturing  
1850 practices.

1851       

~~(q)-(d)~~ Device manufacturer permit.--A device manufacturer  
1852 ~~manufacturer's~~ permit is required for any person that engages in  
1853 the manufacture, repackaging, or assembly of medical devices for  
1854 human use in this state, except that a permit is not required if  
1855 the person is engaged only in manufacturing, repackaging, or  
1856 assembling a medical device pursuant to a practitioner's order



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1857 for a specific patient.

1858 1. A manufacturer or repackager of medical devices in this  
1859 state must comply with all appropriate state and federal good  
1860 manufacturing practices and quality system rules.

1861 2. The department shall adopt rules related to storage,  
1862 handling, and recordkeeping requirements for manufacturers of  
1863 medical devices for human use.

1864 (r) (e) Cosmetic manufacturer permit.--A cosmetic  
1865 manufacturer ~~manufacturer's~~ permit is required for any person  
1866 that manufactures or repackages cosmetics in this state. A person  
1867 that only labels or changes the labeling of a cosmetic but does  
1868 not open the container sealed by the manufacturer of the product  
1869 is exempt from obtaining a permit under this paragraph.

1870 (s) Third party logistics provider permit.--A third party  
1871 logistics provider permit is required for any person that  
1872 contracts with a prescription drug wholesale distributor or  
1873 prescription drug manufacturer to provide warehousing,  
1874 distribution, or other logistics services on behalf of a  
1875 manufacturer or wholesale distributor, but who does not take  
1876 title to the prescription drug or have responsibility to direct  
1877 the sale or disposition of the prescription drug. Each third  
1878 party logistics provider permittee shall comply with all of the  
1879 provisions required of a wholesale distributor under this part,  
1880 with the exception of s. 499.01212 for those wholesale  
1881 distributions described in s. 499.01212(3)(a), and other rules  
1882 that the department requires.

1883 (t) Health care clinic establishment permit.--Effective  
1884 January 1, 2009, a health care clinic establishment permit is  
1885 required for the purchase of a prescription drug by a place of

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1886 business at one general physical location owned and operated by a  
1887 professional corporation or professional limited liability  
1888 company described in chapter 621, or a corporation that employs a  
1889 veterinarian as a qualifying practitioner. For the purpose of  
1890 this paragraph, the term "qualifying practitioner" means a  
1891 licensed health care practitioner defined in s. 456.001 or a  
1892 veterinarian licensed under chapter 474, who is authorized under  
1893 the appropriate practice act to prescribe and administer a  
1894 prescription drug.

1895 1. An establishment must provide, as part of the  
1896 application required under s. 499.012, designation of a  
1897 qualifying practitioner who will be responsible for complying  
1898 with all legal and regulatory requirements related to the  
1899 purchase, recordkeeping, storage, and handling of the  
1900 prescription drugs. In addition, the designated qualifying  
1901 practitioner shall be the practitioner whose name, establishment  
1902 address, and license number is used on all distribution documents  
1903 for prescription drugs purchased or returned by the health care  
1904 clinic establishment. Upon initial appointment of a qualifying  
1905 practitioner, the qualifying practitioner and the health care  
1906 clinic establishment shall notify the department on a form  
1907 furnished by the department within 10 days after such employment.  
1908 In addition, the qualifying practitioner and health care clinic  
1909 establishment shall notify the department within 10 days after  
1910 any subsequent change.

1911 2. The health care clinic establishment must employ a  
1912 qualifying practitioner at each establishment.

1913 3. In addition to the remedies and penalties provided in  
1914 this part, a violation of this chapter by the health care clinic

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1915 establishment or qualifying practitioner constitutes grounds for  
1916 discipline of the qualifying practitioner by the appropriate  
1917 regulatory board.

1918 4. The purchase of prescription drugs by the health care  
1919 clinic establishment is prohibited during any period of time when  
1920 the establishment does not comply with this paragraph.

1921 5. A health care clinic establishment permit is not a  
1922 pharmacy permit or otherwise subject to chapter 465. A health  
1923 care clinic establishment that meets the criteria of a modified  
1924 Class II institutional pharmacy under s. 465.019 is not eligible  
1925 to be permitted under this paragraph.

1926 6. This paragraph does not prohibit a qualifying  
1927 practitioner from purchasing prescription drugs.

1928 Section 11. Section 499.012, Florida Statutes, is amended  
1929 and subsections (2) through (8) of section 499.01, Florida  
1930 States, are redesignated as subsections (1) through (7) of that  
1931 section and amended, to read:

1932 499.012 Permit application ~~Wholesale distribution;~~  
1933 ~~definitions; permits; applications; general requirements.--~~

1934 ~~(1) As used in this section, the term:~~

1935 ~~(2)(a)~~ (a) A permit issued pursuant to this part ~~ss. 499.001-~~  
1936 ~~499.081~~ may be issued only to a natural person who is at least 18  
1937 years of age or to an applicant that is not a natural person if  
1938 each person who, directly or indirectly, manages, controls, or  
1939 oversees the operation of that applicant is at least 18 years of  
1940 age.

1941 (b) An establishment that is a place of residence may not  
1942 receive a permit and may not operate under this part ~~ss. 499.001-~~  
1943 ~~499.081.~~

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1944 (c) A person that applies for or renews a permit to  
1945 manufacture or distribute prescription ~~legend~~ drugs may not use a  
1946 name identical to the name used by any other establishment or  
1947 licensed person authorized to purchase prescription drugs in this  
1948 state, except that a restricted drug distributor permit issued to  
1949 a health care entity will be issued in the name in which the  
1950 institutional pharmacy permit is issued and a retail pharmacy  
1951 drug wholesale distributor ~~wholesaler~~ will be issued a permit in  
1952 the name of its retail pharmacy permit.

1953 (d) A permit for a prescription drug manufacturer,  
1954 prescription drug repackager, prescription drug wholesale  
1955 distributor ~~wholesaler~~, limited prescription drug veterinary  
1956 wholesale distributor ~~wholesaler~~, or retail pharmacy drug  
1957 wholesale distributor ~~wholesaler~~ may not be issued to the address  
1958 of a health care entity or to a pharmacy licensed under chapter  
1959 465, except as provided in this paragraph. The department may  
1960 issue a prescription drug manufacturer permit to an applicant at  
1961 the same address as a licensed nuclear pharmacy, which is a  
1962 health care entity, for the purpose of manufacturing prescription  
1963 drugs used in positron emission tomography or other  
1964 radiopharmaceuticals, as listed in a rule adopted by the  
1965 department pursuant to this paragraph. The purpose of this  
1966 exemption is to assure availability of state-of-the-art  
1967 pharmaceuticals that would pose a significant danger to the  
1968 public health if manufactured at a separate establishment address  
1969 from the nuclear pharmacy from which the prescription drugs are  
1970 dispensed. The department may also issue a retail pharmacy drug  
1971 wholesale distributor ~~wholesaler~~ permit to the address of a  
1972 community pharmacy licensed under chapter 465 which does not meet

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1973 the definition of a closed pharmacy in s. 499.003.

1974 (e) A county or municipality may not issue an occupational  
1975 license for any licensing period beginning on or after October 1,  
1976 2003, for any establishment that requires a permit pursuant to  
1977 this part ~~ss. 499.001-499.081~~, unless the establishment exhibits  
1978 a current permit issued by the department for the establishment.  
1979 Upon presentation of the requisite permit issued by the  
1980 department, an occupational license may be issued by the  
1981 municipality or county in which application is made. The  
1982 department shall furnish to local agencies responsible for  
1983 issuing occupational licenses a current list of all  
1984 establishments licensed pursuant to this part ~~ss. 499.001-~~  
1985 ~~499.081~~.

1986 (2)~~(3)~~ Notwithstanding subsection (6) ~~(7)~~, a permitted  
1987 person in good standing may change the type of permit issued to  
1988 that person by completing a new application for the requested  
1989 permit, paying the amount of the difference in the permit fees if  
1990 the fee for the new permit is more than the fee for the original  
1991 permit, and meeting the applicable permitting conditions for the  
1992 new permit type. The new permit expires on the expiration date of  
1993 the original permit being changed; however, a new permit for a  
1994 prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
1995 state prescription drug wholesale distributor ~~wholesaler~~, or a  
1996 retail pharmacy drug wholesale distributor ~~wholesaler~~ shall  
1997 expire on the expiration date of the original permit or 1 year  
1998 after the date of issuance of the new permit, whichever is  
1999 earlier. A refund may not be issued if the fee for the new permit  
2000 is less than the fee that was paid for the original permit.

2001 (3)~~(4)~~ A written application for a permit or to renew a

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2002 permit must be filed with the department on forms furnished by  
2003 the department. The department shall establish, by rule, the form  
2004 and content of the application to obtain or renew a permit. The  
2005 applicant must submit to the department with the application a  
2006 statement that swears or affirms that the information is true and  
2007 correct.

2008 (4) ~~(5)~~(a) Except for a permit for a prescription drug  
2009 wholesale distributor ~~wholesaler~~ or an out-of-state prescription  
2010 drug wholesale distributor ~~wholesaler~~, an application for a  
2011 permit must include:

2012 1. The name, full business address, and telephone number of  
2013 the applicant;

2014 2. All trade or business names used by the applicant;

2015 3. The address, telephone numbers, and the names of contact  
2016 persons for each facility used by the applicant for the storage,  
2017 handling, and distribution of prescription drugs;

2018 4. The type of ownership or operation, such as a  
2019 partnership, corporation, or sole proprietorship; and

2020 5. The names of the owner and the operator of the  
2021 establishment, including:

2022 a. If an individual, the name of the individual;

2023 b. If a partnership, the name of each partner and the name  
2024 of the partnership;

2025 c. If a corporation, the name and title of each corporate  
2026 officer and director, the corporate names, and the name of the  
2027 state of incorporation;

2028 d. If a sole proprietorship, the full name of the sole  
2029 proprietor and the name of the business entity;

2030 e. If a limited liability company, the name of each member,

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2031 the name of each manager, the name of the limited liability  
2032 company, and the name of the state in which the limited liability  
2033 company was organized; and

2034 f. Any other relevant information that the department  
2035 requires.

2036 (b) Upon approval of the application by the department and  
2037 payment of the required fee, the department shall issue a permit  
2038 to the applicant, if the applicant meets the requirements of this  
2039 part ~~ss. 499.001-499.081~~ and rules adopted under this part ~~those~~  
2040 ~~sections~~.

2041 (c) Any change in information required under paragraph (a)  
2042 must be submitted to the department before the change occurs.

2043 (d) The department shall consider, at a minimum, the  
2044 following factors in reviewing the qualifications of persons to  
2045 be permitted under this part ~~ss. 499.001-499.081~~:

2046 1. The applicant's having been found guilty, regardless of  
2047 adjudication, in a court of this state or other jurisdiction, of  
2048 a violation of a law that directly relates to a drug, device, or  
2049 cosmetic. A plea of nolo contendere constitutes a finding of  
2050 guilt for purposes of this subparagraph.

2051 2. The applicant's having been disciplined by a regulatory  
2052 agency in any state for any offense that would constitute a  
2053 violation of this part ~~ss. 499.001-499.081~~.

2054 3. Any felony conviction of the applicant under a federal,  
2055 state, or local law;

2056 4. The applicant's past experience in manufacturing or  
2057 distributing drugs, devices, or cosmetics;

2058 5. The furnishing by the applicant of false or fraudulent  
2059 material in any application made in connection with manufacturing

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2060 or distributing drugs, devices, or cosmetics;

2061 6. Suspension or revocation by a federal, state, or local  
2062 government of any permit currently or previously held by the  
2063 applicant for the manufacture or distribution of any drugs,  
2064 devices, or cosmetics;

2065 7. Compliance with permitting requirements under any  
2066 previously granted permits;

2067 8. Compliance with requirements to maintain or make  
2068 available to the state permitting authority or to federal, state,  
2069 or local law enforcement officials those records required under  
2070 this section; and

2071 9. Any other factors or qualifications the department  
2072 considers relevant to and consistent with the public health and  
2073 safety.

2074 (5)~~(6)~~ Except for a permit ~~permits~~ for a prescription drug  
2075 wholesale distributor ~~wholesalers~~ or an out-of-state prescription  
2076 drug wholesale distributor ~~wholesalers~~:

2077 (a) The department shall adopt rules for the biennial  
2078 renewal of permits.

2079 (b) The department shall renew a permit upon receipt of the  
2080 renewal application and renewal fee if the applicant meets the  
2081 requirements established under this part ~~ss. 499.001-499.081~~ and  
2082 the rules adopted under this part ~~those sections~~.

2083 (c) A permit, unless sooner suspended or revoked,  
2084 automatically expires 2 years after the last day of the  
2085 anniversary month in which the permit was originally issued. A  
2086 permit issued under this part ~~ss. 499.001-499.081~~ may be renewed  
2087 by making application for renewal on forms furnished by the  
2088 department and paying the appropriate fees. If a renewal



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2089 application and fee are submitted and postmarked after the  
2090 expiration date of the permit, the permit may be renewed only  
2091 upon payment of a late renewal delinquent fee of \$100, plus the  
2092 required renewal fee, not later than 60 days after the expiration  
2093 date.

2094 (d) Failure to renew a permit in accordance with this  
2095 section precludes any future renewal of that permit. If a permit  
2096 issued pursuant to this part ~~section~~ has expired and cannot be  
2097 renewed, before an establishment may engage in activities that  
2098 require a permit under this part ~~ss. 499.001-499.081~~, the  
2099 establishment must submit an application for a new permit, pay  
2100 the applicable application fee, the initial permit fee, and all  
2101 applicable penalties, and be issued a new permit by the  
2102 department.

2103 (6)~~(7)~~ A permit issued by the department is  
2104 nontransferable. Each permit is valid only for the person or  
2105 governmental unit to which it is issued and is not subject to  
2106 sale, assignment, or other transfer, voluntarily or  
2107 involuntarily; nor is a permit valid for any establishment other  
2108 than the establishment for which it was originally issued.

2109 (a) A person permitted under this part ~~ss. 499.001-499.081~~  
2110 must notify the department before making a change of address. The  
2111 department shall set a change of location fee not to exceed \$100.

2112 (b)1. An application for a new permit is required when a  
2113 majority of the ownership or controlling interest of a permitted  
2114 establishment is transferred or assigned or when a lessee agrees  
2115 to undertake or provide services to the extent that legal  
2116 liability for operation of the establishment will rest with the  
2117 lessee. The application for the new permit must be made before

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2118 | the date of the sale, transfer, assignment, or lease.

2119 |         2. A permittee that is authorized to distribute  
2120 | prescription legend drugs may transfer such drugs to the new  
2121 | owner or lessee under subparagraph 1. only after the new owner or  
2122 | lessee has been approved for a permit to distribute prescription  
2123 | ~~legend~~ drugs.

2124 |         (c) If an establishment permitted under this part ss.  
2125 | ~~499.001-499.081~~ closes, the owner must notify the department in  
2126 | writing before the effective date of closure and must:

2127 |             1. Return the permit to the department;

2128 |             2. If the permittee is authorized to distribute  
2129 | prescription legend drugs, indicate the disposition of such  
2130 | drugs, including the name, address, and inventory, and provide  
2131 | the name and address of a person to contact regarding access to  
2132 | records that are required to be maintained under this part ss.  
2133 | ~~499.001-499.081~~. Transfer of ownership of prescription legend  
2134 | drugs may be made only to persons authorized to possess  
2135 | prescription legend drugs under this part ss. ~~499.001-499.081~~.

2136

2137 | The department may revoke the permit of any person that fails to  
2138 | comply with the requirements of this subsection.

2139 |         ~~(7)(8)~~ A permit must be posted in a conspicuous place on  
2140 | the licensed premises.

2141 |         ~~(8)(3)~~ An application for a permit or to renew a permit for  
2142 | a prescription drug wholesale distributor ~~wholesaler~~ or an out-  
2143 | of-state prescription drug wholesale distributor ~~wholesaler~~  
2144 | submitted to the department must include:

2145 |             (a) The name, full business address, and telephone number  
2146 | of the applicant.

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2147 (b) All trade or business names used by the applicant.

2148 (c) The address, telephone numbers, and the names of  
2149 contact persons for each facility used by the applicant for the  
2150 storage, handling, and distribution of prescription drugs.

2151 (d) The type of ownership or operation, such as a  
2152 partnership, corporation, or sole proprietorship.

2153 (e) The names of the owner and the operator of the  
2154 establishment, including:

2155 1. If an individual, the name of the individual.

2156 2. If a partnership, the name of each partner and the name  
2157 of the partnership.

2158 3. If a corporation:

2159 a. The name, address, and title of each corporate officer  
2160 and director.

2161 b. The name and address of the corporation, resident agent  
2162 of the corporation, the resident agent's address, and the  
2163 corporation's state of incorporation.

2164 c. The name and address of each shareholder of the  
2165 corporation that owns 5 percent or more of the outstanding stock  
2166 of the corporation.

2167 4. If a sole proprietorship, the full name of the sole  
2168 proprietor and the name of the business entity.

2169 5. If a limited liability company:

2170 a. The name and address of each member.

2171 b. The name and address of each manager.

2172 c. The name and address of the limited liability company,  
2173 the resident agent of the limited liability company, and the name  
2174 of the state in which the limited liability company was  
2175 organized.

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2176 (f) If applicable, the name and address of each member of  
2177 the affiliated group of which the applicant is a member.

2178 (g)1. For an application for a new permit, the estimated  
2179 annual dollar volume of prescription drug sales of the applicant,  
2180 the estimated annual percentage of the applicant's total company  
2181 sales that are prescription drugs, the applicant's estimated  
2182 annual total dollar volume of purchases of prescription drugs,  
2183 and the applicant's estimated annual total dollar volume of  
2184 prescription drug purchases directly from manufacturers.

2185 2. For an application to renew a permit, the total dollar  
2186 volume of prescription drug sales in the previous year, the total  
2187 dollar volume of prescription drug sales made in the previous 6  
2188 months, the percentage of total company sales that were  
2189 prescription drugs in the previous year, the total dollar volume  
2190 of purchases of prescription drugs in the previous year, and the  
2191 total dollar volume of prescription drug purchases directly from  
2192 manufacturers in the previous year.

2193  
2194 Such portions of the information required pursuant to this  
2195 paragraph which are a trade secret, as defined in s. 812.081,  
2196 shall be maintained by the department as trade secret information  
2197 is required to be maintained under s. 499.051.

2198 (h) The tax year of the applicant.

2199 (i) A copy of the deed for the property on which  
2200 applicant's establishment is located, if the establishment is  
2201 owned by the applicant, or a copy of the applicant's lease for  
2202 the property on which applicant's establishment is located that  
2203 has an original term of not less than 1 calendar year, if the  
2204 establishment is not owned by the applicant.

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2205 (j) A list of all licenses and permits issued to the  
2206 applicant by any other state which authorize the applicant to  
2207 purchase or possess prescription drugs.

2208 (k) The name of the manager of the establishment that is  
2209 applying for the permit or to renew the permit, the next four  
2210 highest ranking employees responsible for prescription drug  
2211 wholesale operations for the establishment, and the name of all  
2212 affiliated parties for the establishment, together with the  
2213 personal information statement and fingerprints required pursuant  
2214 to subsection (9) ~~(4)~~ for each of such persons.

2215 (l) The name of each of the applicant's designated  
2216 representatives as required by subsection (16) ~~(11)~~, together  
2217 with the personal information statement and fingerprints required  
2218 pursuant to subsection (9) ~~(4)~~ for each such person.

2219 (m) For an applicant that is a secondary wholesale  
2220 distributor ~~wholesaler~~, each of the following:

2221 1. A personal background information statement containing  
2222 the background information and fingerprints required pursuant to  
2223 subsection (9) ~~(4)~~ for each person named in the applicant's  
2224 response to paragraphs (k) and (l) and for each affiliated party  
2225 of the applicant.

2226 2. If any of the five largest shareholders of the  
2227 corporation seeking the permit is a corporation, the name,  
2228 address, and title of each corporate officer and director of each  
2229 such corporation; the name and address of such corporation; the  
2230 name of such corporation's resident agent, such corporation's  
2231 resident agent's address, and such corporation's state of its  
2232 incorporation; and the name and address of each shareholder of  
2233 such corporation that owns 5 percent or more of the stock of such

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2234 corporation.

2235 3. The name and address of all financial institutions in  
2236 which the applicant has an account which is used to pay for the  
2237 operation of the establishment or to pay for drugs purchased for  
2238 the establishment, together with the names of all persons that  
2239 are authorized signatories on such accounts. The portions of the  
2240 information required pursuant to this subparagraph which are a  
2241 trade secret, as defined in s. 812.081, shall be maintained by  
2242 the department as trade secret information is required to be  
2243 maintained under s. 499.051.

2244 4. The sources of all funds and the amounts of such funds  
2245 used to purchase or finance purchases of prescription drugs or to  
2246 finance the premises on which the establishment is to be located.

2247 5. If any of the funds identified in subparagraph 4. were  
2248 borrowed, copies of all promissory notes or loans used to obtain  
2249 such funds.

2250 (n) Any other relevant information that the department  
2251 requires, including, but not limited to, any information related  
2252 to whether the applicant satisfies the definition of a primary  
2253 wholesale distributor ~~wholesaler~~ or a secondary wholesale  
2254 distributor ~~wholesaler~~.

2255 (9) ~~(4)~~ (a) Each person required by subsection (8) ~~(3)~~ to  
2256 provide a personal information statement and fingerprints shall  
2257 provide the following information to the department on forms  
2258 prescribed by the department:

- 2259 1. The person's places of residence for the past 7 years.  
2260 2. The person's date and place of birth.  
2261 3. The person's occupations, positions of employment, and  
2262 offices held during the past 7 years.

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2263 4. The principal business and address of any business,  
2264 corporation, or other organization in which each such office of  
2265 the person was held or in which each such occupation or position  
2266 of employment was carried on.

2267 5. Whether the person has been, during the past 7 years,  
2268 the subject of any proceeding for the revocation of any license  
2269 and, if so, the nature of the proceeding and the disposition of  
2270 the proceeding.

2271 6. Whether, during the past 7 years, the person has been  
2272 enjoined, either temporarily or permanently, by a court of  
2273 competent jurisdiction from violating any federal or state law  
2274 regulating the possession, control, or distribution of  
2275 prescription drugs, together with details concerning any such  
2276 event.

2277 7. A description of any involvement by the person with any  
2278 business, including any investments, other than the ownership of  
2279 stock in a publicly traded company or mutual fund, during the  
2280 past 7 years, which manufactured, administered, prescribed,  
2281 distributed, or stored pharmaceutical products and any lawsuits  
2282 in which such businesses were named as a party.

2283 8. A description of any felony criminal offense of which  
2284 the person, as an adult, was found guilty, regardless of whether  
2285 adjudication of guilt was withheld or whether the person pled  
2286 guilty or nolo contendere. A criminal offense committed in  
2287 another jurisdiction which would have been a felony in this state  
2288 must be reported. If the person indicates that a criminal  
2289 conviction is under appeal and submits a copy of the notice of  
2290 appeal of that criminal offense, the applicant must, within 15  
2291 days after the disposition of the appeal, submit to the

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2292 department a copy of the final written order of disposition.

2293 9. A photograph of the person taken in the previous 30  
2294 days.

2295 10. A set of fingerprints for the person on a form and  
2296 under procedures specified by the department, together with  
2297 payment of an amount equal to the costs incurred by the  
2298 department for the criminal record check of the person.

2299 11. The name, address, occupation, and date and place of  
2300 birth for each member of the person's immediate family who is 18  
2301 years of age or older. As used in this subparagraph, the term  
2302 "member of the person's immediate family" includes the person's  
2303 spouse, children, parents, siblings, the spouses of the person's  
2304 children, and the spouses of the person's siblings.

2305 12. Any other relevant information that the department  
2306 requires.

2307 (b) The information required pursuant to paragraph (a)  
2308 shall be provided under oath.

2309 (c) The department shall submit the fingerprints provided  
2310 by a person for initial licensure to the Department of Law  
2311 Enforcement for a statewide criminal record check and for  
2312 forwarding to the Federal Bureau of Investigation for a national  
2313 criminal record check of the person. The department shall submit  
2314 the fingerprints provided by a person as a part of a renewal  
2315 application to the Department of Law Enforcement for a statewide  
2316 criminal record check, and for forwarding to the Federal Bureau  
2317 of Investigation for a national criminal record check, for the  
2318 initial renewal of a permit after January 1, 2004; for any  
2319 subsequent renewal of a permit, the department shall submit the  
2320 required information for a statewide and national criminal record



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2321 | check of the person. Any person who as a part of an initial  
2322 | permit application or initial permit renewal after January 1,  
2323 | 2004, submits to the department a set of fingerprints required  
2324 | for the criminal record check required in this paragraph shall  
2325 | not be required to provide a subsequent set of fingerprints for a  
2326 | criminal record check to the department, if the person has  
2327 | undergone a criminal record check as a condition of the issuance  
2328 | of an initial permit or the initial renewal of a permit of an  
2329 | applicant after January 1, 2004.

2330 |       (10)~~(5)~~ The department may deny an application for a permit  
2331 | or refuse to renew a permit for a prescription drug wholesale  
2332 | distributor ~~wholesaler~~ or an out-of-state prescription drug  
2333 | wholesale distributor ~~wholesaler~~ if:

2334 |           (a) The applicant has not met the requirements for the  
2335 | permit.

2336 |           (b) The management, officers, or directors of the applicant  
2337 | or any affiliated party are found by the department to be  
2338 | incompetent or untrustworthy.

2339 |           (c) The applicant is so lacking in experience in managing a  
2340 | wholesale distributor as to make the issuance of the proposed  
2341 | permit hazardous to the public health.

2342 |           (d) The applicant is so lacking in experience in managing a  
2343 | wholesale distributor as to jeopardize the reasonable promise of  
2344 | successful operation of the wholesale distributor.

2345 |           (e) The applicant is lacking in experience in the  
2346 | distribution of prescription drugs.

2347 |           (f) The applicant's past experience in manufacturing or  
2348 | distributing prescription drugs indicates that the applicant  
2349 | poses a public health risk.

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2350 (g) The applicant is affiliated directly or indirectly  
2351 through ownership, control, or other business relations, with any  
2352 person or persons whose business operations are or have been  
2353 detrimental to the public health.

2354 (h) The applicant, or any affiliated party, has been found  
2355 guilty of or has pleaded guilty or nolo contendere to any felony  
2356 or crime punishable by imprisonment for 1 year or more under the  
2357 laws of the United States, any state, or any other country,  
2358 regardless of whether adjudication of guilt was withheld.

2359 (i) The applicant or any affiliated party has been charged  
2360 with a felony in a state or federal court and the disposition of  
2361 that charge is pending during the application review or renewal  
2362 review period.

2363 (j) The applicant has furnished false or fraudulent  
2364 information or material in any application made in this state or  
2365 any other state in connection with obtaining a permit or license  
2366 to manufacture or distribute drugs, devices, or cosmetics.

2367 (k) That a federal, state, or local government permit  
2368 currently or previously held by the applicant, or any affiliated  
2369 party, for the manufacture or distribution of any drugs, devices,  
2370 or cosmetics has been disciplined, suspended, or revoked and has  
2371 not been reinstated.

2372 (l) The applicant does not possess the financial or  
2373 physical resources to operate in compliance with the permit being  
2374 sought, this chapter, and the rules adopted under this chapter.

2375 (m) The applicant or any affiliated party receives,  
2376 directly or indirectly, financial support and assistance from a  
2377 person who was an affiliated party of a permittee whose permit  
2378 was subject to discipline or was suspended or revoked, other than

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2379 through the ownership of stock in a publicly traded company or a  
2380 mutual fund.

2381 (n) The applicant or any affiliated party receives,  
2382 directly or indirectly, financial support and assistance from a  
2383 person who has been found guilty of any violation of this part  
2384 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,  
2385 any rules adopted under any of this part ~~those sections~~ or those  
2386 chapters, any federal or state drug law, or any felony where the  
2387 underlying facts related to drugs, regardless of whether the  
2388 person has been pardoned, had her or his civil rights restored,  
2389 or had adjudication withheld, other than through the ownership of  
2390 stock in a publicly traded company or a mutual fund.

2391 (o) The applicant for renewal of a permit under s.  
2392 499.01(2)(d) ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~  
2393 has not actively engaged in the wholesale distribution of  
2394 prescription drugs, as demonstrated by the regular and systematic  
2395 distribution of prescription drugs throughout the year as  
2396 evidenced by not fewer than 12 wholesale distributions in the  
2397 previous year and not fewer than three wholesale distributions in  
2398 the previous 6 months.

2399 (p) Information obtained in response to s. 499.01(2)(d)  
2400 ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~ demonstrates  
2401 it would not be in the best interest of the public health,  
2402 safety, and welfare to issue a permit.

2403 (q) The applicant does not possess the financial standing  
2404 and business experience for the successful operation of the  
2405 applicant.

2406 (r) The applicant or any affiliated party has failed to  
2407 comply with the requirements for manufacturing or distributing

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2408 prescription drugs under this part ~~ss. 499.001-499.081~~, similar  
2409 federal laws, similar laws in other states, or the rules adopted  
2410 under such laws.

2411 ~~(11)(6)~~ Upon approval of the application by the department  
2412 and payment of the required fee, the department shall issue or  
2413 renew a prescription drug wholesale distributor ~~wholesaler~~ or an  
2414 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2415 permit to the applicant.

2416 ~~(12)(7)~~ For a permit ~~permits~~ for a prescription drug  
2417 wholesale distributor ~~wholesalers~~ or an out-of-state prescription  
2418 drug wholesale distributor ~~wholesalers~~:

2419 (a) The department shall adopt rules for the annual renewal  
2420 of permits. At least 90 days before the expiration of a permit,  
2421 the department shall forward a permit renewal notification and  
2422 renewal application to the prescription drug wholesale  
2423 distributor ~~wholesaler~~ or out-of-state prescription drug  
2424 wholesale distributor ~~wholesaler~~ at the mailing address of the  
2425 permitted establishment on file with the department. The permit  
2426 renewal notification must state conspicuously the date on which  
2427 the permit for the establishment will expire and that the  
2428 establishment may not operate unless the permit for the  
2429 establishment is renewed timely.

2430 (b) A permit, unless sooner suspended or revoked,  
2431 automatically expires 1 year after the last day of the  
2432 anniversary month in which the permit was originally issued. A  
2433 permit may be renewed by making application for renewal on forms  
2434 furnished by the department and paying the appropriate fees. If a  
2435 renewal application and fee are submitted and postmarked after 45  
2436 days prior to the expiration date of the permit, the permit may

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2437 | be renewed only upon payment of a late renewal fee of \$100, plus  
2438 | the required renewal fee. A permittee that has submitted a  
2439 | renewal application in accordance with this paragraph may  
2440 | continue to operate under its permit, unless the permit is  
2441 | suspended or revoked, until final disposition of the renewal  
2442 | application.

2443 |       (c) Failure to renew a permit in accordance with this  
2444 | section precludes any future renewal of that permit. If a permit  
2445 | issued pursuant to this section has expired and cannot be  
2446 | renewed, before an establishment may engage in activities that  
2447 | require a permit under this part ~~ss. 499.001-499.081~~, the  
2448 | establishment must submit an application for a new permit; pay  
2449 | the applicable application fee, initial permit fee, and all  
2450 | applicable penalties; and be issued a new permit by the  
2451 | department.

2452 |       (13) ~~(8)~~ A person that engages in wholesale distribution of  
2453 | prescription drugs in this state must have a wholesale  
2454 | distributor's permit issued by the department, except as noted in  
2455 | this section. Each establishment must be separately permitted  
2456 | except as noted in this subsection.

2457 |       (a) A separate establishment permit is not required when a  
2458 | permitted prescription drug wholesale distributor ~~wholesaler~~  
2459 | consigns a prescription drug to a pharmacy that is permitted  
2460 | under chapter 465 and located in this state, provided that:

2461 |           1. The consignor wholesale distributor ~~wholesaler~~ notifies  
2462 | the department in writing of the contract to consign prescription  
2463 | drugs to a pharmacy along with the identity and location of each  
2464 | consignee pharmacy;

2465 |           2. The pharmacy maintains its permit under chapter 465;

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2466 3. The consignor wholesale distributor ~~wholesaler~~, which  
2467 has no legal authority to dispense prescription drugs, complies  
2468 with all wholesale distribution requirements of ss. ~~s.~~ 499.0121  
2469 and 499.01212 with respect to the consigned drugs and maintains  
2470 records documenting the transfer of title or other completion of  
2471 the wholesale distribution of the consigned prescription drugs;

2472 4. The distribution of the prescription drug is otherwise  
2473 lawful under this chapter and other applicable law;

2474 5. Open packages containing prescription drugs within a  
2475 pharmacy are the responsibility of the pharmacy, regardless of  
2476 how the drugs are titled; and

2477 6. The pharmacy dispenses the consigned prescription drug  
2478 in accordance with the limitations of its permit under chapter  
2479 465 or returns the consigned prescription drug to the consignor  
2480 wholesale distributor ~~wholesaler~~. In addition, a person who holds  
2481 title to prescription drugs may transfer the drugs to a person  
2482 permitted or licensed to handle the reverse distribution or  
2483 destruction of drugs. Any other distribution by and means of the  
2484 consigned prescription drug by any person, not limited to the  
2485 consignor wholesale distributor ~~wholesaler~~ or consignee pharmacy,  
2486 to any other person is prohibited.

2487 (b) A wholesale distributor's permit is not required for  
2488 the one-time transfer of title of a pharmacy's lawfully acquired  
2489 prescription drug inventory by a pharmacy with a valid permit  
2490 issued under chapter 465 to a consignor prescription drug  
2491 wholesale distributor ~~wholesaler~~, permitted under this chapter,  
2492 in accordance with a written consignment agreement between the  
2493 pharmacy and that wholesale distributor ~~wholesaler~~ if+ the  
2494 permitted pharmacy and the permitted prescription drug wholesale

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2495 distributor ~~wholesaler~~ comply with all of the provisions of  
2496 paragraph (a) and the prescription drugs continue to be within  
2497 the permitted pharmacy's inventory for dispensing in accordance  
2498 with the limitations of the pharmacy permit under chapter 465. A  
2499 consignor drug wholesale distributor ~~wholesaler~~ may not use the  
2500 pharmacy as a wholesale distributor through which it distributes  
2501 the prescription ~~legend~~ drugs to other pharmacies. Nothing in  
2502 this section is intended to prevent a wholesale ~~drug~~ distributor  
2503 from obtaining this inventory in the event of nonpayment by the  
2504 pharmacy.

2505 (c) A separate establishment permit is not required when a  
2506 permitted prescription drug wholesale distributor operates  
2507 temporary transit storage facilities for the sole purpose of  
2508 storage, for a period not to exceed 12 hours, of a delivery of  
2509 prescription drugs when the wholesale distributor was temporarily  
2510 unable to complete the delivery to the recipient.

2511 (d) ~~(e)~~ The department shall require information from each  
2512 wholesale distributor as part of the permit and renewal of such  
2513 permit, as required under ~~s. 499.01~~ ~~or~~ this section.

2514 (14) ~~(9)~~ Personnel employed in wholesale distribution must  
2515 have appropriate education and experience to enable them to  
2516 perform their duties in compliance with state permitting  
2517 requirements.

2518 (15) ~~(10)~~ The name of a permittee or establishment on a  
2519 prescription drug wholesale distributor ~~wholesaler~~ permit or an  
2520 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2521 permit may not include any indicia of attainment of any  
2522 educational degree, any indicia that the permittee or  
2523 establishment possesses a professional license, or any name or

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2524 abbreviation that the department determines is likely to cause  
2525 confusion or mistake or that the department determines is  
2526 deceptive, including that of any other entity authorized to  
2527 purchase prescription drugs.

2528 (16)~~(11)~~(a) Each establishment that is issued an initial or  
2529 renewal permit as a prescription drug wholesale distributor  
2530 ~~wholesaler~~ or an out-of-state prescription drug wholesale  
2531 distributor ~~wholesaler~~ must designate in writing to the  
2532 department at least one natural person to serve as the designated  
2533 representative of the wholesale distributor ~~wholesaler~~. Such  
2534 person must have an active certification as a designated  
2535 representative from the department.

2536 (b) To be certified as a designated representative, a  
2537 natural person must:

- 2538 1. Submit an application on a form furnished by the  
2539 department and pay the appropriate fees;
- 2540 2. Be at least 18 years of age;
- 2541 3. Have not less than 2 years of verifiable full-time work  
2542 experience in a pharmacy licensed in this state or another state,  
2543 where the person's responsibilities included, but were not  
2544 limited to, recordkeeping for prescription drugs, or have not  
2545 less than 2 years of verifiable full-time managerial experience  
2546 with a prescription drug wholesale distributor ~~wholesaler~~  
2547 licensed in this state or in another state;
- 2548 4. Receive a passing score of at least 75 percent on an  
2549 examination given by the department regarding federal laws  
2550 governing distribution of prescription drugs and this part ~~ss.~~  
2551 ~~499.001-499.081~~ and the rules adopted by the department governing  
2552 the wholesale distribution of prescription drugs. This



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2553 requirement shall be effective 1 year after the results of the  
2554 initial examination are mailed to the persons that took the  
2555 examination. The department shall offer such examinations at  
2556 least four times each calendar year; and

2557 5. Provide the department with a personal information  
2558 statement and fingerprints pursuant to subsection (9)~~(4)~~.

2559 (c) The department may deny an application for  
2560 certification as a designated representative or may suspend or  
2561 revoke a certification of a designated representative pursuant to  
2562 s. 499.067.

2563 (d) A designated representative:

2564 1. Must be actively involved in and aware of the actual  
2565 daily operation of the wholesale distributor.

2566 2. Must be employed full time in a managerial position by  
2567 the wholesale distributor.

2568 3. Must be physically present at the establishment during  
2569 normal business hours, except for time periods when absent due to  
2570 illness, family illness or death, scheduled vacation, or other  
2571 authorized absence.

2572 4. May serve as a designated representative for only one  
2573 wholesale distributor at any one time.

2574 (e) A wholesale distributor must notify the department when  
2575 a designated representative leaves the employ of the wholesale  
2576 distributor. Such notice must be provided to the department  
2577 within 10 business days after the last day of designated  
2578 representative's employment with the wholesale distributor.

2579 (f) A wholesale distributor may not operate under a  
2580 prescription drug wholesale distributor ~~wholesaler~~ permit or an  
2581 out-of-state prescription drug wholesale distributor ~~wholesaler~~

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2582 permit for more than 10 business days after the designated  
2583 representative leaves the employ of the wholesale distributor,  
2584 unless the wholesale distributor employs another designated  
2585 representative and notifies the department within 10 business  
2586 days of the identity of the new designated representative.

2587 Section 12. Section 499.01201, Florida Statutes, is amended  
2588 to read:

2589 499.01201 Agency for Health Care Administration review and  
2590 use of statute and rule violation or compliance  
2591 data.--Notwithstanding any other provisions of law to the  
2592 contrary, the Agency for Health Care Administration may not:

2593 (1) Review or use any violation or alleged violation of s.  
2594 499.0121(6) or s. 499.01212, or any rules adopted under those  
2595 sections ~~that section~~, as a ground for denying or withholding any  
2596 payment of a Medicaid reimbursement to a pharmacy licensed under  
2597 chapter 465; or

2598 (2) Review or use compliance with s. 499.0121(6) or s.  
2599 499.01212, or any rules adopted under those sections ~~that~~  
2600 ~~section~~, as the subject of any audit of Medicaid-related records  
2601 held by a pharmacy licensed under chapter 465.

2602 Section 13. Section 499.0121, Florida Statutes, is amended,  
2603 and subsection (4) of section 499.013, Florida Statutes, is  
2604 redesignated as paragraph (d) of subsection (6) of that section  
2605 and amended, to read:

2606 499.0121 Storage and handling of prescription drugs;  
2607 recordkeeping.--The department shall adopt rules to implement  
2608 this section as necessary to protect the public health, safety,  
2609 and welfare. Such rules shall include, but not be limited to,  
2610 requirements for the storage and handling of prescription drugs

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2611 and for the establishment and maintenance of prescription drug  
2612 distribution records.

2613 (1) ESTABLISHMENTS.--An establishment at which prescription  
2614 drugs are stored, warehoused, handled, held, offered, marketed,  
2615 or displayed must:

2616 (a) Be of suitable size and construction to facilitate  
2617 cleaning, maintenance, and proper operations;

2618 (b) Have storage areas designed to provide adequate  
2619 lighting, ventilation, temperature, sanitation, humidity, space,  
2620 equipment, and security conditions;

2621 (c) Have a quarantine area for storage of prescription  
2622 drugs that are outdated, damaged, deteriorated, misbranded, or  
2623 adulterated, or that are in immediate or sealed, secondary  
2624 containers that have been opened;

2625 (d) Be maintained in a clean and orderly condition; and

2626 (e) Be free from infestation by insects, rodents, birds, or  
2627 vermin of any kind.

2628 (2) SECURITY.--

2629 (a) An establishment that is used for wholesale drug  
2630 distribution must be secure from unauthorized entry.

2631 1. Access from outside the premises must be kept to a  
2632 minimum and be well-controlled.

2633 2. The outside perimeter of the premises must be well-  
2634 lighted.

2635 3. Entry into areas where prescription drugs are held must  
2636 be limited to authorized personnel.

2637 (b) An establishment that is used for wholesale drug  
2638 distribution must be equipped with:

2639 1. An alarm system to detect entry after hours; however,

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2640 the department may exempt by rule establishments that only hold a  
2641 permit as prescription drug wholesale distributor-brokers  
2642 ~~wholesaler-brokers~~ and establishments that only handle medical  
2643 oxygen; and

2644 2. A security system that will provide suitable protection  
2645 against theft and diversion. When appropriate, the security  
2646 system must provide protection against theft or diversion that is  
2647 facilitated or hidden by tampering with computers or electronic  
2648 records.

2649 (c) Any vehicle that contains prescription drugs must be  
2650 secure from unauthorized access to the prescription drugs in the  
2651 vehicle.

2652 (3) STORAGE.--All prescription drugs shall be stored at  
2653 appropriate temperatures and under appropriate conditions in  
2654 accordance with requirements, if any, in the labeling of such  
2655 drugs, or with requirements in the official compendium.

2656 (a) If no storage requirements are established for a  
2657 prescription drug, the drug may be held at "controlled" room  
2658 temperature, as defined in the official compendium, to help  
2659 ensure that its identity, strength, quality, and purity are not  
2660 adversely affected.

2661 (b) Appropriate manual, electromechanical, or electronic  
2662 temperature and humidity recording equipment, devices, or logs  
2663 must be used to document proper storage of prescription drugs.

2664 (c) The recordkeeping requirements in subsection (6) must  
2665 be followed for all stored prescription drugs.

2666 (4) EXAMINATION OF MATERIALS AND RECORDS.--

2667 (a) Upon receipt, each outside shipping container must be  
2668 visually examined for identity and to prevent the acceptance of

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2669 contaminated prescription drugs that are otherwise unfit for  
2670 distribution. This examination must be adequate to reveal  
2671 container damage that would suggest possible contamination or  
2672 other damage to the contents.

2673 (b) Each outgoing shipment must be carefully inspected for  
2674 identity of the prescription drug products and to ensure that  
2675 there is no delivery of prescription drugs that have expired or  
2676 been damaged in storage or held under improper conditions.

2677 (c) The recordkeeping requirements in subsection (6) must  
2678 be followed for all incoming and outgoing prescription drugs.

2679 (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must  
2680 review records required under this section for the acquisition of  
2681 prescription drugs for accuracy and completeness, considering the  
2682 total facts and circumstances surrounding the transactions and  
2683 the wholesale distributors involved. This includes authenticating  
2684 each transaction listed on a pedigree paper, as defined in s.  
2685 499.003(35) ~~s. 499.001(31)~~.

2686 (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--

2687 (a)1. Prescription drugs that are outdated, damaged,  
2688 deteriorated, misbranded, or adulterated must be quarantined and  
2689 physically separated from other prescription drugs until they are  
2690 destroyed or returned to their supplier. A quarantine section  
2691 must be separate and apart from other sections where prescription  
2692 drugs are stored so that prescription drugs in this section are  
2693 not confused with usable prescription drugs.

2694 2. Prescription drugs must be examined at least every 12  
2695 months, and drugs for which the expiration date has passed must  
2696 be removed and quarantined.

2697 (b) Any prescription drugs of which the immediate or sealed

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2698 outer containers or sealed secondary containers have been opened  
2699 or used must be identified as such and must be quarantined and  
2700 physically separated from other prescription drugs until they are  
2701 either destroyed or returned to the supplier.

2702 (c) If the conditions under which a prescription drug has  
2703 been returned cast doubt on the drug's safety, identity,  
2704 strength, quality, or purity, the drug must be destroyed or  
2705 returned to the supplier, unless examination, testing, or other  
2706 investigation proves that the drug meets appropriate standards of  
2707 safety, identity, strength, quality, and purity. In determining  
2708 whether the conditions under which a drug has been returned cast  
2709 doubt on the drug's safety, identity, strength, quality, or  
2710 purity, the wholesale ~~drug~~ distributor must consider, among other  
2711 things, the conditions under which the drug has been held,  
2712 stored, or shipped before or during its return and the conditions  
2713 of the drug and its container, carton, or labeling, as a result  
2714 of storage or shipping.

2715 (d) The recordkeeping requirements in subsection (6) must  
2716 be followed for all outdated, damaged, deteriorated, misbranded,  
2717 or adulterated prescription drugs.

2718 (6) RECORDKEEPING.--The department shall adopt rules that  
2719 require keeping such records of prescription drugs as are  
2720 necessary for the protection of the public health.

2721 (a) Wholesale ~~drug~~ distributors must establish and maintain  
2722 inventories and records of all transactions regarding the receipt  
2723 and distribution or other disposition of prescription drugs.  
2724 These records must provide a complete audit trail from receipt to  
2725 sale or other disposition, be readily retrievable for inspection,  
2726 and include, at a minimum, the following information:

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2727 1. The source of the drugs, including the name and  
2728 principal address of the seller or transferor, and the address of  
2729 the location from which the drugs were shipped;

2730 2. The name, principal address, and state license permit or  
2731 registration number of the person authorized to purchase  
2732 prescription drugs;

2733 3. The name, strength, dosage form, and quantity of the  
2734 drugs received and distributed or disposed of;

2735 4. The dates of receipt and distribution or other  
2736 disposition of the drugs; and

2737 5. Any financial documentation supporting the transaction.

2738 (b) Inventories and records must be made available for  
2739 inspection and photocopying by authorized federal, state, or  
2740 local officials for a period of 2 years following disposition of  
2741 the drugs or 3 years after the creation of the records, whichever  
2742 period is longer.

2743 (c) Records described in this section that are kept at the  
2744 inspection site or that can be immediately retrieved by computer  
2745 or other electronic means must be readily available for  
2746 authorized inspection during the retention period. Records that  
2747 are kept at a central location outside of this state and that are  
2748 not electronically retrievable must be made available for  
2749 inspection within 2 working days after a request by an authorized  
2750 official of a federal, state, or local law enforcement agency.  
2751 Records that are maintained at a central location within this  
2752 state must be maintained at an establishment that is permitted  
2753 pursuant to this part ~~ss. 499.001-499.081~~ and must be readily  
2754 available.

2755 (d)~~(4)~~ Each manufacturer or repackager of medical devices,

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2756 over-the-counter drugs, or cosmetics must maintain records that  
2757 include the name and principal address of the seller or  
2758 transferor of the product, the address of the location from which  
2759 the product was shipped, the date of the transaction, the name  
2760 and quantity of the product involved, and the name and principal  
2761 address of the person who purchased the product.

2762 (e) A wholesale distributor must maintain pedigree papers  
2763 separate and distinct from other records required under this  
2764 chapter.

2765 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~  
2766 ~~the wholesale distribution of a prescription drug and who is not~~  
2767 ~~the manufacturer of that drug must, before each wholesale~~  
2768 ~~distribution of such drug, provide to the person who receives the~~  
2769 ~~drug a pedigree paper as defined in s. 499.003(31).~~

2770 ~~2. A repackager must comply with this paragraph.~~

2771 ~~3. The pedigree paper requirements in this paragraph do not~~  
2772 ~~apply to compressed medical gases or veterinary legend drugs.~~

2773 ~~4. Each wholesale distributor of prescription drugs must~~  
2774 ~~maintain separate and distinct from other required records all~~  
2775 ~~statements that are required under subparagraph 1.~~

2776 ~~5. Subparagraph 1. is satisfied when a wholesale~~  
2777 ~~distributor takes title to, but not possession of, a prescription~~  
2778 ~~drug and the prescription drug's manufacturer ships the~~  
2779 ~~prescription drug directly to a person authorized by law to~~  
2780 ~~purchase prescription drugs for the purpose of administering or~~  
2781 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~  
2782 ~~affiliated group, as described in paragraph (f), with the~~  
2783 ~~exception of a repackager.~~

2784 ~~a. The wholesale distributor must deliver to the recipient~~



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2785 ~~of the prescription drug, within 14 days after the shipment~~  
2786 ~~notification from the manufacturer, an invoice and the following~~  
2787 ~~sworn statement: "This wholesale distributor purchased the~~  
2788 ~~specific unit of the prescription drug listed on the invoice~~  
2789 ~~directly from the manufacturer, and the specific unit of~~  
2790 ~~prescription drug was shipped by the manufacturer directly to a~~  
2791 ~~person authorized by law to administer or dispense the legend~~  
2792 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~  
2793 ~~an affiliated group, as described in s. 499.0121(6) (f), Florida~~  
2794 ~~Statutes, with the exception of a repackager." The invoice must~~  
2795 ~~contain a unique cross-reference to the shipping document sent by~~  
2796 ~~the manufacturer to the recipient of the prescription drug.~~

2797 ~~b. The manufacturer of the prescription drug shipped~~  
2798 ~~directly to the recipient under this section must provide and the~~  
2799 ~~recipient of the prescription drug must acquire, within 14 days~~  
2800 ~~after receipt of the prescription drug, a shipping document from~~  
2801 ~~the manufacturer that contains, at a minimum:~~

2802 ~~(I) The name and address of the manufacturer, including the~~  
2803 ~~point of origin of the shipment, and the names and addresses of~~  
2804 ~~the wholesaler and the purchaser.~~

2805 ~~(II) The name of the prescription drug as it appears on the~~  
2806 ~~label.~~

2807 ~~(III) The quantity, dosage form, and strength of the~~  
2808 ~~prescription drug.~~

2809 ~~(IV) The date of the shipment from the manufacturer.~~

2810 ~~e. The wholesale distributor must also maintain and make~~  
2811 ~~available to the department, upon request, the lot number of such~~  
2812 ~~drug if not contained in the shipping document acquired by the~~  
2813 ~~recipient.~~

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2814           ~~6. Failure of the manufacturer to provide, the recipient to~~  
2815 ~~acquire, or the wholesale distributor to deliver, the~~  
2816 ~~documentation required under subparagraph 5. shall constitute~~  
2817 ~~failure to acquire or deliver a pedigree paper under s. 499.0051.~~  
2818 ~~Forgery by the manufacturer, the recipient, or the wholesale~~  
2819 ~~distributor of the documentation required to be acquired or~~  
2820 ~~delivered under subparagraph 5. shall constitute forgery of a~~  
2821 ~~pedigree paper under s. 499.0051.~~

2822           ~~7. The department may, by rule, specify alternatives to~~  
2823 ~~compliance with subparagraph 1. for a prescription drug in the~~  
2824 ~~inventory of a permitted prescription drug wholesaler as of June~~  
2825 ~~30, 2006, and the return of a prescription drug purchased prior~~  
2826 ~~to July 1, 2006. The department may specify time limits for such~~  
2827 ~~alternatives.~~

2828           ~~(7)(e)~~ PRESCRIPTION DRUG PURCHASE LIST.--Each wholesale  
2829 distributor, except for a manufacturer, shall annually provide  
2830 the department with a written list of all wholesale distributors  
2831 and manufacturers from whom the wholesale distributor purchases  
2832 prescription drugs. A wholesale distributor, except a  
2833 manufacturer, shall notify the department not later than 10 days  
2834 after any change to either list. Such portions of the information  
2835 required pursuant to this subsection ~~paragraph~~ which are a trade  
2836 secret, as defined in s. 812.081, shall be maintained by the  
2837 department as trade secret information is required to be  
2838 maintained under s. 499.051.

2839           ~~(f)1. This paragraph applies only to an affiliated group,~~  
2840 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~  
2841 ~~amended, which is composed of chain drug entities, including at~~  
2842 ~~least 50 retail pharmacies, warehouses, or repackagers, which are~~

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2843 ~~members of the same affiliated group, if the affiliated group:~~

2844 ~~a. Discloses to the department the names of all its~~  
2845 ~~members; and~~

2846 ~~b. Agrees in writing to provide records on prescription~~  
2847 ~~drug purchases by members of the affiliated group not later than~~  
2848 ~~48 hours after the department requests such records, regardless~~  
2849 ~~of the location where the records are stored.~~

2850 ~~2. Each warehouse within the affiliated group must comply~~  
2851 ~~with all applicable federal and state drug wholesale permit~~  
2852 ~~requirements and must purchase, receive, hold, and distribute~~  
2853 ~~prescription drugs only to a retail pharmacy or warehouse within~~  
2854 ~~the affiliated group. Such a warehouse is exempt from providing a~~  
2855 ~~pedigree paper in accordance with paragraph (d) to its affiliated~~  
2856 ~~group member warehouse or retail pharmacy, provided that:~~

2857 ~~a. Any affiliated group member that purchases or receives a~~  
2858 ~~prescription drug from outside the affiliated group must receive~~  
2859 ~~a pedigree paper if the prescription drug is distributed in or~~  
2860 ~~into this state and a pedigree paper is required under this~~  
2861 ~~section and must authenticate the documentation as required in~~  
2862 ~~subsection (4), regardless of whether the affiliated group member~~  
2863 ~~is directly subject to regulation under this chapter; and~~

2864 ~~b. The affiliated group makes available to the department~~  
2865 ~~on request all records related to the purchase or acquisition of~~  
2866 ~~prescription drugs by members of the affiliated group, regardless~~  
2867 ~~of the location where the records are stored, if the prescription~~  
2868 ~~drugs were distributed in or into this state.~~

2869 ~~3. If a repackager repackages prescription drugs solely for~~  
2870 ~~distribution to its affiliated group members for the exclusive~~  
2871 ~~distribution to and among retail pharmacies that are members of~~

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2872 the affiliated group to which the repackager is a member:

2873 a. ~~The repackager must:~~

2874 (I) ~~In lieu of the written statement required by paragraph~~

2875 ~~(d), for all repackaged prescription drugs distributed in or into~~

2876 ~~this state, state in writing under oath with each distribution of~~

2877 ~~a repackaged prescription drug to an affiliated group member~~

2878 ~~warehouse or repackager: "All repackaged prescription drugs are~~

2879 ~~purchased by the affiliated group directly from the manufacturer~~

2880 ~~or from a prescription drug wholesaler that purchased the~~

2881 ~~prescription drugs directly from the manufacturer.";~~

2882 (II) ~~Purchase all prescription drugs it repackages:~~

2883 (A) ~~Directly from the manufacturer; or~~

2884 (B) ~~From a prescription drug wholesaler that purchased the~~

2885 ~~prescription drugs directly from the manufacturer; and~~

2886 (III) ~~Maintain records in accordance with this section to~~

2887 ~~document that it purchased the prescription drugs directly from~~

2888 ~~the manufacturer or that its prescription drug wholesale supplier~~

2889 ~~purchased the prescription drugs directly from the manufacturer.~~

2890 b. ~~All members of the affiliated group must provide to~~

2891 ~~agents of the department on request records of purchases by all~~

2892 ~~members of the affiliated group of prescription drugs that have~~

2893 ~~been repackaged, regardless of the location where the records are~~

2894 ~~stored or where the repackager is located.~~

2895 (8) ~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale drug

2896 distributors must establish, maintain, and adhere to written

2897 policies and procedures, which must be followed for the receipt,

2898 security, storage, inventory, and distribution of prescription

2899 drugs, including policies and procedures for identifying,

2900 recording, and reporting losses or thefts, and for correcting all

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2901 errors and inaccuracies in inventories. Wholesale ~~drug~~  
2902 distributors must include in their written policies and  
2903 procedures:

2904 (a) A procedure whereby the oldest approved stock of a  
2905 prescription drug product is distributed first. The procedure may  
2906 permit deviation from this requirement, if the deviation is  
2907 temporary and appropriate.

2908 (b) A procedure to be followed for handling recalls and  
2909 withdrawals of prescription drugs. Such procedure must be  
2910 adequate to deal with recalls and withdrawals due to:

2911 1. Any action initiated at the request of the Food and Drug  
2912 Administration or any other federal, state, or local law  
2913 enforcement or other government agency, including the department.

2914 2. Any voluntary action by the manufacturer or repackager  
2915 to remove defective or potentially defective drugs from the  
2916 market; or

2917 3. Any action undertaken to promote public health and  
2918 safety by replacing existing merchandise with an improved product  
2919 or new package design.

2920 (c) A procedure to ensure that wholesale ~~drug~~ distributors  
2921 prepare for, protect against, and handle any crisis that affects  
2922 security or operation of any facility if a strike, fire, flood,  
2923 or other natural disaster, or a local, state, or national  
2924 emergency, occurs.

2925 (d) A procedure to ensure that any outdated prescription  
2926 drugs are segregated from other drugs and either returned to the  
2927 manufacturer or repackager or destroyed. This procedure must  
2928 provide for written documentation of the disposition of outdated  
2929 prescription drugs. This documentation must be maintained for 2

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2930 | years after disposition of the outdated drugs.

2931 |       (9)~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors  
2932 | must establish and maintain lists of officers, directors,  
2933 | managers, designated representatives, and other persons in charge  
2934 | of wholesale drug distribution, storage, and handling, including  
2935 | a description of their duties and a summary of their  
2936 | qualifications.

2937 |       (10)~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A  
2938 | wholesale ~~drug~~ distributor must operate in compliance with  
2939 | applicable federal, state, and local laws and regulations.

2940 |       (a) A wholesale ~~drug~~ distributor must allow the department  
2941 | and authorized federal, state, and local officials to enter and  
2942 | inspect its premises and delivery vehicles, and to audit its  
2943 | records and written operating procedures, at reasonable times and  
2944 | in a reasonable manner, to the extent authorized by law.

2945 |       (b) A wholesale ~~drug~~ distributor that deals in controlled  
2946 | substances must register with the Drug Enforcement Administration  
2947 | and must comply with all applicable state, local, and federal  
2948 | laws. A wholesale ~~drug~~ distributor that distributes any substance  
2949 | controlled under chapter 893 must notify the department when  
2950 | registering with the Drug Enforcement Administration pursuant to  
2951 | that chapter and must provide the department with its DEA number.

2952 |       (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~  
2953 | distributor is subject to any applicable federal, state, or local  
2954 | laws or regulations that relate to prescription drug product  
2955 | salvaging or reprocessing.

2956 |       (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person  
2957 | responsible for shipment and transportation of a prescription  
2958 | drug in a wholesale distribution may use a common carrier; its

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2959 | own vehicle or employee acting within the scope of employment if  
2960 | authorized under s. 499.03 for the possession of prescription  
2961 | drugs in this state; or, in the case of a prescription drug  
2962 | intended for domestic distribution, an independent contractor who  
2963 | must be the agent of the authorized seller or recipient  
2964 | responsible for shipping and transportation as set forth in a  
2965 | written contract between the parties. A person selling a  
2966 | prescription drug for export must obtain documentation, such as a  
2967 | validated airway bill, bill of lading, or other appropriate  
2968 | documentation that the prescription drug was exported. A person  
2969 | responsible for shipping or transporting prescription drugs is  
2970 | not required to maintain documentation from a common carrier that  
2971 | the designated recipient received the prescription drugs;  
2972 | however, the person must obtain such documentation from the  
2973 | common carrier and make it available to the department upon  
2974 | request of the department.

2975 |        (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing  
2976 | any prescription drugs from another wholesale ~~drug~~ distributor, a  
2977 | prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
2978 | state prescription drug wholesale distributor ~~wholesaler~~, or a  
2979 | prescription drug repackager must:

2980 |        (a) Enter an agreement with the selling wholesale ~~drug~~  
2981 | distributor by which the selling wholesale ~~drug~~ distributor will  
2982 | indemnify the purchasing wholesale ~~drug~~ distributor for any loss  
2983 | caused to the purchasing wholesale ~~drug~~ distributor related to  
2984 | the purchase of drugs from the selling wholesale ~~drug~~ distributor  
2985 | which are determined to be counterfeit or to have been  
2986 | distributed in violation of any federal or state law governing  
2987 | the distribution of drugs.

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2988 (b) Determine that the selling wholesale ~~drug~~ distributor  
2989 has insurance coverage of not less than the greater of 1 percent  
2990 of the amount of total dollar volume of the prescription drug  
2991 sales reported to the department under s. 499.012(8)(g) ~~s.~~  
2992 ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed  
2993 \$2 million.

2994 (c) Obtain information from the selling wholesale ~~drug~~  
2995 distributor, including the length of time the selling wholesale  
2996 ~~drug~~ distributor has been licensed in this state, a copy of the  
2997 selling wholesale ~~drug~~ distributor's licenses or permits, and  
2998 background information concerning the ownership of the selling  
2999 wholesale ~~drug~~ distributor, including the experience of the  
3000 wholesale distributor in the wholesale distribution of  
3001 prescription drugs.

3002 (d) Verify that the selling wholesale ~~drug~~ distributor's  
3003 Florida permit is valid.

3004 (e) Inspect the selling wholesale ~~drug~~ distributor's  
3005 licensed establishment to document that it has a policies and  
3006 procedures manual relating to the distribution of drugs, the  
3007 appropriate temperature controlled environment for drugs  
3008 requiring temperature control, an alarm system, appropriate  
3009 access restrictions, and procedures to ensure that records  
3010 related to the wholesale distribution of prescription drugs are  
3011 maintained as required by law:

3012 1. Before purchasing any drug from the wholesale ~~drug~~  
3013 distributor, and at least once each subsequent year; or

3014 2. Before purchasing any drug from the wholesale ~~drug~~  
3015 distributor, and each subsequent year obtain a complete copy of  
3016 the most recent inspection report for the establishment which was



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3017 prepared by the department or the regulatory authority  
3018 responsible for wholesale ~~drug~~ distributors in the state in which  
3019 the establishment is located.

3020 Section 14. Section 499.01211, Florida Statutes, is amended  
3021 to read:

3022 499.01211 Drug Wholesale Distributor ~~Wholesaler~~ Advisory  
3023 Council.--

3024 (1) There is created the Drug Wholesale Distributor  
3025 ~~Wholesaler~~ Advisory Council within the department. The council  
3026 shall meet at least once each calendar quarter. Staff for the  
3027 council shall be provided by the department. The council shall  
3028 consist of 11 members who shall serve without compensation. The  
3029 council shall elect a chairperson and a vice chairperson  
3030 annually.

3031 (2) The State Surgeon General, or his or her designee, and  
3032 the Secretary of Health Care Administration, or her or his  
3033 designee, shall be members of the council. The State Surgeon  
3034 General shall appoint nine additional members to the council who  
3035 shall be appointed to a term of 4 years each, as follows:

3036 (a) Three different persons each of whom is employed by a  
3037 different prescription drug wholesale distributor ~~wholesaler~~  
3038 licensed under this part ~~chapter~~ which operates nationally and is  
3039 a primary wholesale distributor ~~wholesaler~~, as defined in s.  
3040 499.003(46) ~~s. 499.012(1)(d)~~.

3041 (b) One person employed by a prescription drug wholesale  
3042 distributor ~~wholesaler~~ licensed under this part ~~chapter~~ which is  
3043 a secondary wholesale distributor ~~wholesaler~~, as defined in s.  
3044 499.003(51) ~~s. 499.012(1)(f)~~.

3045 (c) One person employed by a retail pharmacy chain located

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3046 | in this state.

3047 |       (d) One person who is a member of the Board of Pharmacy and  
3048 | is a pharmacist licensed under chapter 465.

3049 |       (e) One person who is a physician licensed pursuant to  
3050 | chapter 458 or chapter 459.

3051 |       (f) One person who is an employee of a hospital licensed  
3052 | pursuant to chapter 395 and is a pharmacist licensed pursuant to  
3053 | chapter 465.

3054 |       (g) One person who is an employee of a pharmaceutical  
3055 | manufacturer.

3056 |       (3) The council shall review this part ~~ss. 499.001-499.081~~  
3057 | and the rules adopted to administer this part ~~ss. 499.001-499.081~~  
3058 | annually, provide input to the department regarding all proposed  
3059 | rules to administer this part ~~ss. 499.001-499.081~~, make  
3060 | recommendations to the department to improve the protection of  
3061 | the prescription drugs and public health, make recommendations to  
3062 | improve coordination with other states' regulatory agencies and  
3063 | the federal government concerning the wholesale distribution of  
3064 | drugs, and make recommendations to minimize the impact of  
3065 | regulation of the wholesale distribution industry while ensuring  
3066 | protection of the public health.

3067 |       Section 15. Section 499.01212, Florida Statutes, is created  
3068 | to read:

3069 |       499.01212 Pedigree paper.--

3070 |       (1) APPLICATION.--Each person who is engaged in the  
3071 | wholesale distribution of a prescription drug must, prior to or  
3072 | simultaneous with each wholesale distribution, provide a pedigree  
3073 | paper to the person who receives the drug.

3074 |       (2) FORMAT.--A pedigree paper must contain the following

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3075 information:

3076 (a) For the wholesale distribution of a prescription drug  
3077 within the normal distribution chain:

3078 1. The following statement: "This wholesale distributor  
3079 purchased the specific unit of the prescription drug directly  
3080 from the manufacturer."

3081 2. The manufacturer's national drug code identifier and the  
3082 name and address of the wholesale distributor and the purchaser  
3083 of the prescription drug.

3084 3. The name of the prescription drug as it appears on the  
3085 label.

3086 4. The quantity, dosage form, and strength of the  
3087 prescription drug.

3088  
3089 The wholesale distributor must also maintain and make available  
3090 to the department, upon request, the point of origin of the  
3091 prescription drugs, including intracompany transfers, the date of  
3092 the shipment from the manufacturer to the wholesale distributor,  
3093 the lot numbers of such drugs, and the invoice numbers from the  
3094 manufacturer.

3095 (b) For all other wholesale distributions of prescription  
3096 drugs:

3097 1. The quantity, dosage form, and strength of the  
3098 prescription drugs.

3099 2. The lot numbers of the prescription drugs.

3100 3. The name and address of each owner of the prescription  
3101 drug and his or her signature.

3102 4. Shipping information, including the name and address of  
3103 each person certifying delivery or receipt of the prescription

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3104 | drug.

3105 |       5. An invoice number, a shipping document number, or  
3106 | another number uniquely identifying the transaction.

3107 |       6. A certification that the recipient wholesale distributor  
3108 | has authenticated the pedigree papers.

3109 |       7. The unique serialization of the prescription drug, if  
3110 | the manufacturer or repackager has uniquely serialized the  
3111 | individual prescription drug unit.

3112 |       8. The name, address, telephone number, and, if available,  
3113 | e-mail contact information of each wholesale distributor involved  
3114 | in the chain of the prescription drug's custody.

3115 |       (3) EXCEPTIONS.--A pedigree paper is not required for:

3116 |       (a) The wholesale distribution of a prescription drug by  
3117 | the manufacturer or by a third party logistics provider  
3118 | performing a wholesale distribution of a prescription drug for a  
3119 | manufacturer.

3120 |       (b) The wholesale distribution of a prescription drug by a  
3121 | freight forwarder.

3122 |       (c) The wholesale distribution of a prescription drug by a  
3123 | limited prescription drug veterinary wholesale distributor to a  
3124 | veterinarian.

3125 |       (d) The wholesale distribution of a compressed medical gas.

3126 |       (e) The wholesale distribution of a veterinary prescription  
3127 | drug.

3128 |       (f) A drop shipment, provided:

3129 |       1. The wholesale distributor delivers to the recipient of  
3130 | the prescription drug, within 14 days after the shipment  
3131 | notification from the manufacturer, an invoice and the following  
3132 | sworn statement: "This wholesale distributor purchased the

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3133 specific unit of the prescription drug listed on the invoice  
3134 directly from the manufacturer, and the specific unit of  
3135 prescription drug was shipped by the manufacturer directly to a  
3136 person authorized by law to administer or dispense the legend  
3137 drug, as defined in s. 465.003, Florida Statutes, or a member of  
3138 an affiliated group, with the exception of a repackager." The  
3139 invoice must contain a unique cross-reference to the shipping  
3140 document sent by the manufacturer to the recipient of the  
3141 prescription drug.

3142 2. The manufacturer of the prescription drug shipped  
3143 directly to the recipient provides and the recipient of the  
3144 prescription drug acquires, within 14 days after receipt of the  
3145 prescription drug, a shipping document from the manufacturer that  
3146 contains, at a minimum:

3147 a. The name and address of the manufacturer, including the  
3148 point of origin of the shipment, and the names and addresses of  
3149 the wholesale distributor and the purchaser.

3150 b. The name of the prescription drug as it appears on the  
3151 label.

3152 c. The quantity, dosage form, and strength of the  
3153 prescription drug.

3154 d. The date of the shipment from the manufacturer.

3155 3. The wholesale distributor maintains and makes available  
3156 to the department, upon request, the lot number of such drug if  
3157 not contained in the shipping document acquired by the recipient.

3158  
3159 Failure of the manufacturer to provide, the recipient to acquire,  
3160 or the wholesale distributor to deliver the documentation  
3161 required under this paragraph shall constitute failure to acquire

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3162 or deliver a pedigree paper under ss. 499.005(28) and 499.0051.  
3163 Forgery by the manufacturer, the recipient, or the wholesale  
3164 distributor of the documentation required to be acquired or  
3165 delivered under this paragraph shall constitute forgery of a  
3166 pedigree paper under s. 499.0051.

3167 4. The wholesale distributor that takes title to, but not  
3168 possession of, the prescription drug is not a member of the  
3169 affiliated group that receives the prescription drug directly  
3170 from the manufacturer.

3171 (g) The wholesale distribution of a prescription drug by a  
3172 warehouse within an affiliated group to a warehouse or retail  
3173 pharmacy within its affiliated group, provided:

3174 1. Any affiliated group member that purchases or receives a  
3175 prescription drug from outside the affiliated group must receive  
3176 a pedigree paper if the prescription drug is distributed in or  
3177 into this state and a pedigree paper is required under this  
3178 section and must authenticate the documentation as required in s.  
3179 499.0121(4), regardless of whether the affiliated group member is  
3180 directly subject to regulation under this part; and

3181 2. The affiliated group makes available, within 48 hours,  
3182 to the department on request to one or more of its members all  
3183 records related to the purchase or acquisition of prescription  
3184 drugs by members of the affiliated group, regardless of the  
3185 location where the records are stored, if the prescription drugs  
3186 were distributed in or into this state.

3187 (h) The repackaging of prescription drugs by a repackager  
3188 solely for distribution to its affiliated group members for the  
3189 exclusive distribution to and among retail pharmacies that are  
3190 members of the affiliated group to which the repackager is a

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3191 member.

3192 1. The repackager must:

3193 a. For all repackaged prescription drugs distributed in or

3194 into this state, state in writing under oath with each

3195 distribution of a repackaged prescription drug to an affiliated

3196 group member warehouse or repackager: "All repackaged

3197 prescription drugs are purchased by the affiliated group directly

3198 from the manufacturer or from a prescription drug wholesale

3199 distributor that purchased the prescription drugs directly from

3200 the manufacturer."

3201 b. Purchase all prescription drugs it repackages:

3202 (I) Directly from the manufacturer; or

3203 (II) From a prescription drug wholesale distributor that

3204 purchased the prescription drugs directly from the manufacturer.

3205 c. Maintain records in accordance with this section to

3206 document that it purchased the prescription drugs directly from

3207 the manufacturer or that its prescription drug wholesale supplier

3208 purchased the prescription drugs directly from the manufacturer.

3209 2. All members of the affiliated group must provide, within

3210 48 hours, to agents of the department on request to one or more

3211 of its members records of purchases by all members of the

3212 affiliated group of prescription drugs that have been repackaged,

3213 regardless of the location at which the records are stored or at

3214 which the repackager is located.

3215 Section 16. Section 499.0122, Florida Statutes, is

3216 repealed.

3217 Section 17. Section 499.013, Florida Statutes, is repealed.

3218 Section 18. Subsections (1), (3), (4), (6), (8), and (9) of

3219 section 499.015, Florida Statutes, are amended to read:

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3220 499.015 Registration of drugs, devices, and cosmetics;  
3221 issuance of certificates of free sale.--

3222 (1) (a) Except for those persons exempted from the  
3223 definition of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, any  
3224 person who manufactures, packages, repackages, labels, or  
3225 relabels a drug, device, or cosmetic in this state must register  
3226 such drug, device, or cosmetic biennially with the department;  
3227 pay a fee in accordance with the fee schedule provided by s.  
3228 499.041; and comply with this section. The registrant must list  
3229 each separate and distinct drug, device, or cosmetic at the time  
3230 of registration.

3231 (b) The department may not register any product that does  
3232 not comply with the Federal Food, Drug, and Cosmetic Act, as  
3233 amended, or Title 21 C.F.R. Registration of a product by the  
3234 department does not mean that the product does in fact comply  
3235 with all provisions of the Federal Food, Drug, and Cosmetic Act,  
3236 as amended.

3237 (3) Except for those persons exempted from the definition  
3238 of manufacturer in s. 499.003(31) ~~s. 499.003(28)~~, a person may  
3239 not sell any product that he or she has failed to register in  
3240 conformity with this section. Such failure to register subjects  
3241 such drug, device, or cosmetic product to seizure and  
3242 condemnation as provided in s. 499.062 ~~ss. 499.062-499.064~~, and  
3243 subjects such person to the penalties and remedies provided in  
3244 this part ~~ss. 499.001-499.081~~.

3245 (4) Unless a registration is renewed, it expires 2 years  
3246 after the last day of the month in which it was issued. The  
3247 department may issue a stop-sale notice or order against a person  
3248 that is subject to the requirements of this section and that



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3249 fails to comply with this section within 31 days after the date  
3250 the registration expires. The notice or order shall prohibit such  
3251 person from selling or causing to be sold any drugs, devices, or  
3252 cosmetics covered by this part ~~ss. 499.001-499.081~~ until he or  
3253 she complies with the requirements of this section.

3254 (6) The department may issue a certificate of free sale for  
3255 any product that is required to be registered under this part ~~ss.~~  
3256 ~~499.001-499.081~~.

3257 (8) Notwithstanding any requirements set forth in this part  
3258 ~~ss. 499.001-499.081~~, a manufacturer of medical devices that is  
3259 registered with the federal Food and Drug Administration is  
3260 exempt from this section and s. 499.041(6) if:

3261 (a) The manufacturer's medical devices are approved for  
3262 marketing by, or listed with the federal Food and Drug  
3263 Administration in accordance with federal law for commercial  
3264 distribution; or

3265 (b) The manufacturer subcontracts with a manufacturer of  
3266 medical devices to manufacture components of such devices.

3267 (9) However, the manufacturer must submit evidence of such  
3268 registration, listing, or approval with its initial application  
3269 for a permit to do business in this state, as required in s.  
3270 499.01 ~~s. 499.013~~ and any changes to such information previously  
3271 submitted at the time of renewal of the permit. Evidence of  
3272 approval, listing, and registration by the federal Food and Drug  
3273 Administration must include:

3274 (a) For Class II devices, a copy of the pre-market  
3275 notification letter (510K);

3276 (b) For Class III devices, a Federal Drug Administration  
3277 pre-market approval number;

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3278 (c) For a manufacturer who subcontracts with a manufacturer  
3279 of medical devices to manufacture components of such devices, a  
3280 Federal Drug Administration registration number; or

3281 (d) For a manufacturer of medical devices whose devices are  
3282 exempt from pre-market approval by the Federal Drug  
3283 Administration, a Federal Drug Administration registration  
3284 number.

3285 Section 19. Subsections (3), (5), and (6) of section  
3286 499.024, Florida Statutes, are amended to read:

3287 499.024 Drug product classification.--The State Surgeon  
3288 General shall adopt rules to classify drug products intended for  
3289 use by humans which the United States Food and Drug  
3290 Administration has not classified in the federal act or the Code  
3291 of Federal Regulations.

3292 (3) Any product that falls under the definition of drug in  
3293 s. 499.003(19) ~~definition, s. 499.003(17)~~, may be classified  
3294 under the authority of this section. This section does not  
3295 subject portable emergency oxygen inhalators to classification;  
3296 however, this section does not exempt any person from ss. 499.01  
3297 and 499.015.

3298 (5) The department may by rule reclassify drugs subject to  
3299 this part ~~ss. 499.001-499.081~~ when such classification action is  
3300 necessary to protect the public health.

3301 (6) The department may adopt rules that exempt from any  
3302 labeling or packaging requirements of this part ~~ss. 499.001-~~  
3303 ~~499.081~~ drugs classified under this section if those requirements  
3304 are not necessary to protect the public health.

3305 Section 20. Subsections (7), (12), and (15) of section  
3306 499.028, Florida Statutes, are amended to read:

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3307 499.028 Drug samples or complimentary drugs; starter packs;  
3308 permits to distribute.--

3309 (7) A drug manufacturer or distributor must report to the  
3310 department any conviction of itself or of its assigns, agents,  
3311 employees, or representatives for a violation of s. 503(c)(1) of  
3312 the federal act or of this part ~~ss. 499.001-499.081~~ because of  
3313 the sale, purchase, or trade of a drug sample or the offer to  
3314 sell, purchase, or trade a drug sample.

3315 (12) The department may suspend or revoke a permit issued  
3316 under this section, after giving notice and an opportunity to be  
3317 heard pursuant to chapter 120, when:

3318 (a) Such permit was obtained by misrepresentation or fraud  
3319 or through a mistake of the department.

3320 (b) The holder of the permit has distributed or disposed of  
3321 any prescription legend drug, directly or through its agents,  
3322 employees, or independent contractors, to any person not  
3323 authorized to possess such drug.

3324 (c) The holder of the permit, or its agents, employees, or  
3325 independent contractors, has distributed or possessed any  
3326 prescription legend drug except in the usual course of its  
3327 business.

3328 (d) The holder of the permit, or its agents, employees, or  
3329 independent contractors, has distributed any prescription legend  
3330 drug that is misbranded or adulterated under this part ~~ss.~~  
3331 ~~499.001-499.081~~.

3332 (e) The holder of the permit, or its agents, employees, or  
3333 independent contractors, has distributed any prescription legend  
3334 drug without written request, when a written request is required  
3335 by this section.

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3336 (f) The holder of the permit has in its employ, or uses as  
3337 agent or independent contractor for the purpose of distributing  
3338 or disposing of drugs, any person who has:

3339 1. Violated the requirements of this section or any rule  
3340 adopted under this section.

3341 2. Been convicted in any of the courts of this state, the  
3342 United States, or any other state of a felony or any other crime  
3343 involving moral turpitude or involving those drugs named or  
3344 described in chapter 893.

3345 (15) A person may not possess a prescription drug sample  
3346 unless:

3347 (a) The drug sample was prescribed to her or him as  
3348 evidenced by the label required in s. 465.0276(5).

3349 (b) She or he is the employee of a complimentary drug  
3350 distributor that holds a permit issued under this part ~~ss-~~  
3351 ~~499.001-499.081~~.

3352 (c) She or he is a person to whom prescription drug samples  
3353 may be distributed pursuant to this section.

3354 (d) He or she is an officer or employee of a federal,  
3355 state, or local government acting within the scope of his or her  
3356 employment.

3357 Section 21. Subsections (2) and (3) of section 499.029,  
3358 Florida Statutes, are amended to read:

3359 499.029 Cancer Drug Donation Program.--

3360 (2) There is created a Cancer Drug Donation Program within  
3361 the department ~~of Health~~ for the purpose of authorizing and  
3362 facilitating the donation of cancer drugs and supplies to  
3363 eligible patients.

3364 (3) As used in this section:

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3365 (a) "Cancer drug" means a prescription drug that has been  
3366 approved under s. 505 of the federal Food, Drug, and Cosmetic Act  
3367 and is used to treat cancer or its side effects or is used to  
3368 treat the side effects of a prescription drug used to treat  
3369 cancer or its side effects. "Cancer drug" does not include a  
3370 substance listed in Schedule II, Schedule III, Schedule IV, or  
3371 Schedule V of s. 893.03.

3372 (b) "Closed drug delivery system" means a system in which  
3373 the actual control of the unit-dose medication package is  
3374 maintained by the facility rather than by the individual patient.

3375 ~~(c) "Department" means the Department of Health.~~

3376 (c) ~~(d)~~ "Donor" means a patient or patient representative  
3377 who donates cancer drugs or supplies needed to administer cancer  
3378 drugs that have been maintained within a closed drug delivery  
3379 system; health care facilities, nursing homes, hospices, or  
3380 hospitals with closed drug delivery systems; or pharmacies, drug  
3381 manufacturers, medical device manufacturers or suppliers, or  
3382 wholesalers of drugs or supplies, in accordance with this  
3383 section. "Donor" includes a physician licensed under chapter 458  
3384 or chapter 459 who receives cancer drugs or supplies directly  
3385 from a drug manufacturer, wholesale distributor ~~drug wholesaler~~,  
3386 or pharmacy.

3387 (d) ~~(e)~~ "Eligible patient" means a person who the department  
3388 determines is eligible to receive cancer drugs from the program.

3389 (e) ~~(k)~~ "Participant facility" means a class II hospital  
3390 pharmacy that has elected to participate in the program and that  
3391 accepts donated cancer drugs and supplies under the rules adopted  
3392 by the department for the program.

3393 (f) ~~(n)~~ "Prescribing practitioner" means a physician

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3394 licensed under chapter 458 or chapter 459 or any other medical  
3395 professional with authority under state law to prescribe cancer  
3396 medication.

3397 ~~(e) "Prescription drug" means a drug as defined in s.~~  
3398 ~~465.003(8).~~

3399 (g) ~~(p)~~ "Program" means the Cancer Drug Donation Program  
3400 created by this section.

3401 (h) ~~(q)~~ "Supplies" means any supplies used in the  
3402 administration of a cancer drug.

3403 Section 22. Subsection (1) of section 499.03, Florida  
3404 Statutes, is amended to read:

3405 499.03 Possession of certain drugs without prescriptions  
3406 unlawful; exemptions and exceptions.--

3407 (1) A person may not possess, or possess with intent to  
3408 sell, dispense, or deliver, any habit-forming, toxic, harmful, or  
3409 new drug subject to s. 499.003(32) ~~s. 499.003(29)~~, or  
3410 prescription ~~legend~~ drug as defined in s. 499.003(42) ~~s.~~  
3411 ~~499.003(25)~~, unless the possession of the drug has been obtained  
3412 by a valid prescription of a practitioner licensed by law to  
3413 prescribe the drug. However, this section does not apply to the  
3414 delivery of such drugs to persons included in any of the classes  
3415 named in this subsection, or to the agents or employees of such  
3416 persons, for use in the usual course of their businesses or  
3417 practices or in the performance of their official duties, as the  
3418 case may be; nor does this section apply to the possession of  
3419 such drugs by those persons or their agents or employees for such  
3420 use:

3421 (a) A licensed pharmacist or any person under the licensed  
3422 pharmacist's supervision while acting within the scope of the

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3423 licensed pharmacist's practice;

3424 (b) A licensed practitioner authorized by law to prescribe  
3425 prescription ~~legend~~ drugs or any person under the licensed  
3426 practitioner's supervision while acting within the scope of the  
3427 licensed practitioner's practice;

3428 (c) A qualified person who uses prescription ~~legend~~ drugs  
3429 for lawful research, teaching, or testing, and not for resale;

3430 (d) A licensed hospital or other institution that procures  
3431 such drugs for lawful administration or dispensing by  
3432 practitioners;

3433 (e) An officer or employee of a federal, state, or local  
3434 government; or

3435 (f) A person that holds a valid permit issued by the  
3436 department pursuant to this part ~~ss. 499.001-499.081~~ which  
3437 authorizes that person to possess prescription drugs.

3438 Section 23. Section 499.032, Florida Statutes, is amended  
3439 to read:

3440 499.032 Phenylalanine; prescription  
3441 required.--Phenylalanine restricted formula is declared to be a  
3442 prescription ~~legend~~ drug and may be dispensed only upon the  
3443 prescription of a practitioner authorized by law to prescribe  
3444 prescription ~~medicinal~~ drugs.

3445 Section 24. Subsection (1) of section 499.033, Florida  
3446 Statutes, is amended to read:

3447 499.033 Ephedrine; prescription required.--Ephedrine is  
3448 declared to be a prescription drug.

3449 (1) Except as provided in subsection (2), any product that  
3450 contains any quantity of ephedrine, a salt of ephedrine, an  
3451 optical isomer of ephedrine, or a salt of an optical isomer of

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3452 ephedrine may be dispensed only upon the prescription of a duly  
3453 licensed practitioner authorized by the laws of the state to  
3454 prescribe prescription ~~medicinal~~ drugs.

3455 Section 25. Subsections (1) and (3) of section 499.039,  
3456 Florida Statutes, are amended to read:

3457 499.039 Sale, distribution, or transfer of harmful chemical  
3458 substances; penalties; authority for enforcement.--It is unlawful  
3459 for a person to sell, deliver, or give to a person under the age  
3460 of 18 years any compound, liquid, or chemical containing toluol,  
3461 hexane, trichloroethylene, acetone, toluene, ethyl acetate,  
3462 methyl ethyl ketone, trichloroethane, isopropanol, methyl  
3463 isobutyl ketone, ethylene glycol monomethyl ether acetate,  
3464 cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites  
3465 (butyl nitrite), or any similar substance for the purpose of  
3466 inducing by breathing, inhaling, or ingesting a condition of  
3467 intoxication or which is intended to distort or disturb the  
3468 auditory, visual, or other physical or mental processes.

3469 (1) On the first violation of this section, the department  
3470 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if the  
3471 violation has not caused temporary or permanent physical or  
3472 mental injury to the user.

3473 (3) The department ~~of Health~~ shall adopt rules to implement  
3474 this section.

3475 Section 26. Section 499.04, Florida Statutes, is amended to  
3476 read:

3477 499.04 Fee authority.--The department may collect fees for  
3478 all drug, device, and cosmetic applications, permits, product  
3479 registrations, and free-sale certificates. The total amount of  
3480 fees collected from all permits, applications, product



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3481 | registrations, and free-sale certificates must be adequate to  
3482 | fund the expenses incurred by the department in carrying out this  
3483 | part ~~ss. 499.001-499.081~~. The department shall, by rule,  
3484 | establish a schedule of fees that are within the ranges provided  
3485 | in this section and shall adjust those fees from time to time  
3486 | based on the costs associated with administering this part ~~ss.~~  
3487 | ~~499.001-499.081~~. The fees are payable to the department to be  
3488 | deposited into the Florida Drug, Device, and Cosmetic Trust Fund  
3489 | for the sole purpose of carrying out the provisions of this part  
3490 | ~~ss. 499.001-499.081~~.

3491 |       Section 27. Subsections (1) through (5), (8), and (10) of  
3492 | section 499.041, Florida Statutes, are amended to read:

3493 |       499.041 Schedule of fees for drug, device, and cosmetic  
3494 | applications and permits, product registrations, and free-sale  
3495 | certificates.--

3496 |       (1) The department shall assess applicants requiring a  
3497 | manufacturing permit an annual fee within the ranges established  
3498 | in this section for the specific type of manufacturer.

3499 |       (a) The fee for a prescription drug manufacturer  
3500 | ~~manufacturer's~~ permit may not be less than \$500 or more than \$750  
3501 | annually.

3502 |       (b) The fee for a device manufacturer ~~manufacturer's~~ permit  
3503 | may not be less than \$500 or more than \$600 annually.

3504 |       (c) The fee for a cosmetic manufacturer ~~manufacturer's~~  
3505 | permit may not be less than \$250 or more than \$400 annually.

3506 |       (d) The fee for an over-the-counter drug manufacturer  
3507 | ~~manufacturer's~~ permit may not be less than \$300 or more than \$400  
3508 | annually.

3509 |       (e) The fee for a compressed medical gas manufacturer

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3510 ~~manufacturer's~~ permit may not be less than \$400 or more than \$500  
3511 annually.

3512 (f) The fee for a prescription drug repackager ~~repackager's~~  
3513 permit may not be less than \$500 or more than \$750 annually.

3514 (g) A manufacturer may not be required to pay more than one  
3515 fee per establishment to obtain an additional manufacturing  
3516 permit, but each manufacturer must pay the highest fee applicable  
3517 to his or her operation in each establishment.

3518 (2) The department shall assess an applicant that is  
3519 required to have a wholesaling permit an annual fee within the  
3520 ranges established in this section for the specific type of  
3521 wholesaling.

3522 (a) The fee for a prescription drug wholesale distributor  
3523 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800  
3524 annually.

3525 (b) The fee for a compressed medical gas wholesale  
3526 distributor ~~wholesaler's~~ permit may not be less than \$200 or more  
3527 than \$300 annually.

3528 (c) The fee for an out-of-state prescription drug wholesale  
3529 distributor ~~wholesaler's~~ permit may not be less than \$300 or more  
3530 than \$800 annually.

3531 (d) The fee for a nonresident prescription drug  
3532 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or  
3533 more than \$500 annually.

3534 (e) The fee for a retail pharmacy drug wholesale  
3535 distributor ~~wholesaler's~~ permit may not be less than \$35 or more  
3536 than \$50 annually.

3537 (f) The fee for a freight forwarder ~~forwarder's~~ permit may  
3538 not be less than \$200 or more than \$300 annually.

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3539 (g) The fee for a veterinary prescription drug wholesale  
3540 distributor ~~wholesaler's~~ permit may not be less than \$300 or more  
3541 than \$500 annually.

3542 (h) The fee for a limited prescription drug veterinary  
3543 wholesale distributor ~~wholesaler's~~ permit may not be less than  
3544 \$300 or more than \$500 annually.

3545 (i) The fee for a third part logistics provider permit may  
3546 not be less than \$200 or more than \$300 annually.

3547 (3) The department shall assess an applicant that is  
3548 required to have a retail establishment permit an annual fee  
3549 within the ranges established in this section for the specific  
3550 type of retail establishment.

3551 (a) The fee for a veterinary prescription ~~legend~~ drug  
3552 retail establishment permit may not be less than \$200 or more  
3553 than \$300 annually.

3554 (b) The fee for a medical oxygen retail establishment  
3555 permit may not be less than \$200 or more than \$300 annually.

3556 (c) The fee for a health care clinic establishment permit  
3557 may not be less than \$125 or more than \$250 annually.

3558 (4) The department shall assess an applicant that is  
3559 required to have a restricted prescription drug distributor  
3560 ~~distributor's~~ permit an annual fee of not less than \$200 or more  
3561 than \$300.

3562 (5) In addition to the fee charged for a permit required by  
3563 this part ~~ss. 499.001-499.081~~, the department shall assess  
3564 applicants an initial application fee of \$150 for each new permit  
3565 issued by the department which requires an onsite inspection.

3566 (8) The department shall assess an out-of-state  
3567 prescription drug wholesale distributor ~~wholesaler~~ applicant or

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3568 | permittee an onsite inspection fee of not less than \$1,000 or  
3569 | more than \$3,000 annually, to be based on the actual cost of the  
3570 | inspection if an onsite inspection is performed by agents of the  
3571 | department.

3572 |         (10) The department shall assess other fees as provided in  
3573 | this part ~~ss. 499.001-499.081~~.

3574 |         Section 28. Section 499.05, Florida Statutes, is amended;  
3575 | subsection (3) of section 499.013, Florida Statutes, is  
3576 | redesignated as paragraph (k) of subsection (1) of that section  
3577 | and amended; paragraph (b) of subsection (2) of section 499.0122,  
3578 | Florida Statutes, is redesignated as paragraph (l) of subsection  
3579 | (1) of that section and amended; and subsection (12) of section  
3580 | 499.012, Florida Statutes, is redesignated as paragraph (m) of  
3581 | subsection (1) of that section and amended, to read:

3582 |         499.05 Rules.--

3583 |         (1) The department shall adopt rules to implement and  
3584 | enforce this part ~~ss. 499.001-499.081~~ with respect to:

3585 |         (a) The definition of terms used in this part ~~ss. 499.001-~~  
3586 | ~~499.081~~, and used in the rules adopted under this part ~~ss.~~  
3587 | ~~499.001-499.081~~, when the use of the term is not its usual and  
3588 | ordinary meaning.

3589 |         (b) Labeling requirements for drugs, devices, and  
3590 | cosmetics.

3591 |         (c) The establishment of fees authorized in this part ~~ss.~~  
3592 | ~~499.001-499.081~~.

3593 |         (d) The identification of permits that require an initial  
3594 | application and onsite inspection or other prerequisites for  
3595 | permitting which demonstrate that the establishment and person  
3596 | are in compliance with the requirements of this part ~~ss. 499.001-~~

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3597 | ~~499.081.~~

3598 |       (e) The application processes and forms for product  
3599 | registration.

3600 |       (f) Procedures for requesting and issuing certificates of  
3601 | free sale.

3602 |       (g) Inspections and investigations conducted under s.  
3603 | 499.051, and the identification of information claimed to be a  
3604 | trade secret and exempt from the public records law as provided  
3605 | in s. 499.051(7).

3606 |       (h) The establishment of a range of penalties, as provided  
3607 | in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of  
3608 | the potential impact of a violation of this part ~~ss. 499.001-~~  
3609 | ~~499.081~~; and a process for the uncontested settlement of alleged  
3610 | violations.

3611 |       (i) Additional conditions that qualify as an emergency  
3612 | medical reason under s. 499.003(53)(b)2. ~~s. 499.012(1)(a)2.b.~~

3613 |       (j) Procedures and forms relating to the pedigree paper  
3614 | requirement of s. 499.01212.

3615 |       ~~(k)(3) The department may adopt such rules as are necessary~~  
3616 | ~~for~~ The protection of the public health, safety, and welfare  
3617 | regarding good manufacturing practices that manufacturers and  
3618 | repackagers must follow to ensure the safety of the products.

3619 |       ~~(l)(b) The department shall adopt rules relating to~~  
3620 | Information required from each retail establishment pursuant to  
3621 | s. 499.012(3) ~~s. 499.01(4)~~, including requirements for  
3622 | prescriptions or orders.

3623 |       ~~(m)(12) The department may adopt rules governing~~ The  
3624 | recordkeeping, storage, and handling with respect to each of the  
3625 | distributions of prescription drugs specified in s.

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3626 499.003(53)(a)-(d) subparagraphs (1)(a)1.-4.

3627 (n) Alternatives to compliance with s. 499.01212 for a  
3628 prescription drug in the inventory of a permitted prescription  
3629 drug wholesale distributor as of June 30, 2006, and the return of  
3630 a prescription drug purchased prior to July 1, 2006. The  
3631 department may specify time limits for such alternatives.

3632 (2) With respect to products in interstate commerce, those  
3633 rules must not be inconsistent with rules and regulations of  
3634 federal agencies unless specifically otherwise directed by the  
3635 Legislature.

3636 (3) The department shall adopt rules regulating  
3637 recordkeeping for and the storage, handling, and distribution of  
3638 medical devices and over-the-counter drugs to protect the public  
3639 from adulterated products.

3640 Section 29. Section 499.051, Florida Statutes, is amended  
3641 to read:

3642 499.051 Inspections and investigations.--

3643 (1) The agents of the department ~~of Health~~ and of the  
3644 Department of Law Enforcement, after they present proper  
3645 identification, may inspect, monitor, and investigate any  
3646 establishment permitted pursuant to this part ~~ss. 499.001-499.081~~  
3647 during business hours for the purpose of enforcing this part ~~ss.~~  
3648 ~~499.001-499.081~~, chapters 465, 501, and 893, and the rules of the  
3649 department that protect the public health, safety, and welfare.

3650 (2) In addition to the authority set forth in subsection  
3651 (1), the department and any duly designated officer or employee  
3652 of the department may enter and inspect any other establishment  
3653 for the purpose of determining compliance with this part ~~ss.~~  
3654 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~

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3655 regarding any drug, device, or cosmetic product.

3656 (3) Any application for a permit or product registration or  
3657 for renewal of such permit or registration made pursuant to this  
3658 part ss. 499.001-499.081 and rules adopted under this part ~~those~~  
3659 ~~sections~~ constitutes permission for any entry or inspection of  
3660 the premises in order to verify compliance with this part ~~these~~  
3661 ~~sections~~ and rules; to discover, investigate, and determine the  
3662 existence of compliance; or to elicit, receive, respond to, and  
3663 resolve complaints and violations.

3664 (4) Any application for a permit made pursuant to s.  
3665 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that  
3666 section ~~these sections~~ constitutes permission for agents of the  
3667 department ~~of Health~~ and the Department of Law Enforcement, after  
3668 presenting proper identification, to inspect, review, and copy  
3669 any financial document or record related to the manufacture,  
3670 repackaging, or distribution of a drug as is necessary to verify  
3671 compliance with this part ss. 499.001-499.081 and the rules  
3672 adopted by the department to administer this part ~~those sections~~,  
3673 in order to discover, investigate, and determine the existence of  
3674 compliance, or to elicit, receive, respond to, and resolve  
3675 complaints and violations.

3676 (5) The authority to inspect under this section includes  
3677 the authority to access, review, and copy any and all financial  
3678 documents related to the activity of manufacturing, repackaging,  
3679 or distributing prescription drugs.

3680 (6) The authority to inspect under this section includes  
3681 the authority to secure:

3682 (a) Samples or specimens of any drug, device, or cosmetic;  
3683 or

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3684 (b) Such other evidence as is needed for any action to  
3685 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted under  
3686 this part ~~those sections~~.

3687 (7) The complaint and all information obtained pursuant to  
3688 the investigation by the department are confidential and exempt  
3689 from the provisions of s. 119.07(1) and s. 24(a), Art. I of the  
3690 State Constitution until the investigation and the enforcement  
3691 action are completed. However, trade secret information contained  
3692 therein as defined by s. 812.081(1)(c) shall remain confidential  
3693 and exempt from the provisions of s. 119.07(1) and s. 24(a), Art.  
3694 I of the State Constitution, as long as the information is  
3695 retained by the department. This subsection does not prohibit the  
3696 department from using such information for regulatory or  
3697 enforcement proceedings under this chapter or from providing such  
3698 information to any law enforcement agency or any other regulatory  
3699 agency. However, the receiving agency shall keep such records  
3700 confidential and exempt as provided in this subsection. In  
3701 addition, this subsection is not intended to prevent compliance  
3702 with the provisions of s. 499.01212 ~~s. 499.0121(6)(d)~~, and the  
3703 pedigree papers required in that section ~~subsection~~ shall not be  
3704 deemed a trade secret.

3705 Section 30. Section 499.052, Florida Statutes, is amended  
3706 to read:

3707 499.052 Records of interstate shipment.--For the purpose of  
3708 enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in  
3709 interstate commerce and persons receiving drugs, devices, or  
3710 cosmetics in interstate commerce must, upon the request, in the  
3711 manner set out below, by an officer or employee duly designated  
3712 by the department, permit the officer or employee to have access



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3713 to and to copy all records showing the movement in interstate  
3714 commerce of any drug, device, or cosmetic, and the quantity,  
3715 shipper, and consignee thereof.

3716 Section 31. Subsection (4) of section 499.055, Florida  
3717 Statutes, is amended to read:

3718 499.055 Reports and dissemination of information by  
3719 department.--

3720 (4) The department shall publish on the department's  
3721 website and update at least monthly:

3722 (a) A list of the prescription drug wholesale distributors  
3723 ~~wholesalers~~, out-of-state prescription drug wholesale  
3724 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
3725 distributors ~~wholesalers~~ against whom the department has  
3726 initiated enforcement action pursuant to this part ~~ss. 499.001-~~  
3727 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or  
3728 otherwise file an administrative complaint and the permit number  
3729 of each such wholesale distributor ~~wholesaler~~.

3730 (b) A list of the prescription drug wholesale distributors  
3731 ~~wholesalers~~, out-of-state prescription drug wholesale  
3732 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
3733 distributors ~~wholesalers~~ to which the department has issued a  
3734 permit, including the date on which each permit will expire.

3735 (c) A list of the prescription drug wholesale distributor  
3736 ~~wholesalers~~, out-of-state prescription drug wholesale distributor  
3737 ~~wholesalers~~, and retail pharmacy drug wholesale distributor  
3738 ~~wholesalers~~ permits that have been returned to the department,  
3739 were suspended, were revoked, have expired, or were not renewed  
3740 in the previous year.

3741 Section 32. Subsections (1) and (3) of section 499.06,

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3742 Florida Statutes, are amended to read:

3743 499.06 Embargoing, detaining, or destroying article or  
3744 processing equipment which is in violation of law or rule.--

3745 (1) When a duly authorized agent of the department finds,  
3746 or has probable cause to believe, that any drug, device, or  
3747 cosmetic is in violation of any provision of this part ~~ss.~~  
3748 ~~499.001-499.081~~ or any rule adopted under this part ~~such sections~~  
3749 so as to be dangerous, unwholesome, or fraudulent within the  
3750 meaning of this part ~~ss. 499.001-499.081~~, she or he may issue and  
3751 enforce a stop-sale, stop-use, removal, or hold order, which  
3752 order gives notice that such article or processing equipment is,  
3753 or is suspected of being, in violation and has been detained or  
3754 embargoed, and which order warns all persons not to remove, use,  
3755 or dispose of such article or processing equipment by sale or  
3756 otherwise until permission for removal, use, or disposal is given  
3757 by such agent or the court. It is unlawful for any person to  
3758 remove, use, or dispose of such detained or embargoed article or  
3759 processing equipment by sale or otherwise without such  
3760 permission; and such act is a felony of the second degree,  
3761 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3762 (3) If the court finds that the detained or embargoed  
3763 article or processing equipment is in violation, such article or  
3764 processing equipment shall, after entry of the court order, be  
3765 destroyed or made sanitary at the expense of the claimant  
3766 thereof, under the supervision of such agent; and all court  
3767 costs, fees, and storage and other proper expenses shall be taxed  
3768 against the claimant of such article or processing equipment or  
3769 her or his agent. However, when the violation can be corrected by  
3770 proper labeling of the article or sanitizing of the processing

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3771 equipment, and after such costs, fees, and expenses have been  
3772 paid and a good and sufficient bond, conditioned that such  
3773 article be so labeled or processed or such processing equipment  
3774 be so sanitized, has been executed, the court may by order direct  
3775 that such article or processing equipment be delivered to the  
3776 claimant thereof for such labeling, processing, or sanitizing,  
3777 under the supervision of an agent of the department. The expense  
3778 of such supervision shall be paid by the claimant. Such bond  
3779 shall be returned to the claimant of the article or processing  
3780 equipment upon representation to the court by the department that  
3781 the article or processing equipment is no longer in violation of  
3782 this part ss. 499.001-499.081 and that the expenses of such  
3783 supervision have been paid.

3784 Section 33. Section 499.062, Florida Statutes, is amended;  
3785 section 499.063, Florida Statutes, is redesignated as section (2)  
3786 of that section and amended; and section 499.064, Florida  
3787 Statutes, is redesignated as paragraphs (a) and (b) of subsection  
3788 (2) of that section and amended, to read:

3789 499.062 ~~Cause for~~ Seizure and condemnation of drugs,  
3790 devices, or cosmetics.--

3791 (1) Any article of any drug, device, or cosmetic that is  
3792 adulterated or misbranded under this part ss. 499.001-499.081 is  
3793 subject to seizure and condemnation by the department or by its  
3794 duly authorized agents designated for that purpose in regard to  
3795 drugs, devices, or cosmetics.

3796 (2) ~~499.063 Seizure; procedure; prohibition on sale or~~  
3797 ~~disposal of article; penalty.--~~Whenever a duly authorized officer  
3798 or employee of the department finds cause, or has probable cause  
3799 to believe that cause exists, for the seizure of any drug,

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3800 device, or cosmetic, as set out in this part ~~ss. 499.001-499.081~~,  
3801 he or she shall affix to the article a tag, stamp, or other  
3802 appropriate marking, giving notice that the article is, or is  
3803 suspected of being, subject to seizure under this part ~~ss.~~  
3804 ~~499.001-499.081~~ and that the article has been detained and seized  
3805 by the department. Such officer or employee shall also warn all  
3806 persons not to remove or dispose of the article, by sale or  
3807 otherwise, until permission is given by the department or the  
3808 court. Any person who violates this subsection ~~section~~ is guilty  
3809 of a felony of the second degree, punishable as provided in s.  
3810 775.082, s. 775.083, or s. 775.084.

3811 (a) ~~499.064~~ ~~Condemnation and sale; release of seized~~  
3812 ~~article.--(1)~~ When any article detained or seized under this  
3813 subsection ~~s. 499.063~~ has been found by the department to be  
3814 subject to seizure and condemnation ~~under s. 499.063~~, the  
3815 department shall petition the court for an order of condemnation  
3816 or sale, as the court directs. The proceeds of the sale of drugs,  
3817 devices, and cosmetics, less the legal costs and charges, shall  
3818 be deposited into the Florida Drug, Device, and Cosmetic Trust  
3819 Fund.

3820 (b) ~~(2)~~ If the department finds that any article seized  
3821 under this subsection ~~s. 499.063~~ was not subject to seizure ~~under~~  
3822 ~~that section~~, the department or the designated officer or  
3823 employee shall remove the tag or marking.

3824 Section 34. Section 499.065, Florida Statutes, is amended  
3825 to read:

3826 499.065 Inspections; imminent danger.--

3827 (1) Notwithstanding s. 499.051, the department shall  
3828 inspect each prescription drug wholesale distributor

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3829 establishment, prescription drug repackager establishment,  
3830 veterinary prescription drug wholesale distributor establishment,  
3831 limited prescription drug veterinary wholesale distributor  
3832 ~~wholesaler~~ establishment, and retail pharmacy drug wholesale  
3833 distributor ~~wholesaler~~ establishment that is required to be  
3834 permitted under this part ~~chapter~~ as often as necessary to ensure  
3835 compliance with applicable laws and rules. The department shall  
3836 have the right of entry and access to these facilities at any  
3837 reasonable time.

3838 (2) To protect the public from prescription drugs that are  
3839 adulterated or otherwise unfit for human or animal consumption,  
3840 the department may examine, sample, seize, and stop the sale or  
3841 use of prescription drugs to determine the condition of those  
3842 drugs. The department may immediately seize and remove any  
3843 prescription drugs if the State Surgeon General or his or her  
3844 designee determines that the prescription drugs represent a  
3845 threat to the public health. The owner of any property seized  
3846 under this section may, within 10 days after the seizure, apply  
3847 to a court of competent jurisdiction for whatever relief is  
3848 appropriate. At any time after 10 days, the department may  
3849 destroy the drugs as contraband.

3850 (3) The department may determine that a prescription drug  
3851 wholesale distributor establishment, prescription drug repackager  
3852 establishment, veterinary prescription drug wholesale distributor  
3853 establishment, limited prescription drug veterinary wholesale  
3854 distributor ~~wholesaler~~ establishment, or retail pharmacy drug  
3855 wholesale distributor ~~wholesaler~~ establishment that is required  
3856 to be permitted under this part ~~chapter~~ is an imminent danger to  
3857 the public health and shall require its immediate closure if the

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3858 establishment fails to comply with applicable laws and rules and,  
3859 because of the failure, presents an imminent threat to the  
3860 public's health, safety, or welfare. Any establishment so deemed  
3861 and closed shall remain closed until allowed by the department or  
3862 by judicial order to reopen.

3863 (4) For purposes of this section, a refusal to allow entry  
3864 to the department for inspection at reasonable times, or a  
3865 failure or refusal to provide the department with required  
3866 documentation for purposes of inspection, constitutes an imminent  
3867 danger to the public health.

3868 Section 35. Subsections (1) through (4) of section 499.066,  
3869 Florida Statutes, are amended to read:

3870 499.066 Penalties; remedies.--In addition to other  
3871 penalties and other enforcement provisions:

3872 (1) The department may institute such suits or other legal  
3873 proceedings as are required to enforce any provision of this part  
3874 ~~ss. 499.001-499.081~~. If it appears that a person has violated any  
3875 provision of this part ~~ss. 499.001-499.081~~ for which criminal  
3876 prosecution is provided, the department may provide the  
3877 appropriate state attorney or other prosecuting agency having  
3878 jurisdiction with respect to such prosecution with the relevant  
3879 information in the department's possession.

3880 (2) If any person engaged in any activity covered by this  
3881 part ~~ss. 499.001-499.081~~ violates any provision of this part  
3882 ~~those sections~~, any rule adopted under this part ~~those sections~~,  
3883 or a cease and desist order as provided by this part ~~those~~  
3884 ~~sections~~, the department may obtain an injunction in the circuit  
3885 court of the county in which the violation occurred or in which  
3886 the person resides or has its principal place of business, and

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3887 may apply in that court for such temporary and permanent orders  
3888 as the department considers necessary to restrain the person from  
3889 engaging in any such activities until the person complies with  
3890 this part ss. 499.001-499.081, the rules adopted under this part  
3891 ~~those sections~~, and the orders of the department authorized by  
3892 this part ~~those sections~~ or to mandate compliance with this part  
3893 ~~ss. 499.001-499.081~~, the rules adopted under this part ~~those~~  
3894 ~~sections~~, and any order or permit issued by the department under  
3895 this part ~~those sections~~.

3896 (3) The department may impose an administrative fine, not  
3897 to exceed \$5,000 per violation per day, for the violation of any  
3898 provision of this part ss. 499.001-499.081 or rules adopted under  
3899 this part ~~those sections~~. Each day a violation continues  
3900 constitutes a separate violation, and each separate violation is  
3901 subject to a separate fine. All amounts collected pursuant to  
3902 this section shall be deposited into the Florida Drug, Device,  
3903 and Cosmetic Trust Fund and are appropriated for the use of the  
3904 department in administering this part ss. 499.001-499.081. In  
3905 determining the amount of the fine to be levied for a violation,  
3906 the department shall consider:

- 3907 (a) The severity of the violation;  
3908 (b) Any actions taken by the person to correct the  
3909 violation or to remedy complaints; and  
3910 (c) Any previous violations.

3911 (4) The department shall deposit any rewards, fines, or  
3912 collections that are due the department and which derive from  
3913 joint enforcement activities with other state and federal  
3914 agencies which relate to this part ss. 499.001-499.081, chapter  
3915 893, or the federal act, into the Florida Drug, Device, and

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3916 Cosmetic Trust Fund. The proceeds of those rewards, fines, and  
3917 collections are appropriated for the use of the department in  
3918 administering this part ~~ss. 499.001-499.081~~.

3919 Section 36. Section 499.0661, Florida Statutes, is amended  
3920 to read:

3921 499.0661 Cease and desist orders; removal of certain  
3922 persons.--

3923 (1) ~~(2)~~ CEASE AND DESIST ORDERS.--

3924 (a) In addition to any authority otherwise provided in this  
3925 chapter, the department may issue and serve a complaint stating  
3926 charges upon any permittee or upon any affiliated party, whenever  
3927 the department has reasonable cause to believe that the person or  
3928 individual named therein is engaging in or has engaged in conduct  
3929 that is:

3930 1. An act that demonstrates a lack of fitness or  
3931 trustworthiness to engage in the business authorized under the  
3932 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
3933 hazardous to the public health, or constitutes business  
3934 operations that are a detriment to the public health;

3935 2. A violation of any provision of this part ~~ss. 499.001-~~  
3936 ~~499.081~~;

3937 3. A violation of any rule of the department;

3938 4. A violation of any order of the department; or

3939 5. A breach of any written agreement with the department.

3940 (b) The complaint must contain a statement of facts and  
3941 notice of opportunity for a hearing pursuant to ss. 120.569 and  
3942 120.57.

3943 (c) If a hearing is not requested within the time allowed  
3944 by ss. 120.569 and 120.57, or if a hearing is held and the



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3945 department finds that any of the charges are proven, the  
3946 department may enter an order directing the permittee or the  
3947 affiliated party named in the complaint to cease and desist from  
3948 engaging in the conduct complained of and take corrective action  
3949 to remedy the effects of past improper conduct and assure future  
3950 compliance.

3951 (d) A contested or default cease and desist order is  
3952 effective when reduced to writing and served upon the permittee  
3953 or affiliated party named therein. An uncontested cease and  
3954 desist order is effective as agreed.

3955 (e) Whenever the department finds that conduct described in  
3956 paragraph (a) is likely to cause an immediate threat to the  
3957 public health, it may issue an emergency cease and desist order  
3958 requiring the permittee or any affiliated party to immediately  
3959 cease and desist from engaging in the conduct complained of and  
3960 to take corrective and remedial action. The emergency order is  
3961 effective immediately upon service of a copy of the order upon  
3962 the permittee or affiliated party named therein and remains  
3963 effective for 90 days. If the department begins nonemergency  
3964 cease and desist proceedings under this subsection, the emergency  
3965 order remains effective until the conclusion of the proceedings  
3966 under ss. 120.569 and 120.57.

3967 (2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

3968 (a) The department may issue and serve a complaint stating  
3969 charges upon any affiliated party and upon the permittee involved  
3970 whenever the department has reason to believe that an affiliated  
3971 party is engaging in or has engaged in conduct that constitutes:

3972 1. An act that demonstrates a lack of fitness or  
3973 trustworthiness to engage in the business authorized under the

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3974 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
3975 hazardous to the public health, or constitutes business  
3976 operations that are a detriment to the public health;

3977 2. A willful violation of this part ~~ss. 499.001-499.081~~;  
3978 however, if the violation constitutes a misdemeanor, a complaint  
3979 may not be served as provided in this section until the  
3980 affiliated party is notified in writing of the matter of the  
3981 violation and has been afforded a reasonable period of time, as  
3982 set forth in the notice, to correct the violation and has failed  
3983 to do so;

3984 3. A violation of any other law involving fraud or moral  
3985 turpitude which constitutes a felony;

3986 4. A willful violation of any rule of the department;

3987 5. A willful violation of any order of the department; or

3988 6. A material misrepresentation of fact, made knowingly and  
3989 willfully or made with reckless disregard for the truth of the  
3990 matter.

3991 (b) The complaint must contain a statement of facts and  
3992 notice of opportunity for a hearing pursuant to ss. 120.569 and  
3993 120.57.

3994 (c) If a hearing is not requested within the time allotted  
3995 by ss. 120.569 and 120.57, or if a hearing is held and the  
3996 department finds that any of the charges in the complaint are  
3997 proven true, the department may enter an order removing the  
3998 affiliated party or restricting or prohibiting participation by  
3999 the person in the affairs of that permittee or of any other  
4000 permittee.

4001 (d) A contested or default order of removal, restriction,  
4002 or prohibition is effective when reduced to writing and served on

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4003 the permittee and the affiliated party. An uncontested order of  
4004 removal, restriction, or prohibition is effective as agreed.

4005 (e)1. The chief executive officer, designated  
4006 representative, or the person holding the equivalent office, of a  
4007 permittee shall promptly notify the department if she or he has  
4008 actual knowledge that any affiliated party is charged with a  
4009 felony in a state or federal court.

4010 2. Whenever any affiliated party is charged with a felony  
4011 in a state or federal court or with the equivalent of a felony in  
4012 the courts of any foreign country with which the United States  
4013 maintains diplomatic relations, and the charge alleges violation  
4014 of any law involving prescription drugs, pharmaceuticals, fraud,  
4015 theft, or moral turpitude, the department may enter an emergency  
4016 order suspending the affiliated party or restricting or  
4017 prohibiting participation by the affiliated party in the affairs  
4018 of the particular permittee or of any other permittee upon  
4019 service of the order upon the permittee and the affiliated party  
4020 charged. The order must contain notice of opportunity for a  
4021 hearing pursuant to ss. 120.569 and 120.57, where the affiliated  
4022 party may request a postsuspension hearing to show that continued  
4023 service to or participation in the affairs of the permittee does  
4024 not pose a threat to the public health or the interests of the  
4025 permittee and does not threaten to impair public confidence in  
4026 the permittee. In accordance with applicable departmental rules,  
4027 the department shall notify the affiliated party whether the  
4028 order suspending or prohibiting the person from participation in  
4029 the affairs of a permittee will be rescinded or otherwise  
4030 modified. The emergency order remains in effect, unless otherwise  
4031 modified by the department, until the criminal charge is disposed

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4032 of. The acquittal of the person charged, or the final, unappealed  
4033 dismissal of all charges against the person, dissolves the  
4034 emergency order but does not prohibit the department from  
4035 instituting proceedings under paragraph (a). If the person  
4036 charged is convicted or pleads guilty or nolo contendere, whether  
4037 or not an adjudication of guilt is entered by the court, the  
4038 emergency order shall become final.

4039 (f) Any affiliated party removed pursuant to this section  
4040 is not eligible for reemployment by the permittee or to be an  
4041 affiliated party of any permittee except upon the written consent  
4042 of the department. Any affiliated party who is removed,  
4043 restricted, or prohibited from participating in the affairs of a  
4044 permittee pursuant to this section may petition the department  
4045 for modification or termination of the removal, restriction, or  
4046 prohibition.

4047 Section 37. Section 499.067, Florida Statutes, is amended  
4048 to read:

4049 499.067 Denial, suspension, or revocation of permit,  
4050 certification, or registration.--

4051 (1)(a) The department may deny, suspend, or revoke a permit  
4052 if it finds that there has been a substantial failure to comply  
4053 with this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501,  
4054 or chapter 893, the rules adopted under this part ~~any of those~~  
4055 ~~sections~~ or those chapters, any final order of the department, or  
4056 applicable federal laws or regulations or other state laws or  
4057 rules governing drugs, devices, or cosmetics.

4058 (b) The department may deny an application for a permit or  
4059 certification, or suspend or revoke a permit or certification, if  
4060 the department finds that:

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4061 1. The applicant is not of good moral character or that it  
4062 would be a danger or not in the best interest of the public  
4063 health, safety, and welfare if the applicant were issued a permit  
4064 or certification.

4065 2. The applicant has not met the requirements for the  
4066 permit or certification.

4067 3. The applicant is not eligible for a permit or  
4068 certification for any of the reasons enumerated in s. 499.012 ~~s.~~  
4069 ~~499.01~~ or ~~s. 499.012(5)~~.

4070 4. The applicant, permittee, or person certified under s.  
4071 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions  
4072 enumerated in s. 499.012 ~~s. 499.01~~ or ~~s. 499.012(5)~~.

4073 5. The applicant, permittee, or person certified under s.  
4074 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.  
4075 499.005-499.0054.

4076 (2) The department may deny, suspend, or revoke any  
4077 registration required by the provisions of this part ~~ss. 499.001-~~  
4078 ~~499.081~~ for the violation of any provision of this part ~~ss.~~  
4079 ~~499.001-499.081~~ or of any rules adopted under this part ~~those~~  
4080 ~~sections~~.

4081 (3) The department may revoke or suspend a permit:

4082 (a) If the permit was obtained by misrepresentation or  
4083 fraud or through a mistake of the department;

4084 (b) If the permit was procured, or attempted to be  
4085 procured, for any other person by making or causing to be made  
4086 any false representation; or

4087 (c) If the permittee has violated any provision of this  
4088 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~those~~  
4089 ~~sections~~.

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4090 (4) If any permit issued under this part ~~ss. 499.001-~~  
4091 ~~499.081~~ is revoked or suspended, the owner, manager, operator, or  
4092 proprietor of the establishment shall cease to operate as the  
4093 permit authorized, from the effective date of the suspension or  
4094 revocation until the person is again registered with the  
4095 department and possesses the required permit. If a permit is  
4096 revoked or suspended, the owner, manager, or proprietor shall  
4097 remove all signs and symbols that identify the operation as  
4098 premises permitted as a drug wholesaling establishment; drug,  
4099 device, or cosmetic manufacturing establishment; or retail  
4100 establishment. The department shall determine the length of time  
4101 for which the permit is to be suspended. If a permit is revoked,  
4102 the person that owns or operates the establishment may not apply  
4103 for any permit under this part ~~ss. 499.001-499.081~~ for a period  
4104 of 1 year after the date of the revocation. A revocation of a  
4105 permit may be permanent if the department considers that to be in  
4106 the best interest of the public health.

4107 (5) The department may deny, suspend, or revoke a permit  
4108 issued under this part ~~ss. 499.001-499.081~~ which authorizes the  
4109 permittee to purchase prescription drugs, if any owner, officer,  
4110 employee, or other person who participates in administering or  
4111 operating the establishment has been found guilty of any  
4112 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,  
4113 chapter 501, or chapter 893, any rules adopted under this part  
4114 ~~any of those sections~~ or those chapters, or any federal or state  
4115 drug law, regardless of whether the person has been pardoned, had  
4116 her or his civil rights restored, or had adjudication withheld.

4117 (6) The department shall deny, suspend, or revoke the  
4118 permit of any person or establishment if the assignment, sale,

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4119 transfer, or lease of an establishment permitted under this part  
4120 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil  
4121 action, or criminal prosecution.

4122 (7) Notwithstanding s. 120.60(5), if a permittee fails to  
4123 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may revoke  
4124 the permit of the permittee and shall provide notice of the  
4125 intended agency action by posting a notice at the department's  
4126 headquarters and by mailing a copy of the notice of intended  
4127 agency action by certified mail to the most recent mailing  
4128 address on record with the department and, if the permittee is  
4129 not a natural person, to the permittee's registered agent on file  
4130 with the Department of State.

4131 Section 38. Paragraph (a) of subsection (1) of section  
4132 409.9201, Florida Statutes, is amended to read:

4133 409.9201 Medicaid fraud.--

4134 (1) As used in this section, the term:

4135 (a) "Prescription Legend drug ~~Legend drug~~" means any drug, including,  
4136 but not limited to, finished dosage forms or active ingredients  
4137 that are subject to, defined by, or described by s. 503(b) of the  
4138 Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s.  
4139 499.007(13) ~~s. 499.007(12)~~, or s. 499.003(45) or (52) ~~s.~~  
4140 ~~499.0122(1)(b) or (c).~~

4141  
4142 The value of individual items of the legend drugs or goods or  
4143 services involved in distinct transactions committed during a  
4144 single scheme or course of conduct, whether involving a single  
4145 person or several persons, may be aggregated when determining the  
4146 punishment for the offense.

4147 Section 39. Paragraph (c) of subsection (9) of section

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4148 460.403, Florida Statutes, is amended to read:

4149 460.403 Definitions.--As used in this chapter, the term:

4150 (9)

4151 (c)1. Chiropractic physicians may adjust, manipulate, or  
4152 treat the human body by manual, mechanical, electrical, or  
4153 natural methods; by the use of physical means or physiotherapy,  
4154 including light, heat, water, or exercise; by the use of  
4155 acupuncture; or by the administration of foods, food  
4156 concentrates, food extracts, and items for which a prescription  
4157 is not required and may apply first aid and hygiene, but  
4158 chiropractic physicians are expressly prohibited from prescribing  
4159 or administering to any person any legend drug except as  
4160 authorized under subparagraph 2., from performing any surgery  
4161 except as stated herein, or from practicing obstetrics.

4162 2. Notwithstanding the prohibition against prescribing and  
4163 administering legend drugs under subparagraph 1. ~~r~~ or s.

4164 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic  
4165 physicians may order, store, and administer, for emergency  
4166 purposes only at the chiropractic physician's office or place of  
4167 business, prescription medical oxygen and may also order, store,  
4168 and administer the following topical anesthetics in aerosol form:

4169 a. Any solution consisting of 25 percent ethylchloride and  
4170 75 percent dichlorodifluoromethane.

4171 b. Any solution consisting of 15 percent  
4172 dichlorodifluoromethane and 85 percent  
4173 trichloromonofluoromethane.

4174

4175 However, this paragraph does not authorize a chiropractic  
4176 physician to prescribe medical oxygen as defined in chapter 499.



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4177 Section 40. Subsection (3) of section 465.0265, Florida  
4178 Statutes, is amended to read:

4179 465.0265 Centralized prescription filling.--

4180 (3) The filling, delivery, and return of a prescription by  
4181 one pharmacy for another pursuant to this section shall not be  
4182 construed as the filling of a transferred prescription as set  
4183 forth in s. 465.026 or as a wholesale distribution as set forth  
4184 in s. 499.003(53) ~~s. 499.012(1)(a)~~.

4185 Section 41. Section 794.075, Florida Statutes, is amended  
4186 to read:

4187 794.075 Sexual predators; erectile dysfunction drugs.--

4188 (1) A person may not possess a prescription drug, as  
4189 defined in s. 499.003(42) ~~s. 499.003(25)~~, for the purpose of  
4190 treating erectile dysfunction if the person is designated as a  
4191 sexual predator under s. 775.21.

4192 (2) A person who violates a provision of this section for  
4193 the first time commits a misdemeanor of the second degree,  
4194 punishable as provided in s. 775.082 or s. 775.083. A person who  
4195 violates a provision of this section a second or subsequent time  
4196 commits a misdemeanor of the first degree, punishable as provided  
4197 in s. 775.082 or s. 775.083.

4198 Section 42. Paragraph (a) of subsection (1) of section  
4199 895.02, Florida Statutes, is amended to read:

4200 895.02 Definitions.--As used in ss. 895.01-895.08, the  
4201 term:

4202 (1) "Racketeering activity" means to commit, to attempt to  
4203 commit, to conspire to commit, or to solicit, coerce, or  
4204 intimidate another person to commit:

4205 (a) Any crime that is chargeable by indictment or

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4206 information under the following provisions of the Florida  
4207 Statutes:

- 4208 1. Section 210.18, relating to evasion of payment of  
4209 cigarette taxes.
- 4210 2. Section 403.727(3)(b), relating to environmental  
4211 control.
- 4212 3. Section 409.920 or s. 409.9201, relating to Medicaid  
4213 fraud.
- 4214 4. Section 414.39, relating to public assistance fraud.
- 4215 5. Section 440.105 or s. 440.106, relating to workers'  
4216 compensation.
- 4217 6. Section 443.071(4), relating to creation of a fictitious  
4218 employer scheme to commit unemployment compensation fraud.
- 4219 7. Section 465.0161, relating to distribution of medicinal  
4220 drugs without a permit as an Internet pharmacy.
- 4221 8. Section 499.0051 ~~Sections 499.0051, 499.0052, 499.00535,~~  
4222 ~~499.00545, and 499.0691,~~ relating to crimes involving contraband  
4223 and adulterated drugs.
- 4224 9. Part IV of chapter 501, relating to telemarketing.
- 4225 10. Chapter 517, relating to sale of securities and  
4226 investor protection.
- 4227 11. Section 550.235, s. 550.3551, or s. 550.3605, relating  
4228 to dogracing and horseracing.
- 4229 12. Chapter 550, relating to jai alai frontons.
- 4230 13. Section 551.109, relating to slot machine gaming.
- 4231 14. Chapter 552, relating to the manufacture, distribution,  
4232 and use of explosives.
- 4233 15. Chapter 560, relating to money transmitters, if the  
4234 violation is punishable as a felony.

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- 4235 16. Chapter 562, relating to beverage law enforcement.
- 4236 17. Section 624.401, relating to transacting insurance
- 4237 without a certificate of authority, s. 624.437(4)(c)1., relating
- 4238 to operating an unauthorized multiple-employer welfare
- 4239 arrangement, or s. 626.902(1)(b), relating to representing or
- 4240 aiding an unauthorized insurer.
- 4241 18. Section 655.50, relating to reports of currency
- 4242 transactions, when such violation is punishable as a felony.
- 4243 19. Chapter 687, relating to interest and usurious
- 4244 practices.
- 4245 20. Section 721.08, s. 721.09, or s. 721.13, relating to
- 4246 real estate timeshare plans.
- 4247 21. Chapter 782, relating to homicide.
- 4248 22. Chapter 784, relating to assault and battery.
- 4249 23. Chapter 787, relating to kidnapping or human
- 4250 trafficking.
- 4251 24. Chapter 790, relating to weapons and firearms.
- 4252 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.
- 4253 796.05, or s. 796.07, relating to prostitution and sex
- 4254 trafficking.
- 4255 26. Chapter 806, relating to arson.
- 4256 27. Section 810.02(2)(c), relating to specified burglary of
- 4257 a dwelling or structure.
- 4258 28. Chapter 812, relating to theft, robbery, and related
- 4259 crimes.
- 4260 29. Chapter 815, relating to computer-related crimes.
- 4261 30. Chapter 817, relating to fraudulent practices, false
- 4262 pretenses, fraud generally, and credit card crimes.
- 4263 31. Chapter 825, relating to abuse, neglect, or

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4264 exploitation of an elderly person or disabled adult.  
4265 32. Section 827.071, relating to commercial sexual  
4266 exploitation of children.  
4267 33. Chapter 831, relating to forgery and counterfeiting.  
4268 34. Chapter 832, relating to issuance of worthless checks  
4269 and drafts.  
4270 35. Section 836.05, relating to extortion.  
4271 36. Chapter 837, relating to perjury.  
4272 37. Chapter 838, relating to bribery and misuse of public  
4273 office.  
4274 38. Chapter 843, relating to obstruction of justice.  
4275 39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or  
4276 s. 847.07, relating to obscene literature and profanity.  
4277 40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.  
4278 849.25, relating to gambling.  
4279 41. Chapter 874, relating to criminal street gangs.  
4280 42. Chapter 893, relating to drug abuse prevention and  
4281 control.  
4282 43. Chapter 896, relating to offenses related to financial  
4283 transactions.  
4284 44. Sections 914.22 and 914.23, relating to tampering with  
4285 a witness, victim, or informant, and retaliation against a  
4286 witness, victim, or informant.  
4287 45. Sections 918.12 and 918.13, relating to tampering with  
4288 jurors and evidence.  
4289 Section 43. Paragraphs (d), (f), (h), (i), and (j) of  
4290 subsection (3) of section 921.0022, Florida Statutes, are amended  
4291 to read:  
4292 921.0022 Criminal Punishment Code; offense severity ranking

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4293	chart.--		
4294	(3)	OFFENSE SEVERITY RANKING CHART	
4295	(d)	LEVEL 4	
4296			
	Florida	Felony	Description
	Statute	Degree	
4297			
	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.
4298			
	499.0051(1)	3rd	Failure to maintain or deliver pedigree papers.
4299			
	499.0051(2)	3rd	Failure to authenticate pedigree papers.
4300			
	499.0051(6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband <u>prescription</u> <del>legend</del> drugs.
4301			
	784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4302			
	784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
4303			

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4304	784.075	3rd	Battery on detention or commitment facility staff.
4305	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
4306	784.08 (2) (c)	3rd	Battery on a person 65 years of age or older.
4307	784.081 (3)	3rd	Battery on specified official or employee.
4308	784.082 (3)	3rd	Battery by detained person on visitor or other detainee.
4309	784.083 (3)	3rd	Battery on code inspector.
4310	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
4311	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
4312	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.

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4313	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4314	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4315	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
4316	790.115 (2) (c)	3rd	Possessing firearm on school property.
4317	800.04 (7) (d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4318	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
4319	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
4320	810.06	3rd	Burglary; possession of tools.
	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.

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4321	812.014(2)(c)3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4322	812.014(2)(c)4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4323	812.0195(2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4324	817.563(1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
4325	817.568(2)(a)	3rd	Fraudulent use of personal identification information.
4326	817.625(2)(a)	3rd	Fraudulent use of scanning device or reencoder.
4327	828.125(1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
4328	837.02(1)	3rd	Perjury in official proceedings.
4329	837.021(1)	3rd	Make contradictory statements in official proceedings.



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4330	838.022	3rd	Official misconduct.
4331	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4332	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4333	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4334	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
4335	843.15 (1) (a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
4336	874.05 (1)	3rd	Encouraging or recruiting another to join a criminal street gang.
4337	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).
4338	914.14 (2)	3rd	Witnesses accepting bribes.
4339			

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4340	914.22 (1)	3rd	Force, threaten, etc., witness, victim, or informant.
4341	914.23 (2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4342	918.12	3rd	Tampering with jurors.
4343	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
4344	(f) LEVEL 6		
4345			
4346	Florida Statute	Felony Degree	Description
4347	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
4348	499.0051 (3)	2nd	<u>Knowing</u> forgery of pedigree papers.
4349	499.0051 (4)	2nd	<u>Knowing</u> purchase or receipt of <u>prescription</u> <del>legend</del> drug from unauthorized person.
4350	499.0051 (5)	2nd	<u>Knowing</u> sale <u>or transfer</u> of <u>prescription</u> <del>legend</del> drug to unauthorized person.
	775.0875 (1)	3rd	Taking firearm from law enforcement

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officer.

4351			officer.
	784.021 (1) (a)	3rd	Aggravated assault; deadly weapon without intent to kill.
4352			
	784.021 (1) (b)	3rd	Aggravated assault; intent to commit felony.
4353			
	784.041	3rd	Felony battery; domestic battery by strangulation.
4354			
	784.048 (3)	3rd	Aggravated stalking; credible threat.
4355			
	784.048 (5)	3rd	Aggravated stalking of person under 16.
4356			
	784.07 (2) (c)	2nd	Aggravated assault on law enforcement officer.
4357			
	784.074 (1) (b)	2nd	Aggravated assault on sexually violent predators facility staff.
4358			
	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
4359			
	784.081 (2)	2nd	Aggravated assault on specified official or employee.
4360			
	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.

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4361	784.083 (2)	2nd	Aggravated assault on code inspector.
4362	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4363	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
4364	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
4365	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
4366	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
4367	794.011 (8) (a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
4368	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
4369	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.

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4370	800.04 (6) (b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
4371	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
4372	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
4373	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
4374	812.014 (6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.
4375	812.015 (9) (a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
4376	812.015 (9) (b)	2nd	Retail theft; property stolen \$3,000 or more; coordination of others.
4377	812.13 (2) (c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
4378	817.034 (4) (a) 1.	1st	Communications fraud, value greater than \$50,000.
4379			

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4380	817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
4381	825.102(1)	3rd	Abuse of an elderly person or disabled adult.
4382	825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
4383	825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
4384	825.103(2)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4385	827.03(1)	3rd	Abuse of a child.
4386	827.03(3)(c)	3rd	Neglect of a child.
4387	827.071(2)&(3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
4388	836.05	2nd	Threats; extortion.
	836.10	2nd	Written threats to kill or do bodily injury.

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4389	843.12	3rd	Aids or assists person to escape.
4390	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
4391	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
4392	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.
4393	944.40	2nd	Escapes.
4394	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
4395	944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
4396	951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
4397			
4398	(h)	LEVEL 8	

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4399	Florida Statute	Felony Degree	Description
4400	316.193 (3) (c) 3.a.	2nd	DUI manslaughter.
4401	316.1935 (4) (b)	1st	Aggravated fleeing or attempted eluding with serious bodily injury or death.
4402	327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
4403	<u>499.0051 (8)</u> <del>499.0051 (7)</del>	1st	<u>Knowing</u> forgery of prescription labels or <u>prescription</u> legend drug labels.
4404	<u>499.0051 (7)</u> <del>499.0052</del>	1st	<u>Knowing</u> trafficking in contraband <u>prescription</u> legend drugs.
4405	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.
4406	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.



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4407	655.50 (10) (b) 2.	2nd	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by financial institutions.
4408	777.03 (2) (a)	1st	Accessory after the fact, capital felony.
4409	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.
4410	782.051 (2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04 (3).
4411	782.071 (1) (b)	1st	Committing vehicular homicide and failing to render aid or give information.
4412	782.072 (2)	1st	Committing vessel homicide and failing to render aid or give information.
4413			

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4414	790.161 (3)	1st	Discharging a destructive device which results in bodily harm or property damage.
4415	794.011 (5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.
4416	794.08 (3)	2nd	Female genital mutilation, removal of a victim younger than 18 years of age from this state.
4417	800.04 (4)	2nd	Lewd or lascivious battery.
4418	806.01 (1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4419	810.02 (2) (a)	1st, PBL	Burglary with assault or battery.
4420	810.02 (2) (b)	1st, PBL	Burglary; armed with explosives or dangerous weapon.
4421	810.02 (2) (c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
	812.014 (2) (a) 2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st

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			degree.
4422			
	812.13 (2) (b)	1st	Robbery with a weapon.
4423			
	812.135 (2) (c)	1st	Home-invasion robbery, no firearm, deadly weapon, or other weapon.
4424			
	817.568 (6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4425			
	825.102 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4426			
	825.1025 (2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4427			
	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4428			
	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4429			
	837.021 (2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.
4430			

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4431	860.121(2)(c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
4432	860.16	1st	Aircraft piracy.
4433	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).
4434	893.13(2)(b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4435	893.13(6)(c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4436	893.135(1)(a)2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
4437	893.135(1)(b)1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
4438	893.135(1)(c)1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.
	893.135(1)(d)1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.

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4439	893.135(1)(e)1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
4440	893.135(1)(f)1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4441	893.135(1)(g)1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4442	893.135(1)(h)1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4443	893.135(1)(j)1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4444	893.135(1)(k)2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4445	895.03(1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
4446	895.03(2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.

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4447	895.03 (3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.
4448	896.101 (5) (b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
4449	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.
4450			
4451	(i) LEVEL 9		
4452			
	Florida Statute	Felony Degree	Description
4453	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
4454	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
4455	<u>499.0051 (9)</u> <del>499.00535</del>	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> <del>legend</del> drugs resulting in great bodily harm.

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4456	560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
4457	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
4458	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4459	775.0844	1st	Aggravated white collar crime.
4460	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
4461	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4462	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3).
4463			

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4464	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
4465	787.01 (1) (a) 1.	1st, PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
4466	787.01 (1) (a) 2.	1st, PBL	Kidnapping with intent to commit or facilitate commission of any felony.
4467	787.01 (1) (a) 4.	1st, PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
4468	787.02 (3) (a)	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
4469	790.161	1st	Attempted capital destructive device offense.
4470	790.166 (2)	1st, PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.



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4471	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
4472	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4473	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
4474	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4475	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4476	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4477	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
4478	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4479	817.568 (7)	2nd, PBL	Fraudulent use of personal

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			identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.
4480	827.03 (2)	1st	Aggravated child abuse.
4481	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
4482	847.0145 (2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
4483	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.
4484	893.135	1st	Attempted capital trafficking offense.
4485	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
4486	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4487			

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4488	893.135(1)(c)1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4489	893.135(1)(d)1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
4490	893.135(1)(e)1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4491	893.135(1)(f)1.c.	1st	Trafficking in amphetamine, more than 200 grams.
4492	893.135(1)(h)1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
4493	893.135(1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
4494	893.135(1)(k)2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
4495	896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
	896.104(4)(a)3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions

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totaling or exceeding \$100,000.

4496

4497 (j) LEVEL 10

4498

Florida	Felony	Description
Statute	Degree	

4499

<u>499.0051(10)</u>	1st	<u>Knowing</u> sale or purchase of contraband
<del>499.00545</del>		<u>prescription</u> <del>legend</del> drugs resulting in
		death.

4500

782.04(2)	1st,PBL	Unlawful killing of human; act is
		homicide, unpremeditated.

4501

787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or
		terrorize victim.

4502

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.

4503

782.07(3)	1st	Aggravated manslaughter of a child.
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4504

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.

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4505

812.135 (2) (a) 1st, PBL Home-invasion robbery with firearm or  
other deadly weapon.

4506

876.32 1st Treason against the state.

4507

4508

Section 44. This act shall take effect July 1, 2008.