



181182

CHAMBER ACTION

<u>Senate</u>	.	<u>House</u>
Comm: RCS	.	
4/1/2008	.	
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1 The Committee on Health Regulation (Peaden) recommended the  
 2 following **amendment**:

3  
 4 **Senate Amendment (with title amendment)**

5 Delete everything after the enacting clause  
 6 and insert:

7 Section 1. Section 499.002, Florida Statutes, is amended;  
 8 section 499.004, Florida Statutes, is redesignated as subsection  
 9 (2) of that section and amended; section 499.0053, Florida  
 10 Statutes, is redesignated as subsection (3) of that section and  
 11 amended; section 499.07, Florida Statutes, is redesignated as  
 12 subsection (4) of that section and amended; section 499.071,  
 13 Florida Statutes, is redesignated as subsection (5) of that  
 14 section and amended; and section 499.081, Florida Statutes, is  
 15 redesignated as subsection (6) of that section and amended, to  
 16 read:

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17           499.002 Purpose, administration, and enforcement of and  
18 exemption from this part ss. 499.001-499.081.--

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

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

23           (b) ~~(2)~~ Provide uniform legislation to be administered so  
24 far as practicable in conformity with the provisions of, and  
25 regulations issued under the authority of, the Federal Food,  
26 Drug, and Cosmetic Act and that portion of the Federal Trade  
27 Commission Act which expressly prohibits the false advertisement  
28 of drugs, devices, and cosmetics.

29           (c) ~~(3)~~ Promote thereby uniformity of such state and federal  
30 laws, and their administration and enforcement, throughout the  
31 United States.

32           (2) ~~499.004 Administration and enforcement by~~  
33 ~~department.~~--The department of Health shall administer and  
34 enforce this part ss. 499.001-499.081 to prevent fraud,  
35 adulteration, misbranding, or false advertising in the  
36 preparation, manufacture, repackaging, or distribution of drugs,  
37 devices, and cosmetics.

38           (3) ~~499.0053 Power to administer oaths, take depositions,~~  
39 ~~and issue and serve subpoenas.~~--For the purpose of any  
40 investigation or proceeding conducted by the department under  
41 this part ss. 499.001-499.081, the department may administer  
42 oaths, take depositions, issue and serve subpoenas, and compel  
43 the attendance of witnesses and the production of books, papers,  
44 documents, or other evidence. The department shall exercise this  
45 power on its own initiative. Challenges to, and enforcement of,



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46 the subpoenas and orders shall be handled as provided in s.  
47 120.569.

48 (4) ~~499.07 Duty of prosecuting officer.~~ Each state  
49 attorney, county attorney, or municipal attorney to whom the  
50 department or its designated agent reports any violation of this  
51 part ss. 499.001-499.081 shall cause appropriate proceedings to  
52 be instituted in the proper courts without delay and to be  
53 prosecuted in the manner required by law.

54 (5) ~~499.071 Issuance of warnings for minor~~  
55 ~~violations.~~ This part does Sections ~~499.001-499.081~~ do not  
56 require the department to report, for the institution of  
57 proceedings under this part ss. 499.001-499.081, minor violations  
58 of this part ss. 499.001-499.081 when it believes that the public  
59 interest will be adequately served in the circumstances by a  
60 suitable written notice or warning.

61 (6) ~~499.081 Carriers in interstate commerce exempted from~~  
62 ~~ss. 499.001-499.081.~~ Carriers engaged in interstate commerce are  
63 not subject to this part ss. 499.001-499.081 if they are engaged  
64 in the usual course of business as carriers.

65 Section 2. Section 499.003, Florida Statutes, is amended;  
66 paragraphs (a) through (f) of subsection (1) of section 499.012,  
67 Florida Statutes, are redesignated as subsections (55), (56),  
68 (52), and (48), paragraph (c) of subsection (48), and subsection  
69 (53), respectively, of that section and amended; paragraphs (f)  
70 through (j) and (l) through (n) of subsection (3) of section  
71 499.029, Florida Statutes, are redesignated as subsections (25),  
72 (23), (26), (27), (35), (40), (41), and (43), respectively, of  
73 that section and amended; and subsection (1) of section 499.0661,  
74 Florida Statutes, is redesignated as subsection (38) of that  
75 section and amended, to read:



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76 499.003 Definitions of terms used in this part ~~ss. 499.001-~~  
77 ~~499.081~~.--As used in this part ~~ss. 499.001-499.081~~, the term:

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

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

88 (3)~~(2)~~ "Affiliated party" means:

89 (a) A director, officer, trustee, partner, or committee  
90 member of a permittee or applicant or a subsidiary or service  
91 corporation of the permittee or applicant;

92 (b) A person who, directly or indirectly, manages,  
93 controls, or oversees the operation of a permittee or applicant,  
94 regardless of whether such person is a partner, shareholder,  
95 manager, member, officer, director, independent contractor, or  
96 employee of the permittee or applicant;

97 (c) A person who has filed or is required to file a  
98 personal information statement pursuant to s. 499.012(9) ~~s.~~  
99 ~~499.012(4)~~ or is required to be identified in an application for  
100 a permit or to renew a permit pursuant to s. 499.012(8) ~~s.~~  
101 ~~499.012(3)~~; or

102 (d) The five largest natural shareholders that own at least  
103 5 percent of the permittee or applicant.

104 (4)~~(3)~~ "Applicant" means a person applying for a permit or  
105 certification under this part ~~ss. 499.001-499.081~~.



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106        (5)(4)- "Authenticate" means to affirmatively verify upon  
107 receipt before any distribution of a prescription legend drug  
108 occurs that each transaction listed on the pedigree paper  
109 described in s. 499.01212(2)(b) has occurred. A wholesale  
110 distributor is not required to open a sealed, medical convenience  
111 kit to authenticate a pedigree paper for a prescription drug  
112 contained within the kit.

113        (6)(5)- "Certificate of free sale" means a document prepared  
114 by the department which certifies a drug, device, or cosmetic,  
115 that is registered with the department, as one that can be  
116 legally sold in the state.

117        (7) "Chain pharmacy warehouse" means a wholesale  
118 distributor permitted pursuant to s. 499.01 that maintains a  
119 physical location for prescription drugs that functions solely as  
120 a central warehouse to perform intracompany transfers of such  
121 drugs to a member of its affiliated group.

122        (8)(6)- "Closed pharmacy" means a pharmacy that is licensed  
123 under chapter 465 and purchases prescription drugs for use by a  
124 limited patient population and not for wholesale distribution or  
125 sale to the public. The term does not include retail pharmacies.

126        (9)(7)- "Color" includes black, white, and intermediate  
127 grays.

128        (10)(8)- "Color additive" means, with the exception of any  
129 material that has been or hereafter is exempt under the federal  
130 act, a material that:

131        (a) Is a dye pigment, or other substance, made by a process  
132 of synthesis or similar artifice, or extracted, isolated, or  
133 otherwise derived, with or without intermediate or final change  
134 of identity from a vegetable, animal, mineral, or other source;  
135 or

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

139  
140 ~~except that the term does not include any material which has been~~  
141 ~~or hereafter is exempt under the federal act.~~

142 (11)-(9) "Compressed medical gas" means any liquefied or  
143 vaporized gas that is a prescription drug, whether it is alone or  
144 in combination with other gases.

145 (12)-(10) "Contraband prescription ~~legend~~ drug" means any  
146 adulterated drug, as defined in s. 499.006, any counterfeit drug,  
147 as defined in this section, and also means any prescription  
148 ~~legend~~ drug for which a pedigree paper does not exist, or for  
149 which the pedigree paper in existence has been forged,  
150 counterfeited, falsely created, or contains any altered, false,  
151 or misrepresented matter.

152 (13)-(11) "Cosmetic" means an article, with the exception of  
153 soap, that is:

154 (a) Intended to be rubbed, poured, sprinkled, or sprayed  
155 on; introduced into; or otherwise applied to the human body or  
156 any part thereof for cleansing, beautifying, promoting  
157 attractiveness, or altering the appearance; or

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

159  
160 except that the term does not include soap.

161 (14)-(12) "Counterfeit drug," "counterfeit device," or  
162 "counterfeit drug, counterfeit device, or counterfeit cosmetic"  
163 means a drug, device, or cosmetic which, or the container, seal,  
164 or labeling of which, without authorization, bears the trademark,  
165 trade name, or other identifying mark, imprint, or device, or any

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166 likeness thereof, of a drug, device, or cosmetic manufacturer,  
167 processor, packer, or distributor other than the person that in  
168 fact manufactured, processed, packed, or distributed that drug,  
169 device, or cosmetic and which thereby falsely purports or is  
170 represented to be the product of, or to have been packed or  
171 distributed by, that other drug, device, or cosmetic  
172 manufacturer, processor, packer, or distributor.

173 ~~(15)-(13)~~ "Department" means the Department of Health.

174 ~~(16)-(14)~~ "Device" means any instrument, apparatus,  
175 implement, machine, contrivance, implant, in vitro reagent, or  
176 other similar or related article, including its components,  
177 parts, or accessories, which is:

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

180 (b) Intended for use in the diagnosis, cure, mitigation,  
181 treatment, therapy, or prevention of disease in humans or other  
182 animals, or

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

185

186 and that ~~which~~ does not achieve any of its principal intended  
187 purposes through chemical action within or on the body of humans  
188 or other animals and which is not dependent upon being  
189 metabolized for the achievement of any of its principal intended  
190 purposes.

191 ~~(17)-(15)~~ "Distribute or distribution" or "distribution"  
192 means to sell; offer to sell; give away; transfer, whether by  
193 passage of title, physical movement, or both; deliver; or offer  
194 to deliver. The term does not mean to administer or dispense.

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195        (18) "Drop shipment" means the sale of a prescription drug  
196 from a manufacturer to a wholesale distributor, where the  
197 wholesale distributor takes title to, but not possession of, the  
198 prescription drug and the manufacturer of the prescription drug  
199 ships the prescription drug directly to a chain pharmacy  
200 warehouse or a person authorized by law to purchase prescription  
201 drugs for the purpose of administering or dispensing the drug, as  
202 defined in s. 465.003.

203        ~~(16) "Diverted from the legal channels of distribution for~~  
204 ~~prescription drugs" means an adulterated drug pursuant to s.~~  
205 ~~499.006(10).~~

206        (19)~~(17)~~ "Drug" means an article that is:

207        (a) Recognized in the current edition of the United States  
208 Pharmacopoeia and National Formulary, official Homeopathic  
209 Pharmacopoeia of the United States, or any supplement to any of  
210 those publications;

211        (b) Intended for use in the diagnosis, cure, mitigation,  
212 treatment, therapy, or prevention of disease in humans or other  
213 animals;

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

216        (d) Intended for use as a component of any article  
217 specified in paragraph (a), paragraph (b), or paragraph (c), but  
218 does not include devices or their components, parts, or  
219 accessories.

220        (20)~~(18)~~ "Establishment" means a place of business at one  
221 general physical location.

222        (21)~~(19)~~ "Federal act" means the Federal Food, Drug, and  
223 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.





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224        ~~(22)-(20)~~ "Freight forwarder" means a person who receives  
225 prescription legend ~~legend~~ drugs which are owned by another person and  
226 designated by that person for export, and exports those  
227 prescription legend ~~legend~~ drugs.

228        ~~(23)-(9)~~ "Health care clinic" means a health care clinic  
229 licensed under part X of chapter 400.

230        ~~(24)-(21)~~ "Health care entity" means a closed pharmacy or  
231 any person, organization, or business entity that provides  
232 diagnostic, medical, surgical, or dental treatment or care, or  
233 chronic or rehabilitative care, but does not include any  
234 wholesale distributor or retail pharmacy licensed under state law  
235 to deal in prescription drugs.

236        ~~(25)-(f)~~ "Health care facility" means a health care facility  
237 licensed under chapter 395.

238        ~~(26)-(h)~~ "Hospice" means a corporation licensed under part  
239 IV of chapter 400.

240        ~~(27)-(i)~~ "Hospital" means a facility as defined in s.  
241 395.002 and licensed under chapter 395.

242        ~~(28)-(22)~~ "Immediate container" does not include package  
243 liners.

244        ~~(29)-(23)~~ "Label" means a display of written, printed, or  
245 graphic matter upon the immediate container of any drug, device,  
246 or cosmetic. A requirement made by or under authority of this  
247 part ss. 499.001-499.081 or rules adopted under this part ~~these~~  
248 ~~sections~~ that any word, statement, or other information appear on  
249 the label is not complied with unless such word, statement, or  
250 other information also appears on the outside container or  
251 wrapper, if any, of the retail package of such drug, device, or  
252 cosmetic or is easily legible through the outside container or  
253 wrapper.



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254        ~~(30)-(24)~~ "Labeling" means all labels and other written,  
255 printed, or graphic matters:

256            (a) Upon a drug, device, or cosmetic, or any of its  
257 containers or wrappers; or

258            (b) Accompanying or related to such drug, device, or  
259 cosmetic.

260        ~~(25) "Legend drug," "prescription drug," or "medicinal  
261 drug" means any drug, including, but not limited to, finished  
262 dosage forms, or active ingredients subject to, defined by, or  
263 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
264 Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or  
265 (c).~~

266        ~~(26) "Legend drug label" means any display of written,  
267 printed, or graphic matter upon the immediate container of any  
268 legend drug prior to its dispensing to an individual patient  
269 pursuant to a prescription of a practitioner authorized by law to  
270 prescribe.~~

271        ~~(31)-(27)~~ "Manufacture" means the preparation, deriving,  
272 compounding, propagation, processing, producing, or fabrication  
273 of any drug, device, or cosmetic.

274        ~~(32)-(28)~~ "Manufacturer" means a person who prepares,  
275 derives, manufactures, or produces a drug, device, or cosmetic.  
276 "Manufacturer" also means the holder or holders of a New Drug  
277 Application (NDA), an Abbreviated New Drug Application (ANDA), a  
278 Biologics License Application (BLA), or a New Animal Drug  
279 Application (NADA), provided that such application has become  
280 effective or is otherwise approved consistent with s. 499.023; a  
281 private label distributor for whom the private label  
282 distributor's prescription drugs are originally manufactured and  
283 labeled for the distributor and have not been repackaged; or the

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284 distribution point for the manufacturer, contract manufacturer or  
285 private label distributor whether the establishment is a member  
286 of the manufacturer's affiliated group or is a contract  
287 distribution site.

288  
289 The term excludes pharmacies that are operating in compliance  
290 with pharmacy practice standards as defined in chapter 465 and  
291 rules adopted under that chapter.

292 (33)-(29) "New drug" means:

293 (a) Any drug the composition of which is such that the drug  
294 is not generally recognized, among experts qualified by  
295 scientific training and experience to evaluate the safety and  
296 effectiveness of drugs, as safe and effective for use under the  
297 conditions prescribed, recommended, or suggested in the labeling  
298 of that drug; or

299 (b) Any drug the composition of which is such that the  
300 drug, as a result of investigations to determine its safety and  
301 effectiveness for use under certain conditions, has been  
302 recognized for use under such conditions, but which drug has not,  
303 other than in those investigations, been used to a material  
304 extent or for a material time under such conditions.

305 (34) "Normal distribution chain" means a wholesale  
306 distribution of a prescription drug where the wholesale  
307 distributor or its wholly owned subsidiary purchases and receives  
308 the specific unit of the prescription drug directly from the  
309 manufacturer and distributes the prescription drug directly, or  
310 through up to two intracompany transfers, to a chain pharmacy  
311 warehouse or a person authorized by law to purchase prescription  
312 drugs for the purpose of administering or dispensing the drug, as  
313 defined in s. 465.003. For purposes of this subsection,



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314 "intracompany transfer" means any transaction or transfer between  
315 any parent, division, or subsidiary wholly owned by a corporate  
316 entity.

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

319 ~~(36)(30)~~ "Official compendium" means the current edition of  
320 the official United States Pharmacopoeia and National Formulary,  
321 or any supplement thereto.

322 ~~(37)(31)~~ "Pedigree paper" means:

323 ~~(a) Effective July 1, 2006, a document in written or~~  
324 ~~electronic form approved by the department that contains of~~  
325 ~~Health and containing information required by s. 499.01212~~  
326 ~~regarding the sale and that records each distribution of any~~  
327 ~~given prescription legend drug., from sale by a pharmaceutical~~  
328 ~~manufacturer, through acquisition and sale by any wholesaler or~~  
329 ~~repackager, until final sale to a pharmacy or other person~~  
330 ~~administering or dispensing the drug. The information required to~~  
331 ~~be included on the form approved by the department pursuant to~~  
332 ~~this paragraph must at least detail the amount of the legend~~  
333 ~~drug; its dosage form and strength; its lot numbers; the name and~~  
334 ~~address of each owner of the legend drug and his or her~~  
335 ~~signature; its shipping information, including the name and~~  
336 ~~address of each person certifying delivery or receipt of the~~  
337 ~~legend drug; an invoice number, a shipping document number, or~~  
338 ~~another number uniquely identifying the transaction; and a~~  
339 ~~certification that the recipient wholesaler has authenticated the~~  
340 ~~pedigree papers. If the manufacturer or repackager has uniquely~~  
341 ~~serialized the individual legend drug unit, that identifier must~~  
342 ~~also be included on the form approved pursuant to this paragraph.~~  
343 ~~It must also include the name, address, telephone number and, if~~



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344 ~~available, e-mail contact information of each wholesaler involved~~  
345 ~~in the chain of the legend drug's custody; or~~

346 ~~(b) A statement, under oath, in written or electronic form,~~  
347 ~~confirming that a wholesale distributor purchases and receives~~  
348 ~~the specific unit of the prescription drug directly from the~~  
349 ~~manufacturer of the prescription drug and distributes the~~  
350 ~~prescription drug directly, or through an intracompany transfer,~~  
351 ~~to a chain pharmacy warehouse or a person authorized by law to~~  
352 ~~purchase prescription drugs for the purpose of administering or~~  
353 ~~dispensing the drug, as defined in s. 465.003. For purposes of~~  
354 ~~this subsection, the term "chain pharmacy warehouse" means a~~  
355 ~~wholesale distributor permitted pursuant to s. 499.01 that~~  
356 ~~maintains a physical location for prescription drugs that~~  
357 ~~functions solely as a central warehouse to perform intracompany~~  
358 ~~transfers of such drugs to a member of its affiliated group as~~  
359 ~~described in s. 499.0121(6)(f)1.~~

360 ~~1. The information required to be included pursuant to this~~  
361 ~~paragraph must include:~~

362 ~~a. The following statement: "This wholesale distributor~~  
363 ~~purchased the specific unit of the prescription drug directly~~  
364 ~~from the manufacturer."~~

365 ~~b. The manufacturer's national drug code identifier and the~~  
366 ~~name and address of the wholesaler and the purchaser of the~~  
367 ~~prescription drug.~~

368 ~~e. The name of the prescription drug as it appears on the~~  
369 ~~label.~~

370 ~~d. The quantity, dosage form, and strength of the~~  
371 ~~prescription drug.~~

372 ~~2. The wholesale distributor must also maintain and make~~  
373 ~~available to the department, upon request, the point of origin of~~

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374 ~~the prescription drugs, including intracompany transfers; the~~  
375 ~~date of the shipment from the manufacturer to the wholesale~~  
376 ~~distributor; the lot numbers of such drugs; and the invoice~~  
377 ~~numbers from the manufacturer.~~

378

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

381 ~~(38)(1) DEFINITION. As used in this section, the term~~  
382 ~~"Permittee" means any person holding a permit issued pursuant to~~  
383 ~~s. 499.012.~~

384 ~~(39)(32)~~ "Person" means any individual, child, joint  
385 venture, syndicate, fiduciary, partnership, corporation, division  
386 of a corporation, firm, trust, business trust, company, estate,  
387 public or private institution, association, organization, group,  
388 city, county, city and county, political subdivision of this  
389 state, other governmental agency within this state, and any  
390 representative, agent, or agency of any of the foregoing, or any  
391 other group or combination of the foregoing.

392 (40) "Person authorized by law" to "purchase," "posses,"  
393 "administer" or "receive" prescription or legend drugs means:

394 (a) A person authorized by law to administer the drug, as  
395 defined in s. 465.003; and

396 (b) An entity of which a person authorized by law to  
397 administer the drug, as defined in s. 465.003, is a member,  
398 officer, employee or agent, including but not limited to, a  
399 professional corporation or a professional limited liability  
400 company described in chapter 621 of the Business Organizations  
401 Code, provided that:



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402       1. The entity provides to the seller of the drug with a  
403 copy of the license under which the person authorized to  
404 administer the drug may purchase the drug;

405       2. The entity designates, to the seller of the drug, a  
406 person employed by the entity who will be responsible for  
407 complying with all legal and regulatory requirements with respect  
408 to the purchase, storage and handling of the drug; and

409       3. If the entity fails to designate the person described in  
410 subparagraph 2., the person whose license was provided to the  
411 seller under subparagraph 1. is deemed the person responsible for  
412 complying with all legal and regulatory requirements with respect  
413 to the purchase, storage and handling of the drug.

414       ~~(41)-(l)~~ "Pharmacist" means a person licensed under chapter  
415 465.

416       ~~(42)-(m)~~ "Pharmacy" means an entity licensed under chapter  
417 465.

418       ~~(43)-(33)~~ "Prepackaged drug product" means a drug that  
419 originally was in finished packaged form sealed by a manufacturer  
420 and that is placed in a properly labeled container by a pharmacy  
421 or practitioner authorized to dispense pursuant to chapter 465  
422 for the purpose of dispensing in the establishment in which the  
423 prepackaging occurred.

424       ~~(44)-(n)~~ "Prescribing practitioner" means a physician  
425 licensed under chapter 458 or chapter 459 or any other medical  
426 professional with authority under state law to prescribe cancer  
427 medication.

428       (45) "Prescription drug" means a prescription, medicinal,  
429 or legend drug, including, but not limited to, finished dosage  
430 forms or active ingredients subject to, defined by, or described  
431 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s.

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432 465.003(8), s. 499.007(13), or subsection (11), subsection (48),  
433 or subsection (55).

434 (46) "Prescription drug label" means any display of  
435 written, printed, or graphic matter upon the immediate container  
436 of any prescription drug prior to its dispensing to an individual  
437 patient pursuant to a prescription of a practitioner authorized  
438 by law to prescribe.

439 (47)-(34) "Prescription label" means any display of written,  
440 printed, or graphic matter upon the immediate container of any  
441 prescription ~~legend~~ drug dispensed pursuant to a prescription of  
442 a practitioner authorized by law to prescribe.

443 (48)-(35) "Prescription medical oxygen" means oxygen USP  
444 which is a drug that can only be sold on the order or  
445 prescription of a practitioner authorized by law to prescribe.  
446 The label of prescription medical oxygen must comply with current  
447 labeling requirements for oxygen under the Federal Food, Drug,  
448 and Cosmetic Act.

449 (49)-(d) "Primary wholesale distributor ~~wholesaler~~" means  
450 any wholesale distributor that:

451 (a)1- Purchased 90 percent or more of the total dollar  
452 volume of its purchases of prescription drugs directly from  
453 manufacturers in the previous year; and

454 (b)1.2.a- Directly purchased prescription drugs from not  
455 fewer than 50 different prescription drug manufacturers in the  
456 previous year; or

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

460 (c)-(e) For purposes of this subsection, "directly from  
461 manufacturers ~~a manufacturer~~" means:



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

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

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

470 b. The wholesale distributor discloses to the department  
471 the names of all members of the affiliated group of which the  
472 wholesale distributor is a member and the affiliated group agrees  
473 in writing to provide records on prescription drug purchases by  
474 the members of the affiliated group not later than 48 hours after  
475 the department requests access to such records, regardless of the  
476 location where the records are stored.

477 ~~(50)-(36)~~ "Proprietary drug," or "OTC drug," means a patent  
478 or over-the-counter drug in its unbroken, original package, which  
479 drug is sold to the public by, or under the authority of, the  
480 manufacturer or primary distributor thereof, is not misbranded  
481 under the provisions of this part ~~ss. 499.001-499.081~~, and can be  
482 purchased without a prescription.

483 ~~(51)-(37)~~ "Repackage" includes repacking or otherwise  
484 changing the container, wrapper, or labeling to further the  
485 distribution of the drug, device, or cosmetic.

486 ~~(52)-(38)~~ "Repackager" means a person who repackages. The  
487 term excludes pharmacies that are operating in compliance with  
488 pharmacy practice standards as defined in chapter 465 and rules  
489 adopted under that chapter.

490 ~~(53)-(e)~~ "Retail pharmacy" means a community pharmacy  
491 licensed under chapter 465 that purchases prescription drugs at

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492 fair market prices and provides prescription services to the  
493 public.

494 ~~(54)(f)~~ "Secondary wholesale distributor ~~wholesaler~~" means  
495 a wholesale distributor that is not a primary wholesale  
496 distributor ~~wholesaler~~.

497 ~~(55)(39)~~ "Veterinary prescription drug" means a  
498 prescription ~~legend~~ drug intended solely for veterinary use. The  
499 label of the drug must bear the statement, "Caution: Federal law  
500 restricts this drug to sale by or on the order of a licensed  
501 veterinarian."

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

505 ~~(56)(a)~~ "Wholesale distribution" means distribution of  
506 prescription drugs to persons other than a consumer or patient,  
507 but does not include:

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

511 ~~1.a.~~ The purchase or other acquisition by a hospital or  
512 other health care entity that is a member of a group purchasing  
513 organization of a prescription drug for its own use from the  
514 group purchasing organization or from other hospitals or health  
515 care entities that are members of that organization.

516 ~~2.b.~~ The sale, purchase, or trade of a prescription drug or  
517 an offer to sell, purchase, or trade a prescription drug by a  
518 charitable organization described in s. 501(c)(3) of the Internal  
519 Revenue Code of 1986, as amended and revised, to a nonprofit  
520 affiliate of the organization to the extent otherwise permitted  
521 by law.



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522        ~~3.e.~~ The sale, purchase, or trade of a prescription drug or  
523 an offer to sell, purchase, or trade a prescription drug among  
524 hospitals or other health care entities that are under common  
525 control. For purposes of this subparagraph ~~section~~, "common  
526 control" means the power to direct or cause the direction of the  
527 management and policies of a person or an organization, whether  
528 by ownership of stock, by voting rights, by contract, or  
529 otherwise.

530        ~~4.d.~~ The sale, purchase, trade, or other transfer of a  
531 prescription drug from or for any federal, state, or local  
532 government agency or any entity eligible to purchase prescription  
533 drugs at public health services prices pursuant to Pub. L. No.  
534 102-585, s. 602 to a contract provider or its subcontractor for  
535 eligible patients of the agency or entity under the following  
536 conditions:

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

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

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

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

548        ~~e.(V)~~ The contract provider and subcontractor must maintain  
549 and produce immediately for inspection all records of movement or  
550 transfer of all the prescription drugs belonging to the agency or  
551 entity, including, but not limited to, the records of receipt and



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552 disposition of prescription drugs. Each contractor and  
553 subcontractor dispensing or administering these drugs must  
554 maintain and produce records documenting the dispensing or  
555 administration. Records that are required to be maintained  
556 include, but are not limited to, a perpetual inventory itemizing  
557 drugs received and drugs dispensed by prescription number or  
558 administered by patient identifier, which must be submitted to  
559 the agency or entity quarterly.

560 ~~f.(VI)~~ The contract provider or subcontractor may  
561 administer or dispense the prescription drugs only to the  
562 eligible patients of the agency or entity or must return the  
563 prescription drugs for or to the agency or entity. The contract  
564 provider or subcontractor must require proof from each person  
565 seeking to fill a prescription or obtain treatment that the  
566 person is an eligible patient of the agency or entity and must,  
567 at a minimum, maintain a copy of this proof as part of the  
568 records of the contractor or subcontractor required under sub-  
569 subparagraph e. ~~sub-sub-subparagraph (V).~~

570 ~~g.(VII)~~ In addition to the departmental inspection  
571 authority set forth in s. 499.051, the establishment of the  
572 contract provider and subcontractor and all records pertaining to  
573 prescription drugs subject to this subparagraph ~~sub-subparagraph~~  
574 shall be subject to inspection by the agency or entity. All  
575 records relating to prescription drugs of a manufacturer under  
576 this subparagraph ~~sub-subparagraph~~ shall be subject to audit by  
577 the manufacturer of those drugs, without identifying individual  
578 patient information.

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



582        ~~1.a.~~ The sale, purchase, or trade of a prescription drug  
583 among federal, state, or local government health care entities  
584 that are under common control and are authorized to purchase such  
585 prescription drug.

586        ~~2.b.~~ The sale, purchase, or trade of a prescription drug or  
587 an offer to sell, purchase, or trade a prescription drug for  
588 emergency medical reasons. For purposes of this subparagraph ~~sub-~~  
589 ~~subparagraph~~, the term "emergency medical reasons" includes  
590 transfers of prescription drugs by a retail pharmacy to another  
591 retail pharmacy to alleviate a temporary shortage.

592        ~~3.e.~~ The transfer of a prescription drug acquired by a  
593 medical director on behalf of a licensed emergency medical  
594 services provider to that emergency medical services provider and  
595 its transport vehicles for use in accordance with the provider's  
596 license under chapter 401.

597        ~~4.d.~~ The revocation of a sale or the return of a  
598 prescription drug to the person's prescription drug wholesale  
599 supplier.

600        ~~5.e.~~ The donation of a prescription drug by a health care  
601 entity to a charitable organization that has been granted an  
602 exemption under s. 501(c)(3) of the Internal Revenue Code of  
603 1986, as amended, and that is authorized to possess prescription  
604 drugs.

605        ~~6.f.~~ The transfer of a prescription drug by a person  
606 authorized to purchase or receive prescription drugs to a person  
607 licensed or permitted to handle reverse distributions or  
608 destruction under the laws of the jurisdiction in which the  
609 person handling the reverse distribution or destruction receives  
610 the drug.



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611        ~~7.g.~~ The transfer of a prescription drug by a hospital or  
612 other health care entity to a person licensed under this part  
613 ~~chapter~~ to repackage prescription drugs for the purpose of  
614 repackaging the prescription drug for use by that hospital, or  
615 other health care entity and other health care entities that are  
616 under common control, if ownership of the prescription drugs  
617 remains with the hospital or other health care entity at all  
618 times. In addition to the recordkeeping requirements of s.  
619 499.0121(6), the hospital or health care entity that transfers  
620 prescription drugs pursuant to this subparagraph ~~sub-subparagraph~~  
621 must reconcile all drugs transferred and returned and resolve any  
622 discrepancies in a timely manner.

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

626        ~~(d)4.~~ The sale, purchase, or trade of blood and blood  
627 components intended for transfusion. As used in this paragraph  
628 ~~subparagraph~~, the term "blood" means whole blood collected from a  
629 single donor and processed either for transfusion or further  
630 manufacturing, and the term "blood components" means that part of  
631 the blood separated by physical or mechanical means.

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

634        ~~(f)6.~~ The sale, purchase, or trade of a prescription drug  
635 between pharmacies as a result of a sale, transfer, merger, or  
636 consolidation of all or part of the business of the pharmacies  
637 from or with another pharmacy, whether accomplished as a purchase  
638 and sale of stock or of business assets.

639        ~~(57)(b)~~ "Wholesale distributor" means any person engaged in  
640 wholesale distribution of prescription drugs in or into this



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641 state, including, but not limited to, manufacturers; repackagers;  
642 own-label distributors; jobbers; private-label distributors;  
643 brokers; warehouses, including manufacturers' and distributors'  
644 warehouses, chain drug warehouses, and wholesale drug warehouses;  
645 independent wholesale drug traders; exporters; retail pharmacies;  
646 and the agents thereof that conduct wholesale distributions.

647 Section 3. Subsections (4), (10), (11), (12), (14), (15),  
648 (18), (19), (20), (22), (24), (28), and (29) of section 499.005,  
649 Florida Statutes, are amended to read:

650 499.005 Prohibited acts.--It is unlawful for a person to  
651 perform or cause the performance of any of the following acts in  
652 this state:

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

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

661 (11) The use, on the labeling of any drug or in any  
662 advertisement relating to such drug, of any representation or  
663 suggestion that an application of the drug is effective when it  
664 is not or that the drug complies with this part ~~ss. 499.001-~~  
665 ~~499.081~~ when it does not.

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

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



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670 distribute prescription ~~legend~~ drugs to that purchaser or  
671 recipient.

672 (15) The sale or transfer of a prescription ~~legend~~ drug to  
673 a person that is not authorized under the law of the jurisdiction  
674 in which the person receives the drug to purchase or possess  
675 prescription ~~legend~~ drugs from the person selling or transferring  
676 the prescription ~~legend~~ drug.

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

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

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

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

689 (24) The distribution of a prescription ~~legend~~ device to  
690 the patient or ultimate consumer without a prescription or order  
691 from a practitioner licensed by law to use or prescribe the  
692 device.

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

695 (29) The receipt of a prescription drug pursuant to a  
696 wholesale distribution without having previously received or  
697 simultaneously ~~either first~~ receiving a pedigree paper that was  
698 attested to as accurate and complete by the wholesale distributor





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699 as required under this part ~~or complying with the provisions of~~  
700 ~~s. 499.0121(6)(d)5.~~

701 Section 4. Section 499.0051, Florida Statutes, is amended;  
702 section 499.0052, Florida Statutes, is redesignated as subsection  
703 (7) of that section and amended; section 499.00535, Florida  
704 Statutes, is redesignated as subsection (9) of that section and  
705 amended; section 499.00545, Florida Statutes, is redesignated as  
706 subsection (10) of that section and amended; section 499.069,  
707 Florida Statutes, is redesignated as subsection (11) of that  
708 section and amended; and section 499.0691, Florida Statutes, is  
709 redesignated as subsections (12) through (15) of that section and  
710 amended, to read:

711 499.0051 Criminal acts ~~involving contraband or adulterated~~  
712 ~~drugs.--~~

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

714 (a) A person, other than a manufacturer, engaged in the  
715 wholesale distribution of prescription legend ~~legend~~ drugs who fails to  
716 deliver to another person complete and accurate pedigree papers  
717 concerning a prescription legend ~~legend~~ drug or contraband prescription  
718 ~~legend~~ drug prior to, or simultaneous with, the transfer of  
719 ~~transferring~~ the prescription legend ~~legend~~ drug or contraband  
720 prescription legend ~~legend~~ drug to another person commits a felony of  
721 the third degree, punishable as provided in s. 775.082, s.  
722 775.083, or s. 775.084.

723 (b) A person engaged in the wholesale distribution of  
724 prescription legend ~~legend~~ drugs who fails to acquire complete and  
725 accurate pedigree papers concerning a prescription legend ~~legend~~ drug or  
726 contraband prescription legend ~~legend~~ drug prior to, or simultaneous  
727 with, the receipt of obtaining the prescription legend ~~legend~~ drug or  
728 contraband prescription legend ~~legend~~ drug from another person commits a



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729 felony of the third degree, punishable as provided in s. 775.082,  
730 s. 775.083, or s. 775.084.

731 (c) Any person who knowingly destroys, alters, conceals, or  
732 fails to maintain complete and accurate pedigree papers  
733 concerning any prescription legend drug or contraband  
734 prescription legend drug in his or her possession commits a  
735 felony of the third degree, punishable as provided in s. 775.082,  
736 s. 775.083, or s. 775.084.

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

739 (a) A person engaged in the wholesale distribution of  
740 prescription legend drugs who is in possession of pedigree papers  
741 concerning prescription legend drugs or contraband prescription  
742 legend drugs and who fails to authenticate the matters contained  
743 in the pedigree papers and who nevertheless attempts to further  
744 distribute prescription legend drugs or contraband prescription  
745 legend drugs commits a felony of the third degree, punishable as  
746 provided in s. 775.082, s. 775.083, or s. 775.084.

747 (b) A person in possession of pedigree papers concerning  
748 prescription legend drugs or contraband prescription legend drugs  
749 who falsely swears or certifies that he or she has authenticated  
750 the matters contained in the pedigree papers commits a felony of  
751 the third degree, punishable as provided in s. 775.082, s.  
752 775.083, or s. 775.084.

753 (3) KNOWING FORGERY OF PEDIGREE PAPERS.--A person who  
754 knowingly forges, counterfeits, or falsely creates any pedigree  
755 paper; who falsely represents any factual matter contained on any  
756 pedigree paper; or who knowingly omits to record material  
757 information required to be recorded in a pedigree paper, commits



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758 a felony of the second degree, punishable as provided in s.  
759 775.082, s. 775.083, or s. 775.084.

760 (4) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION ~~LEGEND~~ DRUG  
761 FROM UNAUTHORIZED PERSON.--A person who knowingly purchases or  
762 receives from a person not authorized to distribute prescription  
763 ~~legend~~ drugs under this chapter a prescription legend drug in a  
764 wholesale distribution transaction commits a felony of the second  
765 degree, punishable as provided in s. 775.082, s. 775.083, or s.  
766 775.084.

767 (5) KNOWING SALE OR TRANSFER OF PRESCRIPTION ~~LEGEND~~ DRUG TO  
768 UNAUTHORIZED PERSON.--A person who knowingly sells or transfers  
769 to a person not authorized to purchase or possess prescription  
770 ~~legend~~ drugs, under the law of the jurisdiction in which the  
771 person receives the drug, a prescription legend drug in a  
772 wholesale distribution transaction commits a felony of the second  
773 degree, punishable as provided in s. 775.082, s. 775.083, or s.  
774 775.084.

775 (6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO  
776 SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is  
777 knowingly in actual or constructive possession of any amount of  
778 contraband prescription legend drugs, who knowingly sells or  
779 delivers, or who possesses with intent to sell or deliver any  
780 amount of contraband prescription legend drugs, commits a felony  
781 of the second degree, punishable as provided in s. 775.082, s.  
782 775.083, or s. 775.084.

783 (7) ~~499.0052~~ KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION  
784 LEGEND DRUGS.--A person who knowingly sells, purchases,  
785 manufactures, delivers, or brings into this state, or who is  
786 knowingly in actual or constructive possession of any amount of  
787 contraband prescription legend drugs valued at \$25,000 or more



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

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

792 1.(1) If the value of contraband prescription ~~legend~~ drugs  
793 involved is \$25,000 or more, but less than \$100,000, the  
794 defendant shall pay a mandatory fine of \$25,000. If the defendant  
795 is a corporation or other person that is not a natural person, it  
796 shall pay a mandatory fine of \$75,000.

797 2.(2) If the value of contraband prescription ~~legend~~ drugs  
798 involved is \$100,000 or more, but less than \$250,000, the  
799 defendant shall pay a mandatory fine of \$100,000. If the  
800 defendant is a corporation or other person that is not a natural  
801 person, it shall pay a mandatory fine of \$300,000.

802 3.(3) If the value of contraband prescription ~~legend~~ drugs  
803 involved is \$250,000 or more, the defendant shall pay a mandatory  
804 fine of \$200,000. If the defendant is a corporation or other  
805 person that is not a natural person, it shall pay a mandatory  
806 fine of \$600,000.

807 (b) As used in this subsection ~~section~~, the term "value"  
808 means the market value of the property at the time and place of  
809 the offense or, if such cannot be satisfactorily ascertained, the  
810 cost of replacement of the property within a reasonable time  
811 after the offense. Amounts of value of separate contraband  
812 prescription ~~legend~~ drugs involved in distinct transactions for  
813 the distribution of the contraband prescription ~~legend~~ drugs  
814 committed pursuant to one scheme or course of conduct, whether  
815 involving the same person or several persons, may be aggregated  
816 in determining the punishment of the offense.

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817           (8)(7) KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION  
818 ~~LEGEND~~ DRUG LABELS.--A person who knowingly forges, counterfeits,  
819 or falsely creates any prescription label or prescription legend  
820 drug label, or who falsely represents any factual matter  
821 contained on any prescription label or prescription legend drug  
822 label, commits a felony of the first degree, punishable as  
823 provided in s. 775.082, s. 775.083, or s. 775.084.

824           (9) ~~499.00535~~ KNOWING Sale or purchase of contraband  
825 prescription legend drugs resulting in great bodily harm.--A  
826 person who knowingly sells, purchases, manufactures, delivers, or  
827 brings into this state, or who is knowingly in actual or  
828 constructive possession of any amount of contraband prescription  
829 ~~legend~~ drugs, and whose acts in violation of this subsection  
830 ~~section~~ result in great bodily harm to a person, commits a felony  
831 of the first degree, as provided in s. 775.082, s. 775.083, or s.  
832 775.084.

833           (10) ~~499.00545~~ Knowing Sale or purchase of contraband  
834 prescription legend drugs resulting in death.--A person who  
835 knowingly manufactures, sells, purchases, delivers, or brings  
836 into this state, or who is knowingly in actual or constructive  
837 possession of any amount of contraband prescription legend drugs,  
838 and whose acts in violation of this subsection ~~section~~ result in  
839 the death of a person, commits a felony of the first degree,  
840 punishable by a term of years not exceeding life, as provided in  
841 s. 775.082, s. 775.083, or s. 775.084.

842           (11) ~~499.069~~ ~~Criminal punishment for~~ VIOLATIONS OF S.  
843 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE  
844 ADVERTISEMENT.--

845           (a) ~~(1)~~ Any person who violates any of the provisions of s.  
846 499.005 with respect to a device or cosmetic commits a



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847 | misdemeanor of the second degree, punishable as provided in s.  
848 | 775.082 or s. 775.083; but, if the violation is committed after a  
849 | conviction of such person under this subsection ~~section~~ has  
850 | become final, such person is guilty of a misdemeanor of the first  
851 | degree, punishable as provided in s. 775.082 or s. 775.083 or as  
852 | otherwise provided in this part ~~ss. 499.001-499.081~~, except that  
853 | any person who violates s. 499.005(8) or (10) ~~subsection (8) or~~  
854 | ~~subsection (10) of s. 499.005~~ with respect to a device or  
855 | cosmetic commits a felony of the third degree, punishable as  
856 | provided in s. 775.082, s. 775.083, or s. 775.084, or as  
857 | otherwise provided in this part ~~ss. 499.001-499.081~~.

858 | (b)(2) A publisher, radio broadcast licensee, or agency or  
859 | medium for the dissemination of an advertisement, except the  
860 | manufacturer, wholesaler, or seller of the article to which a  
861 | false advertisement relates, is not liable under this subsection  
862 | ~~section~~ by reason of the dissemination by him or her of such  
863 | false advertisement, unless he or she has refused, on the request  
864 | of the department, to furnish to the department the name and post  
865 | office address of the manufacturer, wholesaler, seller, or  
866 | advertising agency that asked him or her to disseminate such  
867 | advertisement.

868 | (12) ~~499.0691~~ ADULTERATED AND MISBRANDED DRUGS; FALSE  
869 | ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS  
870 | ~~Criminal punishment for violations related to drugs;~~  
871 | ~~dissemination of false advertisement.~~ ~~--(1)~~ Any person who  
872 | violates any of the following provisions commits a misdemeanor of  
873 | the second degree, punishable as provided in s. 775.082 or s.  
874 | 775.083; but, if the violation is committed after a conviction of  
875 | such person under this subsection ~~section~~ has become final, such  
876 | person commits a misdemeanor of the first degree, punishable as

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877 provided in s. 775.082 or s. 775.083, or as otherwise provided in  
878 this part ~~ss. 499.001-499.081~~:

879 (a) The manufacture, repackaging, sale, delivery, or  
880 holding or offering for sale of any drug that is adulterated or  
881 misbranded or has otherwise been rendered unfit for human or  
882 animal use.

883 (b) The adulteration or misbranding of any drug intended  
884 for further distribution.

885 (c) The receipt of any drug that is adulterated or  
886 misbranded, and the delivery or proffered delivery of such drug,  
887 for pay or otherwise.

888 (d) The dissemination of any false or misleading  
889 advertisement of a drug.

890 (e) The use, on the labeling of any drug or in any  
891 advertisement relating to such drug, of any representation or  
892 suggestion that an application of the drug is effective when it  
893 is not or that the drug complies with this part ~~ss. 499.001-~~  
894 ~~499.081~~ when it does not.

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

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

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

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



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

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

914           1. The department to enter or inspect an establishment in  
915 which drugs are manufactured, processed, repackaged, sold,  
916 brokered, or held;

917           2. Inspection of any record of that establishment;

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

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

921           (b) The sale, purchase, or trade, or the offer to sell,  
922 purchase, or trade, a drug sample as defined in s. 499.028; the  
923 distribution of a drug sample in violation of s. 499.028; or the  
924 failure to otherwise comply with s. 499.028.

925           (c) Providing the department with false or fraudulent  
926 records, or making false or fraudulent statements, regarding any  
927 matter within the provisions of this part ~~chapter~~ related to a  
928 drug.

929           (d) The failure to receive, maintain, or provide invoices  
930 and shipping documents, other than pedigree papers, if  
931 applicable, related to the distribution of a prescription ~~legend~~  
932 drug.

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



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936 (f) The wholesale distribution of a ~~any~~ prescription drug  
937 that was:

938 1. Purchased by a public or private hospital or other  
939 health care entity; or

940 2. Donated or supplied at a reduced price to a charitable  
941 organization.

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

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

947 (i) The purchase or sale of a prescription drug ~~drugs~~ for  
948 wholesale distribution in exchange for currency, as defined in s.  
949 560.103(6).

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

954 (a) Knowingly manufacturing, repackaging, selling,  
955 delivering, or holding or offering for sale any drug that is  
956 adulterated or misbranded or has otherwise been rendered unfit  
957 for human or animal use.

958 (b) Knowingly adulterating a drug that is intended for  
959 further distribution.

960 (c) Knowingly receiving a drug that is adulterated and  
961 delivering or proffering delivery of such drug for pay or  
962 otherwise.

963 (d) Committing any act that causes a drug to be a  
964 counterfeit drug, or selling, dispensing, or knowingly holding  
965 for sale a counterfeit drug.



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966 (e) Forging, counterfeiting, simulating, or falsely  
967 representing any drug, or, without the authority of the  
968 manufacturer, using any mark, stamp, tag, label, or other  
969 identification device authorized or required by rules adopted  
970 under this part ss. 499.001-499.081.

971 (f) Knowingly obtaining or attempting to obtain a  
972 prescription drug for wholesale distribution by fraud, deceit,  
973 misrepresentation, or subterfuge, or engaging in  
974 misrepresentation or fraud in the distribution of a drug.

975 (g) Removing a pharmacy's dispensing label from a dispensed  
976 prescription drug with the intent to further distribute the  
977 prescription drug.

978 (h) Knowingly distributing a prescription drug that was  
979 previously dispensed by a licensed pharmacy, unless such  
980 distribution was authorized in chapter 465 or the rules adopted  
981 under chapter 465.

982 (15) FALSE ADVERTISEMENT.--(4) A publisher, radio  
983 broadcast licensee, or agency or medium for the dissemination of  
984 an advertisement, except the manufacturer, repackager, wholesale  
985 distributor ~~wholesaler~~, or seller of the article to which a false  
986 advertisement relates, is not liable under subsection (12),  
987 subsection (13), or subsection (14) ~~this section~~ by reason of the  
988 dissemination by him or her of such false advertisement, unless  
989 he or she has refused, on the request of the department, to  
990 furnish to the department the name and post office address of the  
991 manufacturer, repackager, wholesale distributor ~~wholesaler~~,  
992 seller, or advertising agency that asked him or her to  
993 disseminate such advertisement.

994 Section 5. Section 499.0054, Florida Statutes, is amended;  
995 section 499.0055, Florida Statutes, is redesignated as subsection



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996 (2) of that section and amended; and section 499.0057, Florida  
997 Statutes, is redesignated as subsection (3) of that section and  
998 amended, to read:

999 499.0054 Advertising and labeling of drugs, devices, and  
1000 cosmetics; exemptions.--

1001 (1) It is a violation of the Florida Drug and Cosmetic Act  
1002 to perform or cause the performance of any of the following acts:

1003 (a) ~~(1)~~ The dissemination of any false advertisement of any  
1004 drug, device, or cosmetic. An advertisement is false if it is  
1005 false or misleading in any way.

1006 (b) ~~(2)~~ The distribution in commerce of any drug, device, or  
1007 cosmetic, if its labeling or advertising is in violation of this  
1008 part ss. 499.001-499.081.

1009 (c) ~~(3)~~ The manufacturing, repackaging, packaging, selling,  
1010 delivery, holding, or offering for sale of any drug, device, or  
1011 cosmetic for which the advertising or labeling is false or  
1012 misleading.

1013 (d) ~~(4)~~ The advertising of any drug, device, or cosmetic  
1014 that is adulterated or misbranded.

1015 (e) ~~(5)~~ The receiving in commerce of any drug, device, or  
1016 cosmetic that is falsely advertised or labeled or the delivering  
1017 or proffering for delivery of any such drug, device, or cosmetic.

1018 (f) ~~(6)~~ The advertising or labeling of any product  
1019 containing ephedrine, a salt of ephedrine, an isomer of  
1020 ephedrine, or a salt of an isomer of ephedrine, for the  
1021 indication of stimulation, mental alertness, weight loss,  
1022 appetite control, energy, or other indications not approved by  
1023 the pertinent United States Food and Drug Administration Over-  
1024 the-Counter Final or Tentative Final Monograph or approved new  
1025 drug application under the federal act. In determining compliance



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1026 with this requirement, the department may consider the following  
1027 factors:

1028 1.~~(a)~~ The packaging of the product.

1029 2.~~(b)~~ The name and labeling of the product.

1030 3.~~(c)~~ The manner of distribution, advertising, and  
1031 promotion of the product, including verbal representations at the  
1032 point of sale.

1033 4.~~(d)~~ The duration, scope, and significance of abuse of the  
1034 particular product.

1035 (g)~~(7)~~ The advertising of any drug or device represented to  
1036 have any effect in any of the following conditions, disorders,  
1037 diseases, or processes:

1038 1.~~(a)~~ Blood disorders.

1039 2.~~(b)~~ Bone or joint diseases.

1040 3.~~(c)~~ Kidney diseases or disorders.

1041 4.~~(d)~~ Cancer.

1042 5.~~(e)~~ Diabetes.

1043 6.~~(f)~~ Gall bladder diseases or disorders.

1044 7.~~(g)~~ Heart and vascular diseases.

1045 8.~~(h)~~ High blood pressure.

1046 9.~~(i)~~ Diseases or disorders of the ear or auditory  
1047 apparatus, including hearing loss or deafness.

1048 10.~~(j)~~ Mental disease or mental retardation.

1049 11.~~(k)~~ Paralysis.

1050 12.~~(l)~~ Prostate gland disorders.

1051 13.~~(m)~~ Conditions of the scalp affecting hair loss.

1052 14.~~(n)~~ Baldness.

1053 15.~~(o)~~ Endocrine disorders.

1054 16.~~(p)~~ Sexual impotence.

1055 17.~~(q)~~ Tumors.



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- 1056        18.~~(r)~~ Venereal diseases.
- 1057        19.~~(s)~~ Varicose ulcers.
- 1058        20.~~(t)~~ Breast enlargement.
- 1059        21.~~(u)~~ Purifying blood.
- 1060        22.~~(v)~~ Metabolic disorders.
- 1061        23.~~(w)~~ Immune system disorders or conditions affecting the  
1062 immune system.
- 1063        24.~~(x)~~ Extension of life expectancy.
- 1064        25.~~(y)~~ Stress and tension.
- 1065        26.~~(z)~~ Brain stimulation or performance.
- 1066        27.~~(aa)~~ The body's natural defense mechanisms.
- 1067        28.~~(bb)~~ Blood flow.
- 1068        29.~~(cc)~~ Depression.
- 1069        30.~~(dd)~~ Human immunodeficiency virus or acquired immune  
1070 deficiency syndrome or related disorders or conditions.
- 1071        (h)~~(8)~~ The representation or suggestion in labeling or  
1072 advertising that an article is approved under this part ss.  
1073 ~~499.001-499.081~~, when such is not the case.
- 1074        (2)~~499.0055 False or misleading advertisement.~~ In  
1075 determining whether an advertisement is false or misleading, the  
1076 department shall review the representations made or suggested by  
1077 statement, word, design, device, sound, or any combination  
1078 thereof within the advertisement and the extent to which the  
1079 advertisement fails to reveal material facts with respect to  
1080 consequences that can result from the use of the drug, device, or  
1081 cosmetic to which the advertisement relates under the conditions  
1082 of use prescribed in the labeling or advertisement.
- 1083        (3)~~499.0057 Advertisement exemptions.~~

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1084           ~~(a)(1)~~ An advertisement that is not prohibited under  
1085 paragraph (1)(a) ~~s. 499.0054(1)~~ is not prohibited under paragraph  
1086 (1)(g) ~~s. 499.0054(7)~~ if it is disseminated:

1087           1. To the public solely to advertise the product for those  
1088 indications that are safe and effective indications and the  
1089 product is safe and effective for self-medication, as established  
1090 by the United States Food and Drug Administration; or

1091           2. ~~if it is disseminated~~ Only to members of the medical,  
1092 dental, pharmaceutical, or veterinary professions or appears only  
1093 in the scientific periodicals of these professions.

1094           ~~(b)(2)~~ Compliance with this part ~~ss. 499.001-499.081~~ and  
1095 the rules adopted under this part ~~those sections~~ creates no legal  
1096 presumption that a drug or device is safe or effective.

1097           Section 6. Subsections (3), (10), and (11) of section  
1098 499.006, Florida Statutes, are amended to read:

1099           499.006 Adulterated drug or device.--A drug or device is  
1100 adulterated:

1101           (3) If it is a drug and the methods used in, or the  
1102 facilities or controls used for, its manufacture, processing,  
1103 packing, or holding do not conform to, or are not operated or  
1104 administered in conformity with, current good manufacturing  
1105 practices to assure that the drug meets the requirements of this  
1106 part ~~ss. 499.001-499.081~~ and that the drug has the identity and  
1107 strength, and meets the standard of quality and purity, which it  
1108 purports or is represented to possess;

1109           (10) If it is a prescription ~~legend~~ drug for which the  
1110 required pedigree paper is nonexistent, fraudulent, or incomplete  
1111 under the requirements of this part ~~ss. 499.001-499.081~~ or  
1112 applicable rules, or that has been purchased, held, sold, or

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1113 distributed at any time by a person not authorized under federal  
1114 or state law to do so; or

1115 (11) If it is a prescription drug subject to, defined by,  
1116 or described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
1117 Act which has been returned by a veterinarian to a limited  
1118 prescription drug veterinary wholesale distributor ~~wholesaler~~.

1119 Section 7. Section 499.007, Florida Statutes, is amended to  
1120 read:

1121 499.007 Misbranded drug or device.--A drug or device is  
1122 misbranded:

1123 (1) If its labeling is in any way false or misleading.

1124 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a  
1125 label containing:

1126 (a) The name and place of business of the manufacturer,  
1127 repackager, or distributor of the finished dosage form of the  
1128 drug. For the purpose of this paragraph, the finished dosage form  
1129 of a prescription medicinal drug is that form of the drug which  
1130 is, or is intended to be, dispensed or administered to the  
1131 patient and requires no further manufacturing or processing other  
1132 than packaging, reconstitution, and labeling; and

1133 (b) An accurate statement of the quantity of the contents  
1134 in terms of weight, measure, or numerical count. ~~;~~ However, under  
1135 this section, reasonable variations are permitted, and the  
1136 department shall establish by rule exemptions for small packages.

1137 (3) If it is an active pharmaceutical ingredient in bulk  
1138 form and does not bear a label containing:

1139 (a) The name and place of business of the manufacturer,  
1140 repackager, or distributor; and

1141 (b) An accurate statement of the quantity of the contents  
1142 in terms of weight, measure, or numerical count.



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1143        ~~(4)~~(3) If any word, statement, or other information  
1144 required by or under this part ~~ss. 499.001-499.081~~ to appear on  
1145 the label or labeling is not prominently placed thereon with such  
1146 conspicuousness as compared with other words, statements,  
1147 designs, or devices in the labeling, and in such terms, as to  
1148 render the word, statement, or other information likely to be  
1149 read and understood under customary conditions of purchase and  
1150 use.

1151        ~~(5)~~(4) If it is a drug and is not designated solely by a  
1152 name recognized in an official compendium and, ~~unless~~ its label  
1153 does not bear ~~bears~~:

1154            (a) The common or usual name of the drug, if any; and

1155            (b) In case it is fabricated from two or more ingredients,  
1156 the common or usual name and quantity of each active ingredient.

1157        ~~(6)~~(5) If ~~Unless~~ its labeling does not bear ~~bears~~:

1158            (a) Adequate directions for use; and

1159            (b) Adequate warnings against use in those pathological  
1160 conditions in which its use may be dangerous to health or against  
1161 use by children if its use may be dangerous to health, or against  
1162 unsafe dosage or methods or duration of administration or  
1163 application, in such manner and form as are necessary for the  
1164 protection of users.

1165        ~~(7)~~(6) If it purports to be a drug the name of which is  
1166 recognized in the official compendium and, ~~unless~~ it is not  
1167 packaged and labeled as prescribed therein. ~~‡~~ However, the method  
1168 of packaging may be modified with the consent of the department.

1169        ~~(8)~~(7) If it has been found by the department to be a drug  
1170 liable to deterioration and, ~~unless~~ it is not packaged in such  
1171 form and manner, and its label bears a statement of such  
1172 precautions, as the department by rule requires as necessary to





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1173 protect the public health. Such rule may not be established for  
1174 any drug recognized in an official compendium until the  
1175 department has informed the appropriate body charged with the  
1176 revision of such compendium of the need for such packaging or  
1177 labeling requirements and that body has failed within a  
1178 reasonable time to prescribe such requirements.

1179 ~~(9)~~<sup>(8)</sup> If it is:

1180 (a) A drug and its container or finished dosage form is so  
1181 made, formed, or filled as to be misleading;

1182 (b) An imitation of another drug; or

1183 (c) Offered for sale under the name of another drug.

1184 ~~(10)~~<sup>(9)</sup> If it is dangerous to health when used in the  
1185 dosage or with the frequency or duration prescribed, recommended,  
1186 or suggested in the labeling of the drug.

1187 ~~(11)~~<sup>(10)</sup> If it is, purports to be, or is represented as a  
1188 drug composed wholly or partly of insulin and, ~~unless~~:

1189 ~~(a)~~ it is not from a batch with respect to which a  
1190 certificate has been issued pursuant to s. 506 of the federal  
1191 act, which; ~~and~~

1192 ~~(b)~~ ~~The~~ certificate is in effect with respect to the drug.

1193 ~~(12)~~<sup>(11)</sup> If it is, purports to be, or is represented as a  
1194 drug composed wholly or partly of any kind of antibiotic  
1195 requiring certification under the federal act and ~~unless~~:

1196 ~~(a)~~ it is not from a batch with respect to which a  
1197 certificate has been issued pursuant to s. 507 of the federal  
1198 act, which; ~~and~~

1199 ~~(b)~~ the certificate is in effect with respect to the drug. ~~+~~

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1201 However, this subsection does not apply to any drug or class of  
1202 drugs exempted by regulations adopted under s. 507(c) or (d) of  
1203 the federal act.

1204 ~~(13)-(12)~~ If it is a drug intended for use by humans which  
1205 is a habit-forming drug or which, because of its toxicity or  
1206 other potentiality for harmful effect, or the method of its use,  
1207 or the collateral measures necessary to its use, is not safe for  
1208 use except under the supervision of a practitioner licensed by  
1209 law to administer such drugs, ~~+~~ or which is limited by an  
1210 effective application under s. 505 of the federal act to use  
1211 under the professional supervision of a practitioner licensed by  
1212 law to prescribe such drug, if ~~unless~~ it is not dispensed only:

1213 (a) Upon the written prescription of a practitioner  
1214 licensed by law to prescribe such drug;

1215 (b) Upon an oral prescription of such practitioner, which  
1216 is reduced promptly to writing and filled by the pharmacist; or

1217 (c) By refilling any such written or oral prescription, if  
1218 such refilling is authorized by the prescriber either in the  
1219 original prescription or by oral order which is reduced promptly  
1220 to writing and filled by the pharmacist.

1221  
1222 This subsection does not relieve any person from any requirement  
1223 prescribed by law with respect to controlled substances as  
1224 defined in the applicable federal and state laws.

1225 ~~(14)-(13)~~ If it is a drug that is subject to paragraph  
1226 ~~(13)-(12)~~(a), and if, at any time before it is dispensed, its  
1227 label does not ~~fails to~~ bear the statement:

1228 (a) "Caution: Federal Law Prohibits Dispensing Without  
1229 Prescription";

1230 (b) "Rx Only";



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1231 (c) The prescription symbol followed by the word "Only"; or

1232 (d) "Caution: State Law Prohibits Dispensing Without  
1233 Prescription."

1234 ~~(15)-(14)~~ If it is a drug that is not subject to paragraph  
1235 ~~(13)-(12)~~(a), if at any time before it is dispensed its label  
1236 bears the statement of caution required in subsection ~~(14)~~ ~~(13)~~.

1237 ~~(16)-(15)~~ If it is a color additive, the intended use of  
1238 which in or on drugs is for the purpose of coloring only ~~and~~  
1239 ~~unless~~ its packaging and labeling are not in conformity with the  
1240 packaging and labeling requirements that apply to such color  
1241 additive and are prescribed under the federal act.

1242 (17) A drug dispensed by filling or refilling a written or  
1243 oral prescription of a practitioner licensed by law to prescribe  
1244 such drug is exempt from the requirements of this section, except  
1245 subsections (1), (9) ~~(8)~~, (11) ~~(10)~~, and (12) ~~(11)~~ and the  
1246 packaging requirements of subsections (7) ~~(6)~~ and (8) ~~(7)~~, if the  
1247 drug bears a label that contains the name and address of the  
1248 dispenser or seller, the prescription number and the date the  
1249 prescription was written or filled, the name of the prescriber  
1250 and the name of the patient, and the directions for use and  
1251 cautionary statements. This exemption does not apply to any drug  
1252 dispensed in the course of the conduct of a business of  
1253 dispensing drugs pursuant to diagnosis by mail or to any drug  
1254 dispensed in violation of subsection (13) ~~(12)~~. The department  
1255 may, by rule, exempt drugs subject to s. 499.062 ~~ss. 499.062-~~  
1256 ~~499.064~~ from subsection (13) ~~(12)~~ if compliance with that  
1257 subsection is not necessary to protect the public health, safety,  
1258 and welfare.

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1259 Section 8. Subsection (1) of section 499.008, Florida  
1260 Statutes, is amended and subsection (5) is added to that section  
1261 to read:

1262 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

1263 (1) If it bears or contains any poisonous or deleterious  
1264 substance that is injurious to users under the conditions of use  
1265 prescribed in the labeling or advertisement thereof or under such  
1266 conditions of use as are customary or usual; however, this  
1267 subsection does not apply to coal-tar hair dye:

1268 (a) The label of which bears the following legend  
1269 conspicuously displayed thereon: "Caution: This product contains  
1270 ingredients which may cause skin irritation on certain  
1271 individuals, and a preliminary test according to accompanying  
1272 directions should first be made. This product must not be used  
1273 for dyeing the eyelashes or eyebrows; to do so may cause  
1274 blindness"; and

1275 (b) The labeling of which bears adequate directions for  
1276 such preliminary testing.

1277

1278 ~~For the purposes of this subsection and subsection (4), the term~~  
1279 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1280 (5) For the purposes of subsections (1) and (4), the term  
1281 "hair dye" does not include eyelash dyes or eyebrow dyes.

1282 Section 9. Subsections (2), (3), and (5) of section  
1283 499.009, Florida Statutes, are amended to read:

1284 499.009 Misbranded cosmetics.--A cosmetic is misbranded:

1285 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a  
1286 label containing:

1287 (a) The name and place of business of the manufacturer,  
1288 packer, or distributor;



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1289 (b) An accurate statement of the quantity of the contents  
1290 in terms of weight, measure, or numerical count; however, under  
1291 this paragraph reasonable variations are permitted, and the  
1292 department shall establish by rule exemptions for small packages;  
1293 and

1294 (c) A declaration of ingredients in descending order of  
1295 predominance, or as otherwise required by federal law.

1296 (3) If any word, statement, or other information required  
1297 by or under authority of this part ~~ss. 499.001-499.081~~ to appear  
1298 on the label or labeling is not prominently placed thereon with  
1299 such conspicuousness as compared with other words, statements,  
1300 designs, or devices in the labeling, and in such terms, as to  
1301 render the word, statement, or other information likely to be  
1302 read and understood by an individual under customary conditions  
1303 of purchase and use.

1304 (5) ~~Unless,~~ If it is a color additive, its packaging and  
1305 labeling are not in conformity with the packaging and labeling  
1306 requirements applicable to that color additive prescribed under  
1307 the federal act. This subsection does not apply to packages of  
1308 color additives that, with respect to their use for cosmetics,  
1309 are marketed and intended for use only in or on hair dyes.

1310 Section 10. Section 499.01, Florida Statutes, is amended;  
1311 the introductory paragraph and paragraphs (a) through (h) of  
1312 subsection (2) of section 499.012, Florida Statutes, are  
1313 redesignated as the introductory paragraph and paragraphs (d),  
1314 (n), (e), (f), (c), (i), (k), and (l), respectively, of  
1315 subsection (2) of that section and amended; paragraphs (b)  
1316 through (e) of subsection (2) of section 499.013, Florida  
1317 Statutes, are redesignated as paragraphs (p), (o), (q), and (r),  
1318 respectively, of subsection (2) of that section and amended; and

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1319 section 499.014, Florida Statutes, is redesignated as paragraph  
1320 (g) of subsection (2) of that section and amended, to read:

1321 499.01 Permits; ~~applications; renewal; general~~  
1322 ~~requirements.~~--

1323 (1) Prior to operating, a permit is required for each  
1324 person and establishment that intends to operate as:

1325 (a) A prescription drug manufacturer;

1326 (b) A prescription drug repackager;

1327 (c) A nonresident prescription drug manufacturer;

1328 (d) A prescription drug wholesale distributor;

1329 (e) An out-of-state prescription drug wholesale  
1330 distributor;

1331 (f) A retail pharmacy drug wholesale distributor;

1332 (g) A restricted prescription drug distributor;

1333 (h) A complimentary drug distributor;

1334 (i) A freight forwarder;

1335 (j) A veterinary prescription drug retail establishment;

1336 (k) A veterinary prescription drug wholesale distributor;

1337 (l) A limited prescription drug veterinary wholesale  
1338 distributor;

1339 (m) A medical oxygen retail establishment;

1340 (n) A compressed medical gas wholesale distributor;

1341 (o) A compressed medical gas manufacturer;

1342 (p)(e) An over-the-counter drug manufacturer;

1343 ~~(d) A compressed medical gas manufacturer;~~

1344 (q)(e) A device manufacturer; or

1345 (r)(f) A cosmetic manufacturer.~~†~~

1346 ~~(g) A prescription drug wholesaler;~~

1347 ~~(h) A veterinary prescription drug wholesaler;~~

1348 ~~(i) A compressed medical gas wholesaler;~~



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- 1349 ~~(j) An out-of-state prescription drug wholesaler;~~  
1350 ~~(k) A nonresident prescription drug manufacturer;~~  
1351 ~~(l) A freight forwarder;~~  
1352 ~~(m) A retail pharmacy drug wholesaler;~~  
1353 ~~(n) A veterinary legend drug retail establishment;~~  
1354 ~~(o) A medical oxygen retail establishment;~~  
1355 ~~(p) A complimentary drug distributor;~~  
1356 ~~(q) A restricted prescription drug distributor; or~~  
1357 ~~(r) A limited prescription drug veterinary wholesaler.~~

1358 (2) The following ~~types of wholesaler~~ permits are  
1359 established:

1360 (a) Prescription drug manufacturer permit.--A prescription  
1361 drug manufacturer permit is required for any person that  
1362 manufactures a prescription drug in this state.

1363 1. A person that operates an establishment permitted as a  
1364 prescription drug manufacturer may engage in wholesale  
1365 distribution of prescription drugs manufactured at that  
1366 establishment and must comply with all the provisions of this  
1367 part and the rules adopted under this part that apply to a  
1368 wholesale distributor.

1369 2. A prescription drug manufacturer must comply with all  
1370 appropriate state and federal good manufacturing practices.

1371 (b) Prescription drug repackager permit.--A prescription  
1372 drug repackager permit is required for any person that repackages  
1373 a prescription drug in this state.

1374 1. A person that operates an establishment permitted as a  
1375 prescription drug repackager may engage in wholesale distribution  
1376 of prescription drugs repackaged at that establishment and must  
1377 comply with all the provisions of this part and the rules adopted  
1378 under this part that apply to a wholesale distributor.



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1379           2. A prescription drug repackager must comply with all  
1380 appropriate state and federal good manufacturing practices.

1381           (c)(e) Nonresident prescription drug manufacturer  
1382 permit.--A nonresident prescription drug manufacturer permit is  
1383 required for any person that is a manufacturer of prescription  
1384 drugs, or the distribution point for a manufacturer of  
1385 prescription drugs, and located outside of this state, or that is  
1386 an entity to whom an approved new drug application has been  
1387 issued by the United States Food and Drug Administration, or the  
1388 contracted manufacturer of the approved new drug application  
1389 holder, and located outside the United States, which engages in  
1390 the wholesale distribution in this state of the prescription  
1391 drugs it manufactures or is responsible for manufacturing. Each  
1392 such manufacturer or entity must be permitted by the department  
1393 and comply with all the provisions required of a wholesale  
1394 distributor under this part ss. 499.001-499.081, except s.  
1395 499.01212 s. 499.0121(6)(d).

1396           1. A person that distributes prescription drugs that it did  
1397 not manufacture must also obtain an out-of-state prescription  
1398 drug wholesale distributor wholesaler permit pursuant to this  
1399 section to engage in the wholesale distribution of the  
1400 prescription drugs manufactured by another person and comply with  
1401 the requirements of an out-of-state prescription drug wholesale  
1402 distributor wholesaler.

1403           2. Any such person must comply with the licensing or  
1404 permitting requirements of the jurisdiction in which the  
1405 establishment is located and the federal act, and any product  
1406 wholesaled into this state must comply with this part ss.  
1407 499.001-499.081. If a person intends to import prescription drugs  
1408 from a foreign country into this state, the nonresident





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1409 prescription drug manufacturer must provide to the department a  
1410 list identifying each prescription drug it intends to import and  
1411 document approval by the United States Food and Drug  
1412 Administration for such importation.

1413 (d)(a) A Prescription drug wholesale distributor  
1414 ~~wholesaler's~~ permit.--A prescription drug wholesale distributor  
1415 ~~wholesaler~~ is a wholesale distributor that may engage in the  
1416 wholesale distribution of prescription drugs. A prescription drug  
1417 wholesale distributor ~~wholesaler~~ that applies to the department  
1418 for a new permit or the renewal of a permit must submit a bond of  
1419 \$100,000, or other equivalent means of security acceptable to the  
1420 department, such as an irrevocable letter of credit or a deposit  
1421 in a trust account or financial institution, payable to the  
1422 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the  
1423 bond is to secure payment of any administrative penalties imposed  
1424 by the department and any fees and costs incurred by the  
1425 department regarding that permit which are authorized under state  
1426 law and which the permittee fails to pay 30 days after the fine  
1427 or costs become final. The department may make a claim against  
1428 such bond or security until 1 year after the permittee's license  
1429 ceases to be valid or until 60 days after any administrative or  
1430 legal proceeding authorized in this part ~~ss. 499.001-499.081~~  
1431 which involves the permittee is concluded, including any appeal,  
1432 whichever occurs later. The department may adopt rules for  
1433 issuing a prescription drug wholesale distributor-broker  
1434 ~~wholesaler-broker~~ permit to a person who engages in the wholesale  
1435 distribution of prescription drugs and does not take physical  
1436 possession of any prescription drugs.

1437 (e)(e) An Out-of-state prescription drug wholesale  
1438 distributor ~~wholesaler's~~ permit.--An out-of-state prescription



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1439 drug wholesale distributor ~~wholesaler~~ is a wholesale distributor  
1440 located outside this state which engages in the wholesale  
1441 distribution of prescription drugs into this state and which must  
1442 be permitted by the department and comply with all the provisions  
1443 required of a wholesale distributor under this part ~~ss. 499.001-~~  
1444 ~~499.081~~. An out-of-state prescription drug wholesale distributor  
1445 ~~wholesaler~~ that applies to the department for a new permit or the  
1446 renewal of a permit must submit a bond of \$100,000, or other  
1447 equivalent means of security acceptable to the department, such  
1448 as an irrevocable letter of credit or a deposit in a trust  
1449 account or financial institution, payable to the Florida Drug,  
1450 Device, and Cosmetic Trust Fund. The purpose of the bond is to  
1451 secure payment of any administrative penalties imposed by the  
1452 department and any fees and costs incurred by the department  
1453 regarding that permit which are authorized under state law and  
1454 which the permittee fails to pay 30 days after the fine or costs  
1455 become final. The department may make a claim against such bond  
1456 or security until 1 year after the permittee's license ceases to  
1457 be valid or until 60 days after any administrative or legal  
1458 proceeding authorized in this part ~~ss. 499.001-499.081~~ which  
1459 involves the permittee is concluded, including any appeal,  
1460 whichever occurs later.

1461 1. The out-of-state prescription drug wholesale distributor  
1462 ~~wholesaler~~ must maintain at all times a license or permit to  
1463 engage in the wholesale distribution of prescription drugs in  
1464 compliance with laws of the state in which it is a resident.

1465 2. An out-of-state prescription drug wholesale distributor  
1466 ~~wholesaler's~~ permit is not required for an intracompany sale or  
1467 transfer of a prescription drug from an out-of-state  
1468 establishment that is duly licensed as a prescription drug

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1469 wholesale distributor ~~wholesaler~~, in its state of residence, to a  
1470 licensed prescription drug wholesale distributor ~~wholesaler~~ in  
1471 this state, if both wholesale distributors ~~wholesalers~~ conduct  
1472 wholesale distributions of prescription drugs under the same  
1473 business name. The recordkeeping requirements of ss. s-

1474 499.0121(6) and 499.01212 must be followed for this transaction.

1475 (f) (d) A Retail pharmacy drug wholesale distributor  
1476 ~~wholesaler's~~ permit.--A retail pharmacy drug wholesale  
1477 distributor ~~wholesaler~~ is a retail pharmacy engaged in wholesale  
1478 distribution of prescription drugs within this state under the  
1479 following conditions:

1480 1. The pharmacy must obtain a retail pharmacy drug  
1481 wholesale distributor ~~wholesaler's~~ permit pursuant to this part  
1482 ~~ss. 499.001-499.081~~ and the rules adopted under this part ~~those~~  
1483 ~~sections~~.

1484 2. The wholesale distribution activity does not exceed 30  
1485 percent of the total annual purchases of prescription drugs. If  
1486 the wholesale distribution activity exceeds the 30-percent  
1487 maximum, the pharmacy must obtain a prescription drug wholesale  
1488 distributor ~~wholesaler's~~ permit.

1489 3. The transfer of prescription drugs that appear in any  
1490 schedule contained in chapter 893 is subject to chapter 893 and  
1491 the federal Comprehensive Drug Abuse Prevention and Control Act  
1492 of 1970.

1493 4. The transfer is between a retail pharmacy and another  
1494 retail pharmacy, or a Modified Class II institutional pharmacy,  
1495 or a health care practitioner licensed in this state and  
1496 authorized by law to dispense or prescribe prescription drugs.

1497 5. All records of sales of prescription drugs subject to  
1498 this section must be maintained separate and distinct from other

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1499 records and comply with the recordkeeping requirements of this  
1500 part ss. ~~499.001-499.081~~.

1501 (g) ~~499.014~~ Restricted prescription drug distributor permit  
1502 ~~Distribution of legend drugs by hospitals, health care entities,~~  
1503 ~~charitable organizations, and return or destruction companies;~~  
1504 ~~permits, general requirements.--~~

1505 ~~(1)~~ A restricted prescription drug distributor permit is  
1506 required for any person that engages in the distribution of a  
1507 prescription ~~legend~~ drug, which distribution is not considered  
1508 "wholesale distribution" under s. 499.003(56)(a) ~~s.~~  
1509 ~~499.012(1)(a)1.~~

1510 ~~1.(2)~~ A person who engages in the receipt or distribution  
1511 of a prescription ~~legend~~ drug in this state for the purpose of  
1512 processing its return or its destruction must obtain a permit as  
1513 a restricted prescription drug distributor if such person is not  
1514 the person initiating the return, the prescription drug wholesale  
1515 supplier of the person initiating the return, or the manufacturer  
1516 of the drug.

1517 ~~2.(3)~~ Storage, handling, and recordkeeping of these  
1518 distributions must comply with the requirements for wholesale  
1519 distributors under s. 499.0121, but not ~~except~~ those set forth in  
1520 s. 499.01212 ~~s. 499.0121(6)(d)~~.

1521 ~~3.(4)~~ A person who applies for a permit as a restricted  
1522 prescription drug distributor, or for the renewal of such a  
1523 permit, must provide to the department the information required  
1524 under s. 499.012 ~~s. 499.01~~.

1525 ~~4.(5)~~ The department may ~~issue permits to restricted~~  
1526 ~~prescription drug distributors and may~~ adopt rules regarding the  
1527 distribution of prescription drugs by hospitals, health care  
1528 entities, charitable organizations, or other persons not involved



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1529 in wholesale distribution, which rules are necessary for the  
1530 protection of the public health, safety, and welfare.

1531 (h) Complimentary drug distributor permit.--A complimentary  
1532 drug distributor permit is required for any person that engages  
1533 in the distribution of a complimentary drug, subject to the  
1534 requirements of s. 499.028.

1535 (i) ~~(f)~~ Freight forwarder permit.--A freight forwarder  
1536 permit is required for any person that engages in the  
1537 distribution of a prescription ~~legend~~ drug as a freight forwarder  
1538 unless the person is a common carrier. The storage, handling, and  
1539 recordkeeping of such distributions must comply with the  
1540 requirements for wholesale distributors under s. 499.0121, but  
1541 ~~not except~~ those set forth in s. 499.01212 ~~s. 499.0121(6)(d)~~. A  
1542 freight forwarder must provide the source of the prescription  
1543 ~~legend~~ drugs with a validated airway bill, bill of lading, or  
1544 other appropriate documentation to evidence the exportation of  
1545 the product.

1546 (j) Veterinary prescription drug retail establishment  
1547 permit.--A veterinary prescription drug retail establishment  
1548 permit is required for any person that sells veterinary  
1549 prescription drugs to the public but does not include a pharmacy  
1550 licensed under chapter 465.

1551 1. The sale to the public must be based on a valid written  
1552 order from a veterinarian licensed in this state who has a valid  
1553 client-veterinarian relationship with the purchaser's animal.

1554 2. Veterinary prescription drugs may not be sold in excess  
1555 of the amount clearly indicated on the order or beyond the date  
1556 indicated on the order.

1557 3. An order may not be valid for more than 1 year.

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1558        4. A veterinary prescription drug retail establishment may  
1559 not purchase, sell, trade, or possess human prescription drugs or  
1560 any controlled substance as defined in chapter 893.

1561        5. A veterinary prescription drug retail establishment must  
1562 sell a veterinary prescription drug in the original, sealed  
1563 manufacturer's container with all labeling intact and legible.  
1564 The department may adopt by rule additional labeling requirements  
1565 for the sale of a veterinary prescription drug.

1566        6. A veterinary prescription drug retail establishment must  
1567 comply with all of the wholesale distribution requirements of s.  
1568 499.0121.

1569        7. Prescription drugs sold by a veterinary prescription  
1570 drug retail establishment pursuant to a practitioner's order may  
1571 not be returned into the retail establishment's inventory.

1572        (k) ~~(g)~~ A veterinary prescription drug wholesale distributor  
1573 ~~wholesaler~~ permit.--A veterinary prescription drug wholesale  
1574 distributor ~~wholesaler~~ permit is required for any person that  
1575 engages in the distribution of veterinary prescription drugs in  
1576 or into this state. A veterinary prescription drug wholesale  
1577 distributor ~~wholesaler~~ that also distributes prescription drugs  
1578 subject to, defined by, or described by s. 503(b) of the Federal  
1579 Food, Drug, and Cosmetic Act which it did not manufacture must  
1580 obtain a permit as a prescription drug wholesale distributor  
1581 ~~wholesaler~~, an out-of-state prescription drug wholesale  
1582 distributor ~~wholesaler~~, or a limited prescription drug veterinary  
1583 wholesale distributor ~~wholesaler~~ in lieu of the veterinary  
1584 prescription drug wholesale distributor ~~wholesaler~~ permit. A  
1585 veterinary prescription drug wholesale distributor ~~wholesaler~~  
1586 must comply with the requirements for wholesale distributors



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1587 under s. 499.0121, but not except those set forth in s. 499.01212  
1588 ~~s. 499.0121(6)(d)~~.

1589 ~~(1)(h)~~ Limited prescription drug veterinary wholesale  
1590 distributor wholesaler permit.--Unless engaging in the activities  
1591 of and permitted as a prescription drug manufacturer, nonresident  
1592 prescription drug manufacturer, prescription drug wholesale  
1593 distributor wholesaler, or out-of-state prescription drug  
1594 wholesale distributor wholesaler, a limited prescription drug  
1595 veterinary wholesale distributor wholesaler permit is required  
1596 for any person that engages in the distribution in or into this  
1597 state of veterinary prescription drugs and prescription drugs  
1598 subject to, defined by, or described by s. 503(b) of the Federal  
1599 Food, Drug, and Cosmetic Act under the following conditions:

1600 1. The person is engaged in the business of wholesaling  
1601 prescription and veterinary prescription legend drugs to persons:

1602 a. Licensed as veterinarians practicing on a full-time  
1603 basis;

1604 b. Regularly and lawfully engaged in instruction in  
1605 veterinary medicine;

1606 c. Regularly and lawfully engaged in law enforcement  
1607 activities;

1608 d. For use in research not involving clinical use; or

1609 e. For use in chemical analysis or physical testing or for  
1610 purposes of instruction in law enforcement activities, research,  
1611 or testing.

1612 2. No more than 30 percent of total annual prescription  
1613 drug sales may be prescription drugs approved for human use which  
1614 are subject to, defined by, or described by s. 503(b) of the  
1615 Federal Food, Drug, and Cosmetic Act.



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1616 3. The person does not distribute ~~is not permitted,~~  
1617 ~~licensed, or otherwise authorized~~ in any jurisdiction state ~~to~~  
1618 ~~wholesale~~ prescription drugs subject to, defined by, or described  
1619 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any  
1620 person who is authorized to sell, distribute, purchase, trade, or  
1621 use these drugs on or for humans.

1622 4. A limited prescription drug veterinary wholesale  
1623 distributor ~~wholesaler~~ that applies to the department for a new  
1624 permit or the renewal of a permit must submit a bond of \$20,000,  
1625 or other equivalent means of security acceptable to the  
1626 department, such as an irrevocable letter of credit or a deposit  
1627 in a trust account or financial institution, payable to the  
1628 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the  
1629 bond is to secure payment of any administrative penalties imposed  
1630 by the department and any fees and costs incurred by the  
1631 department regarding that permit which are authorized under state  
1632 law and which the permittee fails to pay 30 days after the fine  
1633 or costs become final. The department may make a claim against  
1634 such bond or security until 1 year after the permittee's license  
1635 ceases to be valid or until 60 days after any administrative or  
1636 legal proceeding authorized in this part ~~ss. 499.001-499.081~~  
1637 which involves the permittee is concluded, including any appeal,  
1638 whichever occurs later.

1639 5. A limited prescription drug veterinary wholesale  
1640 distributor ~~wholesaler~~ must maintain at all times a license or  
1641 permit to engage in the wholesale distribution of prescription  
1642 drugs in compliance with laws of the state in which it is a  
1643 resident.

1644 6. A limited prescription drug veterinary wholesale  
1645 distributor ~~wholesaler~~ must comply with the requirements for



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1646 wholesale distributors under ss. ~~s.~~ 499.0121 and 499.01212,

1647 except that a limited prescription drug veterinary wholesale

1648 distributor ~~wholesaler~~ is not required to provide a pedigree

1649 paper as required by s. 499.01212 ~~s. 499.0121(6)(d)~~ upon the

1650 wholesale distribution of a prescription drug to a veterinarian.

1651 7. A limited prescription drug veterinary wholesale

1652 distributor ~~wholesaler~~ may not return to inventory for subsequent

1653 wholesale distribution any prescription drug subject to, defined

1654 by, or described by s. 503(b) of the Federal Food, Drug, and

1655 Cosmetic Act which has been returned by a veterinarian.

1656 8. ~~An out-of-state prescription drug wholesaler's permit or~~

1657 A limited prescription drug veterinary wholesale distributor

1658 ~~wholesaler~~ permit is not required for an intracompany sale or

1659 transfer of a prescription drug from an out-of-state

1660 establishment that is duly licensed to engage in the wholesale

1661 distribution of prescription drugs in its state of residence to a

1662 licensed limited prescription drug veterinary wholesale

1663 distributor ~~wholesaler~~ in this state if both wholesale

1664 distributors ~~wholesalers~~ conduct wholesale distributions of

1665 prescription drugs under the same business name. The

1666 recordkeeping requirements of ss. ~~s.~~ 499.0121(6) and 499.01212

1667 must be followed for this transaction.

1668 (m) Medical oxygen retail establishment permit.--A medical

1669 oxygen retail establishment permit is required for any person

1670 that sells medical oxygen to patients only. The sale must be

1671 based on an order from a practitioner authorized by law to

1672 prescribe. The term does not include a pharmacy licensed under

1673 chapter 465.



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1674 | 1. A medical oxygen retail establishment may not possess,  
1675 | purchase, sell, or trade any prescription drug other than medical  
1676 | oxygen.

1677 | 2. A medical oxygen retail establishment may refill medical  
1678 | oxygen for an individual patient based on an order from a  
1679 | practitioner authorized by law to prescribe. A medical oxygen  
1680 | retail establishment that refills medical oxygen must comply with  
1681 | all appropriate state and federal good manufacturing practices.

1682 | 3. A medical oxygen retail establishment must comply with  
1683 | all of the wholesale distribution requirements of s. 499.0121.

1684 | 4. Prescription medical oxygen sold by a medical oxygen  
1685 | retail establishment pursuant to a practitioner's order may not  
1686 | be returned into the retail establishment's inventory.

1687 | (n) ~~(b)~~ A compressed medical gas wholesale distributor  
1688 | ~~wholesaler's~~ permit.--A compressed medical gas wholesale  
1689 | distributor ~~wholesaler~~ is a wholesale distributor that is limited  
1690 | to the wholesale distribution of compressed medical gases to  
1691 | other than the consumer or patient. The compressed medical gas  
1692 | must be in the original sealed container that was purchased by  
1693 | that wholesale distributor ~~wholesaler~~. A compressed medical gas  
1694 | wholesale distributor ~~wholesaler~~ may not possess or engage in the  
1695 | wholesale distribution of any prescription drug other than  
1696 | compressed medical gases. The department shall adopt rules that  
1697 | govern the wholesale distribution of prescription medical oxygen  
1698 | for emergency use. With respect to the emergency use of  
1699 | prescription medical oxygen, those rules may not be inconsistent  
1700 | with rules and regulations of federal agencies unless the  
1701 | Legislature specifically directs otherwise.

1702 | (o) ~~(e)~~ Compressed medical gas manufacturer permit.--A  
1703 | compressed medical gas manufacturer ~~manufacturer's~~ permit is

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1704 required for any person that engages in the manufacture of  
1705 compressed medical gases or repackages compressed medical gases  
1706 from one container to another.

1707 1. A compressed medical gas manufacturer ~~permittee~~ may not  
1708 manufacture or possess any prescription drug other than  
1709 compressed medical gases.

1710 2. A compressed medical gas manufacturer ~~permittee~~ may  
1711 engage in wholesale distribution of compressed medical gases  
1712 manufactured at that establishment and must comply with all the  
1713 provisions of this part ss. 499.001-499.081 and the rules adopted  
1714 under this part ~~those sections~~ that apply to a wholesale  
1715 distributor.

1716 3. A compressed medical gas manufacturer ~~permittee~~ must  
1717 comply with all appropriate state and federal good manufacturing  
1718 practices.

1719 (p)-(b) Over-the-counter drug manufacturer permit.--An over-  
1720 the-counter drug manufacturer ~~manufacturer's~~ permit is required  
1721 for any person that engages in the manufacture or repackaging of  
1722 an over-the-counter drug.

1723 1. An over-the-counter drug manufacturer ~~permittee~~ may not  
1724 possess or purchase prescription drugs.

1725 2. A pharmacy is exempt from obtaining an over-the-counter  
1726 drug manufacturer ~~manufacturer's~~ permit if it is operating in  
1727 compliance with pharmacy practice standards as defined in chapter  
1728 465 and the rules adopted under that chapter.

1729 3. An over-the-counter drug manufacturer ~~permittee~~ must  
1730 comply with all appropriate state and federal good manufacturing  
1731 practices.

1732 (q)-(d) Device manufacturer permit.--A device manufacturer  
1733 ~~manufacturer's~~ permit is required for any person that engages in



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1734 the manufacture, repackaging, or assembly of medical devices for  
1735 human use in this state, except that a permit is not required if  
1736 the person is engaged only in manufacturing, repackaging, or  
1737 assembling a medical device pursuant to a practitioner's order  
1738 for a specific patient.

1739 1. A manufacturer or repackager of medical devices in this  
1740 state must comply with all appropriate state and federal good  
1741 manufacturing practices and quality system rules.

1742 2. The department shall adopt rules related to storage,  
1743 handling, and recordkeeping requirements for manufacturers of  
1744 medical devices for human use.

1745 ~~(r)(e)~~ Cosmetic manufacturer permit.--A cosmetic  
1746 manufacturer ~~manufacturer's~~ permit is required for any person  
1747 that manufactures or repackages cosmetics in this state. A person  
1748 that only labels or changes the labeling of a cosmetic but does  
1749 not open the container sealed by the manufacturer of the product  
1750 is exempt from obtaining a permit under this paragraph.

1751 Section 11. Section 499.012, Florida Statutes, is amended  
1752 and subsections (2) through (8) of section 499.01, Florida  
1753 States, are redesignated as subsections (1) through (7) of that  
1754 section and amended, to read:

1755 499.012 Permit application ~~Wholesale distribution;~~  
1756 ~~definitions; permits; applications; general requirements.~~--

1757 (1) ~~As used in this section, the term:~~

1758 ~~(2)~~(a) A permit issued pursuant to this part ~~ss. 499.001-~~  
1759 ~~499.081~~ may be issued only to a natural person who is at least 18  
1760 years of age or to an applicant that is not a natural person if  
1761 each person who, directly or indirectly, manages, controls, or  
1762 oversees the operation of that applicant is at least 18 years of  
1763 age.

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1764 (b) An establishment that is a place of residence may not  
1765 receive a permit and may not operate under this part ~~ss. 499.001-~~  
1766 ~~499.081~~.

1767 (c) A person that applies for or renews a permit to  
1768 manufacture or distribute prescription ~~legend~~ drugs may not use a  
1769 name identical to the name used by any other establishment or  
1770 licensed person authorized to purchase prescription drugs in this  
1771 state, except that a restricted drug distributor permit issued to  
1772 a health care entity will be issued in the name in which the  
1773 institutional pharmacy permit is issued and a retail pharmacy  
1774 drug wholesale distributor ~~wholesaler~~ will be issued a permit in  
1775 the name of its retail pharmacy permit.

1776 (d) A permit for a prescription drug manufacturer,  
1777 prescription drug repackager, prescription drug wholesale  
1778 distributor ~~wholesaler~~, limited prescription drug veterinary  
1779 wholesale distributor ~~wholesaler~~, or retail pharmacy drug  
1780 wholesale distributor ~~wholesaler~~ may not be issued to the address  
1781 of a health care entity or to a pharmacy licensed under chapter  
1782 465, except as provided in this paragraph. The department may  
1783 issue a prescription drug manufacturer permit to an applicant at  
1784 the same address as a licensed nuclear pharmacy, which is a  
1785 health care entity, for the purpose of manufacturing prescription  
1786 drugs used in positron emission tomography or other  
1787 radiopharmaceuticals, as listed in a rule adopted by the  
1788 department pursuant to this paragraph. The purpose of this  
1789 exemption is to assure availability of state-of-the-art  
1790 pharmaceuticals that would pose a significant danger to the  
1791 public health if manufactured at a separate establishment address  
1792 from the nuclear pharmacy from which the prescription drugs are  
1793 dispensed. The department may also issue a retail pharmacy drug



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1794 wholesale distributor ~~wholesaler~~ permit to the address of a  
1795 community pharmacy licensed under chapter 465 which does not meet  
1796 the definition of a closed pharmacy in s. 499.003.

1797 (e) A county or municipality may not issue an occupational  
1798 license for any licensing period beginning on or after October 1,  
1799 2003, for any establishment that requires a permit pursuant to  
1800 this part ~~ss. 499.001-499.081~~, unless the establishment exhibits  
1801 a current permit issued by the department for the establishment.  
1802 Upon presentation of the requisite permit issued by the  
1803 department, an occupational license may be issued by the  
1804 municipality or county in which application is made. The  
1805 department shall furnish to local agencies responsible for  
1806 issuing occupational licenses a current list of all  
1807 establishments licensed pursuant to this part ~~ss. 499.001-~~  
1808 ~~499.081~~.

1809 ~~(2)(3)~~ Notwithstanding subsection ~~(6)~~ ~~(7)~~, a permitted  
1810 person in good standing may change the type of permit issued to  
1811 that person by completing a new application for the requested  
1812 permit, paying the amount of the difference in the permit fees if  
1813 the fee for the new permit is more than the fee for the original  
1814 permit, and meeting the applicable permitting conditions for the  
1815 new permit type. The new permit expires on the expiration date of  
1816 the original permit being changed; however, a new permit for a  
1817 prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
1818 state prescription drug wholesale distributor ~~wholesaler~~, or a  
1819 retail pharmacy drug wholesale distributor ~~wholesaler~~ shall  
1820 expire on the expiration date of the original permit or 1 year  
1821 after the date of issuance of the new permit, whichever is  
1822 earlier. A refund may not be issued if the fee for the new permit  
1823 is less than the fee that was paid for the original permit.



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1824        (3)~~(4)~~ A written application for a permit or to renew a  
1825 permit must be filed with the department on forms furnished by  
1826 the department. The department shall establish, by rule, the form  
1827 and content of the application to obtain or renew a permit. The  
1828 applicant must submit to the department with the application a  
1829 statement that swears or affirms that the information is true and  
1830 correct.

1831        (4)~~(5)~~(a) Except for a permit for a prescription drug  
1832 wholesale distributor ~~wholesaler~~ or an out-of-state prescription  
1833 drug wholesale distributor ~~wholesaler~~, an application for a  
1834 permit must include:

1835            1. The name, full business address, and telephone number of  
1836 the applicant;

1837            2. All trade or business names used by the applicant;

1838            3. The address, telephone numbers, and the names of contact  
1839 persons for each facility used by the applicant for the storage,  
1840 handling, and distribution of prescription drugs;

1841            4. The type of ownership or operation, such as a  
1842 partnership, corporation, or sole proprietorship; and

1843            5. The names of the owner and the operator of the  
1844 establishment, including:

1845                a. If an individual, the name of the individual;

1846                b. If a partnership, the name of each partner and the name  
1847 of the partnership;

1848                c. If a corporation, the name and title of each corporate  
1849 officer and director, the corporate names, and the name of the  
1850 state of incorporation;

1851                d. If a sole proprietorship, the full name of the sole  
1852 proprietor and the name of the business entity;



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1853 e. If a limited liability company, the name of each member,  
1854 the name of each manager, the name of the limited liability  
1855 company, and the name of the state in which the limited liability  
1856 company was organized; and

1857 f. Any other relevant information that the department  
1858 requires.

1859 (b) Upon approval of the application by the department and  
1860 payment of the required fee, the department shall issue a permit  
1861 to the applicant, if the applicant meets the requirements of this  
1862 part ~~ss. 499.001-499.081~~ and rules adopted under this part ~~those~~  
1863 ~~sections~~.

1864 (c) Any change in information required under paragraph (a)  
1865 must be submitted to the department before the change occurs.

1866 (d) The department shall consider, at a minimum, the  
1867 following factors in reviewing the qualifications of persons to  
1868 be permitted under this part ~~ss. 499.001-499.081~~:

1869 1. The applicant's having been found guilty, regardless of  
1870 adjudication, in a court of this state or other jurisdiction, of  
1871 a violation of a law that directly relates to a drug, device, or  
1872 cosmetic. A plea of nolo contendere constitutes a finding of  
1873 guilt for purposes of this subparagraph.

1874 2. The applicant's having been disciplined by a regulatory  
1875 agency in any state for any offense that would constitute a  
1876 violation of this part ~~ss. 499.001-499.081~~.

1877 3. Any felony conviction of the applicant under a federal,  
1878 state, or local law;

1879 4. The applicant's past experience in manufacturing or  
1880 distributing drugs, devices, or cosmetics;



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1881           5. The furnishing by the applicant of false or fraudulent  
1882 material in any application made in connection with manufacturing  
1883 or distributing drugs, devices, or cosmetics;

1884           6. Suspension or revocation by a federal, state, or local  
1885 government of any permit currently or previously held by the  
1886 applicant for the manufacture or distribution of any drugs,  
1887 devices, or cosmetics;

1888           7. Compliance with permitting requirements under any  
1889 previously granted permits;

1890           8. Compliance with requirements to maintain or make  
1891 available to the state permitting authority or to federal, state,  
1892 or local law enforcement officials those records required under  
1893 this section; and

1894           9. Any other factors or qualifications the department  
1895 considers relevant to and consistent with the public health and  
1896 safety.

1897           (5) ~~(6)~~ Except for a permit ~~permits~~ for a prescription drug  
1898 wholesale distributor ~~wholesalers~~ or an out-of-state prescription  
1899 drug wholesale distributor ~~wholesalers~~:

1900           (a) The department shall adopt rules for the biennial  
1901 renewal of permits.

1902           (b) The department shall renew a permit upon receipt of the  
1903 renewal application and renewal fee if the applicant meets the  
1904 requirements established under this part ~~ss. 499.001-499.081~~ and  
1905 the rules adopted under this part ~~those sections~~.

1906           (c) A permit, unless sooner suspended or revoked,  
1907 automatically expires 2 years after the last day of the  
1908 anniversary month in which the permit was originally issued. A  
1909 permit issued under this part ~~ss. 499.001-499.081~~ may be renewed  
1910 by making application for renewal on forms furnished by the



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1911 department and paying the appropriate fees. If a renewal  
1912 application and fee are submitted and postmarked after the  
1913 expiration date of the permit, the permit may be renewed only  
1914 upon payment of a late renewal delinquent fee of \$100, plus the  
1915 required renewal fee, not later than 60 days after the expiration  
1916 date.

1917 (d) Failure to renew a permit in accordance with this  
1918 section precludes any future renewal of that permit. If a permit  
1919 issued pursuant to this part ~~section~~ has expired and cannot be  
1920 renewed, before an establishment may engage in activities that  
1921 require a permit under this part ~~ss. 499.001-499.081~~, the  
1922 establishment must submit an application for a new permit, pay  
1923 the applicable application fee, the initial permit fee, and all  
1924 applicable penalties, and be issued a new permit by the  
1925 department.

1926 ~~(6)(7)~~ A permit issued by the department is  
1927 nontransferable. Each permit is valid only for the person or  
1928 governmental unit to which it is issued and is not subject to  
1929 sale, assignment, or other transfer, voluntarily or  
1930 involuntarily; nor is a permit valid for any establishment other  
1931 than the establishment for which it was originally issued.

1932 (a) A person permitted under this part ~~ss. 499.001-499.081~~  
1933 must notify the department before making a change of address. The  
1934 department shall set a change of location fee not to exceed \$100.

1935 (b)1. An application for a new permit is required when a  
1936 majority of the ownership or controlling interest of a permitted  
1937 establishment is transferred or assigned or when a lessee agrees  
1938 to undertake or provide services to the extent that legal  
1939 liability for operation of the establishment will rest with the

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1940 lessee. The application for the new permit must be made before  
1941 the date of the sale, transfer, assignment, or lease.

1942 2. A permittee that is authorized to distribute  
1943 prescription legend drugs may transfer such drugs to the new  
1944 owner or lessee under subparagraph 1. only after the new owner or  
1945 lessee has been approved for a permit to distribute prescription  
1946 legend drugs.

1947 (c) If an establishment permitted under this part ss.  
1948 ~~499.001-499.081~~ closes, the owner must notify the department in  
1949 writing before the effective date of closure and must:

1950 1. Return the permit to the department;

1951 2. If the permittee is authorized to distribute  
1952 prescription legend drugs, indicate the disposition of such  
1953 drugs, including the name, address, and inventory, and provide  
1954 the name and address of a person to contact regarding access to  
1955 records that are required to be maintained under this part ss.  
1956 ~~499.001-499.081~~. Transfer of ownership of prescription legend  
1957 drugs may be made only to persons authorized to possess  
1958 prescription legend drugs under this part ss. ~~499.001-499.081~~.

1959  
1960 The department may revoke the permit of any person that fails to  
1961 comply with the requirements of this subsection.

1962 ~~(7)(8)~~ A permit must be posted in a conspicuous place on  
1963 the licensed premises.

1964 ~~(8)(3)~~ An application for a permit or to renew a permit for  
1965 a prescription drug wholesale distributor ~~wholesaler~~ or an out-  
1966 of-state prescription drug wholesale distributor ~~wholesaler~~  
1967 submitted to the department must include:

1968 (a) The name, full business address, and telephone number  
1969 of the applicant.



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- 1970 (b) All trade or business names used by the applicant.
- 1971 (c) The address, telephone numbers, and the names of  
1972 contact persons for each facility used by the applicant for the  
1973 storage, handling, and distribution of prescription drugs.
- 1974 (d) The type of ownership or operation, such as a  
1975 partnership, corporation, or sole proprietorship.
- 1976 (e) The names of the owner and the operator of the  
1977 establishment, including:
- 1978 1. If an individual, the name of the individual.
- 1979 2. If a partnership, the name of each partner and the name  
1980 of the partnership.
- 1981 3. If a corporation:
- 1982 a. The name, address, and title of each corporate officer  
1983 and director.
- 1984 b. The name and address of the corporation, resident agent  
1985 of the corporation, the resident agent's address, and the  
1986 corporation's state of incorporation.
- 1987 c. The name and address of each shareholder of the  
1988 corporation that owns 5 percent or more of the outstanding stock  
1989 of the corporation.
- 1990 4. If a sole proprietorship, the full name of the sole  
1991 proprietor and the name of the business entity.
- 1992 5. If a limited liability company:
- 1993 a. The name and address of each member.
- 1994 b. The name and address of each manager.
- 1995 c. The name and address of the limited liability company,  
1996 the resident agent of the limited liability company, and the name  
1997 of the state in which the limited liability company was  
1998 organized.



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1999 (f) If applicable, the name and address of each member of  
2000 the affiliated group of which the applicant is a member.

2001 (g)1. For an application for a new permit, the estimated  
2002 annual dollar volume of prescription drug sales of the applicant,  
2003 the estimated annual percentage of the applicant's total company  
2004 sales that are prescription drugs, the applicant's estimated  
2005 annual total dollar volume of purchases of prescription drugs,  
2006 and the applicant's estimated annual total dollar volume of  
2007 prescription drug purchases directly from manufacturers.

2008 2. For an application to renew a permit, the total dollar  
2009 volume of prescription drug sales in the previous year, the total  
2010 dollar volume of prescription drug sales made in the previous 6  
2011 months, the percentage of total company sales that were  
2012 prescription drugs in the previous year, the total dollar volume  
2013 of purchases of prescription drugs in the previous year, and the  
2014 total dollar volume of prescription drug purchases directly from  
2015 manufacturers in the previous year.

2016  
2017 Such portions of the information required pursuant to this  
2018 paragraph which are a trade secret, as defined in s. 812.081,  
2019 shall be maintained by the department as trade secret information  
2020 is required to be maintained under s. 499.051.

2021 (h) The tax year of the applicant.

2022 (i) A copy of the deed for the property on which  
2023 applicant's establishment is located, if the establishment is  
2024 owned by the applicant, or a copy of the applicant's lease for  
2025 the property on which applicant's establishment is located that  
2026 has an original term of not less than 1 calendar year, if the  
2027 establishment is not owned by the applicant.



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2028 (j) A list of all licenses and permits issued to the  
2029 applicant by any other state which authorize the applicant to  
2030 purchase or possess prescription drugs.

2031 (k) The name of the manager of the establishment that is  
2032 applying for the permit or to renew the permit, the next four  
2033 highest ranking employees responsible for prescription drug  
2034 wholesale operations for the establishment, and the name of all  
2035 affiliated parties for the establishment, together with the  
2036 personal information statement and fingerprints required pursuant  
2037 to subsection (9) ~~(4)~~ for each of such persons.

2038 (l) The name of each of the applicant's designated  
2039 representatives as required by subsection (16) ~~(11)~~, together  
2040 with the personal information statement and fingerprints required  
2041 pursuant to subsection (9) ~~(4)~~ for each such person.

2042 (m) For an applicant that is a secondary wholesale  
2043 distributor ~~wholesaler~~, each of the following:

2044 1. A personal background information statement containing  
2045 the background information and fingerprints required pursuant to  
2046 subsection (9) ~~(4)~~ for each person named in the applicant's  
2047 response to paragraphs (k) and (l) and for each affiliated party  
2048 of the applicant.

2049 2. If any of the five largest shareholders of the  
2050 corporation seeking the permit is a corporation, the name,  
2051 address, and title of each corporate officer and director of each  
2052 such corporation; the name and address of such corporation; the  
2053 name of such corporation's resident agent, such corporation's  
2054 resident agent's address, and such corporation's state of its  
2055 incorporation; and the name and address of each shareholder of  
2056 such corporation that owns 5 percent or more of the stock of such  
2057 corporation.

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2058 3. The name and address of all financial institutions in  
2059 which the applicant has an account which is used to pay for the  
2060 operation of the establishment or to pay for drugs purchased for  
2061 the establishment, together with the names of all persons that  
2062 are authorized signatories on such accounts. The portions of the  
2063 information required pursuant to this subparagraph which are a  
2064 trade secret, as defined in s. 812.081, shall be maintained by  
2065 the department as trade secret information is required to be  
2066 maintained under s. 499.051.

2067 4. The sources of all funds and the amounts of such funds  
2068 used to purchase or finance purchases of prescription drugs or to  
2069 finance the premises on which the establishment is to be located.

2070 5. If any of the funds identified in subparagraph 4. were  
2071 borrowed, copies of all promissory notes or loans used to obtain  
2072 such funds.

2073 (n) Any other relevant information that the department  
2074 requires, including, but not limited to, any information related  
2075 to whether the applicant satisfies the definition of a primary  
2076 wholesale distributor ~~wholesaler~~ or a secondary wholesale  
2077 distributor ~~wholesaler~~.

2078 ~~(9)~~ ~~(4)~~ (a) Each person required by subsection ~~(8)~~ ~~(3)~~ to  
2079 provide a personal information statement and fingerprints shall  
2080 provide the following information to the department on forms  
2081 prescribed by the department:

- 2082 1. The person's places of residence for the past 7 years.
- 2083 2. The person's date and place of birth.
- 2084 3. The person's occupations, positions of employment, and  
2085 offices held during the past 7 years.
- 2086 4. The principal business and address of any business,  
2087 corporation, or other organization in which each such office of



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2088 | the person was held or in which each such occupation or position  
2089 | of employment was carried on.

2090 |         5. Whether the person has been, during the past 7 years,  
2091 | the subject of any proceeding for the revocation of any license  
2092 | and, if so, the nature of the proceeding and the disposition of  
2093 | the proceeding.

2094 |         6. Whether, during the past 7 years, the person has been  
2095 | enjoined, either temporarily or permanently, by a court of  
2096 | competent jurisdiction from violating any federal or state law  
2097 | regulating the possession, control, or distribution of  
2098 | prescription drugs, together with details concerning any such  
2099 | event.

2100 |         7. A description of any involvement by the person with any  
2101 | business, including any investments, other than the ownership of  
2102 | stock in a publicly traded company or mutual fund, during the  
2103 | past 7 years, which manufactured, administered, prescribed,  
2104 | distributed, or stored pharmaceutical products and any lawsuits  
2105 | in which such businesses were named as a party.

2106 |         8. A description of any felony criminal offense of which  
2107 | the person, as an adult, was found guilty, regardless of whether  
2108 | adjudication of guilt was withheld or whether the person pled  
2109 | guilty or nolo contendere. A criminal offense committed in  
2110 | another jurisdiction which would have been a felony in this state  
2111 | must be reported. If the person indicates that a criminal  
2112 | conviction is under appeal and submits a copy of the notice of  
2113 | appeal of that criminal offense, the applicant must, within 15  
2114 | days after the disposition of the appeal, submit to the  
2115 | department a copy of the final written order of disposition.

2116 |         9. A photograph of the person taken in the previous 30  
2117 | days.



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2118 |           10. A set of fingerprints for the person on a form and  
2119 | under procedures specified by the department, together with  
2120 | payment of an amount equal to the costs incurred by the  
2121 | department for the criminal record check of the person.

2122 |           11. The name, address, occupation, and date and place of  
2123 | birth for each member of the person's immediate family who is 18  
2124 | years of age or older. As used in this subparagraph, the term  
2125 | "member of the person's immediate family" includes the person's  
2126 | spouse, children, parents, siblings, the spouses of the person's  
2127 | children, and the spouses of the person's siblings.

2128 |           12. Any other relevant information that the department  
2129 | requires.

2130 |           (b) The information required pursuant to paragraph (a)  
2131 | shall be provided under oath.

2132 |           (c) The department shall submit the fingerprints provided  
2133 | by a person for initial licensure to the Department of Law  
2134 | Enforcement for a statewide criminal record check and for  
2135 | forwarding to the Federal Bureau of Investigation for a national  
2136 | criminal record check of the person. The department shall submit  
2137 | the fingerprints provided by a person as a part of a renewal  
2138 | application to the Department of Law Enforcement for a statewide  
2139 | criminal record check, and for forwarding to the Federal Bureau  
2140 | of Investigation for a national criminal record check, for the  
2141 | initial renewal of a permit after January 1, 2004; for any  
2142 | subsequent renewal of a permit, the department shall submit the  
2143 | required information for a statewide and national criminal record  
2144 | check of the person. Any person who as a part of an initial  
2145 | permit application or initial permit renewal after January 1,  
2146 | 2004, submits to the department a set of fingerprints required  
2147 | for the criminal record check required in this paragraph shall



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2148 | not be required to provide a subsequent set of fingerprints for a  
2149 | criminal record check to the department, if the person has  
2150 | undergone a criminal record check as a condition of the issuance  
2151 | of an initial permit or the initial renewal of a permit of an  
2152 | applicant after January 1, 2004.

2153 |        (10)-(5) The department may deny an application for a permit  
2154 | or refuse to renew a permit for a prescription drug wholesale  
2155 | distributor ~~wholesaler~~ or an out-of-state prescription drug  
2156 | wholesale distributor ~~wholesaler~~ if:

2157 |           (a) The applicant has not met the requirements for the  
2158 | permit.

2159 |           (b) The management, officers, or directors of the applicant  
2160 | or any affiliated party are found by the department to be  
2161 | incompetent or untrustworthy.

2162 |           (c) The applicant is so lacking in experience in managing a  
2163 | wholesale distributor as to make the issuance of the proposed  
2164 | permit hazardous to the public health.

2165 |           (d) The applicant is so lacking in experience in managing a  
2166 | wholesale distributor as to jeopardize the reasonable promise of  
2167 | successful operation of the wholesale distributor.

2168 |           (e) The applicant is lacking in experience in the  
2169 | distribution of prescription drugs.

2170 |           (f) The applicant's past experience in manufacturing or  
2171 | distributing prescription drugs indicates that the applicant  
2172 | poses a public health risk.

2173 |           (g) The applicant is affiliated directly or indirectly  
2174 | through ownership, control, or other business relations, with any  
2175 | person or persons whose business operations are or have been  
2176 | detrimental to the public health.



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2177 (h) The applicant, or any affiliated party, has been found  
2178 guilty of or has pleaded guilty or nolo contendere to any felony  
2179 or crime punishable by imprisonment for 1 year or more under the  
2180 laws of the United States, any state, or any other country,  
2181 regardless of whether adjudication of guilt was withheld.

2182 (i) The applicant or any affiliated party has been charged  
2183 with a felony in a state or federal court and the disposition of  
2184 that charge is pending during the application review or renewal  
2185 review period.

2186 (j) The applicant has furnished false or fraudulent  
2187 information or material in any application made in this state or  
2188 any other state in connection with obtaining a permit or license  
2189 to manufacture or distribute drugs, devices, or cosmetics.

2190 (k) That a federal, state, or local government permit  
2191 currently or previously held by the applicant, or any affiliated  
2192 party, for the manufacture or distribution of any drugs, devices,  
2193 or cosmetics has been disciplined, suspended, or revoked and has  
2194 not been reinstated.

2195 (l) The applicant does not possess the financial or  
2196 physical resources to operate in compliance with the permit being  
2197 sought, this chapter, and the rules adopted under this chapter.

2198 (m) The applicant or any affiliated party receives,  
2199 directly or indirectly, financial support and assistance from a  
2200 person who was an affiliated party of a permittee whose permit  
2201 was subject to discipline or was suspended or revoked, other than  
2202 through the ownership of stock in a publicly traded company or a  
2203 mutual fund.

2204 (n) The applicant or any affiliated party receives,  
2205 directly or indirectly, financial support and assistance from a  
2206 person who has been found guilty of any violation of this part

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2207 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,  
2208 any rules adopted under any of this part ~~those sections~~ or those  
2209 chapters, any federal or state drug law, or any felony where the  
2210 underlying facts related to drugs, regardless of whether the  
2211 person has been pardoned, had her or his civil rights restored,  
2212 or had adjudication withheld, other than through the ownership of  
2213 stock in a publicly traded company or a mutual fund.

2214 (o) The applicant for renewal of a permit under s.  
2215 499.01(2)(d) ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(c)~~  
2216 has not actively engaged in the wholesale distribution of  
2217 prescription drugs, as demonstrated by the regular and systematic  
2218 distribution of prescription drugs throughout the year as  
2219 evidenced by not fewer than 12 wholesale distributions in the  
2220 previous year and not fewer than three wholesale distributions in  
2221 the previous 6 months.

2222 (p) Information obtained in response to s. 499.01(2)(d)  
2223 ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(c)~~ demonstrates  
2224 it would not be in the best interest of the public health,  
2225 safety, and welfare to issue a permit.

2226 (q) The applicant does not possess the financial standing  
2227 and business experience for the successful operation of the  
2228 applicant.

2229 (r) The applicant or any affiliated party has failed to  
2230 comply with the requirements for manufacturing or distributing  
2231 prescription drugs under this part ~~ss. 499.001-499.081~~, similar  
2232 federal laws, similar laws in other states, or the rules adopted  
2233 under such laws.

2234 ~~(11)(6)~~ Upon approval of the application by the department  
2235 and payment of the required fee, the department shall issue or  
2236 renew a prescription drug wholesale distributor ~~wholesaler~~ or an

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2237 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2238 permit to the applicant.

2239 (12)(7) For a permit ~~permits~~ for a prescription drug  
2240 wholesale distributor ~~wholesalers~~ or an out-of-state prescription  
2241 drug wholesale distributor ~~wholesalers~~:

2242 (a) The department shall adopt rules for the annual renewal  
2243 of permits. At least 90 days before the expiration of a permit,  
2244 the department shall forward a permit renewal notification and  
2245 renewal application to the prescription drug wholesale  
2246 distributor ~~wholesaler~~ or out-of-state prescription drug  
2247 wholesale distributor ~~wholesaler~~ at the mailing address of the  
2248 permitted establishment on file with the department. The permit  
2249 renewal notification must state conspicuously the date on which  
2250 the permit for the establishment will expire and that the  
2251 establishment may not operate unless the permit for the  
2252 establishment is renewed timely.

2253 (b) A permit, unless sooner suspended or revoked,  
2254 automatically expires 1 year after the last day of the  
2255 anniversary month in which the permit was originally issued. A  
2256 permit may be renewed by making application for renewal on forms  
2257 furnished by the department and paying the appropriate fees. If a  
2258 renewal application and fee are submitted and postmarked after 45  
2259 days prior to the expiration date of the permit, the permit may  
2260 be renewed only upon payment of a late renewal fee of \$100, plus  
2261 the required renewal fee. A permittee that has submitted a  
2262 renewal application in accordance with this paragraph may  
2263 continue to operate under its permit, unless the permit is  
2264 suspended or revoked, until final disposition of the renewal  
2265 application.



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2266 (c) Failure to renew a permit in accordance with this  
2267 section precludes any future renewal of that permit. If a permit  
2268 issued pursuant to this section has expired and cannot be  
2269 renewed, before an establishment may engage in activities that  
2270 require a permit under this part ~~ss. 499.001-499.081~~, the  
2271 establishment must submit an application for a new permit; pay  
2272 the applicable application fee, initial permit fee, and all  
2273 applicable penalties; and be issued a new permit by the  
2274 department.

2275 ~~(13)-(8)~~ A person that engages in wholesale distribution of  
2276 prescription drugs in this state must have a wholesale  
2277 distributor's permit issued by the department, except as noted in  
2278 this section. Each establishment must be separately permitted  
2279 except as noted in this subsection.

2280 (a) A separate establishment permit is not required when a  
2281 permitted prescription drug wholesale distributor ~~wholesaler~~  
2282 consigns a prescription drug to a pharmacy that is permitted  
2283 under chapter 465 and located in this state, provided that:

2284 1. The consignor wholesale distributor ~~wholesaler~~ notifies  
2285 the department in writing of the contract to consign prescription  
2286 drugs to a pharmacy along with the identity and location of each  
2287 consignee pharmacy;

2288 2. The pharmacy maintains its permit under chapter 465;

2289 3. The consignor wholesale distributor ~~wholesaler~~, which  
2290 has no legal authority to dispense prescription drugs, complies  
2291 with all wholesale distribution requirements of ss. ~~s.~~ 499.0121  
2292 and 499.01212 with respect to the consigned drugs and maintains  
2293 records documenting the transfer of title or other completion of  
2294 the wholesale distribution of the consigned prescription drugs;



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2295 4. The distribution of the prescription drug is otherwise  
2296 lawful under this chapter and other applicable law;

2297 5. Open packages containing prescription drugs within a  
2298 pharmacy are the responsibility of the pharmacy, regardless of  
2299 how the drugs are titled; and

2300 6. The pharmacy dispenses the consigned prescription drug  
2301 in accordance with the limitations of its permit under chapter  
2302 465 or returns the consigned prescription drug to the consignor  
2303 wholesale distributor ~~wholesaler~~. In addition, a person who holds  
2304 title to prescription drugs may transfer the drugs to a person  
2305 permitted or licensed to handle the reverse distribution or  
2306 destruction of drugs. Any other distribution by and means of the  
2307 consigned prescription drug by any person, not limited to the  
2308 consignor wholesale distributor ~~wholesaler~~ or consignee pharmacy,  
2309 to any other person is prohibited.

2310 (b) A wholesale distributor's permit is not required for  
2311 the one-time transfer of title of a pharmacy's lawfully acquired  
2312 prescription drug inventory by a pharmacy with a valid permit  
2313 issued under chapter 465 to a consignor prescription drug  
2314 wholesale distributor ~~wholesaler~~, permitted under this chapter,  
2315 in accordance with a written consignment agreement between the  
2316 pharmacy and that wholesale distributor ~~wholesaler~~ if: the  
2317 permitted pharmacy and the permitted prescription drug wholesale  
2318 distributor ~~wholesaler~~ comply with all of the provisions of  
2319 paragraph (a) and the prescription drugs continue to be within  
2320 the permitted pharmacy's inventory for dispensing in accordance  
2321 with the limitations of the pharmacy permit under chapter 465. A  
2322 consignor drug wholesale distributor ~~wholesaler~~ may not use the  
2323 pharmacy as a wholesale distributor through which it distributes  
2324 the prescription ~~legend~~ drugs to other pharmacies. Nothing in

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2325 | this section is intended to prevent a wholesale ~~drug~~ distributor  
2326 | from obtaining this inventory in the event of nonpayment by the  
2327 | pharmacy.

2328 |       (c) The department shall require information from each  
2329 | wholesale distributor as part of the permit and renewal of such  
2330 | permit, as required under ~~s. 499.01~~ or this section.

2331 |       (14) ~~(9)~~ Personnel employed in wholesale distribution must  
2332 | have appropriate education and experience to enable them to  
2333 | perform their duties in compliance with state permitting  
2334 | requirements.

2335 |       (15) ~~(10)~~ The name of a permittee or establishment on a  
2336 | prescription drug wholesale distributor ~~wholesaler~~ permit or an  
2337 | out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2338 | permit may not include any indicia of attainment of any  
2339 | educational degree, any indicia that the permittee or  
2340 | establishment possesses a professional license, or any name or  
2341 | abbreviation that the department determines is likely to cause  
2342 | confusion or mistake or that the department determines is  
2343 | deceptive, including that of any other entity authorized to  
2344 | purchase prescription drugs.

2345 |       (16) ~~(11)~~ (a) Each establishment that is issued an initial or  
2346 | renewal permit as a prescription drug wholesale distributor  
2347 | ~~wholesaler~~ or an out-of-state prescription drug wholesale  
2348 | distributor ~~wholesaler~~ must designate in writing to the  
2349 | department at least one natural person to serve as the designated  
2350 | representative of the wholesale distributor ~~wholesaler~~. Such  
2351 | person must have an active certification as a designated  
2352 | representative from the department.

2353 |       (b) To be certified as a designated representative, a  
2354 | natural person must:





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- 2355 | 1. Submit an application on a form furnished by the  
2356 | department and pay the appropriate fees;
- 2357 | 2. Be at least 18 years of age;
- 2358 | 3. Have not less than 2 years of verifiable full-time work  
2359 | experience in a pharmacy licensed in this state or another state,  
2360 | where the person's responsibilities included, but were not  
2361 | limited to, recordkeeping for prescription drugs, or have not  
2362 | less than 2 years of verifiable full-time managerial experience  
2363 | with a prescription drug wholesale distributor ~~wholesaler~~  
2364 | licensed in this state or in another state;
- 2365 | 4. Receive a passing score of at least 75 percent on an  
2366 | examination given by the department regarding federal laws  
2367 | governing distribution of prescription drugs and this part ss.  
2368 | ~~499.001-499.081~~ and the rules adopted by the department governing  
2369 | the wholesale distribution of prescription drugs. This  
2370 | requirement shall be effective 1 year after the results of the  
2371 | initial examination are mailed to the persons that took the  
2372 | examination. The department shall offer such examinations at  
2373 | least four times each calendar year; and
- 2374 | 5. Provide the department with a personal information  
2375 | statement and fingerprints pursuant to subsection (9) ~~(4)~~.
- 2376 | (c) The department may deny an application for  
2377 | certification as a designated representative or may suspend or  
2378 | revoke a certification of a designated representative pursuant to  
2379 | s. 499.067.
- 2380 | (d) A designated representative:
- 2381 | 1. Must be actively involved in and aware of the actual  
2382 | daily operation of the wholesale distributor.
- 2383 | 2. Must be employed full time in a managerial position by  
2384 | the wholesale distributor.



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2385           3. Must be physically present at the establishment during  
2386 normal business hours, except for time periods when absent due to  
2387 illness, family illness or death, scheduled vacation, or other  
2388 authorized absence.

2389           4. May serve as a designated representative for only one  
2390 wholesale distributor at any one time.

2391           (e) A wholesale distributor must notify the department when  
2392 a designated representative leaves the employ of the wholesale  
2393 distributor. Such notice must be provided to the department  
2394 within 10 business days after the last day of designated  
2395 representative's employment with the wholesale distributor.

2396           (f) A wholesale distributor may not operate under a  
2397 prescription drug wholesale distributor ~~wholesaler~~ permit or an  
2398 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2399 permit for more than 10 business days after the designated  
2400 representative leaves the employ of the wholesale distributor,  
2401 unless the wholesale distributor employs another designated  
2402 representative and notifies the department within 10 business  
2403 days of the identity of the new designated representative.

2404           Section 12. Section 499.01201, Florida Statutes, is amended  
2405 to read:

2406           499.01201 Agency for Health Care Administration review and  
2407 use of statute and rule violation or compliance  
2408 data.--Notwithstanding any other provisions of law to the  
2409 contrary, the Agency for Health Care Administration may not:

2410           (1) Review or use any violation or alleged violation of s.  
2411 499.0121(6) or s. 499.01212, or any rules adopted under those  
2412 sections ~~that section~~, as a ground for denying or withholding any  
2413 payment of a Medicaid reimbursement to a pharmacy licensed under  
2414 chapter 465; or



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2415 (2) Review or use compliance with s. 499.0121(6) or s.  
2416 499.01212, or any rules adopted under those sections ~~that~~  
2417 ~~section~~, as the subject of any audit of Medicaid-related records  
2418 held by a pharmacy licensed under chapter 465.

2419 Section 13. Section 499.0121, Florida Statutes, is amended,  
2420 and subsection (4) of section 499.013, Florida Statutes, is  
2421 redesignated as paragraph (d) of subsection (6) of that section  
2422 and amended, to read:

2423 499.0121 Storage and handling of prescription drugs;  
2424 recordkeeping.--The department shall adopt rules to implement  
2425 this section as necessary to protect the public health, safety,  
2426 and welfare. Such rules shall include, but not be limited to,  
2427 requirements for the storage and handling of prescription drugs  
2428 and for the establishment and maintenance of prescription drug  
2429 distribution records.

2430 (1) ESTABLISHMENTS.--An establishment at which prescription  
2431 drugs are stored, warehoused, handled, held, offered, marketed,  
2432 or displayed must:

2433 (a) Be of suitable size and construction to facilitate  
2434 cleaning, maintenance, and proper operations;

2435 (b) Have storage areas designed to provide adequate  
2436 lighting, ventilation, temperature, sanitation, humidity, space,  
2437 equipment, and security conditions;

2438 (c) Have a quarantine area for storage of prescription  
2439 drugs that are outdated, damaged, deteriorated, misbranded, or  
2440 adulterated, or that are in immediate or sealed, secondary  
2441 containers that have been opened;

2442 (d) Be maintained in a clean and orderly condition; and

2443 (e) Be free from infestation by insects, rodents, birds, or  
2444 vermin of any kind.



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2445 (2) SECURITY.--

2446 (a) An establishment that is used for wholesale drug  
2447 distribution must be secure from unauthorized entry.

2448 1. Access from outside the premises must be kept to a  
2449 minimum and be well-controlled.

2450 2. The outside perimeter of the premises must be well-  
2451 lighted.

2452 3. Entry into areas where prescription drugs are held must  
2453 be limited to authorized personnel.

2454 (b) An establishment that is used for wholesale drug  
2455 distribution must be equipped with:

2456 1. An alarm system to detect entry after hours; however,  
2457 the department may exempt by rule establishments that only hold a  
2458 permit as prescription drug wholesale distributor-brokers  
2459 ~~wholesaler-brokers~~ and establishments that only handle medical  
2460 oxygen; and

2461 2. A security system that will provide suitable protection  
2462 against theft and diversion. When appropriate, the security  
2463 system must provide protection against theft or diversion that is  
2464 facilitated or hidden by tampering with computers or electronic  
2465 records.

2466 (c) Any vehicle that contains prescription drugs must be  
2467 secure from unauthorized access to the prescription drugs in the  
2468 vehicle.

2469 (3) STORAGE.--All prescription drugs shall be stored at  
2470 appropriate temperatures and under appropriate conditions in  
2471 accordance with requirements, if any, in the labeling of such  
2472 drugs, or with requirements in the official compendium.

2473 (a) If no storage requirements are established for a  
2474 prescription drug, the drug may be held at "controlled" room

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2475 | temperature, as defined in the official compendium, to help  
2476 | ensure that its identity, strength, quality, and purity are not  
2477 | adversely affected.

2478 |       (b) Appropriate manual, electromechanical, or electronic  
2479 | temperature and humidity recording equipment, devices, or logs  
2480 | must be used to document proper storage of prescription drugs.

2481 |       (c) The recordkeeping requirements in subsection (6) must  
2482 | be followed for all stored prescription drugs.

2483 |       (4) EXAMINATION OF MATERIALS AND RECORDS.--

2484 |       (a) Upon receipt, each outside shipping container must be  
2485 | visually examined for identity and to prevent the acceptance of  
2486 | contaminated prescription drugs that are otherwise unfit for  
2487 | distribution. This examination must be adequate to reveal  
2488 | container damage that would suggest possible contamination or  
2489 | other damage to the contents.

2490 |       (b) Each outgoing shipment must be carefully inspected for  
2491 | identity of the prescription drug products and to ensure that  
2492 | there is no delivery of prescription drugs that have expired or  
2493 | been damaged in storage or held under improper conditions.

2494 |       (c) The recordkeeping requirements in subsection (6) must  
2495 | be followed for all incoming and outgoing prescription drugs.

2496 |       (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must  
2497 | review records required under this section for the acquisition of  
2498 | prescription drugs for accuracy and completeness, considering the  
2499 | total facts and circumstances surrounding the transactions and  
2500 | the wholesale distributors involved. This includes authenticating  
2501 | each transaction listed on a pedigree paper, as defined in s.  
2502 | 499.003(37) ~~s. 499.001(31)~~.

2503 |       (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--



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2504 (a)1. Prescription drugs that are outdated, damaged,  
2505 deteriorated, misbranded, or adulterated must be quarantined and  
2506 physically separated from other prescription drugs until they are  
2507 destroyed or returned to their supplier. A quarantine section  
2508 must be separate and apart from other sections where prescription  
2509 drugs are stored so that prescription drugs in this section are  
2510 not confused with usable prescription drugs.

2511 2. Prescription drugs must be examined at least every 12  
2512 months, and drugs for which the expiration date has passed must  
2513 be removed and quarantined.

2514 (b) Any prescription drugs of which the immediate or sealed  
2515 outer containers or sealed secondary containers have been opened  
2516 or used must be identified as such and must be quarantined and  
2517 physically separated from other prescription drugs until they are  
2518 either destroyed or returned to the supplier.

2519 (c) If the conditions under which a prescription drug has  
2520 been returned cast doubt on the drug's safety, identity,  
2521 strength, quality, or purity, the drug must be destroyed or  
2522 returned to the supplier, unless examination, testing, or other  
2523 investigation proves that the drug meets appropriate standards of  
2524 safety, identity, strength, quality, and purity. In determining  
2525 whether the conditions under which a drug has been returned cast  
2526 doubt on the drug's safety, identity, strength, quality, or  
2527 purity, the wholesale ~~drug~~ distributor must consider, among other  
2528 things, the conditions under which the drug has been held,  
2529 stored, or shipped before or during its return and the conditions  
2530 of the drug and its container, carton, or labeling, as a result  
2531 of storage or shipping.



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2532 (d) The recordkeeping requirements in subsection (6) must  
2533 be followed for all outdated, damaged, deteriorated, misbranded,  
2534 or adulterated prescription drugs.

2535 (6) RECORDKEEPING.--The department shall adopt rules that  
2536 require keeping such records of prescription drugs as are  
2537 necessary for the protection of the public health.

2538 (a) Wholesale ~~drug~~ distributors must establish and maintain  
2539 inventories and records of all transactions regarding the receipt  
2540 and distribution or other disposition of prescription drugs.  
2541 These records must provide a complete audit trail from receipt to  
2542 sale or other disposition, be readily retrievable for inspection,  
2543 and include, at a minimum, the following information:

2544 1. The source of the drugs, including the name and  
2545 principal address of the seller or transferor, and the address of  
2546 the location from which the drugs were shipped;

2547 2. The name, principal address, and state license permit or  
2548 registration number of the person authorized to purchase  
2549 prescription drugs;

2550 3. The name, strength, dosage form, and quantity of the  
2551 drugs received and distributed or disposed of;

2552 4. The dates of receipt and distribution or other  
2553 disposition of the drugs; and

2554 5. Any financial documentation supporting the transaction.

2555 (b) Inventories and records must be made available for  
2556 inspection and photocopying by authorized federal, state, or  
2557 local officials for a period of 2 years following disposition of  
2558 the drugs or 3 years after the creation of the records, whichever  
2559 period is longer.

2560 (c) Records described in this section that are kept at the  
2561 inspection site or that can be immediately retrieved by computer



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2562 or other electronic means must be readily available for  
2563 authorized inspection during the retention period. Records that  
2564 are kept at a central location outside of this state and that are  
2565 not electronically retrievable must be made available for  
2566 inspection within 2 working days after a request by an authorized  
2567 official of a federal, state, or local law enforcement agency.  
2568 Records that are maintained at a central location within this  
2569 state must be maintained at an establishment that is permitted  
2570 pursuant to this part ~~ss. 499.001-499.081~~ and must be readily  
2571 available.

2572 (d)(4) Each manufacturer or repackager of medical devices,  
2573 over-the-counter drugs, or cosmetics must maintain records that  
2574 include the name and principal address of the seller or  
2575 transferor of the product, the address of the location from which  
2576 the product was shipped, the date of the transaction, the name  
2577 and quantity of the product involved, and the name and principal  
2578 address of the person who purchased the product.

2579 (e) A wholesale distributor must maintain pedigree papers  
2580 separate and distinct from other records required under this  
2581 chapter.

2582 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~  
2583 ~~the wholesale distribution of a prescription drug and who is not~~  
2584 ~~the manufacturer of that drug must, before each wholesale~~  
2585 ~~distribution of such drug, provide to the person who receives the~~  
2586 ~~drug a pedigree paper as defined in s. 499.003(31).~~

2587 ~~2. A repackager must comply with this paragraph.~~

2588 ~~3. The pedigree paper requirements in this paragraph do not~~  
2589 ~~apply to compressed medical gases or veterinary legend drugs.~~





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2590           ~~4. Each wholesale distributor of prescription drugs must~~  
2591 ~~maintain separate and distinct from other required records all~~  
2592 ~~statements that are required under subparagraph 1.~~

2593           ~~5. Subparagraph 1. is satisfied when a wholesale~~  
2594 ~~distributor takes title to, but not possession of, a prescription~~  
2595 ~~drug and the prescription drug's manufacturer ships the~~  
2596 ~~prescription drug directly to a person authorized by law to~~  
2597 ~~purchase prescription drugs for the purpose of administering or~~  
2598 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~  
2599 ~~affiliated group, as described in paragraph (f), with the~~  
2600 ~~exception of a repackager.~~

2601           ~~a. The wholesale distributor must deliver to the recipient~~  
2602 ~~of the prescription drug, within 14 days after the shipment~~  
2603 ~~notification from the manufacturer, an invoice and the following~~  
2604 ~~sworn statement: "This wholesale distributor purchased the~~  
2605 ~~specific unit of the prescription drug listed on the invoice~~  
2606 ~~directly from the manufacturer, and the specific unit of~~  
2607 ~~prescription drug was shipped by the manufacturer directly to a~~  
2608 ~~person authorized by law to administer or dispense the legend~~  
2609 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~  
2610 ~~an affiliated group, as described in s. 499.0121(6)(f), Florida~~  
2611 ~~Statutes, with the exception of a repackager." The invoice must~~  
2612 ~~contain a unique cross-reference to the shipping document sent by~~  
2613 ~~the manufacturer to the recipient of the prescription drug.~~

2614           ~~b. The manufacturer of the prescription drug shipped~~  
2615 ~~directly to the recipient under this section must provide and the~~  
2616 ~~recipient of the prescription drug must acquire, within 14 days~~  
2617 ~~after receipt of the prescription drug, a shipping document from~~  
2618 ~~the manufacturer that contains, at a minimum:~~

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2619 ~~(I) The name and address of the manufacturer, including the~~  
2620 ~~point of origin of the shipment, and the names and addresses of~~  
2621 ~~the wholesaler and the purchaser.~~

2622 ~~(II) The name of the prescription drug as it appears on the~~  
2623 ~~label.~~

2624 ~~(III) The quantity, dosage form, and strength of the~~  
2625 ~~prescription drug.~~

2626 ~~(IV) The date of the shipment from the manufacturer.~~

2627 ~~e. The wholesale distributor must also maintain and make~~  
2628 ~~available to the department, upon request, the lot number of such~~  
2629 ~~drug if not contained in the shipping document acquired by the~~  
2630 ~~recipient.~~

2631 ~~6. Failure of the manufacturer to provide, the recipient to~~  
2632 ~~acquire, or the wholesale distributor to deliver, the~~  
2633 ~~documentation required under subparagraph 5. shall constitute~~  
2634 ~~failure to acquire or deliver a pedigree paper under s. 499.0051.~~  
2635 ~~Forgery by the manufacturer, the recipient, or the wholesale~~  
2636 ~~distributor of the documentation required to be acquired or~~  
2637 ~~delivered under subparagraph 5. shall constitute forgery of a~~  
2638 ~~pedigree paper under s. 499.0051.~~

2639 ~~7. The department may, by rule, specify alternatives to~~  
2640 ~~compliance with subparagraph 1. for a prescription drug in the~~  
2641 ~~inventory of a permitted prescription drug wholesaler as of June~~  
2642 ~~30, 2006, and the return of a prescription drug purchased prior~~  
2643 ~~to July 1, 2006. The department may specify time limits for such~~  
2644 ~~alternatives.~~

2645 ~~(7)(e) PRESCRIPTION DRUG PURCHASE LIST.--Each wholesale~~  
2646 ~~distributor, except for a manufacturer, shall annually provide~~  
2647 ~~the department with a written list of all wholesale distributors~~  
2648 ~~and manufacturers from whom the wholesale distributor purchases~~

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2649 prescription drugs. A wholesale distributor, except a  
2650 manufacturer, shall notify the department not later than 10 days  
2651 after any change to either list. Such portions of the information  
2652 required pursuant to this subsection ~~paragraph~~ which are a trade  
2653 secret, as defined in s. 812.081, shall be maintained by the  
2654 department as trade secret information is required to be  
2655 maintained under s. 499.051.

2656 ~~(f)1. This paragraph applies only to an affiliated group,~~  
2657 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~  
2658 ~~amended, which is composed of chain drug entities, including at~~  
2659 ~~least 50 retail pharmacies, warehouses, or repackagers, which are~~  
2660 ~~members of the same affiliated group, if the affiliated group:~~

2661 ~~a. Discloses to the department the names of all its~~  
2662 ~~members; and~~

2663 ~~b. Agrees in writing to provide records on prescription~~  
2664 ~~drug purchases by members of the affiliated group not later than~~  
2665 ~~48 hours after the department requests such records, regardless~~  
2666 ~~of the location where the records are stored.~~

2667 ~~2. Each warehouse within the affiliated group must comply~~  
2668 ~~with all applicable federal and state drug wholesale permit~~  
2669 ~~requirements and must purchase, receive, hold, and distribute~~  
2670 ~~prescription drugs only to a retail pharmacy or warehouse within~~  
2671 ~~the affiliated group. Such a warehouse is exempt from providing a~~  
2672 ~~pedigree paper in accordance with paragraph (d) to its affiliated~~  
2673 ~~group member warehouse or retail pharmacy, provided that:~~

2674 ~~a. Any affiliated group member that purchases or receives a~~  
2675 ~~prescription drug from outside the affiliated group must receive~~  
2676 ~~a pedigree paper if the prescription drug is distributed in or~~  
2677 ~~into this state and a pedigree paper is required under this~~  
2678 ~~section and must authenticate the documentation as required in~~



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2679 ~~subsection (4), regardless of whether the affiliated group member~~  
2680 ~~is directly subject to regulation under this chapter; and~~

2681 ~~b. The affiliated group makes available to the department~~  
2682 ~~on request all records related to the purchase or acquisition of~~  
2683 ~~prescription drugs by members of the affiliated group, regardless~~  
2684 ~~of the location where the records are stored, if the prescription~~  
2685 ~~drugs were distributed in or into this state.~~

2686 ~~3. If a repackager repackages prescription drugs solely for~~  
2687 ~~distribution to its affiliated group members for the exclusive~~  
2688 ~~distribution to and among retail pharmacies that are members of~~  
2689 ~~the affiliated group to which the repackager is a member:~~

2690 ~~a. The repackager must:~~

2691 ~~(I) In lieu of the written statement required by paragraph~~  
2692 ~~(d), for all repackaged prescription drugs distributed in or into~~  
2693 ~~this state, state in writing under oath with each distribution of~~  
2694 ~~a repackaged prescription drug to an affiliated group member~~  
2695 ~~warehouse or repackager: "All repackaged prescription drugs are~~  
2696 ~~purchased by the affiliated group directly from the manufacturer~~  
2697 ~~or from a prescription drug wholesaler that purchased the~~  
2698 ~~prescription drugs directly from the manufacturer.";~~

2699 ~~(II) Purchase all prescription drugs it repackages:~~

2700 ~~(A) Directly from the manufacturer; or~~

2701 ~~(B) From a prescription drug wholesaler that purchased the~~  
2702 ~~prescription drugs directly from the manufacturer; and~~

2703 ~~(III) Maintain records in accordance with this section to~~  
2704 ~~document that it purchased the prescription drugs directly from~~  
2705 ~~the manufacturer or that its prescription drug wholesale supplier~~  
2706 ~~purchased the prescription drugs directly from the manufacturer.~~

2707 ~~b. All members of the affiliated group must provide to~~  
2708 ~~agents of the department on request records of purchases by all~~



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2709 ~~members of the affiliated group of prescription drugs that have~~  
2710 ~~been repackaged, regardless of the location where the records are~~  
2711 ~~stored or where the repackager is located.~~

2712 (8) ~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale ~~drug~~  
2713 distributors must establish, maintain, and adhere to written  
2714 policies and procedures, which must be followed for the receipt,  
2715 security, storage, inventory, and distribution of prescription  
2716 drugs, including policies and procedures for identifying,  
2717 recording, and reporting losses or thefts, and for correcting all  
2718 errors and inaccuracies in inventories. Wholesale ~~drug~~  
2719 distributors must include in their written policies and  
2720 procedures:

2721 (a) A procedure whereby the oldest approved stock of a  
2722 prescription drug product is distributed first. The procedure may  
2723 permit deviation from this requirement, if the deviation is  
2724 temporary and appropriate.

2725 (b) A procedure to be followed for handling recalls and  
2726 withdrawals of prescription drugs. Such procedure must be  
2727 adequate to deal with recalls and withdrawals due to:

2728 1. Any action initiated at the request of the Food and Drug  
2729 Administration or any other federal, state, or local law  
2730 enforcement or other government agency, including the department.

2731 2. Any voluntary action by the manufacturer or repackager  
2732 to remove defective or potentially defective drugs from the  
2733 market; or

2734 3. Any action undertaken to promote public health and  
2735 safety by replacing existing merchandise with an improved product  
2736 or new package design.

2737 (c) A procedure to ensure that wholesale ~~drug~~ distributors  
2738 prepare for, protect against, and handle any crisis that affects



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2739 security or operation of any facility if a strike, fire, flood,  
2740 or other natural disaster, or a local, state, or national  
2741 emergency, occurs.

2742 (d) A procedure to ensure that any outdated prescription  
2743 drugs are segregated from other drugs and either returned to the  
2744 manufacturer or repackager or destroyed. This procedure must  
2745 provide for written documentation of the disposition of outdated  
2746 prescription drugs. This documentation must be maintained for 2  
2747 years after disposition of the outdated drugs.

2748 ~~(9)~~ ~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors  
2749 must establish and maintain lists of officers, directors,  
2750 managers, designated representatives, and other persons in charge  
2751 of wholesale drug distribution, storage, and handling, including  
2752 a description of their duties and a summary of their  
2753 qualifications.

2754 ~~(10)~~ ~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A  
2755 wholesale ~~drug~~ distributor must operate in compliance with  
2756 applicable federal, state, and local laws and regulations.

2757 (a) A wholesale ~~drug~~ distributor must allow the department  
2758 and authorized federal, state, and local officials to enter and  
2759 inspect its premises and delivery vehicles, and to audit its  
2760 records and written operating procedures, at reasonable times and  
2761 in a reasonable manner, to the extent authorized by law.

2762 (b) A wholesale ~~drug~~ distributor that deals in controlled  
2763 substances must register with the Drug Enforcement Administration  
2764 and must comply with all applicable state, local, and federal  
2765 laws. A wholesale ~~drug~~ distributor that distributes any substance  
2766 controlled under chapter 893 must notify the department when  
2767 registering with the Drug Enforcement Administration pursuant to  
2768 that chapter and must provide the department with its DEA number.



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2769            (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~  
2770 distributor is subject to any applicable federal, state, or local  
2771 laws or regulations that relate to prescription drug product  
2772 salvaging or reprocessing.

2773            (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person  
2774 responsible for shipment and transportation of a prescription  
2775 drug in a wholesale distribution may use a common carrier; its  
2776 own vehicle or employee acting within the scope of employment if  
2777 authorized under s. 499.03 for the possession of prescription  
2778 drugs in this state; or, in the case of a prescription drug  
2779 intended for domestic distribution, an independent contractor who  
2780 must be the agent of the authorized seller or recipient  
2781 responsible for shipping and transportation as set forth in a  
2782 written contract between the parties. A person selling a  
2783 prescription drug for export must obtain documentation, such as a  
2784 validated airway bill, bill of lading, or other appropriate  
2785 documentation that the prescription drug was exported. A person  
2786 responsible for shipping or transporting prescription drugs is  
2787 not required to maintain documentation from a common carrier that  
2788 the designated recipient received the prescription drugs;  
2789 however, the person must obtain such documentation from the  
2790 common carrier and make it available to the department upon  
2791 request of the department.

2792            (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing  
2793 any prescription drugs from another wholesale ~~drug~~ distributor, a  
2794 prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
2795 state prescription drug wholesale distributor ~~wholesaler~~, or a  
2796 prescription drug repackager must:

2797            (a) Enter an agreement with the selling wholesale ~~drug~~  
2798 distributor by which the selling wholesale ~~drug~~ distributor will



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2799 | indemnify the purchasing wholesale ~~drug~~ distributor for any loss  
2800 | caused to the purchasing wholesale ~~drug~~ distributor related to  
2801 | the purchase of drugs from the selling wholesale ~~drug~~ distributor  
2802 | which are determined to be counterfeit or to have been  
2803 | distributed in violation of any federal or state law governing  
2804 | the distribution of drugs.

2805 |       (b) Determine that the selling wholesale ~~drug~~ distributor  
2806 | has insurance coverage of not less than the greater of 1 percent  
2807 | of the amount of total dollar volume of the prescription drug  
2808 | sales reported to the department under s. 499.012(8)(g) ~~s.~~  
2809 | ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed  
2810 | \$2 million.

2811 |       (c) Obtain information from the selling wholesale ~~drug~~  
2812 | distributor, including the length of time the selling wholesale  
2813 | ~~drug~~ distributor has been licensed in this state, a copy of the  
2814 | selling wholesale ~~drug~~ distributor's licenses or permits, and  
2815 | background information concerning the ownership of the selling  
2816 | wholesale ~~drug~~ distributor, including the experience of the  
2817 | wholesale distributor in the wholesale distribution of  
2818 | prescription drugs.

2819 |       (d) Verify that the selling wholesale ~~drug~~ distributor's  
2820 | Florida permit is valid.

2821 |       (e) Inspect the selling wholesale ~~drug~~ distributor's  
2822 | licensed establishment to document that it has a policies and  
2823 | procedures manual relating to the distribution of drugs, the  
2824 | appropriate temperature controlled environment for drugs  
2825 | requiring temperature control, an alarm system, appropriate  
2826 | access restrictions, and procedures to ensure that records  
2827 | related to the wholesale distribution of prescription drugs are  
2828 | maintained as required by law:





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2829 1. Before purchasing any drug from the wholesale ~~drug~~  
2830 distributor, and at least once each subsequent year; or

2831 2. Before purchasing any drug from the wholesale ~~drug~~  
2832 distributor, and each subsequent year obtain a complete copy of  
2833 the most recent inspection report for the establishment which was  
2834 prepared by the department or the regulatory authority  
2835 responsible for wholesale ~~drug~~ distributors in the state in which  
2836 the establishment is located.

2837 Section 14. Section 499.01211, Florida Statutes, is amended  
2838 to read:

2839 499.01211 Drug Wholesale Distributor ~~Wholesaler~~ Advisory  
2840 Council.--

2841 (1) There is created the Drug Wholesale Distributor  
2842 ~~Wholesaler~~ Advisory Council within the department. The council  
2843 shall meet at least once each calendar quarter. Staff for the  
2844 council shall be provided by the department. The council shall  
2845 consist of 11 members who shall serve without compensation. The  
2846 council shall elect a chairperson and a vice chairperson  
2847 annually.

2848 (2) The State Surgeon General, or his or her designee, and  
2849 the Secretary of Health Care Administration, or her or his  
2850 designee, shall be members of the council. The State Surgeon  
2851 General shall appoint nine additional members to the council who  
2852 shall be appointed to a term of 4 years each, as follows:

2853 (a) Three different persons each of whom is employed by a  
2854 different prescription drug wholesale distributor ~~wholesaler~~  
2855 licensed under this part ~~chapter~~ which operates nationally and is  
2856 a primary wholesale distributor ~~wholesaler~~, as defined in s.  
2857 499.003(49) ~~s. 499.012(1)(d)~~.



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2858 (b) One person employed by a prescription drug wholesale  
2859 distributor ~~wholesaler~~ licensed under this part ~~chapter~~ which is  
2860 a secondary wholesale distributor ~~wholesaler~~, as defined in s.  
2861 499.003(54) ~~s. 499.012(1)(f)~~.

2862 (c) One person employed by a retail pharmacy chain located  
2863 in this state.

2864 (d) One person who is a member of the Board of Pharmacy and  
2865 is a pharmacist licensed under chapter 465.

2866 (e) One person who is a physician licensed pursuant to  
2867 chapter 458 or chapter 459.

2868 (f) One person who is an employee of a hospital licensed  
2869 pursuant to chapter 395 and is a pharmacist licensed pursuant to  
2870 chapter 465.

2871 (g) One person who is an employee of a pharmaceutical  
2872 manufacturer.

2873 (3) The council shall review this part ~~ss. 499.001-499.081~~  
2874 and the rules adopted to administer this part ~~ss. 499.001-499.081~~  
2875 annually, provide input to the department regarding all proposed  
2876 rules to administer this part ~~ss. 499.001-499.081~~, make  
2877 recommendations to the department to improve the protection of  
2878 the prescription drugs and public health, make recommendations to  
2879 improve coordination with other states' regulatory agencies and  
2880 the federal government concerning the wholesale distribution of  
2881 drugs, and make recommendations to minimize the impact of  
2882 regulation of the wholesale distribution industry while ensuring  
2883 protection of the public health.

2884 Section 15. Section 499.01212, Florida Statutes, is created  
2885 to read:

2886 499.01212 Pedigree paper.--



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2887       (1) APPLICATION.--Each person who is engaged in the  
2888 wholesale distribution of a prescription drug must, prior to or  
2889 simultaneous with each wholesale distribution, provide a pedigree  
2890 paper to the person who receives the drug.

2891       (2) FORMAT.--A pedigree paper must contain the following  
2892 information:

2893       (a) For the wholesale distribution of a prescription drug  
2894 within the normal distribution chain:

2895           1. The following statement: "This wholesale distributor  
2896 purchased the specific unit of the prescription drug directly  
2897 from the manufacturer."

2898           2. The name of the prescription drug as it appears on the  
2899 label.

2900           3. The quantity, dosage form, and strength of the  
2901 prescription drug.

2902  
2903 The wholesale distributor must also maintain and make available  
2904 to the department, upon request, the point of origin of the  
2905 prescription drugs, including intracompany transfers, the date of  
2906 the shipment from the manufacturer to the wholesale distributor,  
2907 the lot numbers of such drugs, and the invoice numbers from the  
2908 manufacturer.

2909       (b) For all other wholesale distributions of prescription  
2910 drugs:

2911           1. The quantity, dosage form, and strength of the  
2912 prescription drugs.

2913           2. The lot numbers of the prescription drugs.

2914           3. The name and address of each owner of the prescription  
2915 drug and his or her signature.



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2916 4. Shipping information, including the name and address of  
2917 each person certifying delivery or receipt of the prescription  
2918 drug.

2919 5. An invoice number, a shipping document number, or  
2920 another number uniquely identifying the transaction.

2921 6. A certification that the recipient wholesale distributor  
2922 has authenticated the pedigree papers.

2923 7. The unique serialization of the prescription drug, if  
2924 the manufacturer or repackager has uniquely serialized the  
2925 individual prescription drug unit.

2926 8. The name, address, telephone number, and, if available,  
2927 e-mail contact information of each wholesale distributor involved  
2928 in the chain of the prescription drug's custody.

2929 (3) EXCEPTIONS.--A pedigree paper is not required for:

2930 (a) The wholesale distribution of a prescription drug by  
2931 the manufacturer.

2932 (b) The wholesale distribution of a compressed medical gas.

2933 (c) The wholesale distribution of a veterinary prescription  
2934 drug.

2935 (d) A drop shipment, provided:

2936 1. The wholesale distributor delivers to the recipient of  
2937 the prescription drug, within 14 days after the shipment  
2938 notification from the manufacturer, an invoice and the following  
2939 sworn statement: "This wholesale distributor purchased the  
2940 specific unit of the prescription drug listed on the invoice  
2941 directly from the manufacturer, and the specific unit of  
2942 prescription drug was shipped by the manufacturer directly to a  
2943 person authorized by law to administer or dispense the legend  
2944 drug, as defined in s. 465.003, Florida Statutes, or a member of  
2945 an affiliated group, with the exception of a repackager." The

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2946 invoice must contain a unique cross-reference to the shipping  
2947 document sent by the manufacturer to the recipient of the  
2948 prescription drug.

2949 2. The manufacturer of the prescription drug shipped  
2950 directly to the recipient provides and the recipient of the  
2951 prescription drug acquires, within 14 days after receipt of the  
2952 prescription drug, a shipping document from the manufacturer that  
2953 contains, at a minimum:

2954 a. The name and address of the manufacturer, including the  
2955 point of origin of the shipment, and the names and addresses of  
2956 the wholesale distributor and the purchaser.

2957 b. The name of the prescription drug as it appears on the  
2958 label.

2959 c. The quantity, dosage form, and strength of the  
2960 prescription drug.

2961 d. The date of the shipment from the manufacturer.

2962 3. The wholesale distributor maintains and makes available  
2963 to the department, upon request, the lot number of such drug if  
2964 not contained in the shipping document acquired by the recipient.

2965  
2966 Failure of the manufacturer to provide, the recipient to acquire,  
2967 or the wholesale distributor to deliver the documentation  
2968 required under this paragraph shall constitute failure to acquire  
2969 or deliver a pedigree paper under ss. 499.005(28) and 499.0051.

2970 Forgery by the manufacturer, the recipient, or the wholesale  
2971 distributor of the documentation required to be acquired or  
2972 delivered under this paragraph shall constitute forgery of a  
2973 pedigree paper under s. 499.0051.

2974 4. The wholesale distributor that takes title to, but not  
2975 possession of, the prescription drug is not a member of the



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2976 affiliated group that receives the prescription drug directly  
2977 from the manufacturer.

2978 (e) The wholesale distribution of a prescription drug by a  
2979 warehouse within an affiliated group to a warehouse or retail  
2980 pharmacy within its affiliated group, provided:

2981 1. Any affiliated group member that purchases or receives a  
2982 prescription drug from outside the affiliated group must receive  
2983 a pedigree paper if the prescription drug is distributed in or  
2984 into this state and a pedigree paper is required under this  
2985 section and must authenticate the documentation as required in s.  
2986 499.0121(4), regardless of whether the affiliated group member is  
2987 directly subject to regulation under this part; and

2988 2. The affiliated group makes available, within 48 hours,  
2989 to the department on request to one or more of its members all  
2990 records related to the purchase or acquisition of prescription  
2991 drugs by members of the affiliated group, regardless of the  
2992 location where the records are stored, if the prescription drugs  
2993 were distributed in or into this state.

2994 (f) The repackaging of prescription drugs by a repackager  
2995 solely for distribution to its affiliated group members for the  
2996 exclusive distribution to and among retail pharmacies that are  
2997 members of the affiliated group to which the repackager is a  
2998 member.

2999 1. The repackager must:

3000 a. For all repackaged prescription drugs distributed in or  
3001 into this state, state in writing under oath with each  
3002 distribution of a repackaged prescription drug to an affiliated  
3003 group member warehouse or repackager: "All repackaged  
3004 prescription drugs are purchased by the affiliated group directly  
3005 from the manufacturer or from a prescription drug wholesale



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3006 distributor that purchased the prescription drugs directly from  
3007 the manufacturer."

3008 b. Purchase all prescription drugs it repackages:

3009 (I) Directly from the manufacturer; or

3010 (II) From a prescription drug wholesale distributor that  
3011 purchased the prescription drugs directly from the manufacturer.

3012 c. Maintain records in accordance with this section to  
3013 document that it purchased the prescription drugs directly from  
3014 the manufacturer or that its prescription drug wholesale supplier  
3015 purchased the prescription drugs directly from the manufacturer.

3016 2. All members of the affiliated group must provide, within  
3017 48 hours, to agents of the department on request to one or more  
3018 of its members records of purchases by all members of the  
3019 affiliated group of prescription drugs that have been repackaged,  
3020 regardless of the location at which the records are stored or at  
3021 which the repackager is located.

3022 Section 16. Section 499.0122, Florida Statutes, is  
3023 repealed.

3024 Section 17. Section 499.013, Florida Statutes, is repealed.

3025 Section 18. Subsections (1), (3), (4), (6), (8), and (9) of  
3026 section 499.015, Florida Statutes, are amended to read:

3027 499.015 Registration of drugs, devices, and cosmetics;  
3028 issuance of certificates of free sale.--

3029 (1) (a) Except for those persons exempted from the  
3030 definition of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, any  
3031 person who manufactures, packages, repackages, labels, or  
3032 relabels a drug, device, or cosmetic in this state must register  
3033 such drug, device, or cosmetic biennially with the department;  
3034 pay a fee in accordance with the fee schedule provided by s.  
3035 499.041; and comply with this section. The registrant must list

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3036 each separate and distinct drug, device, or cosmetic at the time  
3037 of registration.

3038 (b) The department may not register any product that does  
3039 not comply with the Federal Food, Drug, and Cosmetic Act, as  
3040 amended, or Title 21 C.F.R. Registration of a product by the  
3041 department does not mean that the product does in fact comply  
3042 with all provisions of the Federal Food, Drug, and Cosmetic Act,  
3043 as amended.

3044 (3) Except for those persons exempted from the definition  
3045 of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, a person may  
3046 not sell any product that he or she has failed to register in  
3047 conformity with this section. Such failure to register subjects  
3048 such drug, device, or cosmetic product to seizure and  
3049 condemnation as provided in s. 499.062 ~~ss. 499.062-499.064~~, and  
3050 subjects such person to the penalties and remedies provided in  
3051 this part ~~ss. 499.001-499.081~~.

3052 (4) Unless a registration is renewed, it expires 2 years  
3053 after the last day of the month in which it was issued. The  
3054 department may issue a stop-sale notice or order against a person  
3055 that is subject to the requirements of this section and that  
3056 fails to comply with this section within 31 days after the date  
3057 the registration expires. The notice or order shall prohibit such  
3058 person from selling or causing to be sold any drugs, devices, or  
3059 cosmetics covered by this part ~~ss. 499.001-499.081~~ until he or  
3060 she complies with the requirements of this section.

3061 (6) The department may issue a certificate of free sale for  
3062 any product that is required to be registered under this part ~~ss.~~  
3063 ~~499.001-499.081~~.

3064 (8) Notwithstanding any requirements set forth in this part  
3065 ~~ss. 499.001-499.081~~, a manufacturer of medical devices that is





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3066 registered with the federal Food and Drug Administration is  
3067 exempt from this section and s. 499.041(6) if:

3068 (a) The manufacturer's medical devices are approved for  
3069 marketing by, or listed with the federal Food and Drug  
3070 Administration in accordance with federal law for commercial  
3071 distribution; or

3072 (b) The manufacturer subcontracts with a manufacturer of  
3073 medical devices to manufacture components of such devices.

3074 (9) However, the manufacturer must submit evidence of such  
3075 registration, listing, or approval with its initial application  
3076 for a permit to do business in this state, as required in s.  
3077 499.01 ~~s. 499.013~~ and any changes to such information previously  
3078 submitted at the time of renewal of the permit. Evidence of  
3079 approval, listing, and registration by the federal Food and Drug  
3080 Administration must include:

3081 (a) For Class II devices, a copy of the pre-market  
3082 notification letter (510K);

3083 (b) For Class III devices, a Federal Drug Administration  
3084 pre-market approval number;

3085 (c) For a manufacturer who subcontracts with a manufacturer  
3086 of medical devices to manufacture components of such devices, a  
3087 Federal Drug Administration registration number; or

3088 (d) For a manufacturer of medical devices whose devices are  
3089 exempt from pre-market approval by the Federal Drug  
3090 Administration, a Federal Drug Administration registration  
3091 number.

3092 Section 19. Subsections (3), (5), and (6) of section  
3093 499.024, Florida Statutes, are amended to read:

3094 499.024 Drug product classification.--The State Surgeon  
3095 General shall adopt rules to classify drug products intended for



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3096 use by humans which the United States Food and Drug  
3097 Administration has not classified in the federal act or the Code  
3098 of Federal Regulations.

3099 (3) Any product that falls under the definition of drug in  
3100 s. 499.003(19) definition, s. 499.003(17), may be classified  
3101 under the authority of this section. This section does not  
3102 subject portable emergency oxygen inhalators to classification;  
3103 however, this section does not exempt any person from ss. 499.01  
3104 and 499.015.

3105 (5) The department may by rule reclassify drugs subject to  
3106 this part ss. 499.001-499.081 when such classification action is  
3107 necessary to protect the public health.

3108 (6) The department may adopt rules that exempt from any  
3109 labeling or packaging requirements of this part ss. 499.001-  
3110 499.081 drugs classified under this section if those requirements  
3111 are not necessary to protect the public health.

3112 Section 20. Subsections (7), (12), and (15) of section  
3113 499.028, Florida Statutes, are amended to read:

3114 499.028 Drug samples or complimentary drugs; starter packs;  
3115 permits to distribute.--

3116 (7) A drug manufacturer or distributor must report to the  
3117 department any conviction of itself or of its assigns, agents,  
3118 employees, or representatives for a violation of s. 503(c)(1) of  
3119 the federal act or of this part ss. 499.001-499.081 because of  
3120 the sale, purchase, or trade of a drug sample or the offer to  
3121 sell, purchase, or trade a drug sample.

3122 (12) The department may suspend or revoke a permit issued  
3123 under this section, after giving notice and an opportunity to be  
3124 heard pursuant to chapter 120, when:



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3125 (a) Such permit was obtained by misrepresentation or fraud  
3126 or through a mistake of the department.

3127 (b) The holder of the permit has distributed or disposed of  
3128 any prescription legend drug, directly or through its agents,  
3129 employees, or independent contractors, to any person not  
3130 authorized to possess such drug.

3131 (c) The holder of the permit, or its agents, employees, or  
3132 independent contractors, has distributed or possessed any  
3133 prescription legend drug except in the usual course of its  
3134 business.

3135 (d) The holder of the permit, or its agents, employees, or  
3136 independent contractors, has distributed any prescription legend  
3137 drug that is misbranded or adulterated under this part ss-  
3138 ~~499.001-499.081~~.

3139 (e) The holder of the permit, or its agents, employees, or  
3140 independent contractors, has distributed any prescription legend  
3141 drug without written request, when a written request is required  
3142 by this section.

3143 (f) The holder of the permit has in its employ, or uses as  
3144 agent or independent contractor for the purpose of distributing  
3145 or disposing of drugs, any person who has:

3146 1. Violated the requirements of this section or any rule  
3147 adopted under this section.

3148 2. Been convicted in any of the courts of this state, the  
3149 United States, or any other state of a felony or any other crime  
3150 involving moral turpitude or involving those drugs named or  
3151 described in chapter 893.

3152 (15) A person may not possess a prescription drug sample  
3153 unless:



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3154 (a) The drug sample was prescribed to her or him as  
3155 evidenced by the label required in s. 465.0276(5).

3156 (b) She or he is the employee of a complimentary drug  
3157 distributor that holds a permit issued under this part ~~ss.~~  
3158 ~~499.001-499.081~~.

3159 (c) She or he is a person to whom prescription drug samples  
3160 may be distributed pursuant to this section.

3161 (d) He or she is an officer or employee of a federal,  
3162 state, or local government acting within the scope of his or her  
3163 employment.

3164 Section 21. Subsections (2) and (3) of section 499.029,  
3165 Florida Statutes, are amended to read:

3166 499.029 Cancer Drug Donation Program.--

3167 (2) There is created a Cancer Drug Donation Program within  
3168 the department ~~of Health~~ for the purpose of authorizing and  
3169 facilitating the donation of cancer drugs and supplies to  
3170 eligible patients.

3171 (3) As used in this section:

3172 (a) "Cancer drug" means a prescription drug that has been  
3173 approved under s. 505 of the federal Food, Drug, and Cosmetic Act  
3174 and is used to treat cancer or its side effects or is used to  
3175 treat the side effects of a prescription drug used to treat  
3176 cancer or its side effects. "Cancer drug" does not include a  
3177 substance listed in Schedule II, Schedule III, Schedule IV, or  
3178 Schedule V of s. 893.03.

3179 (b) "Closed drug delivery system" means a system in which  
3180 the actual control of the unit-dose medication package is  
3181 maintained by the facility rather than by the individual patient.

3182 ~~(c) "Department" means the Department of Health.~~



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3183        ~~(c)~~ (d) "Donor" means a patient or patient representative  
3184 who donates cancer drugs or supplies needed to administer cancer  
3185 drugs that have been maintained within a closed drug delivery  
3186 system; health care facilities, nursing homes, hospices, or  
3187 hospitals with closed drug delivery systems; or pharmacies, drug  
3188 manufacturers, medical device manufacturers or suppliers, or  
3189 wholesalers of drugs or supplies, in accordance with this  
3190 section. "Donor" includes a physician licensed under chapter 458  
3191 or chapter 459 who receives cancer drugs or supplies directly  
3192 from a drug manufacturer, wholesale distributor ~~drug wholesaler,~~  
3193 or pharmacy.

3194        ~~(d)~~ (e) "Eligible patient" means a person who the department  
3195 determines is eligible to receive cancer drugs from the program.

3196        ~~(e)~~ (k) "Participant facility" means a class II hospital  
3197 pharmacy that has elected to participate in the program and that  
3198 accepts donated cancer drugs and supplies under the rules adopted  
3199 by the department for the program.

3200        ~~(e)~~ "Prescription drug" ~~means a drug as defined in s.~~  
3201 ~~465.003(8).~~

3202        ~~(f)~~ (p) "Program" means the Cancer Drug Donation Program  
3203 created by this section.

3204        ~~(g)~~ (q) "Supplies" means any supplies used in the  
3205 administration of a cancer drug.

3206        Section 22. Subsection (1) of section 499.03, Florida  
3207 Statutes, is amended to read:

3208        499.03 Possession of certain drugs without prescriptions  
3209 unlawful; exemptions and exceptions.--

3210        (1) A person may not possess, or possess with intent to  
3211 sell, dispense, or deliver, any habit-forming, toxic, harmful, or  
3212 new drug subject to s. 499.003(33) ~~s. 499.003(29)~~, or

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3213 prescription legend drug as defined in s. 499.003(45) ~~s.~~  
3214 ~~499.003(25)~~, unless the possession of the drug has been obtained  
3215 by a valid prescription of a practitioner licensed by law to  
3216 prescribe the drug. However, this section does not apply to the  
3217 delivery of such drugs to persons included in any of the classes  
3218 named in this subsection, or to the agents or employees of such  
3219 persons, for use in the usual course of their businesses or  
3220 practices or in the performance of their official duties, as the  
3221 case may be; nor does this section apply to the possession of  
3222 such drugs by those persons or their agents or employees for such  
3223 use:

3224 (a) A licensed pharmacist or any person under the licensed  
3225 pharmacist's supervision while acting within the scope of the  
3226 licensed pharmacist's practice;

3227 (b) A licensed practitioner authorized by law to prescribe  
3228 prescription legend drugs or any person under the licensed  
3229 practitioner's supervision while acting within the scope of the  
3230 licensed practitioner's practice;

3231 (c) A qualified person who uses prescription legend drugs  
3232 for lawful research, teaching, or testing, and not for resale;

3233 (d) A licensed hospital or other institution that procures  
3234 such drugs for lawful administration or dispensing by  
3235 practitioners;

3236 (e) An officer or employee of a federal, state, or local  
3237 government; or

3238 (f) A person that holds a valid permit issued by the  
3239 department pursuant to this part ~~ss. 499.001-499.081~~ which  
3240 authorizes that person to possess prescription drugs.

3241 Section 23. Section 499.032, Florida Statutes, is amended  
3242 to read:



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3243 499.032 Phenylalanine; prescription  
3244 required.--Phenylalanine restricted formula is declared to be a  
3245 prescription ~~legend~~ drug and may be dispensed only upon the  
3246 prescription of a practitioner authorized by law to prescribe  
3247 prescription medicinal drugs.

3248 Section 24. Subsection (1) of section 499.033, Florida  
3249 Statutes, is amended to read:

3250 499.033 Ephedrine; prescription required.--Ephedrine is  
3251 declared to be a prescription drug.

3252 (1) Except as provided in subsection (2), any product that  
3253 contains any quantity of ephedrine, a salt of ephedrine, an  
3254 optical isomer of ephedrine, or a salt of an optical isomer of  
3255 ephedrine may be dispensed only upon the prescription of a duly  
3256 licensed practitioner authorized by the laws of the state to  
3257 prescribe prescription medicinal drugs.

3258 Section 25. Subsections (1) and (3) of section 499.039,  
3259 Florida Statutes, are amended to read:

3260 499.039 Sale, distribution, or transfer of harmful chemical  
3261 substances; penalties; authority for enforcement.--It is unlawful  
3262 for a person to sell, deliver, or give to a person under the age  
3263 of 18 years any compound, liquid, or chemical containing toluol,  
3264 hexane, trichloroethylene, acetone, toluene, ethyl acetate,  
3265 methyl ethyl ketone, trichloroethane, isopropanol, methyl  
3266 isobutyl ketone, ethylene glycol monomethyl ether acetate,  
3267 cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites  
3268 (butyl nitrite), or any similar substance for the purpose of  
3269 inducing by breathing, inhaling, or ingesting a condition of  
3270 intoxication or which is intended to distort or disturb the  
3271 auditory, visual, or other physical or mental processes.

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3272 (1) On the first violation of this section, the department  
3273 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if the  
3274 violation has not caused temporary or permanent physical or  
3275 mental injury to the user.

3276 (3) The department ~~of Health~~ shall adopt rules to implement  
3277 this section.

3278 Section 26. Section 499.04, Florida Statutes, is amended to  
3279 read:

3280 499.04 Fee authority.--The department may collect fees for  
3281 all drug, device, and cosmetic applications, permits, product  
3282 registrations, and free-sale certificates. The total amount of  
3283 fees collected from all permits, applications, product  
3284 registrations, and free-sale certificates must be adequate to  
3285 fund the expenses incurred by the department in carrying out this  
3286 part ~~ss. 499.001-499.081~~. The department shall, by rule,  
3287 establish a schedule of fees that are within the ranges provided  
3288 in this section and shall adjust those fees from time to time  
3289 based on the costs associated with administering this part ~~ss.~~  
3290 ~~499.001-499.081~~. The fees are payable to the department to be  
3291 deposited into the Florida Drug, Device, and Cosmetic Trust Fund  
3292 for the sole purpose of carrying out the provisions of this part  
3293 ~~ss. 499.001-499.081~~.

3294 Section 27. Subsections (1) through (5), (8), and (10) of  
3295 section 499.041, Florida Statutes, are amended to read:

3296 499.041 Schedule of fees for drug, device, and cosmetic  
3297 applications and permits, product registrations, and free-sale  
3298 certificates.--

3299 (1) The department shall assess applicants requiring a  
3300 manufacturing permit an annual fee within the ranges established  
3301 in this section for the specific type of manufacturer.





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3302 (a) The fee for a prescription drug manufacturer  
3303 ~~manufacturer's~~ permit may not be less than \$500 or more than \$750  
3304 annually.

3305 (b) The fee for a device manufacturer ~~manufacturer's~~ permit  
3306 may not be less than \$500 or more than \$600 annually.

3307 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~  
3308 permit may not be less than \$250 or more than \$400 annually.

3309 (d) The fee for an over-the-counter drug manufacturer  
3310 ~~manufacturer's~~ permit may not be less than \$300 or more than \$400  
3311 annually.

3312 (e) The fee for a compressed medical gas manufacturer  
3313 ~~manufacturer's~~ permit may not be less than \$400 or more than \$500  
3314 annually.

3315 (f) The fee for a prescription drug repackager ~~repackager's~~  
3316 permit may not be less than \$500 or more than \$750 annually.

3317 (g) A manufacturer may not be required to pay more than one  
3318 fee per establishment to obtain an additional manufacturing  
3319 permit, but each manufacturer must pay the highest fee applicable  
3320 to his or her operation in each establishment.

3321 (2) The department shall assess an applicant that is  
3322 required to have a wholesaling permit an annual fee within the  
3323 ranges established in this section for the specific type of  
3324 wholesaling.

3325 (a) The fee for a prescription drug wholesale distributor  
3326 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800  
3327 annually.

3328 (b) The fee for a compressed medical gas wholesale  
3329 distributor ~~wholesaler's~~ permit may not be less than \$200 or more  
3330 than \$300 annually.



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3331 (c) The fee for an out-of-state prescription drug wholesale  
3332 distributor ~~wholesaler's~~ permit may not be less than \$300 or more  
3333 than \$800 annually.

3334 (d) The fee for a nonresident prescription drug  
3335 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or  
3336 more than \$500 annually.

3337 (e) The fee for a retail pharmacy drug wholesale  
3338 distributor ~~wholesaler's~~ permit may not be less than \$35 or more  
3339 than \$50 annually.

3340 (f) The fee for a freight forwarder ~~forwarder's~~ permit may  
3341 not be less than \$200 or more than \$300 annually.

3342 (g) The fee for a veterinary prescription drug wholesale  
3343 distributor ~~wholesaler's~~ permit may not be less than \$300 or more  
3344 than \$500 annually.

3345 (h) The fee for a limited prescription drug veterinary  
3346 wholesale distributor ~~wholesaler's~~ permit may not be less than  
3347 \$300 or more than \$500 annually.

3348 (3) The department shall assess an applicant that is  
3349 required to have a retail establishment permit an annual fee  
3350 within the ranges established in this section for the specific  
3351 type of retail establishment.

3352 (a) The fee for a veterinary prescription ~~legend~~ drug  
3353 retail establishment permit may not be less than \$200 or more  
3354 than \$300 annually.

3355 (b) The fee for a medical oxygen retail establishment  
3356 permit may not be less than \$200 or more than \$300 annually.

3357 (4) The department shall assess an applicant that is  
3358 required to have a restricted prescription drug distributor  
3359 ~~distributor's~~ permit an annual fee of not less than \$200 or more  
3360 than \$300.



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3361 (5) In addition to the fee charged for a permit required by  
3362 this part ss. 499.001-499.081, the department shall assess  
3363 applicants an initial application fee of \$150 for each new permit  
3364 issued by the department which requires an onsite inspection.

3365 (8) The department shall assess an out-of-state  
3366 prescription drug wholesale distributor ~~wholesaler~~ applicant or  
3367 permittee an onsite inspection fee of not less than \$1,000 or  
3368 more than \$3,000 annually, to be based on the actual cost of the  
3369 inspection if an onsite inspection is performed by agents of the  
3370 department.

3371 (10) The department shall assess other fees as provided in  
3372 this part ss. 499.001-499.081.

3373 Section 28. Section 499.05, Florida Statutes, is amended;  
3374 subsection (3) of section 499.013, Florida Statutes, is  
3375 redesignated as paragraph (k) of subsection (1) of that section  
3376 and amended; paragraph (b) of subsection (2) of section 499.0122,  
3377 Florida Statutes, is redesignated as paragraph (l) of subsection  
3378 (1) of that section and amended; and subsection (12) of section  
3379 499.012, Florida Statutes, is redesignated as paragraph (m) of  
3380 subsection (1) of that section and amended, to read:

3381 499.05 Rules.--

3382 (1) The department shall adopt rules to implement and  
3383 enforce this part ss. 499.001-499.081 with respect to:

3384 (a) The definition of terms used in this part ss. 499.001-  
3385 ~~499.081~~, and used in the rules adopted under this part ss.  
3386 ~~499.001-499.081~~, when the use of the term is not its usual and  
3387 ordinary meaning.

3388 (b) Labeling requirements for drugs, devices, and  
3389 cosmetics.



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3390 (c) The establishment of fees authorized in this part ~~ss.~~  
3391 ~~499.001-499.081~~.

3392 (d) The identification of permits that require an initial  
3393 application and onsite inspection or other prerequisites for  
3394 permitting which demonstrate that the establishment and person  
3395 are in compliance with the requirements of this part ~~ss. 499.001-~~  
3396 ~~499.081~~.

3397 (e) The application processes and forms for product  
3398 registration.

3399 (f) Procedures for requesting and issuing certificates of  
3400 free sale.

3401 (g) Inspections and investigations conducted under s.  
3402 499.051, and the identification of information claimed to be a  
3403 trade secret and exempt from the public records law as provided  
3404 in s. 499.051(7).

3405 (h) The establishment of a range of penalties, as provided  
3406 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of  
3407 the potential impact of a violation of this part ~~ss. 499.001-~~  
3408 ~~499.081~~; and a process for the uncontested settlement of alleged  
3409 violations.

3410 (i) Additional conditions that qualify as an emergency  
3411 medical reason under s. 499.003(56)(b)2. ~~s. 499.012(1)(a)2.b.~~

3412 (j) Procedures and forms relating to the pedigree paper  
3413 requirement of s. 499.01212.

3414 ~~(k)(3) The department may adopt such rules as are necessary~~  
3415 ~~for~~ The protection of the public health, safety, and welfare  
3416 regarding good manufacturing practices that manufacturers and  
3417 repackagers must follow to ensure the safety of the products.

3418 ~~(l)(b) The department shall adopt rules relating to~~  
3419 Information required from each retail establishment pursuant to



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3420 s. 499.012(3) ~~s. 499.01(4)~~, including requirements for  
3421 prescriptions or orders.

3422 ~~(m) (12) The department may adopt rules governing~~ The  
3423 recordkeeping, storage, and handling with respect to each of the  
3424 distributions of prescription drugs specified in s.  
3425 499.003(56)(a)-(d) subparagraphs (1)(a)1-4.

3426 (n) Alternatives to compliance with s. 499.01212 for a  
3427 prescription drug in the inventory of a permitted prescription  
3428 drug wholesale distributor as of June 30, 2006, and the return of  
3429 a prescription drug purchased prior to July 1, 2006. The  
3430 department may specify time limits for such alternatives.

3431 (2) With respect to products in interstate commerce, those  
3432 rules must not be inconsistent with rules and regulations of  
3433 federal agencies unless specifically otherwise directed by the  
3434 Legislature.

3435 (3) The department shall adopt rules regulating  
3436 recordkeeping for and the storage, handling, and distribution of  
3437 medical devices and over-the-counter drugs to protect the public  
3438 from adulterated products.

3439 Section 29. Section 499.051, Florida Statutes, is amended  
3440 to read:

3441 499.051 Inspections and investigations.--

3442 (1) The agents of the department ~~of Health~~ and of the  
3443 Department of Law Enforcement, after they present proper  
3444 identification, may inspect, monitor, and investigate any  
3445 establishment permitted pursuant to this part ~~ss. 499.001-499.081~~  
3446 during business hours for the purpose of enforcing this part ~~ss.~~  
3447 ~~499.001-499.081~~, chapters 465, 501, and 893, and the rules of the  
3448 department that protect the public health, safety, and welfare.

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3449 (2) In addition to the authority set forth in subsection  
3450 (1), the department and any duly designated officer or employee  
3451 of the department may enter and inspect any other establishment  
3452 for the purpose of determining compliance with this part ~~ss.~~  
3453 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~  
3454 regarding any drug, device, or cosmetic product.

3455 (3) Any application for a permit or product registration or  
3456 for renewal of such permit or registration made pursuant to this  
3457 part ~~ss. 499.001-499.081~~ and rules adopted under this part ~~those~~  
3458 ~~sections~~ constitutes permission for any entry or inspection of  
3459 the premises in order to verify compliance with this part ~~those~~  
3460 ~~sections~~ and rules; to discover, investigate, and determine the  
3461 existence of compliance; or to elicit, receive, respond to, and  
3462 resolve complaints and violations.

3463 (4) Any application for a permit made pursuant to s.  
3464 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that  
3465 section ~~those sections~~ constitutes permission for agents of the  
3466 department ~~of Health~~ and the Department of Law Enforcement, after  
3467 presenting proper identification, to inspect, review, and copy  
3468 any financial document or record related to the manufacture,  
3469 repackaging, or distribution of a drug as is necessary to verify  
3470 compliance with this part ~~ss. 499.001-499.081~~ and the rules  
3471 adopted by the department to administer this part ~~those sections~~,  
3472 in order to discover, investigate, and determine the existence of  
3473 compliance, or to elicit, receive, respond to, and resolve  
3474 complaints and violations.

3475 (5) The authority to inspect under this section includes  
3476 the authority to access, review, and copy any and all financial  
3477 documents related to the activity of manufacturing, repackaging,  
3478 or distributing prescription drugs.



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3479 (6) The authority to inspect under this section includes  
3480 the authority to secure:

3481 (a) Samples or specimens of any drug, device, or cosmetic;  
3482 or

3483 (b) Such other evidence as is needed for any action to  
3484 enforce this part ~~ss. 499.001-499.081~~ and the rules adopted under  
3485 this part ~~these sections~~.

3486 (7) The complaint and all information obtained pursuant to  
3487 the investigation by the department are confidential and exempt  
3488 from the provisions of s. 119.07(1) and s. 24(a), Art. I of the  
3489 State Constitution until the investigation and the enforcement  
3490 action are completed. However, trade secret information contained  
3491 therein as defined by s. 812.081(1)(c) shall remain confidential  
3492 and exempt from the provisions of s. 119.07(1) and s. 24(a), Art.  
3493 I of the State Constitution, as long as the information is  
3494 retained by the department. This subsection does not prohibit the  
3495 department from using such information for regulatory or  
3496 enforcement proceedings under this chapter or from providing such  
3497 information to any law enforcement agency or any other regulatory  
3498 agency. However, the receiving agency shall keep such records  
3499 confidential and exempt as provided in this subsection. In  
3500 addition, this subsection is not intended to prevent compliance  
3501 with the provisions of s. 499.01212 ~~s. 499.0121(6)(d)~~, and the  
3502 pedigree papers required in that section ~~subsection~~ shall not be  
3503 deemed a trade secret.

3504 Section 30. Section 499.052, Florida Statutes, is amended  
3505 to read:

3506 499.052 Records of interstate shipment.--For the purpose of  
3507 enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in  
3508 interstate commerce and persons receiving drugs, devices, or



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3509 cosmetics in interstate commerce must, upon the request, in the  
3510 manner set out below, by an officer or employee duly designated  
3511 by the department, permit the officer or employee to have access  
3512 to and to copy all records showing the movement in interstate  
3513 commerce of any drug, device, or cosmetic, and the quantity,  
3514 shipper, and consignee thereof.

3515 Section 31. Subsection (4) of section 499.055, Florida  
3516 Statutes, is amended to read:

3517 499.055 Reports and dissemination of information by  
3518 department.--

3519 (4) The department shall publish on the department's  
3520 website and update at least monthly:

3521 (a) A list of the prescription drug wholesale distributors  
3522 ~~wholesalers~~, out-of-state prescription drug wholesale  
3523 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
3524 distributors ~~wholesalers~~ against whom the department has  
3525 initiated enforcement action pursuant to this part ss. 499.001-  
3526 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or  
3527 otherwise file an administrative complaint and the permit number  
3528 of each such wholesale distributor ~~wholesaler~~.

3529 (b) A list of the prescription drug wholesale distributors  
3530 ~~wholesalers~~, out-of-state prescription drug wholesale  
3531 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
3532 distributors ~~wholesalers~~ to which the department has issued a  
3533 permit, including the date on which each permit will expire.

3534 (c) A list of the prescription drug wholesale distributor  
3535 ~~wholesalers~~, out-of-state prescription drug wholesale distributor  
3536 ~~wholesalers~~, and retail pharmacy drug wholesale distributor  
3537 ~~wholesalers~~ permits that have been returned to the department,





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3538 | were suspended, were revoked, have expired, or were not renewed  
3539 | in the previous year.

3540 |       Section 32. Subsections (1) and (3) of section 499.06,  
3541 | Florida Statutes, are amended to read:

3542 |       499.06 Embargoing, detaining, or destroying article or  
3543 | processing equipment which is in violation of law or rule.--

3544 |       (1) When a duly authorized agent of the department finds,  
3545 | or has probable cause to believe, that any drug, device, or  
3546 | cosmetic is in violation of any provision of this part ~~ss.~~  
3547 | ~~499.001-499.081~~ or any rule adopted under this part ~~such sections~~  
3548 | so as to be dangerous, unwholesome, or fraudulent within the  
3549 | meaning of this part ~~ss. 499.001-499.081~~, she or he may issue and  
3550 | enforce a stop-sale, stop-use, removal, or hold order, which  
3551 | order gives notice that such article or processing equipment is,  
3552 | or is suspected of being, in violation and has been detained or  
3553 | embargoed, and which order warns all persons not to remove, use,  
3554 | or dispose of such article or processing equipment by sale or  
3555 | otherwise until permission for removal, use, or disposal is given  
3556 | by such agent or the court. It is unlawful for any person to  
3557 | remove, use, or dispose of such detained or embargoed article or  
3558 | processing equipment by sale or otherwise without such  
3559 | permission; and such act is a felony of the second degree,  
3560 | punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3561 |       (3) If the court finds that the detained or embargoed  
3562 | article or processing equipment is in violation, such article or  
3563 | processing equipment shall, after entry of the court order, be  
3564 | destroyed or made sanitary at the expense of the claimant  
3565 | thereof, under the supervision of such agent; and all court  
3566 | costs, fees, and storage and other proper expenses shall be taxed  
3567 | against the claimant of such article or processing equipment or



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3568 her or his agent. However, when the violation can be corrected by  
3569 proper labeling of the article or sanitizing of the processing  
3570 equipment, and after such costs, fees, and expenses have been  
3571 paid and a good and sufficient bond, conditioned that such  
3572 article be so labeled or processed or such processing equipment  
3573 be so sanitized, has been executed, the court may by order direct  
3574 that such article or processing equipment be delivered to the  
3575 claimant thereof for such labeling, processing, or sanitizing,  
3576 under the supervision of an agent of the department. The expense  
3577 of such supervision shall be paid by the claimant. Such bond  
3578 shall be returned to the claimant of the article or processing  
3579 equipment upon representation to the court by the department that  
3580 the article or processing equipment is no longer in violation of  
3581 this part ss. 499.001-499.081 and that the expenses of such  
3582 supervision have been paid.

3583 Section 33. Section 499.062, Florida Statutes, is amended;  
3584 section 499.063, Florida Statutes, is redesignated as section (2)  
3585 of that section and amended; and section 499.064, Florida  
3586 Statutes, is redesignated as paragraphs (a) and (b) of subsection  
3587 (2) of that section and amended, to read:

3588 499.062 ~~Cause for~~ Seizure and condemnation of drugs,  
3589 devices, or cosmetics.--

3590 (1) Any article of any drug, device, or cosmetic that is  
3591 adulterated or misbranded under this part ss. 499.001-499.081 is  
3592 subject to seizure and condemnation by the department or by its  
3593 duly authorized agents designated for that purpose in regard to  
3594 drugs, devices, or cosmetics.

3595 (2) ~~499.063 Seizure; procedure; prohibition on sale or~~  
3596 ~~disposal of article; penalty.~~ Whenever a duly authorized officer  
3597 or employee of the department finds cause, or has probable cause



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3598 to believe that cause exists, for the seizure of any drug,  
3599 device, or cosmetic, as set out in this part ~~ss. 499.001-499.081~~,  
3600 he or she shall affix to the article a tag, stamp, or other  
3601 appropriate marking, giving notice that the article is, or is  
3602 suspected of being, subject to seizure under this part ~~ss.~~  
3603 ~~499.001-499.081~~ and that the article has been detained and seized  
3604 by the department. Such officer or employee shall also warn all  
3605 persons not to remove or dispose of the article, by sale or  
3606 otherwise, until permission is given by the department or the  
3607 court. Any person who violates this subsection ~~section~~ is guilty  
3608 of a felony of the second degree, punishable as provided in s.  
3609 775.082, s. 775.083, or s. 775.084.

3610 ~~(a) 499.064 Condemnation and sale; release of seized~~  
3611 ~~article.--~~(1) When any article detained or seized under this  
3612 subsection ~~s. 499.063~~ has been found by the department to be  
3613 subject to seizure and condemnation ~~under s. 499.063~~, the  
3614 department shall petition the court for an order of condemnation  
3615 or sale, as the court directs. The proceeds of the sale of drugs,  
3616 devices, and cosmetics, less the legal costs and charges, shall  
3617 be deposited into the Florida Drug, Device, and Cosmetic Trust  
3618 Fund.

3619 ~~(b) (2)~~ If the department finds that any article seized  
3620 under this subsection ~~s. 499.063~~ was not subject to seizure ~~under~~  
3621 ~~that section~~, the department or the designated officer or  
3622 employee shall remove the tag or marking.

3623 Section 34. Section 499.065, Florida Statutes, is amended  
3624 to read:

3625 499.065 Inspections; imminent danger.--

3626 (1) Notwithstanding s. 499.051, the department shall  
3627 inspect each prescription drug wholesale distributor



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3628 establishment, prescription drug repackager establishment,  
3629 veterinary prescription drug wholesale distributor establishment,  
3630 limited prescription drug veterinary wholesale distributor  
3631 ~~wholesaler~~ establishment, and retail pharmacy drug wholesale  
3632 distributor ~~wholesaler~~ establishment that is required to be  
3633 permitted under this part ~~chapter~~ as often as necessary to ensure  
3634 compliance with applicable laws and rules. The department shall  
3635 have the right of entry and access to these facilities at any  
3636 reasonable time.

3637 (2) To protect the public from prescription drugs that are  
3638 adulterated or otherwise unfit for human or animal consumption,  
3639 the department may examine, sample, seize, and stop the sale or  
3640 use of prescription drugs to determine the condition of those  
3641 drugs. The department may immediately seize and remove any  
3642 prescription drugs if the State Surgeon General or his or her  
3643 designee determines that the prescription drugs represent a  
3644 threat to the public health. The owner of any property seized  
3645 under this section may, within 10 days after the seizure, apply  
3646 to a court of competent jurisdiction for whatever relief is  
3647 appropriate. At any time after 10 days, the department may  
3648 destroy the drugs as contraband.

3649 (3) The department may determine that a prescription drug  
3650 wholesale distributor establishment, prescription drug repackager  
3651 establishment, veterinary prescription drug wholesale distributor  
3652 establishment, limited prescription drug veterinary wholesale  
3653 distributor ~~wholesaler~~ establishment, or retail pharmacy drug  
3654 wholesale distributor ~~wholesaler~~ establishment that is required  
3655 to be permitted under this part ~~chapter~~ is an imminent danger to  
3656 the public health and shall require its immediate closure if the  
3657 establishment fails to comply with applicable laws and rules and,

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3658 | because of the failure, presents an imminent threat to the  
3659 | public's health, safety, or welfare. Any establishment so deemed  
3660 | and closed shall remain closed until allowed by the department or  
3661 | by judicial order to reopen.

3662 |       (4) For purposes of this section, a refusal to allow entry  
3663 | to the department for inspection at reasonable times, or a  
3664 | failure or refusal to provide the department with required  
3665 | documentation for purposes of inspection, constitutes an imminent  
3666 | danger to the public health.

3667 |       Section 35. Subsections (1) through (4) of section 499.066,  
3668 | Florida Statutes, are amended to read:

3669 |       499.066 Penalties; remedies.--In addition to other  
3670 | penalties and other enforcement provisions:

3671 |       (1) The department may institute such suits or other legal  
3672 | proceedings as are required to enforce any provision of this part  
3673 | ~~ss. 499.001-499.081~~. If it appears that a person has violated any  
3674 | provision of this part ~~ss. 499.001-499.081~~ for which criminal  
3675 | prosecution is provided, the department may provide the  
3676 | appropriate state attorney or other prosecuting agency having  
3677 | jurisdiction with respect to such prosecution with the relevant  
3678 | information in the department's possession.

3679 |       (2) If any person engaged in any activity covered by this  
3680 | part ~~ss. 499.001-499.081~~ violates any provision of this part  
3681 | ~~those sections~~, any rule adopted under this part ~~those sections~~,  
3682 | or a cease and desist order as provided by this part ~~those~~  
3683 | ~~sections~~, the department may obtain an injunction in the circuit  
3684 | court of the county in which the violation occurred or in which  
3685 | the person resides or has its principal place of business, and  
3686 | may apply in that court for such temporary and permanent orders  
3687 | as the department considers necessary to restrain the person from

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3688 engaging in any such activities until the person complies with  
3689 this part ~~ss. 499.001-499.081~~, the rules adopted under this part  
3690 ~~those sections~~, and the orders of the department authorized by  
3691 this part ~~those sections~~ or to mandate compliance with this part  
3692 ~~ss. 499.001-499.081~~, the rules adopted under this part ~~those~~  
3693 ~~sections~~, and any order or permit issued by the department under  
3694 this part ~~those sections~~.

3695 (3) The department may impose an administrative fine, not  
3696 to exceed \$5,000 per violation per day, for the violation of any  
3697 provision of this part ~~ss. 499.001-499.081~~ or rules adopted under  
3698 this part ~~those sections~~. Each day a violation continues  
3699 constitutes a separate violation, and each separate violation is  
3700 subject to a separate fine. All amounts collected pursuant to  
3701 this section shall be deposited into the Florida Drug, Device,  
3702 and Cosmetic Trust Fund and are appropriated for the use of the  
3703 department in administering this part ~~ss. 499.001-499.081~~. In  
3704 determining the amount of the fine to be levied for a violation,  
3705 the department shall consider:

3706 (a) The severity of the violation;

3707 (b) Any actions taken by the person to correct the  
3708 violation or to remedy complaints; and

3709 (c) Any previous violations.

3710 (4) The department shall deposit any rewards, fines, or  
3711 collections that are due the department and which derive from  
3712 joint enforcement activities with other state and federal  
3713 agencies which relate to this part ~~ss. 499.001-499.081~~, chapter  
3714 893, or the federal act, into the Florida Drug, Device, and  
3715 Cosmetic Trust Fund. The proceeds of those rewards, fines, and  
3716 collections are appropriated for the use of the department in  
3717 administering this part ~~ss. 499.001-499.081~~.



3718 Section 36. Section 499.0661, Florida Statutes, is amended  
3719 to read:

3720 499.0661 Cease and desist orders; removal of certain  
3721 persons.--

3722 (1)~~(2)~~ CEASE AND DESIST ORDERS.--

3723 (a) In addition to any authority otherwise provided in this  
3724 chapter, the department may issue and serve a complaint stating  
3725 charges upon any permittee or upon any affiliated party, whenever  
3726 the department has reasonable cause to believe that the person or  
3727 individual named therein is engaging in or has engaged in conduct  
3728 that is:

3729 1. An act that demonstrates a lack of fitness or  
3730 trustworthiness to engage in the business authorized under the  
3731 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
3732 hazardous to the public health, or constitutes business  
3733 operations that are a detriment to the public health;

3734 2. A violation of any provision of this part ~~ss. 499.001-~~  
3735 ~~499.081~~;

3736 3. A violation of any rule of the department;

3737 4. A violation of any order of the department; or

3738 5. A breach of any written agreement with the department.

3739 (b) The complaint must contain a statement of facts and  
3740 notice of opportunity for a hearing pursuant to ss. 120.569 and  
3741 120.57.

3742 (c) If a hearing is not requested within the time allowed  
3743 by ss. 120.569 and 120.57, or if a hearing is held and the  
3744 department finds that any of the charges are proven, the  
3745 department may enter an order directing the permittee or the  
3746 affiliated party named in the complaint to cease and desist from  
3747 engaging in the conduct complained of and take corrective action



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3748 to remedy the effects of past improper conduct and assure future  
3749 compliance.

3750 (d) A contested or default cease and desist order is  
3751 effective when reduced to writing and served upon the permittee  
3752 or affiliated party named therein. An uncontested cease and  
3753 desist order is effective as agreed.

3754 (e) Whenever the department finds that conduct described in  
3755 paragraph (a) is likely to cause an immediate threat to the  
3756 public health, it may issue an emergency cease and desist order  
3757 requiring the permittee or any affiliated party to immediately  
3758 cease and desist from engaging in the conduct complained of and  
3759 to take corrective and remedial action. The emergency order is  
3760 effective immediately upon service of a copy of the order upon  
3761 the permittee or affiliated party named therein and remains  
3762 effective for 90 days. If the department begins nonemergency  
3763 cease and desist proceedings under this subsection, the emergency  
3764 order remains effective until the conclusion of the proceedings  
3765 under ss. 120.569 and 120.57.

3766 ~~(2)(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

3767 (a) The department may issue and serve a complaint stating  
3768 charges upon any affiliated party and upon the permittee involved  
3769 whenever the department has reason to believe that an affiliated  
3770 party is engaging in or has engaged in conduct that constitutes:

3771 1. An act that demonstrates a lack of fitness or  
3772 trustworthiness to engage in the business authorized under the  
3773 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
3774 hazardous to the public health, or constitutes business  
3775 operations that are a detriment to the public health;

3776 2. A willful violation of this part ~~ss. 499.001-499.081~~;  
3777 however, if the violation constitutes a misdemeanor, a complaint





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3778 | may not be served as provided in this section until the  
3779 | affiliated party is notified in writing of the matter of the  
3780 | violation and has been afforded a reasonable period of time, as  
3781 | set forth in the notice, to correct the violation and has failed  
3782 | to do so;

3783 |         3. A violation of any other law involving fraud or moral  
3784 | turpitude which constitutes a felony;

3785 |         4. A willful violation of any rule of the department;

3786 |         5. A willful violation of any order of the department; or

3787 |         6. A material misrepresentation of fact, made knowingly and  
3788 | willfully or made with reckless disregard for the truth of the  
3789 | matter.

3790 |         (b) The complaint must contain a statement of facts and  
3791 | notice of opportunity for a hearing pursuant to ss. 120.569 and  
3792 | 120.57.

3793 |         (c) If a hearing is not requested within the time allotted  
3794 | by ss. 120.569 and 120.57, or if a hearing is held and the  
3795 | department finds that any of the charges in the complaint are  
3796 | proven true, the department may enter an order removing the  
3797 | affiliated party or restricting or prohibiting participation by  
3798 | the person in the affairs of that permittee or of any other  
3799 | permittee.

3800 |         (d) A contested or default order of removal, restriction,  
3801 | or prohibition is effective when reduced to writing and served on  
3802 | the permittee and the affiliated party. An uncontested order of  
3803 | removal, restriction, or prohibition is effective as agreed.

3804 |         (e)1. The chief executive officer, designated  
3805 | representative, or the person holding the equivalent office, of a  
3806 | permittee shall promptly notify the department if she or he has



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3807 actual knowledge that any affiliated party is charged with a  
3808 felony in a state or federal court.

3809       2. Whenever any affiliated party is charged with a felony  
3810 in a state or federal court or with the equivalent of a felony in  
3811 the courts of any foreign country with which the United States  
3812 maintains diplomatic relations, and the charge alleges violation  
3813 of any law involving prescription drugs, pharmaceuticals, fraud,  
3814 theft, or moral turpitude, the department may enter an emergency  
3815 order suspending the affiliated party or restricting or  
3816 prohibiting participation by the affiliated party in the affairs  
3817 of the particular permittee or of any other permittee upon  
3818 service of the order upon the permittee and the affiliated party  
3819 charged. The order must contain notice of opportunity for a  
3820 hearing pursuant to ss. 120.569 and 120.57, where the affiliated  
3821 party may request a postsuspension hearing to show that continued  
3822 service to or participation in the affairs of the permittee does  
3823 not pose a threat to the public health or the interests of the  
3824 permittee and does not threaten to impair public confidence in  
3825 the permittee. In accordance with applicable departmental rules,  
3826 the department shall notify the affiliated party whether the  
3827 order suspending or prohibiting the person from participation in  
3828 the affairs of a permittee will be rescinded or otherwise  
3829 modified. The emergency order remains in effect, unless otherwise  
3830 modified by the department, until the criminal charge is disposed  
3831 of. The acquittal of the person charged, or the final, unappealed  
3832 dismissal of all charges against the person, dissolves the  
3833 emergency order but does not prohibit the department from  
3834 instituting proceedings under paragraph (a). If the person  
3835 charged is convicted or pleads guilty or nolo contendere, whether



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3836 or not an adjudication of guilt is entered by the court, the  
3837 emergency order shall become final.

3838 (f) Any affiliated party removed pursuant to this section  
3839 is not eligible for reemployment by the permittee or to be an  
3840 affiliated party of any permittee except upon the written consent  
3841 of the department. Any affiliated party who is removed,  
3842 restricted, or prohibited from participating in the affairs of a  
3843 permittee pursuant to this section may petition the department  
3844 for modification or termination of the removal, restriction, or  
3845 prohibition.

3846 Section 37. Section 499.067, Florida Statutes, is amended  
3847 to read:

3848 499.067 Denial, suspension, or revocation of permit,  
3849 certification, or registration.--

3850 (1)(a) The department may deny, suspend, or revoke a permit  
3851 if it finds that there has been a substantial failure to comply  
3852 with this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501,  
3853 or chapter 893, the rules adopted under this part ~~any of those~~  
3854 ~~sections~~ or those chapters, any final order of the department, or  
3855 applicable federal laws or regulations or other state laws or  
3856 rules governing drugs, devices, or cosmetics.

3857 (b) The department may deny an application for a permit or  
3858 certification, or suspend or revoke a permit or certification, if  
3859 the department finds that:

3860 1. The applicant is not of good moral character or that it  
3861 would be a danger or not in the best interest of the public  
3862 health, safety, and welfare if the applicant were issued a permit  
3863 or certification.

3864 2. The applicant has not met the requirements for the  
3865 permit or certification.



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3866 3. The applicant is not eligible for a permit or  
3867 certification for any of the reasons enumerated in s. 499.012 ~~s.~~  
3868 ~~499.01~~ or ~~s. 499.012(5)~~.

3869 4. The applicant, permittee, or person certified under s.  
3870 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions  
3871 enumerated in s. 499.012 ~~s. 499.01~~ or ~~s. 499.012(5)~~.

3872 5. The applicant, permittee, or person certified under s.  
3873 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ss.  
3874 499.005-499.0054.

3875 (2) The department may deny, suspend, or revoke any  
3876 registration required by the provisions of this part ~~ss. 499.001-~~  
3877 ~~499.081~~ for the violation of any provision of this part ~~ss.~~  
3878 ~~499.001-499.081~~ or of any rules adopted under this part ~~these~~  
3879 ~~sections~~.

3880 (3) The department may revoke or suspend a permit:

3881 (a) If the permit was obtained by misrepresentation or  
3882 fraud or through a mistake of the department;

3883 (b) If the permit was procured, or attempted to be  
3884 procured, for any other person by making or causing to be made  
3885 any false representation; or

3886 (c) If the permittee has violated any provision of this  
3887 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~  
3888 ~~sections~~.

3889 (4) If any permit issued under this part ~~ss. 499.001-~~  
3890 ~~499.081~~ is revoked or suspended, the owner, manager, operator, or  
3891 proprietor of the establishment shall cease to operate as the  
3892 permit authorized, from the effective date of the suspension or  
3893 revocation until the person is again registered with the  
3894 department and possesses the required permit. If a permit is  
3895 revoked or suspended, the owner, manager, or proprietor shall



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3896 | remove all signs and symbols that identify the operation as  
3897 | premises permitted as a drug wholesaling establishment; drug,  
3898 | device, or cosmetic manufacturing establishment; or retail  
3899 | establishment. The department shall determine the length of time  
3900 | for which the permit is to be suspended. If a permit is revoked,  
3901 | the person that owns or operates the establishment may not apply  
3902 | for any permit under this part ~~ss. 499.001-499.081~~ for a period  
3903 | of 1 year after the date of the revocation. A revocation of a  
3904 | permit may be permanent if the department considers that to be in  
3905 | the best interest of the public health.

3906 |       (5) The department may deny, suspend, or revoke a permit  
3907 | issued under this part ~~ss. 499.001-499.081~~ which authorizes the  
3908 | permittee to purchase prescription drugs, if any owner, officer,  
3909 | employee, or other person who participates in administering or  
3910 | operating the establishment has been found guilty of any  
3911 | violation of this part ~~ss. 499.001-499.081~~ or chapter 465,  
3912 | chapter 501, or chapter 893, any rules adopted under this part  
3913 | ~~any of those sections~~ or those chapters, or any federal or state  
3914 | drug law, regardless of whether the person has been pardoned, had  
3915 | her or his civil rights restored, or had adjudication withheld.

3916 |       (6) The department shall deny, suspend, or revoke the  
3917 | permit of any person or establishment if the assignment, sale,  
3918 | transfer, or lease of an establishment permitted under this part  
3919 | ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil  
3920 | action, or criminal prosecution.

3921 |       (7) Notwithstanding s. 120.60(5), if a permittee fails to  
3922 | comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may revoke  
3923 | the permit of the permittee and shall provide notice of the  
3924 | intended agency action by posting a notice at the department's  
3925 | headquarters and by mailing a copy of the notice of intended

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3926 agency action by certified mail to the most recent mailing  
3927 address on record with the department and, if the permittee is  
3928 not a natural person, to the permittee's registered agent on file  
3929 with the Department of State.

3930 Section 38. Paragraph (a) of subsection (1) of section  
3931 409.9201, Florida Statutes, is amended to read:

3932 409.9201 Medicaid fraud.--

3933 (1) As used in this section, the term:

3934 (a) "Legend drug" means any drug, including, but not  
3935 limited to, finished dosage forms or active ingredients that are  
3936 subject to, defined by, or described by s. 503(b) of the Federal  
3937 Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.007(13)  
3938 ~~s. 499.007(12)~~, or s. 499.003(48) or (55) ~~s. 499.0122(1)(b) or~~  
3939 ~~(c)~~.

3940  
3941 The value of individual items of the legend drugs or goods or  
3942 services involved in distinct transactions committed during a  
3943 single scheme or course of conduct, whether involving a single  
3944 person or several persons, may be aggregated when determining the  
3945 punishment for the offense.

3946 Section 39. Paragraph (c) of subsection (9) of section  
3947 460.403, Florida Statutes, is amended to read:

3948 460.403 Definitions.--As used in this chapter, the term:

3949 (9)

3950 (c)1. Chiropractic physicians may adjust, manipulate, or  
3951 treat the human body by manual, mechanical, electrical, or  
3952 natural methods; by the use of physical means or physiotherapy,  
3953 including light, heat, water, or exercise; by the use of  
3954 acupuncture; or by the administration of foods, food  
3955 concentrates, food extracts, and items for which a prescription

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3956 | is not required and may apply first aid and hygiene, but  
3957 | chiropractic physicians are expressly prohibited from prescribing  
3958 | or administering to any person any legend drug except as  
3959 | authorized under subparagraph 2., from performing any surgery  
3960 | except as stated herein, or from practicing obstetrics.

3961 |         2. Notwithstanding the prohibition against prescribing and  
3962 | administering legend drugs under subparagraph 1.~~r~~ or s.  
3963 | 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic  
3964 | physicians may order, store, and administer, for emergency  
3965 | purposes only at the chiropractic physician's office or place of  
3966 | business, prescription medical oxygen and may also order, store,  
3967 | and administer the following topical anesthetics in aerosol form:

3968 |         a. Any solution consisting of 25 percent ethylchloride and  
3969 | 75 percent dichlorodifluoromethane.

3970 |         b. Any solution consisting of 15 percent  
3971 | dichlorodifluoromethane and 85 percent  
3972 | trichloromonofluoromethane.

3973 |  
3974 | However, this paragraph does not authorize a chiropractic  
3975 | physician to prescribe medical oxygen as defined in chapter 499.

3976 |         Section 40. Subsection (3) of section 465.0265, Florida  
3977 | Statutes, is amended to read:

3978 |         465.0265 Centralized prescription filling.--

3979 |         (3) The filling, delivery, and return of a prescription by  
3980 | one pharmacy for another pursuant to this section shall not be  
3981 | construed as the filling of a transferred prescription as set  
3982 | forth in s. 465.026 or as a wholesale distribution as set forth  
3983 | in s. 499.003(56) ~~s. 499.012(1)(a)~~.

3984 |         Section 41. Section 794.075, Florida Statutes, is amended  
3985 | to read:



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3986 | 794.075 Sexual predators; erectile dysfunction drugs.--

3987 | (1) A person may not possess a prescription drug, as  
3988 | defined in s. 499.003(45) ~~s. 499.003(25)~~, for the purpose of  
3989 | treating erectile dysfunction if the person is designated as a  
3990 | sexual predator under s. 775.21.

3991 | (2) A person who violates a provision of this section for  
3992 | the first time commits a misdemeanor of the second degree,  
3993 | punishable as provided in s. 775.082 or s. 775.083. A person who  
3994 | violates a provision of this section a second or subsequent time  
3995 | commits a misdemeanor of the first degree, punishable as provided  
3996 | in s. 775.082 or s. 775.083.

3997 | Section 42. Paragraph (a) of subsection (1) of section  
3998 | 895.02, Florida Statutes, is amended to read:

3999 | 895.02 Definitions.--As used in ss. 895.01-895.08, the  
4000 | term:

4001 | (1) "Racketeering activity" means to commit, to attempt to  
4002 | commit, to conspire to commit, or to solicit, coerce, or  
4003 | intimidate another person to commit:

4004 | (a) Any crime that is chargeable by indictment or  
4005 | information under the following provisions of the Florida  
4006 | Statutes:

4007 | 1. Section 210.18, relating to evasion of payment of  
4008 | cigarette taxes.

4009 | 2. Section 403.727(3)(b), relating to environmental  
4010 | control.

4011 | 3. Section 409.920 or s. 409.9201, relating to Medicaid  
4012 | fraud.

4013 | 4. Section 414.39, relating to public assistance fraud.

4014 | 5. Section 440.105 or s. 440.106, relating to workers'  
4015 | compensation.





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- 4016           6. Section 443.071(4), relating to creation of a fictitious  
4017 employer scheme to commit unemployment compensation fraud.
- 4018           7. Section 465.0161, relating to distribution of medicinal  
4019 drugs without a permit as an Internet pharmacy.
- 4020           8. Section 499.0051 ~~Sections 499.0051, 499.0052, 499.00535,~~  
4021 ~~499.00545, and 499.0691,~~ relating to crimes involving contraband  
4022 and adulterated drugs.
- 4023           9. Part IV of chapter 501, relating to telemarketing.
- 4024           10. Chapter 517, relating to sale of securities and  
4025 investor protection.
- 4026           11. Section 550.235, s. 550.3551, or s. 550.3605, relating  
4027 to dogracing and horseracing.
- 4028           12. Chapter 550, relating to jai alai frontons.
- 4029           13. Section 551.109, relating to slot machine gaming.
- 4030           14. Chapter 552, relating to the manufacture, distribution,  
4031 and use of explosives.
- 4032           15. Chapter 560, relating to money transmitters, if the  
4033 violation is punishable as a felony.
- 4034           16. Chapter 562, relating to beverage law enforcement.
- 4035           17. Section 624.401, relating to transacting insurance  
4036 without a certificate of authority, s. 624.437(4)(c)1., relating  
4037 to operating an unauthorized multiple-employer welfare  
4038 arrangement, or s. 626.902(1)(b), relating to representing or  
4039 aiding an unauthorized insurer.
- 4040           18. Section 655.50, relating to reports of currency  
4041 transactions, when such violation is punishable as a felony.
- 4042           19. Chapter 687, relating to interest and usurious  
4043 practices.
- 4044           20. Section 721.08, s. 721.09, or s. 721.13, relating to  
4045 real estate timeshare plans.

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- 4046 21. Chapter 782, relating to homicide.
- 4047 22. Chapter 784, relating to assault and battery.
- 4048 23. Chapter 787, relating to kidnapping or human  
4049 trafficking.
- 4050 24. Chapter 790, relating to weapons and firearms.
- 4051 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.  
4052 796.05, or s. 796.07, relating to prostitution and sex  
4053 trafficking.
- 4054 26. Chapter 806, relating to arson.
- 4055 27. Section 810.02(2)(c), relating to specified burglary of  
4056 a dwelling or structure.
- 4057 28. Chapter 812, relating to theft, robbery, and related  
4058 crimes.
- 4059 29. Chapter 815, relating to computer-related crimes.
- 4060 30. Chapter 817, relating to fraudulent practices, false  
4061 pretenses, fraud generally, and credit card crimes.
- 4062 31. Chapter 825, relating to abuse, neglect, or  
4063 exploitation of an elderly person or disabled adult.
- 4064 32. Section 827.071, relating to commercial sexual  
4065 exploitation of children.
- 4066 33. Chapter 831, relating to forgery and counterfeiting.
- 4067 34. Chapter 832, relating to issuance of worthless checks  
4068 and drafts.
- 4069 35. Section 836.05, relating to extortion.
- 4070 36. Chapter 837, relating to perjury.
- 4071 37. Chapter 838, relating to bribery and misuse of public  
4072 office.
- 4073 38. Chapter 843, relating to obstruction of justice.
- 4074 39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or  
4075 s. 847.07, relating to obscene literature and profanity.



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4076 40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.  
4077 849.25, relating to gambling.

4078 41. Chapter 874, relating to criminal street gangs.

4079 42. Chapter 893, relating to drug abuse prevention and  
4080 control.

4081 43. Chapter 896, relating to offenses related to financial  
4082 transactions.

4083 44. Sections 914.22 and 914.23, relating to tampering with  
4084 a witness, victim, or informant, and retaliation against a  
4085 witness, victim, or informant.

4086 45. Sections 918.12 and 918.13, relating to tampering with  
4087 jurors and evidence.

4088 Section 43. Paragraphs (d), (f), (h), (i), and (j) of  
4089 subsection (3) of section 921.0022, Florida Statutes, are amended  
4090 to read:

4091 921.0022 Criminal Punishment Code; offense severity ranking  
4092 chart.--

4093 (3) OFFENSE SEVERITY RANKING CHART

4094 (d) LEVEL 4

4095

Florida	Felony	Description
Statute	Degree	

4096

316.1935(3) (a)	2nd	Driving at high speed or with wanton disregard for safety while fleeing or attempting to elude law enforcement officer who is in a patrol vehicle with siren and lights activated.
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4097

499.0051(1)	3rd	Failure to maintain or deliver pedigree
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4098			papers.
	499.0051(2)	3rd	Failure to authenticate pedigree papers.
4099			
	499.0051(6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband <u>prescription</u> <del>legend</del> drugs.
4100			
	784.07(2)(b)	3rd	Battery of law enforcement officer, firefighter, intake officer, etc.
4101			
	784.074(1)(c)	3rd	Battery of sexually violent predators facility staff.
4102			
	784.075	3rd	Battery on detention or commitment facility staff.
4103			
	784.078	3rd	Battery of facility employee by throwing, tossing, or expelling certain fluids or materials.
4104			
	784.08(2)(c)	3rd	Battery on a person 65 years of age or older.
4105			
	784.081(3)	3rd	Battery on specified official or employee.
4106			
	784.082(3)	3rd	Battery by detained person on visitor or other detainee.



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4107	784.083 (3)	3rd	Battery on code inspector.
4108	784.085	3rd	Battery of child by throwing, tossing, projecting, or expelling certain fluids or materials.
4109	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
4110	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
4111	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4112	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4113	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
4114	790.115 (2) (c)	3rd	Possessing firearm on school property.
4115	800.04 (7) (d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.



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4116	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
4117	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no assault or battery.
4118	810.06	3rd	Burglary; possession of tools.
4119	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
4120	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4121	812.014 (2) (c) 4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4122	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4123	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03(5) drugs.
4124	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.



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4125	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
4126	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.
4127	837.02 (1)	3rd	Perjury in official proceedings.
4128	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4129	838.022	3rd	Official misconduct.
4130	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4131	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4132	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4133	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
4134	843.15 (1) (a)	3rd	Failure to appear while on bail for felony (bond estreature or bond



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4135			jumping).
4136	874.05 (1)	3rd	Encouraging or recruiting another to join a criminal street gang.
4137	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).
4138	914.14 (2)	3rd	Witnesses accepting bribes.
4139	914.22 (1)	3rd	Force, threaten, etc., witness, victim, or informant.
4140	914.23 (2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4141	918.12	3rd	Tampering with jurors.
4142	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
4143	(f)	LEVEL 6	
4144	Florida Statute	Felony Degree	Description
4145	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.





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4147	499.0051(3)	2nd	<u>Knowing</u> forgery of pedigree papers.
4148	499.0051(4)	2nd	<u>Knowing</u> purchase or receipt of <u>prescription</u> <del>legend</del> drug from unauthorized person.
4149	499.0051(5)	2nd	<u>Knowing</u> sale <u>or transfer</u> of <u>prescription</u> <del>legend</del> drug to unauthorized person.
4150	775.0875(1)	3rd	Taking firearm from law enforcement officer.
4151	784.021(1)(a)	3rd	Aggravated assault; deadly weapon without intent to kill.
4152	784.021(1)(b)	3rd	Aggravated assault; intent to commit felony.
4153	784.041	3rd	Felony battery; domestic battery by strangulation.
4154	784.048(3)	3rd	Aggravated stalking; credible threat.
4155	784.048(5)	3rd	Aggravated stalking of person under 16.
4156	784.07(2)(c)	2nd	Aggravated assault on law enforcement officer.
	784.074(1)(b)	2nd	Aggravated assault on sexually violent predators facility staff.

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4157	784.08 (2) (b)	2nd	Aggravated assault on a person 65 years of age or older.
4158	784.081 (2)	2nd	Aggravated assault on specified official or employee.
4159	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
4160	784.083 (2)	2nd	Aggravated assault on code inspector.
4161	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4162	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
4163	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
4164	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
4165	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
4166	794.011 (8) (a)	3rd	Solicitation of minor to participate in



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sexual activity by custodial adult.

4167	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
4168	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.
4169	800.04 (6) (b)	2nd	Lewd or lascivious conduct; offender 18 years of age or older.
4170	806.031 (2)	2nd	Arson resulting in great bodily harm to firefighter or any other person.
4171	810.02 (3) (c)	2nd	Burglary of occupied structure; unarmed; no assault or battery.
4172	812.014 (2) (b) 1.	2nd	Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.
4173	812.014 (6)	2nd	Theft; property stolen \$3,000 or more; coordination of others.
4174	812.015 (9) (a)	2nd	Retail theft; property stolen \$300 or more; second or subsequent conviction.
4175	812.015 (9) (b)	2nd	Retail theft; property stolen \$3,000 or more; coordination of others.

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4176	812.13(2)(c)	2nd	Robbery, no firearm or other weapon (strong-arm robbery).
4177	817.034(4)(a)1.	1st	Communications fraud, value greater than \$50,000.
4178	817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
4179	825.102(1)	3rd	Abuse of an elderly person or disabled adult.
4180	825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
4181	825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
4182	825.103(2)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4183	827.03(1)	3rd	Abuse of a child.
4184	827.03(3)(c)	3rd	Neglect of a child.
4185	827.071(2)&(3)	2nd	Use or induce a child in a sexual performance, or promote or direct such

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performance.

4186

836.05 2nd Threats; extortion.

4187

836.10 2nd Written threats to kill or do bodily injury.

4188

843.12 3rd Aids or assists person to escape.

4189

847.0135(2) 3rd Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.

4190

914.23 2nd Retaliation against a witness, victim, or informant, with bodily injury.

4191

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.

4192

944.40 2nd Escapes.

4193

944.46 3rd Harboring, concealing, aiding escaped prisoners.

4194

944.47(1)(a)5. 2nd Introduction of contraband (firearm, weapon, or explosive) into correctional facility.



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4195	951.22 (1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
4196			
4197	(h) LEVEL 8		
4198			
	Florida Statute	Felony Degree	Description
4199			
	316.193 (3) (c) 3.a.	2nd	DUI manslaughter.
4200			
	316.1935 (4) (b)	1st	Aggravated fleeing or attempted eluding with serious bodily injury or death.
4201			
	327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
4202			
	<u>499.0051 (8)</u>	1st	<u>Knowing</u> forgery of prescription labels or <u>prescription legend</u> drug labels.
	<del>499.0051 (7)</del>		
4203			
	<u>499.0051 (7)</u>	1st	<u>Knowing</u> trafficking in contraband <u>prescription legend</u> drugs.
	<del>499.0052</del>		
4204			
	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.
4205			
	560.125 (5) (b)	2nd	Money transmitter business by



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4206	655.50(10)(b)2.	2nd	unauthorized person, currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000.
4207	777.03(2)(a)	1st	Failure to report financial transactions totaling or exceeding \$20,000, but less than \$100,000 by financial institutions.
4208	782.04(4)	2nd	Accessory after the fact, capital felony.
4209	782.051(2)	1st	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.
4210	782.071(1)(b)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04(3).
4211	782.072(2)	1st	Committing vehicular homicide and failing to render aid or give information.
			Committing vessel homicide and



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4212 failing to render aid or give  
information.

4213 790.161 (3) 1st Discharging a destructive device  
which results in bodily harm or  
property damage.

4214 794.011 (5) 2nd Sexual battery, victim 12 years or  
over, offender does not use physical  
force likely to cause serious injury.

4215 794.08 (3) 2nd Female genital mutilation, removal of  
a victim younger than 18 years of age  
from this state.

4216 800.04 (4) 2nd Lewd or lascivious battery.

4217 806.01 (1) 1st Maliciously damage dwelling or  
structure by fire or explosive,  
believing person in structure.

4218 810.02 (2) (a) 1st, PBL Burglary with assault or battery.

4219 810.02 (2) (b) 1st, PBL Burglary; armed with explosives or  
dangerous weapon.

4220 810.02 (2) (c) 1st Burglary of a dwelling or structure  
causing structural damage or \$1,000  
or more property damage.





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4221	812.014(2)(a)2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st degree.
4222	812.13(2)(b)	1st	Robbery with a weapon.
4223	812.135(2)(c)	1st	Home-invasion robbery, no firearm, deadly weapon, or other weapon.
4224	817.568(6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4225	825.102(2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4226	825.1025(2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4227	825.103(2)(a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4228	837.02(2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
	837.021(2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.



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4229	860.121(2)(c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
4230	860.16	1st	Aircraft piracy.
4231	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).
4232	893.13(2)(b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4233	893.13(6)(c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4234	893.135(1)(a)2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
4235	893.135(1)(b)1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
4236	893.135(1)(c)1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.
4237	893.135(1)(d)1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.



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4238	893.135(1)(e)1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
4239	893.135(1)(f)1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.
4240	893.135(1)(g)1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4241	893.135(1)(h)1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4242	893.135(1)(j)1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4243	893.135(1)(k)2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4244	895.03(1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
4245	895.03(2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
4246			



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4247	895.03 (3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.
4248	896.101 (5) (b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.
4249	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.
4250	(i) LEVEL 9		
4251	Florida Statute	Felony Degree	Description
4252	316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
4253	327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
4254	<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.
4255	560.123 (8) (b) 3.	1st	Failure to report currency or payment



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4256			instruments totaling or exceeding \$100,000 by money transmitter.
	560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
4257			
	655.50 (10) (b) 3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4258			
	775.0844	1st	Aggravated white collar crime.
4259			
	782.04 (1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
4260			
	782.04 (3)	1st, PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4261			
	782.051 (1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04 (3).
4262			
	782.07 (2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
4263			

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4264	787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
4265	787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
4266	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere with performance of any governmental or political function.
4267	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.
4268	790.161	1st	Attempted capital destructive device offense.
4269	790.166(2)	1st,PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
4270	794.011(2)	1st	Attempted sexual battery; victim less than 12 years of age.
	794.011(2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.

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4271	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4272	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial authority.
4273	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4274	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4275	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4276	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
4277	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4278	817.568 (7)	2nd, PBL	Fraudulent use of personal identification information of an individual under the age of 18 by his or her parent, legal guardian, or person exercising custodial authority.

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4279	827.03(2)	1st	Aggravated child abuse.
4280	847.0145(1)	1st	Selling, or otherwise transferring custody or control, of a minor.
4281	847.0145(2)	1st	Purchasing, or otherwise obtaining custody or control, of a minor.
4282	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.
4283	893.135	1st	Attempted capital trafficking offense.
4284	893.135(1)(a)3.	1st	Trafficking in cannabis, more than 10,000 lbs.
4285	893.135(1)(b)1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4286	893.135(1)(c)1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4287	893.135(1)(d)1.c.	1st	Trafficking in phencyclidine, more than 400 grams.





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4288	893.135(1)(e)1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4289	893.135(1)(f)1.c.	1st	Trafficking in amphetamine, more than 200 grams.
4290	893.135(1)(h)1.c.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.
4291	893.135(1)(j)1.c.	1st	Trafficking in 1,4-Butanediol, 10 kilograms or more.
4292	893.135(1)(k)2.c.	1st	Trafficking in Phenethylamines, 400 grams or more.
4293	896.101(5)(c)	1st	Money laundering, financial instruments totaling or exceeding \$100,000.
4294	896.104(4)(a)3.	1st	Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.

4295  
 4296 (j) LEVEL 10  
 4297

Florida Statute	Felony Degree	Description
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4298



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4299	<u>499.0051(10)</u> <del>499.00545</del>	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> <del>legend</del> drugs resulting in death.
4300	782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.
4301	787.01(1)(a)3.	1st,PBL	Kidnapping; inflict bodily harm upon or terrorize victim.
4302	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.
4303	782.07(3)	1st	Aggravated manslaughter of a child.
4304	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.
4305	812.135(2)(a)	1st,PBL	Home-invasion robbery with firearm or other deadly weapon.
4306	876.32	1st	Treason against the state.
4307	Section 44. This act shall take effect July 1, 2008.		
4308			

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4309 | ===== T I T L E A M E N D M E N T =====

4310 | And the title is amended as follows:

4311 | Delete everything before the enacting clause  
4312 | and insert:

4313 | A bill to be entitled

4314 | An act relating to drugs, devices, and cosmetics; amending  
4315 | and reorganizing provisions in part I of ch. 499, F.S.;  
4316 | amending s. 499.002, F.S.; expanding the provisions of the  
4317 | section to include administration and enforcement of,  
4318 | exemptions from, and purpose of the part; amending and  
4319 | redesignating ss. 499.004, 499.0053, 499.07, 499.071, and  
4320 | 499.081, F.S., as provisions in that section relating to  
4321 | such functions to conform; amending s. 499.003, F.S.;  
4322 | revising and providing definitions; amending and  
4323 | redesignating provisions in ss. 499.012, 499.029, and  
4324 | 499.0661, F.S., relating to definitions, as provisions of  
4325 | that section; amending s. 499.005, F.S.; conforming  
4326 | provisions to changes made by the act, including the  
4327 | substitution of the term "prescription drug" for the term  
4328 | "legend drug"; amending s. 499.0051, F.S.; substituting  
4329 | the term "prescription drug" for the term "legend drug"  
4330 | with regard to criminal acts; consolidating criminal act  
4331 | provisions of part I of ch. 499, F.S.; amending and  
4332 | redesignating ss. 499.0052, 499.00535, 499.00545, 499.069,  
4333 | and 499.0691, F.S., as criminal offense provisions in that  
4334 | section; providing penalties; conforming provisions to  
4335 | changes made by the act; amending s. 499.0054, F.S.,  
4336 | relating to advertising and labeling of drugs, devices,  
4337 | and cosmetics to include certain exemptions; amending and  
4338 | redesignating ss. 499.0055 and 499.0057, F.S., as

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4339 provisions relating to those functions in that section;  
4340 amending s. 499.006, F.S.; conforming provisions to  
4341 changes made by the act; amending s. 499.007, F.S.;  
4342 conforming provisions to changes made by the act;  
4343 providing that a drug or device is misbranded if it is an  
4344 active pharmaceutical ingredient in bulk form and does not  
4345 bear a label containing certain information; amending ss.  
4346 499.008 and 499.009, F.S.; conforming provisions to  
4347 changes made by the act; amending s. 499.01, F.S.;  
4348 providing that the section relates only to permits;  
4349 providing requirements for obtaining a permit to operate  
4350 in certain capacities; deleting certain permit  
4351 requirements; amending and redesignating provisions of ss.  
4352 499.012, 499.013, and 499.014, F.S., relating to such  
4353 functions as provisions of that section; conforming  
4354 provisions and cross-references to changes made by the  
4355 act; amending s. 499.012, F.S.; providing that the section  
4356 relates to permit application requirements; amending the  
4357 provisions to conform; amending and redesignating  
4358 provisions of s. 499.01, F.S., relating to such functions  
4359 as provisions of that section; conforming provisions and  
4360 cross-references to changes made by the act; amending s.  
4361 499.01201, F.S.; conforming provisions to changes made by  
4362 the act; amending s. 499.0121, F.S., relating to storage  
4363 and handling of prescription drugs and recordkeeping;  
4364 directing the department to adopt rules requiring a  
4365 wholesale distributor to maintain pedigree papers separate  
4366 and distinct from other required records; deleting a  
4367 requirement that a person who is engaged in the wholesale  
4368 distribution of a prescription drug and who is not the

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4369 manufacturer of that drug provide a pedigree paper to the  
4370 person who receives the drug; deleting the department's  
4371 requirement to adopt rules with regard to recordkeeping by  
4372 affiliated groups; conforming provisions and cross-  
4373 references to changes made by the act; amending and  
4374 redesignating a provision of s. 499.013, F.S., relating to  
4375 such functions as a provision of that section; amending s.  
4376 499.01211, F.S.; conforming provisions and cross-  
4377 references to changes made by the act; creating s.  
4378 499.01212, F.S.; requiring a person who is engaged in the  
4379 wholesale distribution of a prescription drug to provide a  
4380 pedigree paper to the person who receives the drug;  
4381 requiring certain information in a pedigree paper;  
4382 requiring a wholesale distributor to maintain and make  
4383 available to the department certain information; providing  
4384 exceptions to the requirement of a pedigree paper;  
4385 repealing s. 499.0122, F.S., relating to medical oxygen  
4386 and veterinary legend drug retail establishments;  
4387 repealing s. 499.013, F.S., relating to manufacturers and  
4388 repackagers of drugs, devices, and cosmetics; amending ss.  
4389 499.015, 499.024, 499.028, 499.029, and 499.03, F.S.;  
4390 conforming provisions and cross-references to changes made  
4391 by the act; amending ss. 499.032 and 499.033, F.S.;  
4392 conforming terminology to changes made by the act;  
4393 amending s. 499.039, F.S.; conforming a provision and  
4394 cross-reference; amending ss. 499.04 and 499.041, F.S.;  
4395 conforming provisions to changes made by the act; amending  
4396 s. 499.05, F.S.; conforming provisions to changes made by  
4397 the act; requiring the department to adopt rules with  
4398 regard to procedures and forms relating to pedigree paper



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4399 requirements, alternatives to compliance with the  
4400 requirement of certain pedigree papers, and the return of  
4401 prescription drugs purchased before a specified date;  
4402 amending and redesignating provisions of ss. 499.013 and  
4403 499.0122, F.S., as provisions relating to rulemaking  
4404 functions of that section; amending ss. 499.051, 499.052,  
4405 499.055, and 499.06, F.S.; conforming provisions to  
4406 changes made by the act; amending s. 499.062, F.S.;  
4407 providing that the section relates to seizure and  
4408 condemnation of drugs, devices, or cosmetics; conforming a  
4409 provision to changes made by the act; amending and  
4410 redesignating ss. 499.063 and 499.064, F.S., as provisions  
4411 relating to such functions in that section; amending ss.  
4412 499.065, 499.066, 499.0661, and 499.067, F.S.; conforming  
4413 provisions and cross-references to changes made by the  
4414 act; amending ss. 409.9201, 460.403, 465.0265, 794.075,  
4415 895.02, and 921.0022, F.S.; conforming cross-references to  
4416 changes made by the act; providing an effective date.