



836536

CHAMBER ACTION

<u>Senate</u>	.	<u>House</u>
Comm: RCS	.	
4/21/2008	.	
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1 The Committee on Judiciary (Fasano) recommended the following  
2 **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:



836536

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,



836536

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.~~ Common carriers engaged in interstate  
63 commerce are not subject to this part ss. 499.001-499.081 if they  
64 are engaged in the usual course of business as common 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 (m) of subsection (3) of section  
71 499.029, Florida Statutes, are redesignated as subsections (25),  
72 (26), (27), (35), (40), and (41), and, respectively, of that  
73 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:



836536

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~~.



836536

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 has  
109 occurred.

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

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

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

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

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

129        (9)(7)- "Color" includes black, white, and intermediate  
130 grays.

131        (10)(8)- "Color additive" means, with the exception of any  
132 material that has been or hereafter is exempt under the federal  
133 act, a material that:

134        (a) Is a dye pigment, or other substance, made by a process  
135 of synthesis or similar artifice, or extracted, isolated, or



836536

136 otherwise derived, with or without intermediate or final change  
137 of identity from a vegetable, animal, mineral, or other source;  
138 or

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

142  
143 ~~except that the term does not include any material which has been~~  
144 ~~or hereafter is exempt under the federal act.~~

145 ~~(11)-(9)~~ "Compressed medical gas" means any liquefied or  
146 vaporized gas that is a prescription drug, whether it is alone or  
147 in combination with other gases.

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

155 ~~(13)-(11)~~ "Cosmetic" means an article, with the exception of  
156 soap, that is:

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

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

162  
163 ~~except that the term does not include soap.~~

164 ~~(14)-(12)~~ "Counterfeit drug," "counterfeit device," or  
165 "counterfeit drug, counterfeit device, or counterfeit cosmetic"



836536

166 means a drug, device, or cosmetic which, or the container, seal,  
167 or labeling of which, without authorization, bears the trademark,  
168 trade name, or other identifying mark, imprint, or device, or any  
169 likeness thereof, of a drug, device, or cosmetic manufacturer,  
170 processor, packer, or distributor other than the person that in  
171 fact manufactured, processed, packed, or distributed that drug,  
172 device, or cosmetic and which thereby falsely purports or is  
173 represented to be the product of, or to have been packed or  
174 distributed by, that other drug, device, or cosmetic  
175 manufacturer, processor, packer, or distributor.

176 ~~(15)-(13)~~ "Department" means the Department of Health.

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

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

183 (b) Intended for use in the diagnosis, cure, mitigation,  
184 treatment, therapy, or prevention of disease in humans or other  
185 animals, or

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

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

194 ~~(17)-(15)~~ "Distribute ~~or distribution~~" or "distribution"  
195 means to sell; offer to sell; give away; transfer, whether by



836536

196 passage of title, physical movement, or both; deliver; or offer  
197 to deliver. The term does not mean to administer or dispense.

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

206 ~~(16) "Diverted from the legal channels of distribution for~~  
207 ~~prescription drugs" means an adulterated drug pursuant to s.~~  
208 ~~499.006(10).~~

209 (19)~~(17)~~ "Drug" means an article that is:

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

214 (b) Intended for use in the diagnosis, cure, mitigation,  
215 treatment, therapy, or prevention of disease in humans or other  
216 animals;

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

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

223 (20)~~(18)~~ "Establishment" means a place of business at one  
224 general physical location.





836536

225        ~~(21)-(19)~~ "Federal act" means the Federal Food, Drug, and  
226        Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

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

231        ~~(23)-(21)~~ "Health care entity" means a closed pharmacy or  
232        any person, organization, or business entity that provides  
233        diagnostic, medical, surgical, or dental treatment or care, or  
234        chronic or rehabilitative care, but does not include any  
235        wholesale distributor or retail pharmacy licensed under state law  
236        to deal in prescription drugs.

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

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

241        ~~(26)-(i)~~ "Hospital" means a facility as defined in s.  
242        395.002 and licensed under chapter 395.

243        ~~(27)-(22)~~ "Immediate container" does not include package  
244        liners.

245        ~~(28)-(23)~~ "Label" means a display of written, printed, or  
246        graphic matter upon the immediate container of any drug, device,  
247        or cosmetic. A requirement made by or under authority of this  
248        part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~  
249        ~~sections~~ that any word, statement, or other information appear on  
250        the label is not complied with unless such word, statement, or  
251        other information also appears on the outside container or  
252        wrapper, if any, of the retail package of such drug, device, or  
253        cosmetic or is easily legible through the outside container or  
254        wrapper.



836536

255        ~~(29)-(24)~~ "Labeling" means all labels and other written,  
256 printed, or graphic matters:

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

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

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

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

272        ~~(30)-(27)~~ "Manufacture" means the preparation, deriving,  
273 compounding, propagation, processing, producing, or fabrication  
274 of any drug, device, or cosmetic.

275        ~~(31)-(28)~~ "Manufacturer" means:

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

278            (b) The holder or holders of a New Drug Application (NDA),  
279 an Abbreviated New Drug Application (ANDA), a Biologics License  
280 Application (BLA), or a New Animal Drug Application (NADA),  
281 provided such application has become effective or is otherwise  
282 approved consistent with s. 499.023; a private label distributor  
283 for whom the private label distributor's prescription drugs are  
284 originally manufactured and labeled for the distributor and have



836536

285 not been repackaged; or the distribution point for the  
286 manufacturer, contract manufacturer, or private label distributor  
287 whether the establishment is a member of the manufacturer's  
288 affiliated group or is a contract distribution site.  
289

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

293 (32)-(29) "New drug" means:

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

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

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



836536

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

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

320 ~~(35)(30)~~ "Official compendium" means the current edition of  
321 the official United States Pharmacopoeia and National Formulary,  
322 or any supplement thereto.

323 ~~(36)(31)~~ "Pedigree paper" means:

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



836536

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

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

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

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

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

369 ~~c. The name of the prescription drug as it appears on the~~  
370 ~~label.~~

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

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



836536

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

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

382 ~~(37)(1) DEFINITION. As used in this section, the term~~  
383 ~~"Permittee" means any person holding a permit issued pursuant to~~  
384 ~~s. 499.012.~~

385 ~~(38)(32)~~ "Person" means any individual, child, joint  
386 venture, syndicate, fiduciary, partnership, corporation, division  
387 of a corporation, firm, trust, business trust, company, estate,  
388 public or private institution, association, organization, group,  
389 city, county, city and county, political subdivision of this  
390 state, other governmental agency within this state, and any  
391 representative, agent, or agency of any of the foregoing, or any  
392 other group or combination of the foregoing.

393 ~~(39)(1)~~ "Pharmacist" means a person licensed under chapter  
394 465.

395 ~~(40)(m)~~ "Pharmacy" means an entity licensed under chapter  
396 465.

397 ~~(41)(33)~~ "Prepackaged drug product" means a drug that  
398 originally was in finished packaged form sealed by a manufacturer  
399 and that is placed in a properly labeled container by a pharmacy  
400 or practitioner authorized to dispense pursuant to chapter 465  
401 for the purpose of dispensing in the establishment in which the  
402 prepackaging occurred.

403 (42) "Prescription drug" means a prescription, medicinal,  
404 or legend drug, including, but not limited to, finished dosage



836536

405 forms or active ingredients subject to, defined by, or described  
406 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s.  
407 465.003(8), s. 499.007(13), or subsection (11), subsection (47),  
408 or subsection (54).

409 (43) "Prescription drug label" means any display of  
410 written, printed, or graphic matter upon the immediate container  
411 of any prescription drug prior to its dispensing to an individual  
412 patient pursuant to a prescription of a practitioner authorized  
413 by law to prescribe.

414 (44)-(34) "Prescription label" means any display of written,  
415 printed, or graphic matter upon the immediate container of any  
416 prescription legend drug dispensed pursuant to a prescription of  
417 a practitioner authorized by law to prescribe.

418 (45)-(35) "Prescription medical oxygen" means oxygen USP  
419 which is a drug that can only be sold on the order or  
420 prescription of a practitioner authorized by law to prescribe.  
421 The label of prescription medical oxygen must comply with current  
422 labeling requirements for oxygen under the Federal Food, Drug,  
423 and Cosmetic Act.

424 (46)-(d) "Primary wholesale distributor ~~wholesaler~~" means  
425 any wholesale distributor that:

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

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

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



836536

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

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

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

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

445            b. The wholesale distributor discloses to the department  
446 the names of all members of the affiliated group of which the  
447 wholesale distributor is a member and the affiliated group agrees  
448 in writing to provide records on prescription drug purchases by  
449 the members of the affiliated group not later than 48 hours after  
450 the department requests access to such records, regardless of the  
451 location where the records are stored.

452            (47)(36) "Proprietary drug," or "OTC drug," means a patent  
453 or over-the-counter drug in its unbroken, original package, which  
454 drug is sold to the public by, or under the authority of, the  
455 manufacturer or primary distributor thereof, is not misbranded  
456 under the provisions of this part ~~ss. 499.001-499.081~~, and can be  
457 purchased without a prescription.

458            (48)(37) "Repackage" includes repacking or otherwise  
459 changing the container, wrapper, or labeling to further the  
460 distribution of the drug, device, or cosmetic.

461            (49)(38) "Repackager" means a person who repackages. The  
462 term excludes pharmacies that are operating in compliance with  
463 pharmacy practice standards as defined in chapter 465 and rules  
464 adopted under that chapter.





836536

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

469           ~~(51)(f)~~ "Secondary wholesale distributor ~~wholesaler~~" means  
470 a wholesale distributor that is not a primary wholesale  
471 distributor ~~wholesaler~~.

472           ~~(53)(39)~~ "Veterinary prescription drug" means a  
473 prescription ~~legend~~ drug intended solely for veterinary use. The  
474 label of the drug must bear the statement, "Caution: Federal law  
475 restricts this drug to sale by or on the order of a licensed  
476 veterinarian."

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

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

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

486           ~~1.a.~~ The purchase or other acquisition by a hospital or  
487 other health care entity that is a member of a group purchasing  
488 organization of a prescription drug for its own use from the  
489 group purchasing organization or from other hospitals or health  
490 care entities that are members of that organization.

491           ~~2.b.~~ The sale, purchase, or trade of a prescription drug or  
492 an offer to sell, purchase, or trade a prescription drug by a  
493 charitable organization described in s. 501(c)(3) of the Internal  
494 Revenue Code of 1986, as amended and revised, to a nonprofit



836536

495 affiliate of the organization to the extent otherwise permitted  
496 by law.

497 ~~3.e.~~ The sale, purchase, or trade of a prescription drug or  
498 an offer to sell, purchase, or trade a prescription drug among  
499 hospitals or other health care entities that are under common  
500 control. For purposes of this subparagraph ~~section~~, "common  
501 control" means the power to direct or cause the direction of the  
502 management and policies of a person or an organization, whether  
503 by ownership of stock, by voting rights, by contract, or  
504 otherwise.

505 ~~4.d.~~ The sale, purchase, trade, or other transfer of a  
506 prescription drug from or for any federal, state, or local  
507 government agency or any entity eligible to purchase prescription  
508 drugs at public health services prices pursuant to Pub. L. No.  
509 102-585, s. 602 to a contract provider or its subcontractor for  
510 eligible patients of the agency or entity under the following  
511 conditions:

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

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

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

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

523 ~~e.(V)~~ The contract provider and subcontractor must maintain  
524 and produce immediately for inspection all records of movement or



836536

525 transfer of all the prescription drugs belonging to the agency or  
526 entity, including, but not limited to, the records of receipt and  
527 disposition of prescription drugs. Each contractor and  
528 subcontractor dispensing or administering these drugs must  
529 maintain and produce records documenting the dispensing or  
530 administration. Records that are required to be maintained  
531 include, but are not limited to, a perpetual inventory itemizing  
532 drugs received and drugs dispensed by prescription number or  
533 administered by patient identifier, which must be submitted to  
534 the agency or entity quarterly.

535 f.~~(VI)~~ The contract provider or subcontractor may  
536 administer or dispense the prescription drugs only to the  
537 eligible patients of the agency or entity or must return the  
538 prescription drugs for or to the agency or entity. The contract  
539 provider or subcontractor must require proof from each person  
540 seeking to fill a prescription or obtain treatment that the  
541 person is an eligible patient of the agency or entity and must,  
542 at a minimum, maintain a copy of this proof as part of the  
543 records of the contractor or subcontractor required under sub-  
544 subparagraph e. ~~sub-sub-subparagraph (V).~~

545 g.~~(VII)~~ In addition to the departmental inspection  
546 authority set forth in s. 499.051, the establishment of the  
547 contract provider and subcontractor and all records pertaining to  
548 prescription drugs subject to this subparagraph ~~sub-subparagraph~~  
549 shall be subject to inspection by the agency or entity. All  
550 records relating to prescription drugs of a manufacturer under  
551 this subparagraph ~~sub-subparagraph~~ shall be subject to audit by  
552 the manufacturer of those drugs, without identifying individual  
553 patient information.



836536

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

557        ~~1.a.~~ The sale, purchase, or trade of a prescription drug  
558 among federal, state, or local government health care entities  
559 that are under common control and are authorized to purchase such  
560 prescription drug.

561        ~~2.b.~~ The sale, purchase, or trade of a prescription drug or  
562 an offer to sell, purchase, or trade a prescription drug for  
563 emergency medical reasons. For purposes of this subparagraph ~~sub-~~  
564 ~~subparagraph~~, the term "emergency medical reasons" includes  
565 transfers of prescription drugs by a retail pharmacy to another  
566 retail pharmacy to alleviate a temporary shortage.

567        ~~3.e.~~ The transfer of a prescription drug acquired by a  
568 medical director on behalf of a licensed emergency medical  
569 services provider to that emergency medical services provider and  
570 its transport vehicles for use in accordance with the provider's  
571 license under chapter 401.

572        ~~4.d.~~ The revocation of a sale or the return of a  
573 prescription drug to the person's prescription drug wholesale  
574 supplier.

575        ~~5.e.~~ The donation of a prescription drug by a health care  
576 entity to a charitable organization that has been granted an  
577 exemption under s. 501(c)(3) of the Internal Revenue Code of  
578 1986, as amended, and that is authorized to possess prescription  
579 drugs.

580        ~~6.f.~~ The transfer of a prescription drug by a person  
581 authorized to purchase or receive prescription drugs to a person  
582 licensed or permitted to handle reverse distributions or  
583 destruction under the laws of the jurisdiction in which the



836536

584 person handling the reverse distribution or destruction receives  
585 the drug.

586 ~~7.g.~~ The transfer of a prescription drug by a hospital or  
587 other health care entity to a person licensed under this part  
588 ~~chapter~~ to repackage prescription drugs for the purpose of  
589 repackaging the prescription drug for use by that hospital, or  
590 other health care entity and other health care entities that are  
591 under common control, if ownership of the prescription drugs  
592 remains with the hospital or other health care entity at all  
593 times. In addition to the recordkeeping requirements of s.  
594 499.0121(6), the hospital or health care entity that transfers  
595 prescription drugs pursuant to this subparagraph ~~sub-subparagraph~~  
596 must reconcile all drugs transferred and returned and resolve any  
597 discrepancies in a timely manner.

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

601 ~~(d)4.~~ The sale, purchase, or trade of blood and blood  
602 components intended for transfusion. As used in this paragraph  
603 ~~subparagraph~~, the term "blood" means whole blood collected from a  
604 single donor and processed either for transfusion or further  
605 manufacturing, and the term "blood components" means that part of  
606 the blood separated by physical or mechanical means.

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

609 ~~(f)6.~~ The sale, purchase, or trade of a prescription drug  
610 between pharmacies as a result of a sale, transfer, merger, or  
611 consolidation of all or part of the business of the pharmacies  
612 from or with another pharmacy, whether accomplished as a purchase  
613 and sale of stock or of business assets.



836536

614        ~~(54)(b)~~ "Wholesale distributor" means any person engaged in  
615 wholesale distribution of prescription drugs in or into this  
616 state, including, but not limited to, manufacturers; repackagers;  
617 own-label distributors; jobbers; private-label distributors;  
618 brokers; warehouses, including manufacturers' and distributors'  
619 warehouses, chain drug warehouses, and wholesale drug warehouses;  
620 independent wholesale drug traders; exporters; retail pharmacies;  
621 and the agents thereof that conduct wholesale distributions.

622        Section 3. Subsections (4), (10), (11), (12), (14), (15),  
623 (18), (19), (20), (22), (24), (28), and (29) of section 499.005,  
624 Florida Statutes, are amended to read:

625        499.005 Prohibited acts.--It is unlawful for a person to  
626 perform or cause the performance of any of the following acts in  
627 this state:

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

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

636        (11) The use, on the labeling of any drug or in any  
637 advertisement relating to such drug, of any representation or  
638 suggestion that an application of the drug is effective when it  
639 is not or that the drug complies with this part ~~ss. 499.001-~~  
640 ~~499.081~~ when it does not.

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



836536

643 (14) The purchase or receipt of a prescription ~~legend~~ drug  
644 from a person that is not authorized under this chapter to  
645 distribute prescription ~~legend~~ drugs to that purchaser or  
646 recipient.

647 (15) The sale or transfer of a prescription ~~legend~~ drug to  
648 a person that is not authorized under the law of the jurisdiction  
649 in which the person receives the drug to purchase or possess  
650 prescription ~~legend~~ drugs from the person selling or transferring  
651 the prescription ~~legend~~ drug.

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

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

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

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

664 (24) The distribution of a prescription ~~legend~~ device to  
665 the patient or ultimate consumer without a prescription or order  
666 from a practitioner licensed by law to use or prescribe the  
667 device.

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

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



836536

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

676 Section 4. Section 499.0051, Florida Statutes, is amended;  
677 section 499.0052, Florida Statutes, is redesignated as subsection  
678 (7) of that section and amended; section 499.00535, Florida  
679 Statutes, is redesignated as subsection (9) of that section and  
680 amended; section 499.00545, Florida Statutes, is redesignated as  
681 subsection (10) of that section and amended; section 499.069,  
682 Florida Statutes, is redesignated as subsection (11) of that  
683 section and amended; and section 499.0691, Florida Statutes, is  
684 redesignated as subsections (12) through (15) of that section and  
685 amended, to read:

686 499.0051 Criminal acts ~~involving contraband or adulterated~~  
687 ~~drugs.--~~

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

689 (a) A person, other than a manufacturer, engaged in the  
690 wholesale distribution of prescription legend ~~legend~~ drugs who fails to  
691 deliver to another person complete and accurate pedigree papers  
692 concerning a prescription legend ~~legend~~ drug or contraband prescription  
693 ~~legend~~ drug prior to, or simultaneous with, the transfer of  
694 ~~transferring~~ the prescription legend ~~legend~~ drug or contraband  
695 prescription legend ~~legend~~ drug to another person commits a felony of  
696 the third degree, punishable as provided in s. 775.082, s.  
697 775.083, or s. 775.084.

698 (b) A person engaged in the wholesale distribution of  
699 prescription legend ~~legend~~ drugs who fails to acquire complete and  
700 accurate pedigree papers concerning a prescription legend ~~legend~~ drug or  
701 contraband prescription legend ~~legend~~ drug prior to, or simultaneous  
702 with, the receipt of ~~obtaining~~ the prescription legend ~~legend~~ drug or





836536

703 | contraband prescription ~~legend~~ drug from another person commits a  
704 | felony of the third degree, punishable as provided in s. 775.082,  
705 | s. 775.083, or s. 775.084.

706 |       (c) Any person who knowingly destroys, alters, conceals, or  
707 | fails to maintain complete and accurate pedigree papers  
708 | concerning any prescription ~~legend~~ drug or contraband  
709 | prescription ~~legend~~ drug in his or her possession commits a  
710 | felony of the third degree, punishable as provided in s. 775.082,  
711 | s. 775.083, or s. 775.084.

712 |       (2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.--Effective  
713 | July 1, 2006:

714 |       (a) A person engaged in the wholesale distribution of  
715 | prescription ~~legend~~ drugs who is in possession of pedigree papers  
716 | concerning prescription ~~legend~~ drugs or contraband prescription  
717 | ~~legend~~ drugs and who fails to authenticate the matters contained  
718 | in the pedigree papers and who nevertheless attempts to further  
719 | distribute prescription ~~legend~~ drugs or contraband prescription  
720 | ~~legend~~ drugs commits a felony of the third degree, punishable as  
721 | provided in s. 775.082, s. 775.083, or s. 775.084.

722 |       (b) A person in possession of pedigree papers concerning  
723 | prescription ~~legend~~ drugs or contraband prescription ~~legend~~ drugs  
724 | who falsely swears or certifies that he or she has authenticated  
725 | the matters contained in the pedigree papers commits a felony of  
726 | the third degree, punishable as provided in s. 775.082, s.  
727 | 775.083, or s. 775.084.

728 |       (3) KNOWING FORGERY OF PEDIGREE PAPERS.--A person who  
729 | knowingly forges, counterfeits, or falsely creates any pedigree  
730 | paper; who falsely represents any factual matter contained on any  
731 | pedigree paper; or who knowingly omits to record material  
732 | information required to be recorded in a pedigree paper, commits



836536

733 a felony of the second degree, punishable as provided in s.  
734 775.082, s. 775.083, or s. 775.084.

735 (4) KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION ~~LEGEND~~ DRUG  
736 FROM UNAUTHORIZED PERSON.--A person who knowingly purchases or  
737 receives from a person not authorized to distribute prescription  
738 ~~legend~~ drugs under this chapter a prescription ~~legend~~ drug in a  
739 wholesale distribution transaction commits a felony of the second  
740 degree, punishable as provided in s. 775.082, s. 775.083, or s.  
741 775.084.

742 (5) KNOWING SALE OR TRANSFER OF PRESCRIPTION ~~LEGEND~~ DRUG TO  
743 UNAUTHORIZED PERSON.--A person who knowingly sells or transfers  
744 to a person not authorized to purchase or possess prescription  
745 ~~legend~~ drugs, under the law of the jurisdiction in which the  
746 person receives the drug, a prescription ~~legend~~ drug in a  
747 wholesale distribution transaction commits a felony of the second  
748 degree, punishable as provided in s. 775.082, s. 775.083, or s.  
749 775.084.

750 (6) KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO  
751 SELL, CONTRABAND PRESCRIPTION ~~LEGEND~~ DRUGS.--A person who is  
752 knowingly in actual or constructive possession of any amount of  
753 contraband prescription ~~legend~~ drugs, who knowingly sells or  
754 delivers, or who possesses with intent to sell or deliver any  
755 amount of contraband prescription ~~legend~~ drugs, commits a felony  
756 of the second degree, punishable as provided in s. 775.082, s.  
757 775.083, or s. 775.084.

758 (7) ~~499.0052~~ KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION  
759 ~~LEGEND~~ DRUGS.--A person who knowingly sells, purchases,  
760 manufactures, delivers, or brings into this state, or who is  
761 knowingly in actual or constructive possession of any amount of  
762 contraband prescription ~~legend~~ drugs valued at \$25,000 or more



836536

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

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

767 1.(1) If the value of contraband prescription ~~legend~~ drugs  
768 involved is \$25,000 or more, but less than \$100,000, the  
769 defendant shall pay a mandatory fine of \$25,000. If the defendant  
770 is a corporation or other person that is not a natural person, it  
771 shall pay a mandatory fine of \$75,000.

772 2.(2) If the value of contraband prescription ~~legend~~ drugs  
773 involved is \$100,000 or more, but less than \$250,000, the  
774 defendant shall pay a mandatory fine of \$100,000. If the  
775 defendant is a corporation or other person that is not a natural  
776 person, it shall pay a mandatory fine of \$300,000.

777 3.(3) If the value of contraband prescription ~~legend~~ drugs  
778 involved is \$250,000 or more, the defendant shall pay a mandatory  
779 fine of \$200,000. If the defendant is a corporation or other  
780 person that is not a natural person, it shall pay a mandatory  
781 fine of \$600,000.

782 (b) As used in this subsection ~~section~~, the term "value"  
783 means the market value of the property at the time and place of  
784 the offense or, if such cannot be satisfactorily ascertained, the  
785 cost of replacement of the property within a reasonable time  
786 after the offense. Amounts of value of separate contraband  
787 prescription ~~legend~~ drugs involved in distinct transactions for  
788 the distribution of the contraband prescription ~~legend~~ drugs  
789 committed pursuant to one scheme or course of conduct, whether  
790 involving the same person or several persons, may be aggregated  
791 in determining the punishment of the offense.



836536

792            ~~(8)(7)~~ KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION  
793 ~~LEGEND DRUG LABELS~~.--A person who knowingly forges, counterfeits,  
794 or falsely creates any prescription label or prescription legend  
795 drug label, or who falsely represents any factual matter  
796 contained on any prescription label or prescription legend drug  
797 label, commits a felony of the first degree, punishable as  
798 provided in s. 775.082, s. 775.083, or s. 775.084.

799            ~~(9)499.00535~~ KNOWING Sale or purchase of contraband  
800 prescription legend drugs resulting in great bodily harm.--A  
801 person who knowingly sells, purchases, manufactures, delivers, or  
802 brings into this state, or who is knowingly in actual or  
803 constructive possession of any amount of contraband prescription  
804 ~~legend~~ drugs, and whose acts in violation of this subsection  
805 ~~section~~ result in great bodily harm to a person, commits a felony  
806 of the first degree, as provided in s. 775.082, s. 775.083, or s.  
807 775.084.

808            ~~(10)499.00545~~ Knowing Sale or purchase of contraband  
809 prescription legend drugs resulting in death.--A person who  
810 knowingly manufactures, sells, purchases, delivers, or brings  
811 into this state, or who is knowingly in actual or constructive  
812 possession of any amount of contraband prescription legend drugs,  
813 and whose acts in violation of this subsection ~~section~~ result in  
814 the death of a person, commits a felony of the first degree,  
815 punishable by a term of years not exceeding life, as provided in  
816 s. 775.082, s. 775.083, or s. 775.084.

817            ~~(11)499.069~~ ~~Criminal punishment for~~ violations of s.  
818 499.005 related to devices and cosmetics; dissemination of false  
819 advertisement.--

820            ~~(a)(1)~~ Any person who violates any of the provisions of s.  
821 499.005 with respect to a device or cosmetic commits a



836536

822 | misdemeanor of the second degree, punishable as provided in s.  
823 | 775.082 or s. 775.083; but, if the violation is committed after a  
824 | conviction of such person under this subsection ~~section~~ has  
825 | become final, such person is guilty of a misdemeanor of the first  
826 | degree, punishable as provided in s. 775.082 or s. 775.083 or as  
827 | otherwise provided in this part ~~ss. 499.001-499.081~~, except that  
828 | any person who violates s. 499.005(8) or (10) ~~subsection (8) or~~  
829 | ~~subsection (10) of s. 499.005~~ with respect to a device or  
830 | cosmetic commits a felony of the third degree, punishable as  
831 | provided in s. 775.082, s. 775.083, or s. 775.084, or as  
832 | otherwise provided in this part ~~ss. 499.001-499.081~~.

833 |       **(b)(2)** A publisher, radio broadcast licensee, or agency or  
834 | medium for the dissemination of an advertisement, except the  
835 | manufacturer, wholesaler, or seller of the article to which a  
836 | false advertisement relates, is not liable under this subsection  
837 | ~~section~~ by reason of the dissemination by him or her of such  
838 | false advertisement, unless he or she has refused, on the request  
839 | of the department, to furnish to the department the name and post  
840 | office address of the manufacturer, wholesaler, seller, or  
841 | advertising agency that asked him or her to disseminate such  
842 | advertisement.

843 |       **(12)499.0691** ADULTERATED AND MISBRANDED DRUGS; FALSE  
844 | ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS  
845 | ~~Criminal punishment for violations related to drugs;~~  
846 | ~~dissemination of false advertisement.~~ ~~---(1)~~ Any person who  
847 | violates any of the following provisions commits a misdemeanor of  
848 | the second degree, punishable as provided in s. 775.082 or s.  
849 | 775.083; but, if the violation is committed after a conviction of  
850 | such person under this subsection ~~section~~ has become final, such  
851 | person commits a misdemeanor of the first degree, punishable as



836536

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

854 (a) The manufacture, repackaging, sale, delivery, or  
855 holding or offering for sale of any drug that is adulterated or  
856 misbranded or has otherwise been rendered unfit for human or  
857 animal use.

858 (b) The adulteration or misbranding of any drug intended  
859 for further distribution.

860 (c) The receipt of any drug that is adulterated or  
861 misbranded, and the delivery or proffered delivery of such drug,  
862 for pay or otherwise.

863 (d) The dissemination of any false or misleading  
864 advertisement of a drug.

865 (e) The use, on the labeling of any drug or in any  
866 advertisement relating to such drug, of any representation or  
867 suggestion that an application of the drug is effective when it  
868 is not or that the drug complies with this part ~~ss. 499.001-~~  
869 ~~499.081~~ when it does not.

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

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

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

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



836536

882           (13) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR  
883 TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO  
884 PRESCRIPTION DRUGS.--(2) Any person who violates any of the  
885 following provisions commits a felony of the third degree,  
886 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,  
887 or as otherwise provided in this part: ss. 499.001-499.081.  
888           (a) The refusal or constructive refusal to allow:  
889           1. The department to enter or inspect an establishment in  
890 which drugs are manufactured, processed, repackaged, sold,  
891 brokered, or held;  
892           2. Inspection of any record of that establishment;  
893           3. The department to enter and inspect any vehicle that is  
894 being used to transport drugs; or  
895           4. The department to take samples of any drug.  
896           (b) The sale, purchase, or trade, or the offer to sell,  
897 purchase, or trade, a drug sample as defined in s. 499.028; the  
898 distribution of a drug sample in violation of s. 499.028; or the  
899 failure to otherwise comply with s. 499.028.  
900           (c) Providing the department with false or fraudulent  
901 records, or making false or fraudulent statements, regarding any  
902 matter within the provisions of this part ~~chapter~~ related to a  
903 drug.  
904           (d) The failure to receive, maintain, or provide invoices  
905 and shipping documents, other than pedigree papers, if  
906 applicable, related to the distribution of a prescription ~~legend~~  
907 drug.  
908           (e) The importation of a prescription ~~legend~~ drug for  
909 wholesale distribution, except as provided by s. 801(d) of the  
910 Federal Food, Drug, and Cosmetic Act.



836536

911 (f) The wholesale distribution of a ~~any~~ prescription drug  
912 that was:

913 1. Purchased by a public or private hospital or other  
914 health care entity; or

915 2. Donated or supplied at a reduced price to a charitable  
916 organization.

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

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

922 (i) The purchase or sale of a prescription drug ~~drugs~~ for  
923 wholesale distribution in exchange for currency, as defined in s.  
924 560.103(6).

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

929 (a) Knowingly manufacturing, repackaging, selling,  
930 delivering, or holding or offering for sale any drug that is  
931 adulterated or misbranded or has otherwise been rendered unfit  
932 for human or animal use.

933 (b) Knowingly adulterating a drug that is intended for  
934 further distribution.

935 (c) Knowingly receiving a drug that is adulterated and  
936 delivering or proffering delivery of such drug for pay or  
937 otherwise.

938 (d) Committing any act that causes a drug to be a  
939 counterfeit drug, or selling, dispensing, or knowingly holding  
940 for sale a counterfeit drug.





836536

941 (e) Forging, counterfeiting, simulating, or falsely  
942 representing any drug, or, without the authority of the  
943 manufacturer, using any mark, stamp, tag, label, or other  
944 identification device authorized or required by rules adopted  
945 under this part ss. 499.001-499.081.

946 (f) Knowingly obtaining or attempting to obtain a  
947 prescription drug for wholesale distribution by fraud, deceit,  
948 misrepresentation, or subterfuge, or engaging in  
949 misrepresentation or fraud in the distribution of a drug.

950 (g) Removing a pharmacy's dispensing label from a dispensed  
951 prescription drug with the intent to further distribute the  
952 prescription drug.

953 (h) Knowingly distributing a prescription drug that was  
954 previously dispensed by a licensed pharmacy, unless such  
955 distribution was authorized in chapter 465 or the rules adopted  
956 under chapter 465.

957 (15) FALSE ADVERTISEMENT.--(4) A publisher, radio  
958 broadcast licensee, or agency or medium for the dissemination of  
959 an advertisement, except the manufacturer, repackager, wholesale  
960 distributor ~~wholesaler~~, or seller of the article to which a false  
961 advertisement relates, is not liable under subsection (12),  
962 subsection (13), or subsection (14) ~~this section~~ by reason of the  
963 dissemination by him or her of such false advertisement, unless  
964 he or she has refused, on the request of the department, to  
965 furnish to the department the name and post office address of the  
966 manufacturer, repackager, wholesale distributor ~~wholesaler~~,  
967 seller, or advertising agency that asked him or her to  
968 disseminate such advertisement.

969 Section 5. Section 499.0054, Florida Statutes, is amended;  
970 section 499.0055, Florida Statutes, is redesignated as subsection



836536

971 (2) of that section and amended; and section 499.0057, Florida  
972 Statutes, is redesignated as subsection (3) of that section and  
973 amended, to read:

974 499.0054 Advertising and labeling of drugs, devices, and  
975 cosmetics; exemptions.--

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

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

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

984 (c) ~~(3)~~ The manufacturing, repackaging, packaging, selling,  
985 delivery, holding, or offering for sale of any drug, device, or  
986 cosmetic for which the advertising or labeling is false or  
987 misleading.

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

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

993 (f) ~~(6)~~ The advertising or labeling of any product  
994 containing ephedrine, a salt of ephedrine, an isomer of  
995 ephedrine, or a salt of an isomer of ephedrine, for the  
996 indication of stimulation, mental alertness, weight loss,  
997 appetite control, energy, or other indications not approved by  
998 the pertinent United States Food and Drug Administration Over-  
999 the-Counter Final or Tentative Final Monograph or approved new  
1000 drug application under the federal act. In determining compliance



836536

1001 with this requirement, the department may consider the following  
1002 factors:

- 1003        ~~1.(a)~~ The packaging of the product.
- 1004        ~~2.(b)~~ The name and labeling of the product.
- 1005        ~~3.(c)~~ The manner of distribution, advertising, and  
1006 promotion of the product, including verbal representations at the  
1007 point of sale.
- 1008        ~~4.(d)~~ The duration, scope, and significance of abuse of the  
1009 particular product.
- 1010        ~~(g)(7)~~ The advertising of any drug or device represented to  
1011 have any effect in any of the following conditions, disorders,  
1012 diseases, or processes:
  - 1013           ~~1.(a)~~ Blood disorders.
  - 1014           ~~2.(b)~~ Bone or joint diseases.
  - 1015           ~~3.(c)~~ Kidney diseases or disorders.
  - 1016           ~~4.(d)~~ Cancer.
  - 1017           ~~5.(e)~~ Diabetes.
  - 1018           ~~6.(f)~~ Gall bladder diseases or disorders.
  - 1019           ~~7.(g)~~ Heart and vascular diseases.
  - 1020           ~~8.(h)~~ High blood pressure.
  - 1021           ~~9.(i)~~ Diseases or disorders of the ear or auditory  
1022 apparatus, including hearing loss or deafness.
  - 1023           ~~10.(j)~~ Mental disease or mental retardation.
  - 1024           ~~11.(k)~~ Paralysis.
  - 1025           ~~12.(l)~~ Prostate gland disorders.
  - 1026           ~~13.(m)~~ Conditions of the scalp affecting hair loss.
  - 1027           ~~14.(n)~~ Baldness.
  - 1028           ~~15.(o)~~ Endocrine disorders.
  - 1029           ~~16.(p)~~ Sexual impotence.
  - 1030           ~~17.(q)~~ Tumors.



836536

- 1031        18.~~(r)~~ Venereal diseases.
- 1032        19.~~(s)~~ Varicose ulcers.
- 1033        20.~~(t)~~ Breast enlargement.
- 1034        21.~~(u)~~ Purifying blood.
- 1035        22.~~(v)~~ Metabolic disorders.
- 1036        23.~~(w)~~ Immune system disorders or conditions affecting the  
1037 immune system.
- 1038        24.~~(x)~~ Extension of life expectancy.
- 1039        25.~~(y)~~ Stress and tension.
- 1040        26.~~(z)~~ Brain stimulation or performance.
- 1041        27.~~(aa)~~ The body's natural defense mechanisms.
- 1042        28.~~(bb)~~ Blood flow.
- 1043        29.~~(cc)~~ Depression.
- 1044        30.~~(dd)~~ Human immunodeficiency virus or acquired immune  
1045 deficiency syndrome or related disorders or conditions.
- 1046        (h)~~(8)~~ The representation or suggestion in labeling or  
1047 advertising that an article is approved under this part ss.  
1048 ~~499.001-499.081~~, when such is not the case.
- 1049        (2)~~499.0055~~ ~~False or misleading advertisement.~~ In  
1050 determining whether an advertisement is false or misleading, the  
1051 department shall review the representations made or suggested by  
1052 statement, word, design, device, sound, or any combination  
1053 thereof within the advertisement and the extent to which the  
1054 advertisement fails to reveal material facts with respect to  
1055 consequences that can result from the use of the drug, device, or  
1056 cosmetic to which the advertisement relates under the conditions  
1057 of use prescribed in the labeling or advertisement.
- 1058        (3)~~499.0057~~ ~~Advertisement exemptions.~~



836536

1059            ~~(a)(1)~~ An advertisement that is not prohibited under  
1060 paragraph (1)(a) s. 499.0054(1) is not prohibited under paragraph  
1061 (1)(g) s. 499.0054(7) if it is disseminated:

1062            1. To the public solely to advertise the product for those  
1063 indications that are safe and effective indications and the  
1064 product is safe and effective for self-medication, as established  
1065 by the United States Food and Drug Administration; or

1066            2. ~~if it is disseminated~~ Only to members of the medical,  
1067 dental, pharmaceutical, or veterinary professions or appears only  
1068 in the scientific periodicals of these professions.

1069            ~~(b)(2)~~ Compliance with this part ss. 499.001-499.081 and  
1070 the rules adopted under this part ~~these sections~~ creates no legal  
1071 presumption that a drug or device is safe or effective.

1072            Section 6. Subsections (3), (10), and (11) of section  
1073 499.006, Florida Statutes, are amended to read:

1074            499.006 Adulterated drug or device.--A drug or device is  
1075 adulterated:

1076            (3) If it is a drug and the methods used in, or the  
1077 facilities or controls used for, its manufacture, processing,  
1078 packing, or holding do not conform to, or are not operated or  
1079 administered in conformity with, current good manufacturing  
1080 practices to assure that the drug meets the requirements of this  
1081 part ss. 499.001-499.081 and that the drug has the identity and  
1082 strength, and meets the standard of quality and purity, which it  
1083 purports or is represented to possess;

1084            (10) If it is a prescription ~~legend~~ drug for which the  
1085 required pedigree paper is nonexistent, fraudulent, or incomplete  
1086 under the requirements of this part ss. 499.001-499.081 or  
1087 applicable rules, or that has been purchased, held, sold, or



836536

1088 distributed at any time by a person not authorized under federal  
1089 or state law to do so; or

1090 (11) If it is a prescription drug subject to, defined by,  
1091 or described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
1092 Act which has been returned by a veterinarian to a limited  
1093 prescription drug veterinary wholesale distributor ~~wholesaler~~.

1094 Section 7. Section 499.007, Florida Statutes, is amended to  
1095 read:

1096 499.007 Misbranded drug or device.--A drug or device is  
1097 misbranded:

1098 (1) If its labeling is in any way false or misleading.

1099 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a  
1100 label containing:

1101 (a) The name and place of business of the manufacturer,  
1102 repackager, or distributor of the finished dosage form of the  
1103 drug. For the purpose of this paragraph, the finished dosage form  
1104 of a prescription medicinal drug is that form of the drug which  
1105 is, or is intended to be, dispensed or administered to the  
1106 patient and requires no further manufacturing or processing other  
1107 than packaging, reconstitution, and labeling; and

1108 (b) An accurate statement of the quantity of the contents  
1109 in terms of weight, measure, or numerical count. ~~;~~ However, under  
1110 this section, reasonable variations are permitted, and the  
1111 department shall establish by rule exemptions for small packages.

1112 (3) If it is an active pharmaceutical ingredient in bulk  
1113 form and does not bear a label containing:

1114 (a) The name and place of business of the manufacturer,  
1115 repackager, or distributor; and

1116 (b) An accurate statement of the quantity of the contents  
1117 in terms of weight, measure, or numerical count.



836536

1118        ~~(4)(3)~~ If any word, statement, or other information  
1119 required by or under this part ~~ss. 499.001-499.081~~ to appear on  
1120 the label or labeling is not prominently placed thereon with such  
1121 conspicuousness as compared with other words, statements,  
1122 designs, or devices in the labeling, and in such terms, as to  
1123 render the word, statement, or other information likely to be  
1124 read and understood under customary conditions of purchase and  
1125 use.

1126        ~~(5)(4)~~ If it is a drug and is not designated solely by a  
1127 name recognized in an official compendium and, ~~unless~~ its label  
1128 does not bear ~~bears~~:

- 1129            (a) The common or usual name of the drug, if any; and  
1130            (b) In case it is fabricated from two or more ingredients,  
1131 the common or usual name and quantity of each active ingredient.

1132        ~~(6)(5)~~ If ~~Unless~~ its labeling does not bear ~~bears~~:

- 1133            (a) Adequate directions for use; and  
1134            (b) Adequate warnings against use in those pathological  
1135 conditions in which its use may be dangerous to health or against  
1136 use by children if its use may be dangerous to health, or against  
1137 unsafe dosage or methods or duration of administration or  
1138 application, in such manner and form as are necessary for the  
1139 protection of users.

1140        ~~(7)(6)~~ If it purports to be a drug the name of which is  
1141 recognized in the official compendium and, ~~unless~~ it is not  
1142 packaged and labeled as prescribed therein. ~~‡~~ However, the method  
1143 of packaging may be modified with the consent of the department.

1144        ~~(8)(7)~~ If it has been found by the department to be a drug  
1145 liable to deterioration and, ~~unless~~ it is not packaged in such  
1146 form and manner, and its label bears a statement of such  
1147 precautions, as the department by rule requires as necessary to



836536

1148 protect the public health. Such rule may not be established for  
1149 any drug recognized in an official compendium until the  
1150 department has informed the appropriate body charged with the  
1151 revision of such compendium of the need for such packaging or  
1152 labeling requirements and that body has failed within a  
1153 reasonable time to prescribe such requirements.

1154 ~~(9)~~<sup>(8)</sup> If it is:

1155 (a) A drug and its container or finished dosage form is so  
1156 made, formed, or filled as to be misleading;

1157 (b) An imitation of another drug; or

1158 (c) Offered for sale under the name of another drug.

1159 ~~(10)~~<sup>(9)</sup> If it is dangerous to health when used in the  
1160 dosage or with the frequency or duration prescribed, recommended,  
1161 or suggested in the labeling of the drug.

1162 ~~(11)~~<sup>(10)</sup> If it is, purports to be, or is represented as a  
1163 drug composed wholly or partly of insulin and, ~~unless:~~

1164 ~~(a)~~ it is not from a batch with respect to which a  
1165 certificate has been issued pursuant to s. 506 of the federal  
1166 act, which; ~~and~~

1167 ~~(b)~~ ~~The~~ certificate is in effect with respect to the drug.

1168 ~~(12)~~<sup>(11)</sup> If it is, purports to be, or is represented as a  
1169 drug composed wholly or partly of any kind of antibiotic  
1170 requiring certification under the federal act and ~~unless:~~

1171 ~~(a)~~ it is not from a batch with respect to which a  
1172 certificate has been issued pursuant to s. 507 of the federal  
1173 act, which; ~~and~~

1174 ~~(b)~~ the certificate is in effect with respect to the drug. ~~+~~

1175





836536

1176 However, this subsection does not apply to any drug or class of  
1177 drugs exempted by regulations adopted under s. 507(c) or (d) of  
1178 the federal act.

1179 ~~(13)-(12)~~ If it is a drug intended for use by humans which  
1180 is a habit-forming drug or which, because of its toxicity or  
1181 other potentiality for harmful effect, or the method of its use,  
1182 or the collateral measures necessary to its use, is not safe for  
1183 use except under the supervision of a practitioner licensed by  
1184 law to administer such drugs, ~~+~~ or which is limited by an  
1185 effective application under s. 505 of the federal act to use  
1186 under the professional supervision of a practitioner licensed by  
1187 law to prescribe such drug, if ~~unless~~ it is not dispensed only:

1188 (a) Upon the written prescription of a practitioner  
1189 licensed by law to prescribe such drug;

1190 (b) Upon an oral prescription of such practitioner, which  
1191 is reduced promptly to writing and filled by the pharmacist; or

1192 (c) By refilling any such written or oral prescription, if  
1193 such refilling is authorized by the prescriber either in the  
1194 original prescription or by oral order which is reduced promptly  
1195 to writing and filled by the pharmacist.

1196

1197 This subsection does not relieve any person from any requirement  
1198 prescribed by law with respect to controlled substances as  
1199 defined in the applicable federal and state laws.

1200 ~~(14)-(13)~~ If it is a drug that is subject to paragraph  
1201 ~~(13)-(12)~~(a), and if, at any time before it is dispensed, its  
1202 label does not ~~fails to~~ bear the statement:

1203 (a) "Caution: Federal Law Prohibits Dispensing Without  
1204 Prescription";

1205 (b) "Rx Only";



836536

1206 (c) The prescription symbol followed by the word "Only"; or  
1207 (d) "Caution: State Law Prohibits Dispensing Without  
1208 Prescription."  
1209 ~~(15)-(14)~~ If it is a drug that is not subject to paragraph  
1210 ~~(13)-(12)~~(a), if at any time before it is dispensed its label  
1211 bears the statement of caution required in subsection ~~(14)~~ ~~(13)~~.  
1212 ~~(16)-(15)~~ If it is a color additive, the intended use of  
1213 which in or on drugs is for the purpose of coloring only ~~and~~  
1214 ~~unless~~ its packaging and labeling are not in conformity with the  
1215 packaging and labeling requirements that apply to such color  
1216 additive and are prescribed under the federal act.  
1217 (17) A drug dispensed by filling or refilling a written or  
1218 oral prescription of a practitioner licensed by law to prescribe  
1219 such drug is exempt from the requirements of this section, except  
1220 subsections (1), (9) ~~(8)~~, (11) ~~(10)~~, and (12) ~~(11)~~ and the  
1221 packaging requirements of subsections (7) ~~(6)~~ and (8) ~~(7)~~, if the  
1222 drug bears a label that contains the name and address of the  
1223 dispenser or seller, the prescription number and the date the  
1224 prescription was written or filled, the name of the prescriber  
1225 and the name of the patient, and the directions for use and  
1226 cautionary statements. This exemption does not apply to any drug  
1227 dispensed in the course of the conduct of a business of  
1228 dispensing drugs pursuant to diagnosis by mail or to any drug  
1229 dispensed in violation of subsection (13) ~~(12)~~. The department  
1230 may, by rule, exempt drugs subject to s. 499.062 ~~ss. 499.062-~~  
1231 ~~499.064~~ from subsection (13) ~~(12)~~ if compliance with that  
1232 subsection is not necessary to protect the public health, safety,  
1233 and welfare.



836536

1234 Section 8. Subsection (1) of section 499.008, Florida  
1235 Statutes, is amended and subsection (5) is added to that section  
1236 to read:

1237 499.008 Adulterated cosmetics.--A cosmetic is adulterated:

1238 (1) If it bears or contains any poisonous or deleterious  
1239 substance that is injurious to users under the conditions of use  
1240 prescribed in the labeling or advertisement thereof or under such  
1241 conditions of use as are customary or usual; however, this  
1242 subsection does not apply to coal-tar hair dye:

1243 (a) The label of which bears the following legend  
1244 conspicuously displayed thereon: "Caution: This product contains  
1245 ingredients which may cause skin irritation on certain  
1246 individuals, and a preliminary test according to accompanying  
1247 directions should first be made. This product must not be used  
1248 for dyeing the eyelashes or eyebrows; to do so may cause  
1249 blindness"; and

1250 (b) The labeling of which bears adequate directions for  
1251 such preliminary testing.

1252

1253 ~~For the purposes of this subsection and subsection (4), the term~~  
1254 ~~"hair dye" does not include eyelash dyes or eyebrow dyes.~~

1255 (5) For the purposes of subsections (1) and (4), the term  
1256 "hair dye" does not include eyelash dyes or eyebrow dyes.

1257 Section 9. Subsections (2), (3), and (5) of section  
1258 499.009, Florida Statutes, are amended to read:

1259 499.009 Misbranded cosmetics.--A cosmetic is misbranded:

1260 (2) ~~Unless,~~ If in package form, it does not bear ~~bears~~ a  
1261 label containing:

1262 (a) The name and place of business of the manufacturer,  
1263 packer, or distributor;



836536

1264 (b) An accurate statement of the quantity of the contents  
1265 in terms of weight, measure, or numerical count; however, under  
1266 this paragraph reasonable variations are permitted, and the  
1267 department shall establish by rule exemptions for small packages;  
1268 and

1269 (c) A declaration of ingredients in descending order of  
1270 predominance, or as otherwise required by federal law.

1271 (3) If any word, statement, or other information required  
1272 by or under authority of this part ~~ss. 499.001-499.081~~ to appear  
1273 on the label or labeling is not prominently placed thereon with  
1274 such conspicuousness as compared with other words, statements,  
1275 designs, or devices in the labeling, and in such terms, as to  
1276 render the word, statement, or other information likely to be  
1277 read and understood by an individual under customary conditions  
1278 of purchase and use.

1279 (5) ~~Unless,~~ If it is a color additive, its packaging and  
1280 labeling are not in conformity with the packaging and labeling  
1281 requirements applicable to that color additive prescribed under  
1282 the federal act. This subsection does not apply to packages of  
1283 color additives that, with respect to their use for cosmetics,  
1284 are marketed and intended for use only in or on hair dyes.

1285 Section 10. Section 499.01, Florida Statutes, is amended;  
1286 the introductory paragraph and paragraphs (a) through (h) of  
1287 subsection (2) of section 499.012, Florida Statutes, are  
1288 redesignated as the introductory paragraph and paragraphs (d),  
1289 (n), (e), (f), (c), (i), (k), and (l), respectively, of  
1290 subsection (2) of that section and amended; paragraphs (b)  
1291 through (e) of subsection (2) of section 499.013, Florida  
1292 Statutes, are redesignated as paragraphs (p), (o), (q), and (r),  
1293 respectively, of subsection (2) of that section and amended; and



836536

1294 section 499.014, Florida Statutes, is redesignated as paragraph  
1295 (g) of subsection (2) of that section and amended, to read:

1296 499.01 Permits; ~~applications; renewal; general~~  
1297 ~~requirements.~~--

1298 (1) Prior to operating, a permit is required for each  
1299 person and establishment that intends to operate as:

1300 (a) A prescription drug manufacturer;

1301 (b) A prescription drug repackager;

1302 (c) A nonresident prescription drug manufacturer;

1303 (d) A prescription drug wholesale distributor;

1304 (e) An out-of-state prescription drug wholesale  
1305 distributor;

1306 (f) A retail pharmacy drug wholesale distributor;

1307 (g) A restricted prescription drug distributor;

1308 (h) A complimentary drug distributor;

1309 (i) A freight forwarder;

1310 (j) A veterinary prescription drug retail establishment;

1311 (k) A veterinary prescription drug wholesale distributor;

1312 (l) A limited prescription drug veterinary wholesale  
1313 distributor;

1314 (m) A medical oxygen retail establishment;

1315 (n) A compressed medical gas wholesale distributor;

1316 (o) A compressed medical gas manufacturer;

1317 (p)(e) An over-the-counter drug manufacturer;

1318 ~~(d) A compressed medical gas manufacturer;~~

1319 (q)(e) A device manufacturer;

1320 (r)(f) A cosmetic manufacturer;

1321 (s) A third party logistic provider; or

1322 (t) A health care clinic establishment.

1323 ~~(g) A prescription drug wholesaler;~~



836536

- 1324 ~~(h) A veterinary prescription drug wholesaler;~~
- 1325 ~~(i) A compressed medical gas wholesaler;~~
- 1326 ~~(j) An out-of-state prescription drug wholesaler;~~
- 1327 ~~(k) A nonresident prescription drug manufacturer;~~
- 1328 ~~(l) A freight forwarder;~~
- 1329 ~~(m) A retail pharmacy drug wholesaler;~~
- 1330 ~~(n) A veterinary legend drug retail establishment;~~
- 1331 ~~(o) A medical oxygen retail establishment;~~
- 1332 ~~(p) A complimentary drug distributor;~~
- 1333 ~~(q) A restricted prescription drug distributor; or~~
- 1334 ~~(r) A limited prescription drug veterinary wholesaler.~~

1335 (2) The following ~~types of wholesaler~~ permits are  
1336 established:

1337 (a) Prescription drug manufacturer permit.--A prescription  
1338 drug manufacturer permit is required for any person that  
1339 manufactures a prescription drug in this state.

1340 1. A person that operates an establishment permitted as a  
1341 prescription drug manufacturer may engage in wholesale  
1342 distribution of prescription drugs manufactured at that  
1343 establishment and must comply with all the provisions of this  
1344 part and the rules adopted under this part that apply to a  
1345 wholesale distributor.

1346 2. A prescription drug manufacturer must comply with all  
1347 appropriate state and federal good manufacturing practices.

1348 (b) Prescription drug repackager permit.--A prescription  
1349 drug repackager permit is required for any person that repackages  
1350 a prescription drug in this state.

1351 1. A person that operates an establishment permitted as a  
1352 prescription drug repackager may engage in wholesale distribution  
1353 of prescription drugs repackaged at that establishment and must



836536

1354 comply with all the provisions of this part and the rules adopted  
1355 under this part that apply to a wholesale distributor.

1356 2. A prescription drug repackager must comply with all  
1357 appropriate state and federal good manufacturing practices.

1358 (c)(e) Nonresident prescription drug manufacturer  
1359 permit.--A nonresident prescription drug manufacturer permit is  
1360 required for any person that is a manufacturer of prescription  
1361 drugs, or the distribution point for a manufacturer of  
1362 prescription drugs, and located outside of this state, or that is  
1363 an entity to whom an approved new drug application has been  
1364 issued by the United States Food and Drug Administration, or the  
1365 contracted manufacturer of the approved new drug application  
1366 holder, and located outside the United States, which engages in  
1367 the wholesale distribution in this state of the prescription  
1368 drugs it manufactures or is responsible for manufacturing. Each  
1369 such manufacturer or entity must be permitted by the department  
1370 and comply with all the provisions required of a wholesale  
1371 distributor under this part ss. 499.001-499.081, except s.  
1372 499.01212 s. 499.0121(6)(d).

1373 1. A person that distributes prescription drugs that it did  
1374 not manufacture must also obtain an out-of-state prescription  
1375 drug wholesale distributor wholesaler permit pursuant to this  
1376 section to engage in the wholesale distribution of the  
1377 prescription drugs manufactured by another person and comply with  
1378 the requirements of an out-of-state prescription drug wholesale  
1379 distributor wholesaler.

1380 2. Any such person must comply with the licensing or  
1381 permitting requirements of the jurisdiction in which the  
1382 establishment is located and the federal act, and any product  
1383 wholesaled into this state must comply with this part ss.



836536

1384 ~~499.001-499.081~~. If a person intends to import prescription drugs  
1385 from a foreign country into this state, the nonresident  
1386 prescription drug manufacturer must provide to the department a  
1387 list identifying each prescription drug it intends to import and  
1388 document approval by the United States Food and Drug  
1389 Administration for such importation.

1390 3. A nonresident prescription drug manufacturer permit is  
1391 not required for a manufacturer to distribute a prescription drug  
1392 active pharmaceutical ingredient that it manufactures to a  
1393 prescription drug manufacturer permitted in this state in limited  
1394 quantities intended for research and development and not for  
1395 resale, or human use other than lawful clinical trials and  
1396 biostudies authorized and regulated by federal law. A  
1397 manufacturer claiming to be exempt from the permit requirements  
1398 of this subparagraph and the prescription drug manufacturer  
1399 purchasing and receiving the active pharmaceutical ingredient  
1400 shall comply with the recordkeeping requirements of s.  
1401 499.0121(6). The prescription drug manufacturer purchasing and  
1402 receiving the active pharmaceutical ingredient shall maintain on  
1403 file a record of the FDA registration number; the out-of-state  
1404 license, permit, or registration number; and, if available, a  
1405 copy of the most current FDA inspection report, for all  
1406 manufacturers from whom they purchase active pharmaceutical  
1407 ingredients under this section. The department shall specify by  
1408 rule the allowable number of transactions within a given period  
1409 of time and the amount of active pharmaceutical ingredients that  
1410 qualify as limited quantities for purposes of this exemption. The  
1411 failure to comply with the requirements of this subparagraph, or  
1412 rules adopted by the department to administer this subparagraph,





836536

1413 for the purchase of prescription drug active pharmaceutical  
1414 ingredients is a violation of s. 499.005(14).

1415 (d) (a) A Prescription drug wholesale distributor  
1416 ~~wholesaler's~~ permit.--A prescription drug wholesale distributor  
1417 ~~wholesaler~~ is a wholesale distributor that may engage in the  
1418 wholesale distribution of prescription drugs. A prescription drug  
1419 wholesale distributor ~~wholesaler~~ that applies to the department  
1420 for a new permit or the renewal of a permit must submit a bond of  
1421 \$100,000, or other equivalent means of security acceptable to the  
1422 department, such as an irrevocable letter of credit or a deposit  
1423 in a trust account or financial institution, payable to the  
1424 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the  
1425 bond is to secure payment of any administrative penalties imposed  
1426 by the department and any fees and costs incurred by the  
1427 department regarding that permit which are authorized under state  
1428 law and which the permittee fails to pay 30 days after the fine  
1429 or costs become final. The department may make a claim against  
1430 such bond or security until 1 year after the permittee's license  
1431 ceases to be valid or until 60 days after any administrative or  
1432 legal proceeding authorized in this part ~~ss. 499.001-499.081~~  
1433 which involves the permittee is concluded, including any appeal,  
1434 whichever occurs later. The department may adopt rules for  
1435 issuing a prescription drug wholesale distributor-broker  
1436 ~~wholesaler-broker~~ permit to a person who engages in the wholesale  
1437 distribution of prescription drugs and does not take physical  
1438 possession of any prescription drugs.

1439 (e) (e) An Out-of-state prescription drug wholesale  
1440 distributor ~~wholesaler's~~ permit.--An out-of-state prescription  
1441 drug wholesale distributor ~~wholesaler~~ is a wholesale distributor  
1442 located outside this state which engages in the wholesale



836536

1443 distribution of prescription drugs into this state and which must  
1444 be permitted by the department and comply with all the provisions  
1445 required of a wholesale distributor under this part ss. 499.001-  
1446 ~~499.081~~. An out-of-state prescription drug wholesale distributor  
1447 ~~wholesaler~~ that applies to the department for a new permit or the  
1448 renewal of a permit must submit a bond of \$100,000, or other  
1449 equivalent means of security acceptable to the department, such  
1450 as an irrevocable letter of credit or a deposit in a trust  
1451 account or financial institution, payable to the Florida Drug,  
1452 Device, and Cosmetic Trust Fund. The purpose of the bond is to  
1453 secure payment of any administrative penalties imposed by the  
1454 department and any fees and costs incurred by the department  
1455 regarding that permit which are authorized under state law and  
1456 which the permittee fails to pay 30 days after the fine or costs  
1457 become final. The department may make a claim against such bond  
1458 or security until 1 year after the permittee's license ceases to  
1459 be valid or until 60 days after any administrative or legal  
1460 proceeding authorized in this part ss. 499.001-499.081 which  
1461 involves the permittee is concluded, including any appeal,  
1462 whichever occurs later.

1463 1. The out-of-state prescription drug wholesale distributor  
1464 ~~wholesaler~~ must maintain at all times a license or permit to  
1465 engage in the wholesale distribution of prescription drugs in  
1466 compliance with laws of the state in which it is a resident.

1467 2. An out-of-state prescription drug wholesale distributor  
1468 ~~wholesaler's~~ permit is not required for an intracompany sale or  
1469 transfer of a prescription drug from an out-of-state  
1470 establishment that is duly licensed as a prescription drug  
1471 wholesale distributor wholesaler, in its state of residence, to a  
1472 licensed prescription drug wholesale distributor wholesaler in



836536

1473 | this state, if both wholesale distributors ~~wholesalers~~ conduct  
1474 | wholesale distributions of prescription drugs under the same  
1475 | business name. The recordkeeping requirements of ss. s.  
1476 | 499.0121(6) and 499.01212 must be followed for this transaction.

1477 |       (f) ~~(d)~~ A Retail pharmacy drug wholesale distributor  
1478 | ~~wholesaler's~~ permit.--A retail pharmacy drug wholesale  
1479 | distributor ~~wholesaler~~ is a retail pharmacy engaged in wholesale  
1480 | distribution of prescription drugs within this state under the  
1481 | following conditions:

1482 |       1. The pharmacy must obtain a retail pharmacy drug  
1483 | wholesale distributor ~~wholesaler's~~ permit pursuant to this part  
1484 | ~~ss. 499.001-499.081~~ and the rules adopted under this part ~~these~~  
1485 | ~~sections.~~

1486 |       2. The wholesale distribution activity does not exceed 30  
1487 | percent of the total annual purchases of prescription drugs. If  
1488 | the wholesale distribution activity exceeds the 30-percent  
1489 | maximum, the pharmacy must obtain a prescription drug wholesale  
1490 | distributor ~~wholesaler's~~ permit.

1491 |       3. The transfer of prescription drugs that appear in any  
1492 | schedule contained in chapter 893 is subject to chapter 893 and  
1493 | the federal Comprehensive Drug Abuse Prevention and Control Act  
1494 | of 1970.

1495 |       4. The transfer is between a retail pharmacy and another  
1496 | retail pharmacy, or a Modified Class II institutional pharmacy,  
1497 | or a health care practitioner licensed in this state and  
1498 | authorized by law to dispense or prescribe prescription drugs.

1499 |       5. All records of sales of prescription drugs subject to  
1500 | this section must be maintained separate and distinct from other  
1501 | records and comply with the recordkeeping requirements of this  
1502 | part ~~ss. 499.001-499.081.~~



836536

1503            (g) 499.014 Restricted prescription drug distributor permit  
1504 ~~Distribution of legend drugs by hospitals, health care entities,~~  
1505 ~~charitable organizations, and return or destruction companies;~~  
1506 ~~permits, general requirements.--~~

1507            ~~(1)~~ A restricted prescription drug distributor permit is  
1508 required for any person that engages in the distribution of a  
1509 prescription legend drug, which distribution is not considered  
1510 "wholesale distribution" under s. 499.003(53)(a) ~~s.~~  
1511 ~~499.012(1)(a)1.~~

1512            1.(2) A person who engages in the receipt or distribution  
1513 of a prescription legend drug in this state for the purpose of  
1514 processing its return or its destruction must obtain a permit as  
1515 a restricted prescription drug distributor if such person is not  
1516 the person initiating the return, the prescription drug wholesale  
1517 supplier of the person initiating the return, or the manufacturer  
1518 of the drug.

1519            2.(3) Storage, handling, and recordkeeping of these  
1520 distributions must comply with the requirements for wholesale  
1521 distributors under s. 499.0121, but not except those set forth in  
1522 s. 499.01212 ~~s. 499.0121(6)(d).~~

1523            3.(4) A person who applies for a permit as a restricted  
1524 prescription drug distributor, or for the renewal of such a  
1525 permit, must provide to the department the information required  
1526 under s. 499.012 ~~s. 499.01.~~

1527            4.(5) The department may ~~issue permits to restricted~~  
1528 ~~prescription drug distributors and may~~ adopt rules regarding the  
1529 distribution of prescription drugs by hospitals, health care  
1530 entities, charitable organizations, or other persons not involved  
1531 in wholesale distribution, which rules are necessary for the  
1532 protection of the public health, safety, and welfare.



836536

1533        (h) Complimentary drug distributor permit.--A complimentary  
1534 drug distributor permit is required for any person that engages  
1535 in the distribution of a complimentary drug, subject to the  
1536 requirements of s. 499.028.

1537        (i) ~~(f)~~ Freight forwarder permit.--A freight forwarder  
1538 permit is required for any person that engages in the  
1539 distribution of a prescription ~~legend~~ drug as a freight forwarder  
1540 unless the person is a common carrier. The storage, handling, and  
1541 recordkeeping of such distributions must comply with the  
1542 requirements for wholesale distributors under s. 499.0121, but  
1543 not ~~except~~ those set forth in s. 499.01212 ~~s. 499.0121(6)(d)~~. A  
1544 freight forwarder must provide the source of the prescription  
1545 ~~legend~~ drugs with a validated airway bill, bill of lading, or  
1546 other appropriate documentation to evidence the exportation of  
1547 the product.

1548        (j) Veterinary prescription drug retail establishment  
1549 permit.--A veterinary prescription drug retail establishment  
1550 permit is required for any person that sells veterinary  
1551 prescription drugs to the public but does not include a pharmacy  
1552 licensed under chapter 465.

1553        1. The sale to the public must be based on a valid written  
1554 order from a veterinarian licensed in this state who has a valid  
1555 client-veterinarian relationship with the purchaser's animal.

1556        2. Veterinary prescription drugs may not be sold in excess  
1557 of the amount clearly indicated on the order or beyond the date  
1558 indicated on the order.

1559        3. An order may not be valid for more than 1 year.

1560        4. A veterinary prescription drug retail establishment may  
1561 not purchase, sell, trade, or possess human prescription drugs or  
1562 any controlled substance as defined in chapter 893.



836536

1563        5. A veterinary prescription drug retail establishment must  
1564 sell a veterinary prescription drug in the original, sealed  
1565 manufacturer's container with all labeling intact and legible.  
1566 The department may adopt by rule additional labeling requirements  
1567 for the sale of a veterinary prescription drug.

1568        6. A veterinary prescription drug retail establishment must  
1569 comply with all of the wholesale distribution requirements of s.  
1570 499.0121.

1571        7. Prescription drugs sold by a veterinary prescription  
1572 drug retail establishment pursuant to a practitioner's order may  
1573 not be returned into the retail establishment's inventory.

1574        (k) ~~(g)~~ A veterinary prescription drug wholesale distributor  
1575 ~~wholesaler~~ permit.--A veterinary prescription drug wholesale  
1576 distributor ~~wholesaler~~ permit is required for any person that  
1577 engages in the distribution of veterinary prescription drugs in  
1578 or into this state. A veterinary prescription drug wholesale  
1579 distributor ~~wholesaler~~ that also distributes prescription drugs  
1580 subject to, defined by, or described by s. 503(b) of the Federal  
1581 Food, Drug, and Cosmetic Act which it did not manufacture must  
1582 obtain a permit as a prescription drug wholesale distributor  
1583 ~~wholesaler~~, an out-of-state prescription drug wholesale  
1584 distributor ~~wholesaler~~, or a limited prescription drug veterinary  
1585 wholesale distributor ~~wholesaler~~ in lieu of the veterinary  
1586 prescription drug wholesale distributor ~~wholesaler~~ permit. A  
1587 veterinary prescription drug wholesale distributor ~~wholesaler~~  
1588 must comply with the requirements for wholesale distributors  
1589 under s. 499.0121, but not except those set forth in s. 499.01212  
1590 ~~s. 499.0121(6)(d).~~

1591        (l) ~~(h)~~ Limited prescription drug veterinary wholesale  
1592 distributor ~~wholesaler~~ permit.--Unless engaging in the activities



836536

1593 of and permitted as a prescription drug manufacturer, nonresident  
1594 prescription drug manufacturer, prescription drug wholesale  
1595 distributor ~~wholesaler~~, or out-of-state prescription drug  
1596 wholesale distributor ~~wholesaler~~, a limited prescription drug  
1597 veterinary wholesale distributor ~~wholesaler~~ permit is required  
1598 for any person that engages in the distribution in or into this  
1599 state of veterinary prescription drugs and prescription drugs  
1600 subject to, defined by, or described by s. 503(b) of the Federal  
1601 Food, Drug, and Cosmetic Act under the following conditions:  
1602       1. The person is engaged in the business of wholesaling  
1603 prescription and veterinary prescription ~~legend~~ drugs to persons:  
1604       a. Licensed as veterinarians practicing on a full-time  
1605 basis;  
1606       b. Regularly and lawfully engaged in instruction in  
1607 veterinary medicine;  
1608       c. Regularly and lawfully engaged in law enforcement  
1609 activities;  
1610       d. For use in research not involving clinical use; or  
1611       e. For use in chemical analysis or physical testing or for  
1612 purposes of instruction in law enforcement activities, research,  
1613 or testing.  
1614       2. No more than 30 percent of total annual prescription  
1615 drug sales may be prescription drugs approved for human use which  
1616 are subject to, defined by, or described by s. 503(b) of the  
1617 Federal Food, Drug, and Cosmetic Act.  
1618       3. The person does not distribute ~~is not permitted,~~  
1619 ~~licensed, or otherwise authorized in any jurisdiction state to~~  
1620 ~~wholesale~~ prescription drugs subject to, defined by, or described  
1621 by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any



836536

1622 person who is authorized to sell, distribute, purchase, trade, or  
1623 use these drugs on or for humans.

1624 4. A limited prescription drug veterinary wholesale  
1625 distributor ~~wholesaler~~ that applies to the department for a new  
1626 permit or the renewal of a permit must submit a bond of \$20,000,  
1627 or other equivalent means of security acceptable to the  
1628 department, such as an irrevocable letter of credit or a deposit  
1629 in a trust account or financial institution, payable to the  
1630 Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the  
1631 bond is to secure payment of any administrative penalties imposed  
1632 by the department and any fees and costs incurred by the  
1633 department regarding that permit which are authorized under state  
1634 law and which the permittee fails to pay 30 days after the fine  
1635 or costs become final. The department may make a claim against  
1636 such bond or security until 1 year after the permittee's license  
1637 ceases to be valid or until 60 days after any administrative or  
1638 legal proceeding authorized in this part ~~ss. 499.001-499.081~~  
1639 which involves the permittee is concluded, including any appeal,  
1640 whichever occurs later.

1641 5. A limited prescription drug veterinary wholesale  
1642 distributor ~~wholesaler~~ must maintain at all times a license or  
1643 permit to engage in the wholesale distribution of prescription  
1644 drugs in compliance with laws of the state in which it is a  
1645 resident.

1646 6. A limited prescription drug veterinary wholesale  
1647 distributor ~~wholesaler~~ must comply with the requirements for  
1648 wholesale distributors under ss. ~~s.~~ 499.0121 and 499.01212,  
1649 except that a limited prescription drug veterinary wholesale  
1650 distributor ~~wholesaler~~ is not required to provide a pedigree





836536

1651 paper as required by s. 499.01212 ~~s. 499.0121(6)(d)~~ upon the  
1652 wholesale distribution of a prescription drug to a veterinarian.

1653 7. A limited prescription drug veterinary wholesale  
1654 distributor ~~wholesaler~~ may not return to inventory for subsequent  
1655 wholesale distribution any prescription drug subject to, defined  
1656 by, or described by s. 503(b) of the Federal Food, Drug, and  
1657 Cosmetic Act which has been returned by a veterinarian.

1658 8. ~~An out-of-state prescription drug wholesaler's permit or~~  
1659 A limited prescription drug veterinary wholesale distributor  
1660 ~~wholesaler~~ permit is not required for an intracompany sale or  
1661 transfer of a prescription drug from an out-of-state  
1662 establishment that is duly licensed to engage in the wholesale  
1663 distribution of prescription drugs in its state of residence to a  
1664 licensed limited prescription drug veterinary wholesale  
1665 distributor ~~wholesaler~~ in this state if both wholesale  
1666 distributors ~~wholesalers~~ conduct wholesale distributions of  
1667 prescription drugs under the same business name. The  
1668 recordkeeping requirements of ss. ~~s.~~ 499.0121(6) and 499.01212  
1669 must be followed for this transaction.

1670 (m) Medical oxygen retail establishment permit.--A medical  
1671 oxygen retail establishment permit is required for any person  
1672 that sells medical oxygen to patients only. The sale must be  
1673 based on an order from a practitioner authorized by law to  
1674 prescribe. The term does not include a pharmacy licensed under  
1675 chapter 465.

1676 1. A medical oxygen retail establishment may not possess,  
1677 purchase, sell, or trade any prescription drug other than medical  
1678 oxygen.

1679 2. A medical oxygen retail establishment may refill medical  
1680 oxygen for an individual patient based on an order from a



836536

1681 practitioner authorized by law to prescribe. A medical oxygen  
1682 retail establishment that refills medical oxygen must comply with  
1683 all appropriate state and federal good manufacturing practices.

1684 3. A medical oxygen retail establishment must comply with  
1685 all of the wholesale distribution requirements of s. 499.0121.

1686 4. Prescription medical oxygen sold by a medical oxygen  
1687 retail establishment pursuant to a practitioner's order may not  
1688 be returned into the retail establishment's inventory.

1689 (n) ~~(b)~~ A compressed medical gas wholesale distributor  
1690 ~~wholesaler's~~ permit.--A compressed medical gas wholesale  
1691 distributor ~~wholesaler~~ is a wholesale distributor that is limited  
1692 to the wholesale distribution of compressed medical gases to  
1693 other than the consumer or patient. The compressed medical gas  
1694 must be in the original sealed container that was purchased by  
1695 that wholesale distributor ~~wholesaler~~. A compressed medical gas  
1696 wholesale distributor ~~wholesaler~~ may not possess or engage in the  
1697 wholesale distribution of any prescription drug other than  
1698 compressed medical gases. The department shall adopt rules that  
1699 govern the wholesale distribution of prescription medical oxygen  
1700 for emergency use. With respect to the emergency use of  
1701 prescription medical oxygen, those rules may not be inconsistent  
1702 with rules and regulations of federal agencies unless the  
1703 Legislature specifically directs otherwise.

1704 (o) ~~(e)~~ Compressed medical gas manufacturer permit.--A  
1705 compressed medical gas manufacturer ~~manufacturer's~~ permit is  
1706 required for any person that engages in the manufacture of  
1707 compressed medical gases or repackages compressed medical gases  
1708 from one container to another.



836536

1709 | 1. A compressed medical gas manufacturer ~~permittee~~ may not  
1710 | manufacture or possess any prescription drug other than  
1711 | compressed medical gases.

1712 | 2. A compressed medical gas manufacturer ~~permittee~~ may  
1713 | engage in wholesale distribution of compressed medical gases  
1714 | manufactured at that establishment and must comply with all the  
1715 | provisions of this part ss. 499.001-499.081 and the rules adopted  
1716 | under this part ~~these sections~~ that apply to a wholesale  
1717 | distributor.

1718 | 3. A compressed medical gas manufacturer ~~permittee~~ must  
1719 | comply with all appropriate state and federal good manufacturing  
1720 | practices.

1721 | ~~(p)-(b)~~ Over-the-counter drug manufacturer permit.--An over-  
1722 | the-counter drug manufacturer ~~manufacturer's~~ permit is required  
1723 | for any person that engages in the manufacture or repackaging of  
1724 | an over-the-counter drug.

1725 | 1. An over-the-counter drug manufacturer ~~permittee~~ may not  
1726 | possess or purchase prescription drugs.

1727 | 2. A pharmacy is exempt from obtaining an over-the-counter  
1728 | drug manufacturer ~~manufacturer's~~ permit if it is operating in  
1729 | compliance with pharmacy practice standards as defined in chapter  
1730 | 465 and the rules adopted under that chapter.

1731 | 3. An over-the-counter drug manufacturer ~~permittee~~ must  
1732 | comply with all appropriate state and federal good manufacturing  
1733 | practices.

1734 | ~~(q)-(d)~~ Device manufacturer permit.--A device manufacturer  
1735 | ~~manufacturer's~~ permit is required for any person that engages in  
1736 | the manufacture, repackaging, or assembly of medical devices for  
1737 | human use in this state, except that a permit is not required if  
1738 | the person is engaged only in manufacturing, repackaging, or



836536

1739 assembling a medical device pursuant to a practitioner's order  
1740 for a specific patient.

1741 1. A manufacturer or repackager of medical devices in this  
1742 state must comply with all appropriate state and federal good  
1743 manufacturing practices and quality system rules.

1744 2. The department shall adopt rules related to storage,  
1745 handling, and recordkeeping requirements for manufacturers of  
1746 medical devices for human use.

1747 (r) (e) Cosmetic manufacturer permit.--A cosmetic  
1748 manufacturer manufacturer's permit is required for any person  
1749 that manufactures or repackages cosmetics in this state. A person  
1750 that only labels or changes the labeling of a cosmetic but does  
1751 not open the container sealed by the manufacturer of the product  
1752 is exempt from obtaining a permit under this paragraph.

1753 (s) Third party logistics provider permit.--A third party  
1754 logistics provider permit is required for any person that  
1755 contracts with a prescription drug wholesale distributor or  
1756 prescription drug manufacturer to provide warehousing,  
1757 distribution, or other logistics services on behalf of a  
1758 manufacturer or wholesale distributor, but who does not take  
1759 title to the prescription drug or have responsibility to direct  
1760 the sale or disposition of the prescription drug. Each third  
1761 party logistics provider permittee shall comply with all of the  
1762 provisions required of a wholesale distributor under this part,  
1763 with the exception of s. 499.01212 for those wholesale  
1764 distributions described in s. 499.01212(3) (a), and other rules  
1765 that the department requires.

1766 (t) Health care clinic establishment permit.--Effective  
1767 January 1, 2009, a health care clinic establishment permit is  
1768 required for the purchase of a prescription drug by a place of



836536

1769 business at one general physical location owned and operated by a  
1770 professional corporation or professional limited liability  
1771 company described in chapter 621. For the purpose of this  
1772 paragraph, the term "qualifying practitioner" means a licensed  
1773 health care practitioner defined in s. 456.001 or a veterinarian  
1774 licensed under chapter 474, who is authorized under the  
1775 appropriate practice act to prescribe and administer a  
1776 prescription drug without supervision or a protocol.

1777 1. An establishment must provide, as part of the  
1778 application required under s. 499.012, designation of a  
1779 qualifying practitioner who will be responsible for complying  
1780 with all legal and regulatory requirements related to the  
1781 purchase, recordkeeping, storage, and handling of the  
1782 prescription drugs. In addition, the designated qualifying  
1783 practitioner shall be the practitioner whose name, establishment  
1784 address, and license number is used on all distribution documents  
1785 for prescription drugs purchased or returned by the health care  
1786 clinic establishment.

1787 2. The health care clinic establishment must employ a  
1788 qualifying practitioner who practices full-time at the  
1789 establishment.

1790 3. Upon employment of a qualifying practitioner, the health  
1791 care clinic establishment shall notify the department on a form  
1792 furnished by the department within 10 days after such employment.  
1793 In addition, the health care clinic establishment shall notify  
1794 the department within 10 days after any subsequent changes in the  
1795 licensure, employment, or practice status of the qualifying  
1796 practitioner.

1797 4. In addition to the remedies and penalties provided in  
1798 this part, a violation of this chapter by the health care clinic



836536

1799 establishment or qualifying practitioner constitutes grounds for  
1800 discipline of the qualifying practitioner by the appropriate  
1801 regulatory board.

1802 5. A health care clinic establishment may not purchase a  
1803 controlled substance as defined under chapter 893.

1804 6. Administration of prescription drugs purchased by the  
1805 health care clinic establishment is prohibited during any period  
1806 of time when the establishment does not comply with this  
1807 paragraph.

1808 Section 11. Section 499.012, Florida Statutes, is amended  
1809 and subsections (2) through (8) of section 499.01, Florida  
1810 States, are redesignated as subsections (1) through (7) of that  
1811 section and amended, to read:

1812 499.012 Permit application ~~Wholesale distribution;~~  
1813 ~~definitions; permits; applications; general requirements.--~~

1814 (1) ~~As used in this section, the term:~~

1815 ~~(2)~~ (a) A permit issued pursuant to this part ss. 499.001-  
1816 ~~499.081~~ may be issued only to a natural person who is at least 18  
1817 years of age or to an applicant that is not a natural person if  
1818 each person who, directly or indirectly, manages, controls, or  
1819 oversees the operation of that applicant is at least 18 years of  
1820 age.

1821 (b) An establishment that is a place of residence may not  
1822 receive a permit and may not operate under this part ss. 499.001-  
1823 ~~499.081~~.

1824 (c) A person that applies for or renews a permit to  
1825 manufacture or distribute prescription ~~legend~~ drugs may not use a  
1826 name identical to the name used by any other establishment or  
1827 licensed person authorized to purchase prescription drugs in this  
1828 state, except that a restricted drug distributor permit issued to



836536

1829 a health care entity will be issued in the name in which the  
1830 institutional pharmacy permit is issued and a retail pharmacy  
1831 drug wholesale distributor ~~wholesaler~~ will be issued a permit in  
1832 the name of its retail pharmacy permit.

1833 (d) A permit for a prescription drug manufacturer,  
1834 prescription drug repackager, prescription drug wholesale  
1835 distributor ~~wholesaler~~, limited prescription drug veterinary  
1836 wholesale distributor ~~wholesaler~~, or retail pharmacy drug  
1837 wholesale distributor ~~wholesaler~~ may not be issued to the address  
1838 of a health care entity or to a pharmacy licensed under chapter  
1839 465, except as provided in this paragraph. The department may  
1840 issue a prescription drug manufacturer permit to an applicant at  
1841 the same address as a licensed nuclear pharmacy, which is a  
1842 health care entity, for the purpose of manufacturing prescription  
1843 drugs used in positron emission tomography or other  
1844 radiopharmaceuticals, as listed in a rule adopted by the  
1845 department pursuant to this paragraph. The purpose of this  
1846 exemption is to assure availability of state-of-the-art  
1847 pharmaceuticals that would pose a significant danger to the  
1848 public health if manufactured at a separate establishment address  
1849 from the nuclear pharmacy from which the prescription drugs are  
1850 dispensed. The department may also issue a retail pharmacy drug  
1851 wholesale distributor ~~wholesaler~~ permit to the address of a  
1852 community pharmacy licensed under chapter 465 which does not meet  
1853 the definition of a closed pharmacy in s. 499.003.

1854 (e) A county or municipality may not issue an occupational  
1855 license for any licensing period beginning on or after October 1,  
1856 2003, for any establishment that requires a permit pursuant to  
1857 this part ~~ss. 499.001-499.081~~, unless the establishment exhibits  
1858 a current permit issued by the department for the establishment.



836536

1859 Upon presentation of the requisite permit issued by the  
1860 department, an occupational license may be issued by the  
1861 municipality or county in which application is made. The  
1862 department shall furnish to local agencies responsible for  
1863 issuing occupational licenses a current list of all  
1864 establishments licensed pursuant to this part ~~ss. 499.001-~~  
1865 ~~499.081~~.

1866 (2) ~~(3)~~ Notwithstanding subsection (6) ~~(7)~~, a permitted  
1867 person in good standing may change the type of permit issued to  
1868 that person by completing a new application for the requested  
1869 permit, paying the amount of the difference in the permit fees if  
1870 the fee for the new permit is more than the fee for the original  
1871 permit, and meeting the applicable permitting conditions for the  
1872 new permit type. The new permit expires on the expiration date of  
1873 the original permit being changed; however, a new permit for a  
1874 prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
1875 state prescription drug wholesale distributor ~~wholesaler~~, or a  
1876 retail pharmacy drug wholesale distributor ~~wholesaler~~ shall  
1877 expire on the expiration date of the original permit or 1 year  
1878 after the date of issuance of the new permit, whichever is  
1879 earlier. A refund may not be issued if the fee for the new permit  
1880 is less than the fee that was paid for the original permit.

1881 (3) ~~(4)~~ A written application for a permit or to renew a  
1882 permit must be filed with the department on forms furnished by  
1883 the department. The department shall establish, by rule, the form  
1884 and content of the application to obtain or renew a permit. The  
1885 applicant must submit to the department with the application a  
1886 statement that swears or affirms that the information is true and  
1887 correct.





836536

1888           (4)~~(5)~~(a) Except for a permit for a prescription drug  
1889 wholesale distributor ~~wholesaler~~ or an out-of-state prescription  
1890 drug wholesale distributor ~~wholesaler~~, an application for a  
1891 permit must include:

1892           1. The name, full business address, and telephone number of  
1893 the applicant;

1894           2. All trade or business names used by the applicant;

1895           3. The address, telephone numbers, and the names of contact  
1896 persons for each facility used by the applicant for the storage,  
1897 handling, and distribution of prescription drugs;

1898           4. The type of ownership or operation, such as a  
1899 partnership, corporation, or sole proprietorship; and

1900           5. The names of the owner and the operator of the  
1901 establishment, including:

1902           a. If an individual, the name of the individual;

1903           b. If a partnership, the name of each partner and the name  
1904 of the partnership;

1905           c. If a corporation, the name and title of each corporate  
1906 officer and director, the corporate names, and the name of the  
1907 state of incorporation;

1908           d. If a sole proprietorship, the full name of the sole  
1909 proprietor and the name of the business entity;

1910           e. If a limited liability company, the name of each member,  
1911 the name of each manager, the name of the limited liability  
1912 company, and the name of the state in which the limited liability  
1913 company was organized; and

1914           f. Any other relevant information that the department  
1915 requires.

1916           (b) Upon approval of the application by the department and  
1917 payment of the required fee, the department shall issue a permit



836536

1918 to the applicant, if the applicant meets the requirements of this  
1919 part ss. ~~499.001-499.081~~ and rules adopted under this part ~~those~~  
1920 ~~sections.~~

1921 (c) Any change in information required under paragraph (a)  
1922 must be submitted to the department before the change occurs.

1923 (d) The department shall consider, at a minimum, the  
1924 following factors in reviewing the qualifications of persons to  
1925 be permitted under this part ss. ~~499.001-499.081~~:

1926 1. The applicant's having been found guilty, regardless of  
1927 adjudication, in a court of this state or other jurisdiction, of  
1928 a violation of a law that directly relates to a drug, device, or  
1929 cosmetic. A plea of nolo contendere constitutes a finding of  
1930 guilt for purposes of this subparagraph.

1931 2. The applicant's having been disciplined by a regulatory  
1932 agency in any state for any offense that would constitute a  
1933 violation of this part ss. ~~499.001-499.081~~.

1934 3. Any felony conviction of the applicant under a federal,  
1935 state, or local law;

1936 4. The applicant's past experience in manufacturing or  
1937 distributing drugs, devices, or cosmetics;

1938 5. The furnishing by the applicant of false or fraudulent  
1939 material in any application made in connection with manufacturing  
1940 or distributing drugs, devices, or cosmetics;

1941 6. Suspension or revocation by a federal, state, or local  
1942 government of any permit currently or previously held by the  
1943 applicant for the manufacture or distribution of any drugs,  
1944 devices, or cosmetics;

1945 7. Compliance with permitting requirements under any  
1946 previously granted permits;



836536

1947           8. Compliance with requirements to maintain or make  
1948 available to the state permitting authority or to federal, state,  
1949 or local law enforcement officials those records required under  
1950 this section; and

1951           9. Any other factors or qualifications the department  
1952 considers relevant to and consistent with the public health and  
1953 safety.

1954           (5)~~(6)~~ Except for a permit ~~permits~~ for a prescription drug  
1955 wholesale distributor ~~wholesalers~~ or an out-of-state prescription  
1956 drug wholesale distributor ~~wholesalers~~:

1957           (a) The department shall adopt rules for the biennial  
1958 renewal of permits.

1959           (b) The department shall renew a permit upon receipt of the  
1960 renewal application and renewal fee if the applicant meets the  
1961 requirements established under this part ~~ss. 499.001-499.081~~ and  
1962 the rules adopted under this part ~~those sections~~.

1963           (c) A permit, unless sooner suspended or revoked,  
1964 automatically expires 2 years after the last day of the  
1965 anniversary month in which the permit was originally issued. A  
1966 permit issued under this part ~~ss. 499.001-499.081~~ may be renewed  
1967 by making application for renewal on forms furnished by the  
1968 department and paying the appropriate fees. If a renewal  
1969 application and fee are submitted and postmarked after the  
1970 expiration date of the permit, the permit may be renewed only  
1971 upon payment of a late renewal delinquent fee of \$100, plus the  
1972 required renewal fee, not later than 60 days after the expiration  
1973 date.

1974           (d) Failure to renew a permit in accordance with this  
1975 section precludes any future renewal of that permit. If a permit  
1976 issued pursuant to this part ~~section~~ has expired and cannot be



836536

1977 renewed, before an establishment may engage in activities that  
1978 require a permit under this part ~~ss. 499.001-499.081~~, the  
1979 establishment must submit an application for a new permit, pay  
1980 the applicable application fee, the initial permit fee, and all  
1981 applicable penalties, and be issued a new permit by the  
1982 department.

1983 ~~(6)(7)~~ A permit issued by the department is  
1984 nontransferable. Each permit is valid only for the person or  
1985 governmental unit to which it is issued and is not subject to  
1986 sale, assignment, or other transfer, voluntarily or  
1987 involuntarily; nor is a permit valid for any establishment other  
1988 than the establishment for which it was originally issued.

1989 (a) A person permitted under this part ~~ss. 499.001-499.081~~  
1990 must notify the department before making a change of address. The  
1991 department shall set a change of location fee not to exceed \$100.

1992 (b)1. An application for a new permit is required when a  
1993 majority of the ownership or controlling interest of a permitted  
1994 establishment is transferred or assigned or when a lessee agrees  
1995 to undertake or provide services to the extent that legal  
1996 liability for operation of the establishment will rest with the  
1997 lessee. The application for the new permit must be made before  
1998 the date of the sale, transfer, assignment, or lease.

1999 2. A permittee that is authorized to distribute  
2000 prescription ~~legend~~ drugs may transfer such drugs to the new  
2001 owner or lessee under subparagraph 1. only after the new owner or  
2002 lessee has been approved for a permit to distribute prescription  
2003 ~~legend~~ drugs.

2004 (c) If an establishment permitted under this part ~~ss.~~  
2005 ~~499.001-499.081~~ closes, the owner must notify the department in  
2006 writing before the effective date of closure and must:



836536

2007 1. Return the permit to the department;  
2008 2. If the permittee is authorized to distribute  
2009 prescription legend drugs, indicate the disposition of such  
2010 drugs, including the name, address, and inventory, and provide  
2011 the name and address of a person to contact regarding access to  
2012 records that are required to be maintained under this part ss.  
2013 ~~499.001-499.081~~. Transfer of ownership of prescription legend  
2014 drugs may be made only to persons authorized to possess  
2015 prescription legend drugs under this part ss. ~~499.001-499.081~~.

2016  
2017 The department may revoke the permit of any person that fails to  
2018 comply with the requirements of this subsection.

2019 ~~(7)-(8)~~ A permit must be posted in a conspicuous place on  
2020 the licensed premises.

2021 ~~(8)-(3)~~ An application for a permit or to renew a permit for  
2022 a prescription drug wholesale distributor ~~wholesaler~~ or an out-  
2023 of-state prescription drug wholesale distributor ~~wholesaler~~  
2024 submitted to the department must include:

2025 (a) The name, full business address, and telephone number  
2026 of the applicant.

2027 (b) All trade or business names used by the applicant.

2028 (c) The address, telephone numbers, and the names of  
2029 contact persons for each facility used by the applicant for the  
2030 storage, handling, and distribution of prescription drugs.

2031 (d) The type of ownership or operation, such as a  
2032 partnership, corporation, or sole proprietorship.

2033 (e) The names of the owner and the operator of the  
2034 establishment, including:

2035 1. If an individual, the name of the individual.



836536

2036           2. If a partnership, the name of each partner and the name  
2037 of the partnership.

2038           3. If a corporation:

2039           a. The name, address, and title of each corporate officer  
2040 and director.

2041           b. The name and address of the corporation, resident agent  
2042 of the corporation, the resident agent's address, and the  
2043 corporation's state of incorporation.

2044           c. The name and address of each shareholder of the  
2045 corporation that owns 5 percent or more of the outstanding stock  
2046 of the corporation.

2047           4. If a sole proprietorship, the full name of the sole  
2048 proprietor and the name of the business entity.

2049           5. If a limited liability company:

2050           a. The name and address of each member.

2051           b. The name and address of each manager.

2052           c. The name and address of the limited liability company,  
2053 the resident agent of the limited liability company, and the name  
2054 of the state in which the limited liability company was  
2055 organized.

2056           (f) If applicable, the name and address of each member of  
2057 the affiliated group of which the applicant is a member.

2058           (g)1. For an application for a new permit, the estimated  
2059 annual dollar volume of prescription drug sales of the applicant,  
2060 the estimated annual percentage of the applicant's total company  
2061 sales that are prescription drugs, the applicant's estimated  
2062 annual total dollar volume of purchases of prescription drugs,  
2063 and the applicant's estimated annual total dollar volume of  
2064 prescription drug purchases directly from manufacturers.



836536

2065           2. For an application to renew a permit, the total dollar  
2066 volume of prescription drug sales in the previous year, the total  
2067 dollar volume of prescription drug sales made in the previous 6  
2068 months, the percentage of total company sales that were  
2069 prescription drugs in the previous year, the total dollar volume  
2070 of purchases of prescription drugs in the previous year, and the  
2071 total dollar volume of prescription drug purchases directly from  
2072 manufacturers in the previous year.

2073  
2074 Such portions of the information required pursuant to this  
2075 paragraph which are a trade secret, as defined in s. 812.081,  
2076 shall be maintained by the department as trade secret information  
2077 is required to be maintained under s. 499.051.

2078           (h) The tax year of the applicant.

2079           (i) A copy of the deed for the property on which  
2080 applicant's establishment is located, if the establishment is  
2081 owned by the applicant, or a copy of the applicant's lease for  
2082 the property on which applicant's establishment is located that  
2083 has an original term of not less than 1 calendar year, if the  
2084 establishment is not owned by the applicant.

2085           (j) A list of all licenses and permits issued to the  
2086 applicant by any other state which authorize the applicant to  
2087 purchase or possess prescription drugs.

2088           (k) The name of the manager of the establishment that is  
2089 applying for the permit or to renew the permit, the next four  
2090 highest ranking employees responsible for prescription drug  
2091 wholesale operations for the establishment, and the name of all  
2092 affiliated parties for the establishment, together with the  
2093 personal information statement and fingerprints required pursuant  
2094 to subsection (9) ~~(4)~~ for each of such persons.



836536

2095 (1) The name of each of the applicant's designated  
2096 representatives as required by subsection (16) ~~(11)~~, together  
2097 with the personal information statement and fingerprints required  
2098 pursuant to subsection (9) ~~(4)~~ for each such person.

2099 (m) For an applicant that is a secondary wholesale  
2100 distributor ~~wholesaler~~, each of the following:

2101 1. A personal background information statement containing  
2102 the background information and fingerprints required pursuant to  
2103 subsection (9) ~~(4)~~ for each person named in the applicant's  
2104 response to paragraphs (k) and (l) and for each affiliated party  
2105 of the applicant.

2106 2. If any of the five largest shareholders of the  
2107 corporation seeking the permit is a corporation, the name,  
2108 address, and title of each corporate officer and director of each  
2109 such corporation; the name and address of such corporation; the  
2110 name of such corporation's resident agent, such corporation's  
2111 resident agent's address, and such corporation's state of its  
2112 incorporation; and the name and address of each shareholder of  
2113 such corporation that owns 5 percent or more of the stock of such  
2114 corporation.

2115 3. The name and address of all financial institutions in  
2116 which the applicant has an account which is used to pay for the  
2117 operation of the establishment or to pay for drugs purchased for  
2118 the establishment, together with the names of all persons that  
2119 are authorized signatories on such accounts. The portions of the  
2120 information required pursuant to this subparagraph which are a  
2121 trade secret, as defined in s. 812.081, shall be maintained by  
2122 the department as trade secret information is required to be  
2123 maintained under s. 499.051.





836536

2124 4. The sources of all funds and the amounts of such funds  
2125 used to purchase or finance purchases of prescription drugs or to  
2126 finance the premises on which the establishment is to be located.

2127 5. If any of the funds identified in subparagraph 4. were  
2128 borrowed, copies of all promissory notes or loans used to obtain  
2129 such funds.

2130 (n) Any other relevant information that the department  
2131 requires, including, but not limited to, any information related  
2132 to whether the applicant satisfies the definition of a primary  
2133 wholesale distributor ~~wholesaler~~ or a secondary wholesale  
2134 distributor ~~wholesaler~~.

2135 (9) ~~(4)~~ (a) Each person required by subsection (8) ~~(3)~~ to  
2136 provide a personal information statement and fingerprints shall  
2137 provide the following information to the department on forms  
2138 prescribed by the department:

2139 1. The person's places of residence for the past 7 years.

2140 2. The person's date and place of birth.

2141 3. The person's occupations, positions of employment, and  
2142 offices held during the past 7 years.

2143 4. The principal business and address of any business,  
2144 corporation, or other organization in which each such office of  
2145 the person was held or in which each such occupation or position  
2146 of employment was carried on.

2147 5. Whether the person has been, during the past 7 years,  
2148 the subject of any proceeding for the revocation of any license  
2149 and, if so, the nature of the proceeding and the disposition of  
2150 the proceeding.

2151 6. Whether, during the past 7 years, the person has been  
2152 enjoined, either temporarily or permanently, by a court of  
2153 competent jurisdiction from violating any federal or state law



836536

2154 | regulating the possession, control, or distribution of  
2155 | prescription drugs, together with details concerning any such  
2156 | event.

2157 |         7. A description of any involvement by the person with any  
2158 | business, including any investments, other than the ownership of  
2159 | stock in a publicly traded company or mutual fund, during the  
2160 | past 7 years, which manufactured, administered, prescribed,  
2161 | distributed, or stored pharmaceutical products and any lawsuits  
2162 | in which such businesses were named as a party.

2163 |         8. A description of any felony criminal offense of which  
2164 | the person, as an adult, was found guilty, regardless of whether  
2165 | adjudication of guilt was withheld or whether the person pled  
2166 | guilty or nolo contendere. A criminal offense committed in  
2167 | another jurisdiction which would have been a felony in this state  
2168 | must be reported. If the person indicates that a criminal  
2169 | conviction is under appeal and submits a copy of the notice of  
2170 | appeal of that criminal offense, the applicant must, within 15  
2171 | days after the disposition of the appeal, submit to the  
2172 | department a copy of the final written order of disposition.

2173 |         9. A photograph of the person taken in the previous 30  
2174 | days.

2175 |         10. A set of fingerprints for the person on a form and  
2176 | under procedures specified by the department, together with  
2177 | payment of an amount equal to the costs incurred by the  
2178 | department for the criminal record check of the person.

2179 |         11. The name, address, occupation, and date and place of  
2180 | birth for each member of the person's immediate family who is 18  
2181 | years of age or older. As used in this subparagraph, the term  
2182 | "member of the person's immediate family" includes the person's



836536

2183 spouse, children, parents, siblings, the spouses of the person's  
2184 children, and the spouses of the person's siblings.

2185 12. Any other relevant information that the department  
2186 requires.

2187 (b) The information required pursuant to paragraph (a)  
2188 shall be provided under oath.

2189 (c) The department shall submit the fingerprints provided  
2190 by a person for initial licensure to the Department of Law  
2191 Enforcement for a statewide criminal record check and for  
2192 forwarding to the Federal Bureau of Investigation for a national  
2193 criminal record check of the person. The department shall submit  
2194 the fingerprints provided by a person as a part of a renewal  
2195 application to the Department of Law Enforcement for a statewide  
2196 criminal record check, and for forwarding to the Federal Bureau  
2197 of Investigation for a national criminal record check, for the  
2198 initial renewal of a permit after January 1, 2004; for any  
2199 subsequent renewal of a permit, the department shall submit the  
2200 required information for a statewide and national criminal record  
2201 check of the person. Any person who as a part of an initial  
2202 permit application or initial permit renewal after January 1,  
2203 2004, submits to the department a set of fingerprints required  
2204 for the criminal record check required in this paragraph shall  
2205 not be required to provide a subsequent set of fingerprints for a  
2206 criminal record check to the department, if the person has  
2207 undergone a criminal record check as a condition of the issuance  
2208 of an initial permit or the initial renewal of a permit of an  
2209 applicant after January 1, 2004.

2210 ~~(10)(5)~~ The department may deny an application for a permit  
2211 or refuse to renew a permit for a prescription drug wholesale



836536

2212 distributor ~~wholesaler~~ or an out-of-state prescription drug  
2213 wholesale distributor ~~wholesaler~~ if:

2214 (a) The applicant has not met the requirements for the  
2215 permit.

2216 (b) The management, officers, or directors of the applicant  
2217 or any affiliated party are found by the department to be  
2218 incompetent or untrustworthy.

2219 (c) The applicant is so lacking in experience in managing a  
2220 wholesale distributor as to make the issuance of the proposed  
2221 permit hazardous to the public health.

2222 (d) The applicant is so lacking in experience in managing a  
2223 wholesale distributor as to jeopardize the reasonable promise of  
2224 successful operation of the wholesale distributor.

2225 (e) The applicant is lacking in experience in the  
2226 distribution of prescription drugs.

2227 (f) The applicant's past experience in manufacturing or  
2228 distributing prescription drugs indicates that the applicant  
2229 poses a public health risk.

2230 (g) The applicant is affiliated directly or indirectly  
2231 through ownership, control, or other business relations, with any  
2232 person or persons whose business operations are or have been  
2233 detrimental to the public health.

2234 (h) The applicant, or any affiliated party, has been found  
2235 guilty of or has pleaded guilty or nolo contendere to any felony  
2236 or crime punishable by imprisonment for 1 year or more under the  
2237 laws of the United States, any state, or any other country,  
2238 regardless of whether adjudication of guilt was withheld.

2239 (i) The applicant or any affiliated party has been charged  
2240 with a felony in a state or federal court and the disposition of



836536

2241 that charge is pending during the application review or renewal  
2242 review period.

2243 (j) The applicant has furnished false or fraudulent  
2244 information or material in any application made in this state or  
2245 any other state in connection with obtaining a permit or license  
2246 to manufacture or distribute drugs, devices, or cosmetics.

2247 (k) That a federal, state, or local government permit  
2248 currently or previously held by the applicant, or any affiliated  
2249 party, for the manufacture or distribution of any drugs, devices,  
2250 or cosmetics has been disciplined, suspended, or revoked and has  
2251 not been reinstated.

2252 (l) The applicant does not possess the financial or  
2253 physical resources to operate in compliance with the permit being  
2254 sought, this chapter, and the rules adopted under this chapter.

2255 (m) The applicant or any affiliated party receives,  
2256 directly or indirectly, financial support and assistance from a  
2257 person who was an affiliated party of a permittee whose permit  
2258 was subject to discipline or was suspended or revoked, other than  
2259 through the ownership of stock in a publicly traded company or a  
2260 mutual fund.

2261 (n) The applicant or any affiliated party receives,  
2262 directly or indirectly, financial support and assistance from a  
2263 person who has been found guilty of any violation of this part  
2264 ~~ss. 499.001-499.081~~ or chapter 465, chapter 501, or chapter 893,  
2265 any rules adopted under any of this part ~~those sections~~ or those  
2266 chapters, any federal or state drug law, or any felony where the  
2267 underlying facts related to drugs, regardless of whether the  
2268 person has been pardoned, had her or his civil rights restored,  
2269 or had adjudication withheld, other than through the ownership of  
2270 stock in a publicly traded company or a mutual fund.



836536

2271 (o) The applicant for renewal of a permit under s.  
2272 499.01(2)(d) ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~  
2273 has not actively engaged in the wholesale distribution of  
2274 prescription drugs, as demonstrated by the regular and systematic  
2275 distribution of prescription drugs throughout the year as  
2276 evidenced by not fewer than 12 wholesale distributions in the  
2277 previous year and not fewer than three wholesale distributions in  
2278 the previous 6 months.

2279 (p) Information obtained in response to s. 499.01(2)(d)  
2280 ~~paragraph (2)(a)~~ or s. 499.01(2)(e) ~~paragraph (2)(e)~~ demonstrates  
2281 it would not be in the best interest of the public health,  
2282 safety, and welfare to issue a permit.

2283 (q) The applicant does not possess the financial standing  
2284 and business experience for the successful operation of the  
2285 applicant.

2286 (r) The applicant or any affiliated party has failed to  
2287 comply with the requirements for manufacturing or distributing  
2288 prescription drugs under this part ss. 499.001-499.081, similar  
2289 federal laws, similar laws in other states, or the rules adopted  
2290 under such laws.

2291 ~~(11)(6)~~ Upon approval of the application by the department  
2292 and payment of the required fee, the department shall issue or  
2293 renew a prescription drug wholesale distributor ~~wholesaler~~ or an  
2294 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2295 permit to the applicant.

2296 ~~(12)(7)~~ For a permit ~~permits~~ for a prescription drug  
2297 wholesale distributor ~~wholesalers~~ or an out-of-state prescription  
2298 drug wholesale distributor ~~wholesalers~~:

2299 (a) The department shall adopt rules for the annual renewal  
2300 of permits. At least 90 days before the expiration of a permit,



836536

2301 | the department shall forward a permit renewal notification and  
2302 | renewal application to the prescription drug wholesale  
2303 | distributor ~~wholesaler~~ or out-of-state prescription drug  
2304 | wholesale distributor ~~wholesaler~~ at the mailing address of the  
2305 | permitted establishment on file with the department. The permit  
2306 | renewal notification must state conspicuously the date on which  
2307 | the permit for the establishment will expire and that the  
2308 | establishment may not operate unless the permit for the  
2309 | establishment is renewed timely.

2310 |       (b) A permit, unless sooner suspended or revoked,  
2311 | automatically expires 1 year after the last day of the  
2312 | anniversary month in which the permit was originally issued. A  
2313 | permit may be renewed by making application for renewal on forms  
2314 | furnished by the department and paying the appropriate fees. If a  
2315 | renewal application and fee are submitted and postmarked after 45  
2316 | days prior to the expiration date of the permit, the permit may  
2317 | be renewed only upon payment of a late renewal fee of \$100, plus  
2318 | the required renewal fee. A permittee that has submitted a  
2319 | renewal application in accordance with this paragraph may  
2320 | continue to operate under its permit, unless the permit is  
2321 | suspended or revoked, until final disposition of the renewal  
2322 | application.

2323 |       (c) Failure to renew a permit in accordance with this  
2324 | section precludes any future renewal of that permit. If a permit  
2325 | issued pursuant to this section has expired and cannot be  
2326 | renewed, before an establishment may engage in activities that  
2327 | require a permit under this part ~~ss. 499.001-499.081~~, the  
2328 | establishment must submit an application for a new permit; pay  
2329 | the applicable application fee, initial permit fee, and all



836536

2330 applicable penalties; and be issued a new permit by the  
2331 department.

2332 ~~(13)(8)~~ A person that engages in wholesale distribution of  
2333 prescription drugs in this state must have a wholesale  
2334 distributor's permit issued by the department, except as noted in  
2335 this section. Each establishment must be separately permitted  
2336 except as noted in this subsection.

2337 (a) A separate establishment permit is not required when a  
2338 permitted prescription drug wholesale distributor ~~wholesaler~~  
2339 consigns a prescription drug to a pharmacy that is permitted  
2340 under chapter 465 and located in this state, provided that:

2341 1. The consignor wholesale distributor ~~wholesaler~~ notifies  
2342 the department in writing of the contract to consign prescription  
2343 drugs to a pharmacy along with the identity and location of each  
2344 consignee pharmacy;

2345 2. The pharmacy maintains its permit under chapter 465;

2346 3. The consignor wholesale distributor ~~wholesaler~~, which  
2347 has no legal authority to dispense prescription drugs, complies  
2348 with all wholesale distribution requirements of ss. s. ~~499.0121~~  
2349 and 499.01212 with respect to the consigned drugs and maintains

2350 records documenting the transfer of title or other completion of  
2351 the wholesale distribution of the consigned prescription drugs;

2352 4. The distribution of the prescription drug is otherwise  
2353 lawful under this chapter and other applicable law;

2354 5. Open packages containing prescription drugs within a  
2355 pharmacy are the responsibility of the pharmacy, regardless of  
2356 how the drugs are titled; and

2357 6. The pharmacy dispenses the consigned prescription drug  
2358 in accordance with the limitations of its permit under chapter  
2359 465 or returns the consigned prescription drug to the consignor





836536

2360 wholesale distributor ~~wholesaler~~. In addition, a person who holds  
2361 title to prescription drugs may transfer the drugs to a person  
2362 permitted or licensed to handle the reverse distribution or  
2363 destruction of drugs. Any other distribution by and means of the  
2364 consigned prescription drug by any person, not limited to the  
2365 consignor wholesale distributor ~~wholesaler~~ or consignee pharmacy,  
2366 to any other person is prohibited.

2367 (b) A wholesale distributor's permit is not required for  
2368 the one-time transfer of title of a pharmacy's lawfully acquired  
2369 prescription drug inventory by a pharmacy with a valid permit  
2370 issued under chapter 465 to a consignor prescription drug  
2371 wholesale distributor ~~wholesaler~~, permitted under this chapter,  
2372 in accordance with a written consignment agreement between the  
2373 pharmacy and that wholesale distributor ~~wholesaler~~ if: the  
2374 permitted pharmacy and the permitted prescription drug wholesale  
2375 distributor ~~wholesaler~~ comply with all of the provisions of  
2376 paragraph (a) and the prescription drugs continue to be within  
2377 the permitted pharmacy's inventory for dispensing in accordance  
2378 with the limitations of the pharmacy permit under chapter 465. A  
2379 consignor drug wholesale distributor ~~wholesaler~~ may not use the  
2380 pharmacy as a wholesale distributor through which it distributes  
2381 the prescription ~~legend~~ drugs to other pharmacies. Nothing in  
2382 this section is intended to prevent a wholesale ~~drug~~ distributor  
2383 from obtaining this inventory in the event of nonpayment by the  
2384 pharmacy.

2385 (c) A separate establishment permit is not required when a  
2386 permitted prescription drug wholesale distributor operates  
2387 temporary transit storage facilities for the sole purpose of  
2388 storage, for a period not to exceed 12 hours, of a delivery of



836536

2389 prescription drugs when the wholesale distributor was temporarily  
2390 unable to complete the delivery to the recipient.

2391 (d)-(e) The department shall require information from each  
2392 wholesale distributor as part of the permit and renewal of such  
2393 permit, as required under ~~s. 499.01~~ or this section.

2394 (14)-(9) Personnel employed in wholesale distribution must  
2395 have appropriate education and experience to enable them to  
2396 perform their duties in compliance with state permitting  
2397 requirements.

2398 (15)-(10) The name of a permittee or establishment on a  
2399 prescription drug wholesale distributor ~~wholesaler~~ permit or an  
2400 out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2401 permit may not include any indicia of attainment of any  
2402 educational degree, any indicia that the permittee or  
2403 establishment possesses a professional license, or any name or  
2404 abbreviation that the department determines is likely to cause  
2405 confusion or mistake or that the department determines is  
2406 deceptive, including that of any other entity authorized to  
2407 purchase prescription drugs.

2408 (16)-(11)(a) Each establishment that is issued an initial or  
2409 renewal permit as a prescription drug wholesale distributor  
2410 ~~wholesaler~~ or an out-of-state prescription drug wholesale  
2411 distributor ~~wholesaler~~ must designate in writing to the  
2412 department at least one natural person to serve as the designated  
2413 representative of the wholesale distributor ~~wholesaler~~. Such  
2414 person must have an active certification as a designated  
2415 representative from the department.

2416 (b) To be certified as a designated representative, a  
2417 natural person must:



836536

- 2418 | 1. Submit an application on a form furnished by the  
2419 | department and pay the appropriate fees;
- 2420 | 2. Be at least 18 years of age;
- 2421 | 3. Have not less than 2 years of verifiable full-time work  
2422 | experience in a pharmacy licensed in this state or another state,  
2423 | where the person's responsibilities included, but were not  
2424 | limited to, recordkeeping for prescription drugs, or have not  
2425 | less than 2 years of verifiable full-time managerial experience  
2426 | with a prescription drug wholesale distributor ~~wholesaler~~  
2427 | licensed in this state or in another state;
- 2428 | 4. Receive a passing score of at least 75 percent on an  
2429 | examination given by the department regarding federal laws  
2430 | governing distribution of prescription drugs and this part ss.  
2431 | ~~499.001-499.081~~ and the rules adopted by the department governing  
2432 | the wholesale distribution of prescription drugs. This  
2433 | requirement shall be effective 1 year after the results of the  
2434 | initial examination are mailed to the persons that took the  
2435 | examination. The department shall offer such examinations at  
2436 | least four times each calendar year; and
- 2437 | 5. Provide the department with a personal information  
2438 | statement and fingerprints pursuant to subsection (9) ~~(4)~~.
- 2439 | (c) The department may deny an application for  
2440 | certification as a designated representative or may suspend or  
2441 | revoke a certification of a designated representative pursuant to  
2442 | s. 499.067.
- 2443 | (d) A designated representative:
- 2444 | 1. Must be actively involved in and aware of the actual  
2445 | daily operation of the wholesale distributor.
- 2446 | 2. Must be employed full time in a managerial position by  
2447 | the wholesale distributor.



836536

2448 | 3. Must be physically present at the establishment during  
2449 | normal business hours, except for time periods when absent due to  
2450 | illness, family illness or death, scheduled vacation, or other  
2451 | authorized absence.

2452 | 4. May serve as a designated representative for only one  
2453 | wholesale distributor at any one time.

2454 | (e) A wholesale distributor must notify the department when  
2455 | a designated representative leaves the employ of the wholesale  
2456 | distributor. Such notice must be provided to the department  
2457 | within 10 business days after the last day of designated  
2458 | representative's employment with the wholesale distributor.

2459 | (f) A wholesale distributor may not operate under a  
2460 | prescription drug wholesale distributor ~~wholesaler~~ permit or an  
2461 | out-of-state prescription drug wholesale distributor ~~wholesaler~~  
2462 | permit for more than 10 business days after the designated  
2463 | representative leaves the employ of the wholesale distributor,  
2464 | unless the wholesale distributor employs another designated  
2465 | representative and notifies the department within 10 business  
2466 | days of the identity of the new designated representative.

2467 | Section 12. Section 499.01201, Florida Statutes, is amended  
2468 | to read:

2469 | 499.01201 Agency for Health Care Administration review and  
2470 | use of statute and rule violation or compliance  
2471 | data.--Notwithstanding any other provisions of law to the  
2472 | contrary, the Agency for Health Care Administration may not:

2473 | (1) Review or use any violation or alleged violation of s.  
2474 | 499.0121(6) or s. 499.01212, or any rules adopted under those  
2475 | sections ~~that section~~, as a ground for denying or withholding any  
2476 | payment of a Medicaid reimbursement to a pharmacy licensed under  
2477 | chapter 465; or



836536

2478 (2) Review or use compliance with s. 499.0121(6) or s.  
2479 499.01212, or any rules adopted under those sections ~~that~~  
2480 ~~section~~, as the subject of any audit of Medicaid-related records  
2481 held by a pharmacy licensed under chapter 465.

2482 Section 13. Section 499.0121, Florida Statutes, is amended,  
2483 and subsection (4) of section 499.013, Florida Statutes, is  
2484 redesignated as paragraph (d) of subsection (6) of that section  
2485 and amended, to read:

2486 499.0121 Storage and handling of prescription drugs;  
2487 recordkeeping.--The department shall adopt rules to implement  
2488 this section as necessary to protect the public health, safety,  
2489 and welfare. Such rules shall include, but not be limited to,  
2490 requirements for the storage and handling of prescription drugs  
2491 and for the establishment and maintenance of prescription drug  
2492 distribution records.

2493 (1) ESTABLISHMENTS.--An establishment at which prescription  
2494 drugs are stored, warehoused, handled, held, offered, marketed,  
2495 or displayed must:

2496 (a) Be of suitable size and construction to facilitate  
2497 cleaning, maintenance, and proper operations;

2498 (b) Have storage areas designed to provide adequate  
2499 lighting, ventilation, temperature, sanitation, humidity, space,  
2500 equipment, and security conditions;

2501 (c) Have a quarantine area for storage of prescription  
2502 drugs that are outdated, damaged, deteriorated, misbranded, or  
2503 adulterated, or that are in immediate or sealed, secondary  
2504 containers that have been opened;

2505 (d) Be maintained in a clean and orderly condition; and

2506 (e) Be free from infestation by insects, rodents, birds, or  
2507 vermin of any kind.



836536

- 2508 (2) SECURITY.--
- 2509 (a) An establishment that is used for wholesale drug
- 2510 distribution must be secure from unauthorized entry.
- 2511 1. Access from outside the premises must be kept to a
- 2512 minimum and be well-controlled.
- 2513 2. The outside perimeter of the premises must be well-
- 2514 lighted.
- 2515 3. Entry into areas where prescription drugs are held must
- 2516 be limited to authorized personnel.
- 2517 (b) An establishment that is used for wholesale drug
- 2518 distribution must be equipped with:
- 2519 1. An alarm system to detect entry after hours; however,
- 2520 the department may exempt by rule establishments that only hold a
- 2521 permit as prescription drug wholesale distributor-brokers
- 2522 ~~wholesaler-brokers~~ and establishments that only handle medical
- 2523 oxygen; and
- 2524 2. A security system that will provide suitable protection
- 2525 against theft and diversion. When appropriate, the security
- 2526 system must provide protection against theft or diversion that is
- 2527 facilitated or hidden by tampering with computers or electronic
- 2528 records.
- 2529 (c) Any vehicle that contains prescription drugs must be
- 2530 secure from unauthorized access to the prescription drugs in the
- 2531 vehicle.
- 2532 (3) STORAGE.--All prescription drugs shall be stored at
- 2533 appropriate temperatures and under appropriate conditions in
- 2534 accordance with requirements, if any, in the labeling of such
- 2535 drugs, or with requirements in the official compendium.
- 2536 (a) If no storage requirements are established for a
- 2537 prescription drug, the drug may be held at "controlled" room



836536

2538 | temperature, as defined in the official compendium, to help  
2539 | ensure that its identity, strength, quality, and purity are not  
2540 | adversely affected.

2541 |       (b) Appropriate manual, electromechanical, or electronic  
2542 | temperature and humidity recording equipment, devices, or logs  
2543 | must be used to document proper storage of prescription drugs.

2544 |       (c) The recordkeeping requirements in subsection (6) must  
2545 | be followed for all stored prescription drugs.

2546 |       (4) EXAMINATION OF MATERIALS AND RECORDS.--

2547 |       (a) Upon receipt, each outside shipping container must be  
2548 | visually examined for identity and to prevent the acceptance of  
2549 | contaminated prescription drugs that are otherwise unfit for  
2550 | distribution. This examination must be adequate to reveal  
2551 | container damage that would suggest possible contamination or  
2552 | other damage to the contents.

2553 |       (b) Each outgoing shipment must be carefully inspected for  
2554 | identity of the prescription drug products and to ensure that  
2555 | there is no delivery of prescription drugs that have expired or  
2556 | been damaged in storage or held under improper conditions.

2557 |       (c) The recordkeeping requirements in subsection (6) must  
2558 | be followed for all incoming and outgoing prescription drugs.

2559 |       (d) Upon receipt, a wholesale distributor ~~wholesaler~~ must  
2560 | review records required under this section for the acquisition of  
2561 | prescription drugs for accuracy and completeness, considering the  
2562 | total facts and circumstances surrounding the transactions and  
2563 | the wholesale distributors involved. This includes authenticating  
2564 | each transaction listed on a pedigree paper, as defined in s.  
2565 | 499.003(35) ~~s. 499.001(31)~~.

2566 |       (5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.--



836536

2567 (a)1. Prescription drugs that are outdated, damaged,  
2568 deteriorated, misbranded, or adulterated must be quarantined and  
2569 physically separated from other prescription drugs until they are  
2570 destroyed or returned to their supplier. A quarantine section  
2571 must be separate and apart from other sections where prescription  
2572 drugs are stored so that prescription drugs in this section are  
2573 not confused with usable prescription drugs.

2574 2. Prescription drugs must be examined at least every 12  
2575 months, and drugs for which the expiration date has passed must  
2576 be removed and quarantined.

2577 (b) Any prescription drugs of which the immediate or sealed  
2578 outer containers or sealed secondary containers have been opened  
2579 or used must be identified as such and must be quarantined and  
2580 physically separated from other prescription drugs until they are  
2581 either destroyed or returned to the supplier.

2582 (c) If the conditions under which a prescription drug has  
2583 been returned cast doubt on the drug's safety, identity,  
2584 strength, quality, or purity, the drug must be destroyed or  
2585 returned to the supplier, unless examination, testing, or other  
2586 investigation proves that the drug meets appropriate standards of  
2587 safety, identity, strength, quality, and purity. In determining  
2588 whether the conditions under which a drug has been returned cast  
2589 doubt on the drug's safety, identity, strength, quality, or  
2590 purity, the wholesale ~~drug~~ distributor must consider, among other  
2591 things, the conditions under which the drug has been held,  
2592 stored, or shipped before or during its return and the conditions  
2593 of the drug and its container, carton, or labeling, as a result  
2594 of storage or shipping.





836536

2595 (d) The recordkeeping requirements in subsection (6) must  
2596 be followed for all outdated, damaged, deteriorated, misbranded,  
2597 or adulterated prescription drugs.

2598 (6) RECORDKEEPING.--The department shall adopt rules that  
2599 require keeping such records of prescription drugs as are  
2600 necessary for the protection of the public health.

2601 (a) Wholesale ~~drug~~ distributors must establish and maintain  
2602 inventories and records of all transactions regarding the receipt  
2603 and distribution or other disposition of prescription drugs.  
2604 These records must provide a complete audit trail from receipt to  
2605 sale or other disposition, be readily retrievable for inspection,  
2606 and include, at a minimum, the following information:

2607 1. The source of the drugs, including the name and  
2608 principal address of the seller or transferor, and the address of  
2609 the location from which the drugs were shipped;

2610 2. The name, principal address, and state license permit or  
2611 registration number of the person authorized to purchase  
2612 prescription drugs;

2613 3. The name, strength, dosage form, and quantity of the  
2614 drugs received and distributed or disposed of;

2615 4. The dates of receipt and distribution or other  
2616 disposition of the drugs; and

2617 5. Any financial documentation supporting the transaction.

2618 (b) Inventories and records must be made available for  
2619 inspection and photocopying by authorized federal, state, or  
2620 local officials for a period of 2 years following disposition of  
2621 the drugs or 3 years after the creation of the records, whichever  
2622 period is longer.

2623 (c) Records described in this section that are kept at the  
2624 inspection site or that can be immediately retrieved by computer



836536

2625 or other electronic means must be readily available for  
2626 authorized inspection during the retention period. Records that  
2627 are kept at a central location outside of this state and that are  
2628 not electronically retrievable must be made available for  
2629 inspection within 2 working days after a request by an authorized  
2630 official of a federal, state, or local law enforcement agency.  
2631 Records that are maintained at a central location within this  
2632 state must be maintained at an establishment that is permitted  
2633 pursuant to this part ss. 499.001-499.081 and must be readily  
2634 available.

2635 (d)(4) Each manufacturer or repackager of medical devices,  
2636 over-the-counter drugs, or cosmetics must maintain records that  
2637 include the name and principal address of the seller or  
2638 transferor of the product, the address of the location from which  
2639 the product was shipped, the date of the transaction, the name  
2640 and quantity of the product involved, and the name and principal  
2641 address of the person who purchased the product.

2642 (e) A wholesale distributor must maintain pedigree papers  
2643 separate and distinct from other records required under this  
2644 chapter.

2645 ~~(d)1. Effective July 1, 2006, each person who is engaged in~~  
2646 ~~the wholesale distribution of a prescription drug and who is not~~  
2647 ~~the manufacturer of that drug must, before each wholesale~~  
2648 ~~distribution of such drug, provide to the person who receives the~~  
2649 ~~drug a pedigree paper as defined in s. 499.003(31).~~

2650 ~~2. A repackager must comply with this paragraph.~~

2651 ~~3. The pedigree paper requirements in this paragraph do not~~  
2652 ~~apply to compressed medical gases or veterinary legend drugs.~~



836536

2653           ~~4. Each wholesale distributor of prescription drugs must~~  
2654 ~~maintain separate and distinct from other required records all~~  
2655 ~~statements that are required under subparagraph 1.~~

2656           ~~5. Subparagraph 1. is satisfied when a wholesale~~  
2657 ~~distributor takes title to, but not possession of, a prescription~~  
2658 ~~drug and the prescription drug's manufacturer ships the~~  
2659 ~~prescription drug directly to a person authorized by law to~~  
2660 ~~purchase prescription drugs for the purpose of administering or~~  
2661 ~~dispensing the drug, as defined in s. 465.003, or a member of an~~  
2662 ~~affiliated group, as described in paragraph (f), with the~~  
2663 ~~exception of a repackager.~~

2664           ~~a. The wholesale distributor must deliver to the recipient~~  
2665 ~~of the prescription drug, within 14 days after the shipment~~  
2666 ~~notification from the manufacturer, an invoice and the following~~  
2667 ~~sworn statement: "This wholesale distributor purchased the~~  
2668 ~~specific unit of the prescription drug listed on the invoice~~  
2669 ~~directly from the manufacturer, and the specific unit of~~  
2670 ~~prescription drug was shipped by the manufacturer directly to a~~  
2671 ~~person authorized by law to administer or dispense the legend~~  
2672 ~~drug, as defined in s. 465.003, Florida Statutes, or a member of~~  
2673 ~~an affiliated group, as described in s. 499.0121(6)(f), Florida~~  
2674 ~~Statutes, with the exception of a repackager." The invoice must~~  
2675 ~~contain a unique cross-reference to the shipping document sent by~~  
2676 ~~the manufacturer to the recipient of the prescription drug.~~

2677           ~~b. The manufacturer of the prescription drug shipped~~  
2678 ~~directly to the recipient under this section must provide and the~~  
2679 ~~recipient of the prescription drug must acquire, within 14 days~~  
2680 ~~after receipt of the prescription drug, a shipping document from~~  
2681 ~~the manufacturer that contains, at a minimum:~~



836536

2682           ~~(I) The name and address of the manufacturer, including the~~  
2683 ~~point of origin of the shipment, and the names and addresses of~~  
2684 ~~the wholesaler and the purchaser.~~

2685           ~~(II) The name of the prescription drug as it appears on the~~  
2686 ~~label.~~

2687           ~~(III) The quantity, dosage form, and strength of the~~  
2688 ~~prescription drug.~~

2689           ~~(IV) The date of the shipment from the manufacturer.~~

2690           ~~e. The wholesale distributor must also maintain and make~~  
2691 ~~available to the department, upon request, the lot number of such~~  
2692 ~~drug if not contained in the shipping document acquired by the~~  
2693 ~~recipient.~~

2694           ~~6. Failure of the manufacturer to provide, the recipient to~~  
2695 ~~acquire, or the wholesale distributor to deliver, the~~  
2696 ~~documentation required under subparagraph 5. shall constitute~~  
2697 ~~failure to acquire or deliver a pedigree paper under s. 499.0051.~~  
2698 ~~Forgery by the manufacturer, the recipient, or the wholesale~~  
2699 ~~distributor of the documentation required to be acquired or~~  
2700 ~~delivered under subparagraph 5. shall constitute forgery of a~~  
2701 ~~pedigree paper under s. 499.0051.~~

2702           ~~7. The department may, by rule, specify alternatives to~~  
2703 ~~compliance with subparagraph 1. for a prescription drug in the~~  
2704 ~~inventory of a permitted prescription drug wholesaler as of June~~  
2705 ~~30, 2006, and the return of a prescription drug purchased prior~~  
2706 ~~to July 1, 2006. The department may specify time limits for such~~  
2707 ~~alternatives.~~

2708           ~~(7)(e) PRESCRIPTION DRUG PURCHASE LIST.--Each wholesale~~  
2709 ~~distributor, except for a manufacturer, shall annually provide~~  
2710 ~~the department with a written list of all wholesale distributors~~  
2711 ~~and manufacturers from whom the wholesale distributor purchases~~



836536

2712 prescription drugs. A wholesale distributor, except a  
2713 manufacturer, shall notify the department not later than 10 days  
2714 after any change to either list. Such portions of the information  
2715 required pursuant to this subsection ~~paragraph~~ which are a trade  
2716 secret, as defined in s. 812.081, shall be maintained by the  
2717 department as trade secret information is required to be  
2718 maintained under s. 499.051.

2719 ~~(f)1. This paragraph applies only to an affiliated group,~~  
2720 ~~as defined by s. 1504 of the Internal Revenue Code of 1986, as~~  
2721 ~~amended, which is composed of chain drug entities, including at~~  
2722 ~~least 50 retail pharmacies, warehouses, or repackagers, which are~~  
2723 ~~members of the same affiliated group, if the affiliated group:~~

2724 ~~a. Discloses to the department the names of all its~~  
2725 ~~members; and~~

2726 ~~b. Agrees in writing to provide records on prescription~~  
2727 ~~drug purchases by members of the affiliated group not later than~~  
2728 ~~48 hours after the department requests such records, regardless~~  
2729 ~~of the location where the records are stored.~~

2730 ~~2. Each warehouse within the affiliated group must comply~~  
2731 ~~with all applicable federal and state drug wholesale permit~~  
2732 ~~requirements and must purchase, receive, hold, and distribute~~  
2733 ~~prescription drugs only to a retail pharmacy or warehouse within~~  
2734 ~~the affiliated group. Such a warehouse is exempt from providing a~~  
2735 ~~pedigree paper in accordance with paragraph (d) to its affiliated~~  
2736 ~~group member warehouse or retail pharmacy, provided that:~~

2737 ~~a. Any affiliated group member that purchases or receives a~~  
2738 ~~prescription drug from outside the affiliated group must receive~~  
2739 ~~a pedigree paper if the prescription drug is distributed in or~~  
2740 ~~into this state and a pedigree paper is required under this~~  
2741 ~~section and must authenticate the documentation as required in~~



836536

2742 ~~subsection (4), regardless of whether the affiliated group member~~  
2743 ~~is directly subject to regulation under this chapter; and~~

2744 ~~b. The affiliated group makes available to the department~~  
2745 ~~on request all records related to the purchase or acquisition of~~  
2746 ~~prescription drugs by members of the affiliated group, regardless~~  
2747 ~~of the location where the records are stored, if the prescription~~  
2748 ~~drugs were distributed in or into this state.~~

2749 ~~3. If a repackager repackages prescription drugs solely for~~  
2750 ~~distribution to its affiliated group members for the exclusive~~  
2751 ~~distribution to and among retail pharmacies that are members of~~  
2752 ~~the affiliated group to which the repackager is a member:~~

2753 ~~a. The repackager must:~~

2754 ~~(I) In lieu of the written statement required by paragraph~~  
2755 ~~(d), for all repackaged prescription drugs distributed in or into~~  
2756 ~~this state, state in writing under oath with each distribution of~~  
2757 ~~a repackaged prescription drug to an affiliated group member~~  
2758 ~~warehouse or repackager: "All repackaged prescription drugs are~~  
2759 ~~purchased by the affiliated group directly from the manufacturer~~  
2760 ~~or from a prescription drug wholesaler that purchased the~~  
2761 ~~prescription drugs directly from the manufacturer.";~~

2762 ~~(II) Purchase all prescription drugs it repackages:~~

2763 ~~(A) Directly from the manufacturer; or~~

2764 ~~(B) From a prescription drug wholesaler that purchased the~~  
2765 ~~prescription drugs directly from the manufacturer; and~~

2766 ~~(III) Maintain records in accordance with this section to~~  
2767 ~~document that it purchased the prescription drugs directly from~~  
2768 ~~the manufacturer or that its prescription drug wholesale supplier~~  
2769 ~~purchased the prescription drugs directly from the manufacturer.~~

2770 ~~b. All members of the affiliated group must provide to~~  
2771 ~~agents of the department on request records of purchases by all~~



836536

2772 ~~members of the affiliated group of prescription drugs that have~~  
2773 ~~been repackaged, regardless of the location where the records are~~  
2774 ~~stored or where the repackager is located.~~

2775 (8) ~~(7)~~ WRITTEN POLICIES AND PROCEDURES.--Wholesale ~~drug~~  
2776 distributors must establish, maintain, and adhere to written  
2777 policies and procedures, which must be followed for the receipt,  
2778 security, storage, inventory, and distribution of prescription  
2779 drugs, including policies and procedures for identifying,  
2780 recording, and reporting losses or thefts, and for correcting all  
2781 errors and inaccuracies in inventories. Wholesale ~~drug~~  
2782 distributors must include in their written policies and  
2783 procedures:

2784 (a) A procedure whereby the oldest approved stock of a  
2785 prescription drug product is distributed first. The procedure may  
2786 permit deviation from this requirement, if the deviation is  
2787 temporary and appropriate.

2788 (b) A procedure to be followed for handling recalls and  
2789 withdrawals of prescription drugs. Such procedure must be  
2790 adequate to deal with recalls and withdrawals due to:

2791 1. Any action initiated at the request of the Food and Drug  
2792 Administration or any other federal, state, or local law  
2793 enforcement or other government agency, including the department.

2794 2. Any voluntary action by the manufacturer or repackager  
2795 to remove defective or potentially defective drugs from the  
2796 market; or

2797 3. Any action undertaken to promote public health and  
2798 safety by replacing existing merchandise with an improved product  
2799 or new package design.

2800 (c) A procedure to ensure that wholesale ~~drug~~ distributors  
2801 prepare for, protect against, and handle any crisis that affects



836536

2802 security or operation of any facility if a strike, fire, flood,  
2803 or other natural disaster, or a local, state, or national  
2804 emergency, occurs.

2805 (d) A procedure to ensure that any outdated prescription  
2806 drugs are segregated from other drugs and either returned to the  
2807 manufacturer or repackager or destroyed. This procedure must  
2808 provide for written documentation of the disposition of outdated  
2809 prescription drugs. This documentation must be maintained for 2  
2810 years after disposition of the outdated drugs.

2811 ~~(9)~~ ~~(8)~~ RESPONSIBLE PERSONS.--Wholesale ~~drug~~ distributors  
2812 must establish and maintain lists of officers, directors,  
2813 managers, designated representatives, and other persons in charge  
2814 of wholesale drug distribution, storage, and handling, including  
2815 a description of their duties and a summary of their  
2816 qualifications.

2817 ~~(10)~~ ~~(9)~~ COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.--A  
2818 wholesale ~~drug~~ distributor must operate in compliance with  
2819 applicable federal, state, and local laws and regulations.

2820 (a) A wholesale ~~drug~~ distributor must allow the department  
2821 and authorized federal, state, and local officials to enter and  
2822 inspect its premises and delivery vehicles, and to audit its  
2823 records and written operating procedures, at reasonable times and  
2824 in a reasonable manner, to the extent authorized by law.

2825 (b) A wholesale ~~drug~~ distributor that deals in controlled  
2826 substances must register with the Drug Enforcement Administration  
2827 and must comply with all applicable state, local, and federal  
2828 laws. A wholesale ~~drug~~ distributor that distributes any substance  
2829 controlled under chapter 893 must notify the department when  
2830 registering with the Drug Enforcement Administration pursuant to  
2831 that chapter and must provide the department with its DEA number.





836536

2832            (11)~~(10)~~ SALVAGING AND REPROCESSING.--A wholesale ~~drug~~  
2833 distributor is subject to any applicable federal, state, or local  
2834 laws or regulations that relate to prescription drug product  
2835 salvaging or reprocessing.

2836            (12)~~(11)~~ SHIPPING AND TRANSPORTATION.--The person  
2837 responsible for shipment and transportation of a prescription  
2838 drug in a wholesale distribution may use a common carrier; its  
2839 own vehicle or employee acting within the scope of employment if  
2840 authorized under s. 499.03 for the possession of prescription  
2841 drugs in this state; or, in the case of a prescription drug  
2842 intended for domestic distribution, an independent contractor who  
2843 must be the agent of the authorized seller or recipient  
2844 responsible for shipping and transportation as set forth in a  
2845 written contract between the parties. A person selling a  
2846 prescription drug for export must obtain documentation, such as a  
2847 validated airway bill, bill of lading, or other appropriate  
2848 documentation that the prescription drug was exported. A person  
2849 responsible for shipping or transporting prescription drugs is  
2850 not required to maintain documentation from a common carrier that  
2851 the designated recipient received the prescription drugs;  
2852 however, the person must obtain such documentation from the  
2853 common carrier and make it available to the department upon  
2854 request of the department.

2855            (13)~~(12)~~ DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing  
2856 any prescription drugs from another wholesale ~~drug~~ distributor, a  
2857 prescription drug wholesale distributor ~~wholesaler~~, an out-of-  
2858 state prescription drug wholesale distributor ~~wholesaler~~, or a  
2859 prescription drug repackager must:

2860            (a) Enter an agreement with the selling wholesale ~~drug~~  
2861 distributor by which the selling wholesale ~~drug~~ distributor will



836536

2862 indemnify the purchasing wholesale ~~drug~~ distributor for any loss  
2863 caused to the purchasing wholesale ~~drug~~ distributor related to  
2864 the purchase of drugs from the selling wholesale ~~drug~~ distributor  
2865 which are determined to be counterfeit or to have been  
2866 distributed in violation of any federal or state law governing  
2867 the distribution of drugs.

2868 (b) Determine that the selling wholesale ~~drug~~ distributor  
2869 has insurance coverage of not less than the greater of 1 percent  
2870 of the amount of total dollar volume of the prescription drug  
2871 sales reported to the department under s. 499.012(8)(g) ~~s.~~  
2872 ~~499.012(3)(g)~~ or \$500,000; however the coverage need not exceed  
2873 \$2 million.

2874 (c) Obtain information from the selling wholesale ~~drug~~  
2875 distributor, including the length of time the selling wholesale  
2876 ~~drug~~ distributor has been licensed in this state, a copy of the  
2877 selling wholesale ~~drug~~ distributor's licenses or permits, and  
2878 background information concerning the ownership of the selling  
2879 wholesale ~~drug~~ distributor, including the experience of the  
2880 wholesale distributor in the wholesale distribution of  
2881 prescription drugs.

2882 (d) Verify that the selling wholesale ~~drug~~ distributor's  
2883 Florida permit is valid.

2884 (e) Inspect the selling wholesale ~~drug~~ distributor's  
2885 licensed establishment to document that it has a policies and  
2886 procedures manual relating to the distribution of drugs, the  
2887 appropriate temperature controlled environment for drugs  
2888 requiring temperature control, an alarm system, appropriate  
2889 access restrictions, and procedures to ensure that records  
2890 related to the wholesale distribution of prescription drugs are  
2891 maintained as required by law:



836536

2892 | 1. Before purchasing any drug from the wholesale ~~drug~~  
2893 | distributor, and at least once each subsequent year; or

2894 | 2. Before purchasing any drug from the wholesale ~~drug~~  
2895 | distributor, and each subsequent year obtain a complete copy of  
2896 | the most recent inspection report for the establishment which was  
2897 | prepared by the department or the regulatory authority  
2898 | responsible for wholesale ~~drug~~ distributors in the state in which  
2899 | the establishment is located.

2900 | Section 14. Section 499.01211, Florida Statutes, is amended  
2901 | to read:

2902 | 499.01211 Drug Wholesale Distributor ~~Wholesaler~~ Advisory  
2903 | Council.--

2904 | (1) There is created the Drug Wholesale Distributor  
2905 | ~~Wholesaler~~ Advisory Council within the department. The council  
2906 | shall meet at least once each calendar quarter. Staff for the  
2907 | council shall be provided by the department. The council shall  
2908 | consist of 11 members who shall serve without compensation. The  
2909 | council shall elect a chairperson and a vice chairperson  
2910 | annually.

2911 | (2) The State Surgeon General, or his or her designee, and  
2912 | the Secretary of Health Care Administration, or her or his  
2913 | designee, shall be members of the council. The State Surgeon  
2914 | General shall appoint nine additional members to the council who  
2915 | shall be appointed to a term of 4 years each, as follows:

2916 | (a) Three different persons each of whom is employed by a  
2917 | different prescription drug wholesale distributor ~~wholesaler~~  
2918 | licensed under this part ~~chapter~~ which operates nationally and is  
2919 | a primary wholesale distributor ~~wholesaler~~, as defined in s.  
2920 | 499.003(46) ~~s. 499.012(1)(d)~~.



836536

2921 (b) One person employed by a prescription drug wholesale  
2922 distributor ~~wholesaler~~ licensed under this part ~~chapter~~ which is  
2923 a secondary wholesale distributor ~~wholesaler~~, as defined in s.  
2924 499.003(51) ~~s. 499.012(1)(f)~~.

2925 (c) One person employed by a retail pharmacy chain located  
2926 in this state.

2927 (d) One person who is a member of the Board of Pharmacy and  
2928 is a pharmacist licensed under chapter 465.

2929 (e) One person who is a physician licensed pursuant to  
2930 chapter 458 or chapter 459.

2931 (f) One person who is an employee of a hospital licensed  
2932 pursuant to chapter 395 and is a pharmacist licensed pursuant to  
2933 chapter 465.

2934 (g) One person who is an employee of a pharmaceutical  
2935 manufacturer.

2936 (3) The council shall review this part ~~ss. 499.001-499.081~~  
2937 and the rules adopted to administer this part ~~ss. 499.001-499.081~~  
2938 annually, provide input to the department regarding all proposed  
2939 rules to administer this part ~~ss. 499.001-499.081~~, make  
2940 recommendations to the department to improve the protection of  
2941 the prescription drugs and public health, make recommendations to  
2942 improve coordination with other states' regulatory agencies and  
2943 the federal government concerning the wholesale distribution of  
2944 drugs, and make recommendations to minimize the impact of  
2945 regulation of the wholesale distribution industry while ensuring  
2946 protection of the public health.

2947 Section 15. Section 499.01212, Florida Statutes, is created  
2948 to read:

2949 499.01212 Pedigree paper.--



836536

2950       (1) APPLICATION.--Each person who is engaged in the  
2951 wholesale distribution of a prescription drug must, prior to or  
2952 simultaneous with each wholesale distribution, provide a pedigree  
2953 paper to the person who receives the drug.

2954       (2) FORMAT.--A pedigree paper must contain the following  
2955 information:

2956       (a) For the wholesale distribution of a prescription drug  
2957 within the normal distribution chain:

2958       1. The following statement: "This wholesale distributor  
2959 purchased the specific unit of the prescription drug directly  
2960 from the manufacturer."

2961       2. The manufacturer's national drug code identifier and the  
2962 name and address of the wholesale distributor and the purchaser  
2963 of the prescription drug.

2964       3. The name of the prescription drug as it appears on the  
2965 label.

2966       4. The quantity, dosage form, and strength of the  
2967 prescription drug.

2968  
2969 The wholesale distributor must also maintain and make available  
2970 to the department, upon request, the point of origin of the  
2971 prescription drugs, including intracompany transfers, the date of  
2972 the shipment from the manufacturer to the wholesale distributor,  
2973 the lot numbers of such drugs, and the invoice numbers from the  
2974 manufacturer.

2975       (b) For all other wholesale distributions of prescription  
2976 drugs:

2977       1. The quantity, dosage form, and strength of the  
2978 prescription drugs.

2979       2. The lot numbers of the prescription drugs.



836536

2980 |       3. The name and address of each owner of the prescription  
2981 | drug and his or her signature.

2982 |       4. Shipping information, including the name and address of  
2983 | each person certifying delivery or receipt of the prescription  
2984 | drug.

2985 |       5. An invoice number, a shipping document number, or  
2986 | another number uniquely identifying the transaction.

2987 |       6. A certification that the recipient wholesale distributor  
2988 | has authenticated the pedigree papers.

2989 |       7. The unique serialization of the prescription drug, if  
2990 | the manufacturer or repackager has uniquely serialized the  
2991 | individual prescription drug unit.

2992 |       8. The name, address, telephone number, and, if available,  
2993 | e-mail contact information of each wholesale distributor involved  
2994 | in the chain of the prescription drug's custody.

2995 |       (3) EXCEPTIONS.--A pedigree paper is not required for:

2996 |       (a) The wholesale distribution of a prescription drug by  
2997 | the manufacturer or by a third party logistics provider  
2998 | performing a wholesale distribution of a prescription drug for a  
2999 | manufacturer.

3000 |       (b) The wholesale distribution of a prescription drug by a  
3001 | freight forwarder.

3002 |       (c) The wholesale distribution of a prescription drug by a  
3003 | limited prescription drug veterinary wholesale distributor to a  
3004 | veterinarian.

3005 |       (d) The wholesale distribution of a compressed medical gas.

3006 |       (e) The wholesale distribution of a veterinary prescription  
3007 | drug.

3008 |       (f) A drop shipment, provided:



836536

3009 | 1. The wholesale distributor delivers to the recipient of  
3010 | the prescription drug, within 14 days after the shipment  
3011 | notification from the manufacturer, an invoice and the following  
3012 | sworn statement: "This wholesale distributor purchased the  
3013 | specific unit of the prescription drug listed on the invoice  
3014 | directly from the manufacturer, and the specific unit of  
3015 | prescription drug was shipped by the manufacturer directly to a  
3016 | person authorized by law to administer or dispense the legend  
3017 | drug, as defined in s. 465.003, Florida Statutes, or a member of  
3018 | an affiliated group, with the exception of a repackager." The  
3019 | invoice must contain a unique cross-reference to the shipping  
3020 | document sent by the manufacturer to the recipient of the  
3021 | prescription drug.

3022 | 2. The manufacturer of the prescription drug shipped  
3023 | directly to the recipient provides and the recipient of the  
3024 | prescription drug acquires, within 14 days after receipt of the  
3025 | prescription drug, a shipping document from the manufacturer that  
3026 | contains, at a minimum:

3027 | a. The name and address of the manufacturer, including the  
3028 | point of origin of the shipment, and the names and addresses of  
3029 | the wholesale distributor and the purchaser.

3030 | b. The name of the prescription drug as it appears on the  
3031 | label.

3032 | c. The quantity, dosage form, and strength of the  
3033 | prescription drug.

3034 | d. The date of the shipment from the manufacturer.

3035 | 3. The wholesale distributor maintains and makes available  
3036 | to the department, upon request, the lot number of such drug if  
3037 | not contained in the shipping document acquired by the recipient.

3038 |



836536

3039 Failure of the manufacturer to provide, the recipient to acquire,  
3040 or the wholesale distributor to deliver the documentation  
3041 required under this paragraph shall constitute failure to acquire  
3042 or deliver a pedigree paper under ss. 499.005(28) and 499.0051.  
3043 Forgery by the manufacturer, the recipient, or the wholesale  
3044 distributor of the documentation required to be acquired or  
3045 delivered under this paragraph shall constitute forgery of a  
3046 pedigree paper under s. 499.0051.

3047 4. The wholesale distributor that takes title to, but not  
3048 possession of, the prescription drug is not a member of the  
3049 affiliated group that receives the prescription drug directly  
3050 from the manufacturer.

3051 (g) The wholesale distribution of a prescription drug by a  
3052 warehouse within an affiliated group to a warehouse or retail  
3053 pharmacy within its affiliated group, provided:

3054 1. Any affiliated group member that purchases or receives a  
3055 prescription drug from outside the affiliated group must receive  
3056 a pedigree paper if the prescription drug is distributed in or  
3057 into this state and a pedigree paper is required under this  
3058 section and must authenticate the documentation as required in s.  
3059 499.0121(4), regardless of whether the affiliated group member is  
3060 directly subject to regulation under this part; and

3061 2. The affiliated group makes available, within 48 hours,  
3062 to the department on request to one or more of its members all  
3063 records related to the purchase or acquisition of prescription  
3064 drugs by members of the affiliated group, regardless of the  
3065 location where the records are stored, if the prescription drugs  
3066 were distributed in or into this state.

3067 (h) The repackaging of prescription drugs by a repackager  
3068 solely for distribution to its affiliated group members for the





836536

3069 exclusive distribution to and among retail pharmacies that are  
3070 members of the affiliated group to which the repackager is a  
3071 member.

3072 1. The repackager must:

3073 a. For all repackaged prescription drugs distributed in or  
3074 into this state, state in writing under oath with each  
3075 distribution of a repackaged prescription drug to an affiliated  
3076 group member warehouse or repackager: "All repackaged  
3077 prescription drugs are purchased by the affiliated group directly  
3078 from the manufacturer or from a prescription drug wholesale  
3079 distributor that purchased the prescription drugs directly from  
3080 the manufacturer."

3081 b. Purchase all prescription drugs it repackages:

3082 (I) Directly from the manufacturer; or

3083 (II) From a prescription drug wholesale distributor that  
3084 purchased the prescription drugs directly from the manufacturer.

3085 c. Maintain records in accordance with this section to  
3086 document that it purchased the prescription drugs directly from  
3087 the manufacturer or that its prescription drug wholesale supplier  
3088 purchased the prescription drugs directly from the manufacturer.

3089 2. All members of the affiliated group must provide, within  
3090 48 hours, to agents of the department on request to one or more  
3091 of its members records of purchases by all members of the  
3092 affiliated group of prescription drugs that have been repackaged,  
3093 regardless of the location at which the records are stored or at  
3094 which the repackager is located.

3095 Section 16. Section 499.0122, Florida Statutes, is  
3096 repealed.

3097 Section 17. Section 499.013, Florida Statutes, is repealed.



836536

3098 Section 18. Subsections (1), (3), (4), (6), (8), and (9) of  
3099 section 499.015, Florida Statutes, are amended to read:

3100 499.015 Registration of drugs, devices, and cosmetics;  
3101 issuance of certificates of free sale.--

3102 (1)(a) Except for those persons exempted from the  
3103 definition of manufacturer in s. 499.003(32) ~~s. 499.003(28)~~, any  
3104 person who manufactures, packages, repackages, labels, or  
3105 relabels a drug, device, or cosmetic in this state must register  
3106 such drug, device, or cosmetic biennially with the department;  
3107 pay a fee in accordance with the fee schedule provided by s.  
3108 499.041; and comply with this section. The registrant must list  
3109 each separate and distinct drug, device, or cosmetic at the time  
3110 of registration.

3111 (b) The department may not register any product that does  
3112 not comply with the Federal Food, Drug, and Cosmetic Act, as  
3113 amended, or Title 21 C.F.R. Registration of a product by the  
3114 department does not mean that the product does in fact comply  
3115 with all provisions of the Federal Food, Drug, and Cosmetic Act,  
3116 as amended.

3117 (3) Except for those persons exempted from the definition  
3118 of manufacturer in s. 499.003(31) ~~s. 499.003(28)~~, a person may  
3119 not sell any product that he or she has failed to register in  
3120 conformity with this section. Such failure to register subjects  
3121 such drug, device, or cosmetic product to seizure and  
3122 condemnation as provided in s. 499.062 ~~ss. 499.062-499.064~~, and  
3123 subjects such person to the penalties and remedies provided in  
3124 this part ~~ss. 499.001-499.081~~.

3125 (4) Unless a registration is renewed, it expires 2 years  
3126 after the last day of the month in which it was issued. The  
3127 department may issue a stop-sale notice or order against a person



836536

3128 that is subject to the requirements of this section and that  
3129 fails to comply with this section within 31 days after the date  
3130 the registration expires. The notice or order shall prohibit such  
3131 person from selling or causing to be sold any drugs, devices, or  
3132 cosmetics covered by this part ~~ss. 499.001-499.081~~ until he or  
3133 she complies with the requirements of this section.

3134 (6) The department may issue a certificate of free sale for  
3135 any product that is required to be registered under this part ~~ss.~~  
3136 ~~499.001-499.081~~.

3137 (8) Notwithstanding any requirements set forth in this part  
3138 ~~ss. 499.001-499.081~~, a manufacturer of medical devices that is  
3139 registered with the federal Food and Drug Administration is  
3140 exempt from this section and s. 499.041(6) if:

3141 (a) The manufacturer's medical devices are approved for  
3142 marketing by, or listed with the federal Food and Drug  
3143 Administration in accordance with federal law for commercial  
3144 distribution; or

3145 (b) The manufacturer subcontracts with a manufacturer of  
3146 medical devices to manufacture components of such devices.

3147 (9) However, the manufacturer must submit evidence of such  
3148 registration, listing, or approval with its initial application  
3149 for a permit to do business in this state, as required in s.  
3150 499.01 ~~s. 499.013~~ and any changes to such information previously  
3151 submitted at the time of renewal of the permit. Evidence of  
3152 approval, listing, and registration by the federal Food and Drug  
3153 Administration must include:

3154 (a) For Class II devices, a copy of the pre-market  
3155 notification letter (510K);

3156 (b) For Class III devices, a Federal Drug Administration  
3157 pre-market approval number;



836536

3158 (c) For a manufacturer who subcontracts with a manufacturer  
3159 of medical devices to manufacture components of such devices, a  
3160 Federal Drug Administration registration number; or

3161 (d) For a manufacturer of medical devices whose devices are  
3162 exempt from pre-market approval by the Federal Drug  
3163 Administration, a Federal Drug Administration registration  
3164 number.

3165 Section 19. Subsections (3), (5), and (6) of section  
3166 499.024, Florida Statutes, are amended to read:

3167 499.024 Drug product classification.--The State Surgeon  
3168 General shall adopt rules to classify drug products intended for  
3169 use by humans which the United States Food and Drug  
3170 Administration has not classified in the federal act or the Code  
3171 of Federal Regulations.

3172 (3) Any product that falls under the definition of drug in  
3173 s. 499.003(19) definition, s. 499.003(17), may be classified  
3174 under the authority of this section. This section does not  
3175 subject portable emergency oxygen inhalators to classification;  
3176 however, this section does not exempt any person from ss. 499.01  
3177 and 499.015.

3178 (5) The department may by rule reclassify drugs subject to  
3179 this part ss. 499.001-499.081 when such classification action is  
3180 necessary to protect the public health.

3181 (6) The department may adopt rules that exempt from any  
3182 labeling or packaging requirements of this part ss. 499.001-  
3183 499.081 drugs classified under this section if those requirements  
3184 are not necessary to protect the public health.

3185 Section 20. Subsections (7), (12), and (15) of section  
3186 499.028, Florida Statutes, are amended to read:



836536

3187 499.028 Drug samples or complimentary drugs; starter packs;  
3188 permits to distribute.--

3189 (7) A drug manufacturer or distributor must report to the  
3190 department any conviction of itself or of its assigns, agents,  
3191 employees, or representatives for a violation of s. 503(c)(1) of  
3192 the federal act or of this part ~~ss. 499.001-499.081~~ because of  
3193 the sale, purchase, or trade of a drug sample or the offer to  
3194 sell, purchase, or trade a drug sample.

3195 (12) The department may suspend or revoke a permit issued  
3196 under this section, after giving notice and an opportunity to be  
3197 heard pursuant to chapter 120, when:

3198 (a) Such permit was obtained by misrepresentation or fraud  
3199 or through a mistake of the department.

3200 (b) The holder of the permit has distributed or disposed of  
3201 any prescription legend drug, directly or through its agents,  
3202 employees, or independent contractors, to any person not  
3203 authorized to possess such drug.

3204 (c) The holder of the permit, or its agents, employees, or  
3205 independent contractors, has distributed or possessed any  
3206 prescription legend drug except in the usual course of its  
3207 business.

3208 (d) The holder of the permit, or its agents, employees, or  
3209 independent contractors, has distributed any prescription legend  
3210 drug that is misbranded or adulterated under this part ~~ss.~~  
3211 ~~499.001-499.081~~.

3212 (e) The holder of the permit, or its agents, employees, or  
3213 independent contractors, has distributed any prescription legend  
3214 drug without written request, when a written request is required  
3215 by this section.



836536

3216 (f) The holder of the permit has in its employ, or uses as  
3217 agent or independent contractor for the purpose of distributing  
3218 or disposing of drugs, any person who has:

3219 1. Violated the requirements of this section or any rule  
3220 adopted under this section.

3221 2. Been convicted in any of the courts of this state, the  
3222 United States, or any other state of a felony or any other crime  
3223 involving moral turpitude or involving those drugs named or  
3224 described in chapter 893.

3225 (15) A person may not possess a prescription drug sample  
3226 unless:

3227 (a) The drug sample was prescribed to her or him as  
3228 evidenced by the label required in s. 465.0276(5).

3229 (b) She or he is the employee of a complimentary drug  
3230 distributor that holds a permit issued under this part ss-  
3231 ~~499.001-499.081~~.

3232 (c) She or he is a person to whom prescription drug samples  
3233 may be distributed pursuant to this section.

3234 (d) He or she is an officer or employee of a federal,  
3235 state, or local government acting within the scope of his or her  
3236 employment.

3237 Section 21. Subsections (2) and (3) of section 499.029,  
3238 Florida Statutes, are amended to read:

3239 499.029 Cancer Drug Donation Program.--

3240 (2) There is created a Cancer Drug Donation Program within  
3241 the department ~~of Health~~ for the purpose of authorizing and  
3242 facilitating the donation of cancer drugs and supplies to  
3243 eligible patients.

3244 (3) As used in this section:



836536

3245 (a) "Cancer drug" means a prescription drug that has been  
3246 approved under s. 505 of the federal Food, Drug, and Cosmetic Act  
3247 and is used to treat cancer or its side effects or is used to  
3248 treat the side effects of a prescription drug used to treat  
3249 cancer or its side effects. "Cancer drug" does not include a  
3250 substance listed in Schedule II, Schedule III, Schedule IV, or  
3251 Schedule V of s. 893.03.

3252 (b) "Closed drug delivery system" means a system in which  
3253 the actual control of the unit-dose medication package is  
3254 maintained by the facility rather than by the individual patient.

3255 ~~(c) "Department" means the Department of Health.~~

3256 (c) ~~(d)~~ "Donor" means a patient or patient representative  
3257 who donates cancer drugs or supplies needed to administer cancer  
3258 drugs that have been maintained within a closed drug delivery  
3259 system; health care facilities, nursing homes, hospices, or  
3260 hospitals with closed drug delivery systems; or pharmacies, drug  
3261 manufacturers, medical device manufacturers or suppliers, or  
3262 wholesalers of drugs or supplies, in accordance with this  
3263 section. "Donor" includes a physician licensed under chapter 458  
3264 or chapter 459 who receives cancer drugs or supplies directly  
3265 from a drug manufacturer, wholesale distributor ~~drug wholesaler~~,  
3266 or pharmacy.

3267 (d) ~~(e)~~ "Eligible patient" means a person who the department  
3268 determines is eligible to receive cancer drugs from the program.

3269 (e) ~~(k)~~ "Participant facility" means a class II hospital  
3270 pharmacy that has elected to participate in the program and that  
3271 accepts donated cancer drugs and supplies under the rules adopted  
3272 by the department for the program.

3273 (f) ~~(n)~~ "Prescribing practitioner" means a physician  
3274 licensed under chapter 458 or chapter 459 or any other medical



836536

3275 professional with authority under state law to prescribe cancer  
3276 medication.

3277 ~~(e) "Prescription drug" means a drug as defined in s.~~  
3278 ~~465.003(8).~~

3279 ~~(g) (p)~~ "Program" means the Cancer Drug Donation Program  
3280 created by this section.

3281 ~~(h) (q)~~ "Supplies" means any supplies used in the  
3282 administration of a cancer drug.

3283 Section 22. Subsection (1) of section 499.03, Florida  
3284 Statutes, is amended to read:

3285 499.03 Possession of certain drugs without prescriptions  
3286 unlawful; exemptions and exceptions.--

3287 (1) A person may not possess, or possess with intent to  
3288 sell, dispense, or deliver, any habit-forming, toxic, harmful, or  
3289 new drug subject to s. 499.003(32) ~~s. 499.003(29)~~, or  
3290 prescription legend ~~legend~~ drug as defined in s. 499.003(42) ~~s.~~  
3291 ~~499.003(25)~~, unless the possession of the drug has been obtained  
3292 by a valid prescription of a practitioner licensed by law to  
3293 prescribe the drug. However, this section does not apply to the  
3294 delivery of such drugs to persons included in any of the classes  
3295 named in this subsection, or to the agents or employees of such  
3296 persons, for use in the usual course of their businesses or  
3297 practices or in the performance of their official duties, as the  
3298 case may be; nor does this section apply to the possession of  
3299 such drugs by those persons or their agents or employees for such  
3300 use:

3301 (a) A licensed pharmacist or any person under the licensed  
3302 pharmacist's supervision while acting within the scope of the  
3303 licensed pharmacist's practice;





836536

3304 (b) A licensed practitioner authorized by law to prescribe  
3305 prescription ~~legend~~ drugs or any person under the licensed  
3306 practitioner's supervision while acting within the scope of the  
3307 licensed practitioner's practice;

3308 (c) A qualified person who uses prescription ~~legend~~ drugs  
3309 for lawful research, teaching, or testing, and not for resale;

3310 (d) A licensed hospital or other institution that procures  
3311 such drugs for lawful administration or dispensing by  
3312 practitioners;

3313 (e) An officer or employee of a federal, state, or local  
3314 government; or

3315 (f) A person that holds a valid permit issued by the  
3316 department pursuant to this part ~~ss. 499.001-499.081~~ which  
3317 authorizes that person to possess prescription drugs.

3318 Section 23. Section 499.032, Florida Statutes, is amended  
3319 to read:

3320 499.032 Phenylalanine; prescription  
3321 required.--Phenylalanine restricted formula is declared to be a  
3322 prescription ~~legend~~ drug and may be dispensed only upon the  
3323 prescription of a practitioner authorized by law to prescribe  
3324 prescription ~~medicinal~~ drugs.

3325 Section 24. Subsection (1) of section 499.033, Florida  
3326 Statutes, is amended to read:

3327 499.033 Ephedrine; prescription required.--Ephedrine is  
3328 declared to be a prescription drug.

3329 (1) Except as provided in subsection (2), any product that  
3330 contains any quantity of ephedrine, a salt of ephedrine, an  
3331 optical isomer of ephedrine, or a salt of an optical isomer of  
3332 ephedrine may be dispensed only upon the prescription of a duly



836536

3333 licensed practitioner authorized by the laws of the state to  
3334 prescribe prescription ~~medicinal~~ drugs.

3335 Section 25. Subsections (1) and (3) of section 499.039,  
3336 Florida Statutes, are amended to read:

3337 499.039 Sale, distribution, or transfer of harmful chemical  
3338 substances; penalties; authority for enforcement.--It is unlawful  
3339 for a person to sell, deliver, or give to a person under the age  
3340 of 18 years any compound, liquid, or chemical containing toluol,  
3341 hexane, trichloroethylene, acetone, toluene, ethyl acetate,  
3342 methyl ethyl ketone, trichloroethane, isopropanol, methyl  
3343 isobutyl ketone, ethylene glycol monomethyl ether acetate,  
3344 cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites  
3345 (butyl nitrite), or any similar substance for the purpose of  
3346 inducing by breathing, inhaling, or ingesting a condition of  
3347 intoxication or which is intended to distort or disturb the  
3348 auditory, visual, or other physical or mental processes.

3349 (1) On the first violation of this section, the department  
3350 may issue a warning according to s. 499.002(5) ~~s. 499.071~~, if the  
3351 violation has not caused temporary or permanent physical or  
3352 mental injury to the user.

3353 (3) The department ~~of Health~~ shall adopt rules to implement  
3354 this section.

3355 Section 26. Section 499.04, Florida Statutes, is amended to  
3356 read:

3357 499.04 Fee authority.--The department may collect fees for  
3358 all drug, device, and cosmetic applications, permits, product  
3359 registrations, and free-sale certificates. The total amount of  
3360 fees collected from all permits, applications, product  
3361 registrations, and free-sale certificates must be adequate to  
3362 fund the expenses incurred by the department in carrying out this



836536

3363 part ss. 499.001-499.081. The department shall, by rule,  
3364 establish a schedule of fees that are within the ranges provided  
3365 in this section and shall adjust those fees from time to time  
3366 based on the costs associated with administering this part ss.  
3367 ~~499.001-499.081~~. The fees are payable to the department to be  
3368 deposited into the Florida Drug, Device, and Cosmetic Trust Fund  
3369 for the sole purpose of carrying out the provisions of this part  
3370 ~~ss. 499.001-499.081~~.

3371 Section 27. Subsections (1) through (5), (8), and (10) of  
3372 section 499.041, Florida Statutes, are amended to read:

3373 499.041 Schedule of fees for drug, device, and cosmetic  
3374 applications and permits, product registrations, and free-sale  
3375 certificates.--

3376 (1) The department shall assess applicants requiring a  
3377 manufacturing permit an annual fee within the ranges established  
3378 in this section for the specific type of manufacturer.

3379 (a) The fee for a prescription drug manufacturer  
3380 ~~manufacturer's~~ permit may not be less than \$500 or more than \$750  
3381 annually.

3382 (b) The fee for a device manufacturer ~~manufacturer's~~ permit  
3383 may not be less than \$500 or more than \$600 annually.

3384 (c) The fee for a cosmetic manufacturer ~~manufacturer's~~  
3385 permit may not be less than \$250 or more than \$400 annually.

3386 (d) The fee for an over-the-counter drug manufacturer  
3387 ~~manufacturer's~~ permit may not be less than \$300 or more than \$400  
3388 annually.

3389 (e) The fee for a compressed medical gas manufacturer  
3390 ~~manufacturer's~~ permit may not be less than \$400 or more than \$500  
3391 annually.



836536

3392 (f) The fee for a prescription drug repackager ~~repackager's~~  
3393 permit may not be less than \$500 or more than \$750 annually.

3394 (g) A manufacturer may not be required to pay more than one  
3395 fee per establishment to obtain an additional manufacturing  
3396 permit, but each manufacturer must pay the highest fee applicable  
3397 to his or her operation in each establishment.

3398 (2) The department shall assess an applicant that is  
3399 required to have a wholesaling permit an annual fee within the  
3400 ranges established in this section for the specific type of  
3401 wholesaling.

3402 (a) The fee for a prescription drug wholesale distributor  
3403 ~~wholesaler's~~ permit may not be less than \$300 or more than \$800  
3404 annually.

3405 (b) The fee for a compressed medical gas wholesale  
3406 distributor ~~wholesaler's~~ permit may not be less than \$200 or more  
3407 than \$300 annually.

3408 (c) The fee for an out-of-state prescription drug wholesale  
3409 distributor ~~wholesaler's~~ permit may not be less than \$300 or more  
3410 than \$800 annually.

3411 (d) The fee for a nonresident prescription drug  
3412 manufacturer ~~manufacturer's~~ permit may not be less than \$300 or  
3413 more than \$500 annually.

3414 (e) The fee for a retail pharmacy drug wholesale  
3415 distributor ~~wholesaler's~~ permit may not be less than \$35 or more  
3416 than \$50 annually.

3417 (f) The fee for a freight forwarder ~~forwarder's~~ permit may  
3418 not be less than \$200 or more than \$300 annually.

3419 (g) The fee for a veterinary prescription drug wholesale  
3420 distributor ~~wholesaler's~~ permit may not be less than \$300 or more  
3421 than \$500 annually.



836536

3422 (h) The fee for a limited prescription drug veterinary  
3423 wholesale distributor ~~wholesaler's~~ permit may not be less than  
3424 \$300 or more than \$500 annually.

3425 (i) The fee for a third part logistics provider permit may  
3426 not be less than \$200 or more than \$300 annually.

3427 (3) The department shall assess an applicant that is  
3428 required to have a retail establishment permit an annual fee  
3429 within the ranges established in this section for the specific  
3430 type of retail establishment.

3431 (a) The fee for a veterinary prescription ~~legend~~ drug  
3432 retail establishment permit may not be less than \$200 or more  
3433 than \$300 annually.

3434 (b) The fee for a medical oxygen retail establishment  
3435 permit may not be less than \$200 or more than \$300 annually.

3436 (c) The fee for a health care clinic establishment permit  
3437 may not be less than \$125 or more than \$250 annually.

3438 (4) The department shall assess an applicant that is  
3439 required to have a restricted prescription drug distributor  
3440 ~~distributor's~~ permit an annual fee of not less than \$200 or more  
3441 than \$300.

3442 (5) In addition to the fee charged for a permit required by  
3443 this part ss. 499.001-499.081, the department shall assess  
3444 applicants an initial application fee of \$150 for each new permit  
3445 issued by the department which requires an onsite inspection.

3446 (8) The department shall assess an out-of-state  
3447 prescription drug wholesale distributor ~~wholesaler~~ applicant or  
3448 permittee an onsite inspection fee of not less than \$1,000 or  
3449 more than \$3,000 annually, to be based on the actual cost of the  
3450 inspection if an onsite inspection is performed by agents of the  
3451 department.



836536

3452 (10) The department shall assess other fees as provided in  
3453 this part ss. 499.001-499.081.

3454 Section 28. Section 499.05, Florida Statutes, is amended;  
3455 subsection (3) of section 499.013, Florida Statutes, is  
3456 redesignated as paragraph (k) of subsection (1) of that section  
3457 and amended; paragraph (b) of subsection (2) of section 499.0122,  
3458 Florida Statutes, is redesignated as paragraph (l) of subsection  
3459 (1) of that section and amended; and subsection (12) of section  
3460 499.012, Florida Statutes, is redesignated as paragraph (m) of  
3461 subsection (1) of that section and amended, to read:

3462 499.05 Rules.--

3463 (1) The department shall adopt rules to implement and  
3464 enforce this part ss. 499.001-499.081 with respect to:

3465 (a) The definition of terms used in this part ss. 499.001-  
3466 499.081, and used in the rules adopted under this part ss.  
3467 499.001-499.081, when the use of the term is not its usual and  
3468 ordinary meaning.

3469 (b) Labeling requirements for drugs, devices, and  
3470 cosmetics.

3471 (c) The establishment of fees authorized in this part ss.  
3472 499.001-499.081.

3473 (d) The identification of permits that require an initial  
3474 application and onsite inspection or other prerequisites for  
3475 permitting which demonstrate that the establishment and person  
3476 are in compliance with the requirements of this part ss. 499.001-  
3477 499.081.

3478 (e) The application processes and forms for product  
3479 registration.

3480 (f) Procedures for requesting and issuing certificates of  
3481 free sale.



836536

3482 (g) Inspections and investigations conducted under s.  
3483 499.051, and the identification of information claimed to be a  
3484 trade secret and exempt from the public records law as provided  
3485 in s. 499.051(7).

3486 (h) The establishment of a range of penalties, as provided  
3487 in s. 499.066 ~~s. 499.006~~; requirements for notifying persons of  
3488 the potential impact of a violation of this part ~~ss. 499.001-~~  
3489 ~~499.001~~; and a process for the uncontested settlement of alleged  
3490 violations.

3491 (i) Additional conditions that qualify as an emergency  
3492 medical reason under s. 499.003(53)(b)2. ~~s. 499.012(1)(a)2.b.~~

3493 (j) Procedures and forms relating to the pedigree paper  
3494 requirement of s. 499.01212.

3495 ~~(k)(3) The department may adopt such rules as are necessary~~  
3496 ~~for~~ The protection of the public health, safety, and welfare  
3497 regarding good manufacturing practices that manufacturers and  
3498 repackagers must follow to ensure the safety of the products.

3499 ~~(l)(b) The department shall adopt rules relating to~~  
3500 Information required from each retail establishment pursuant to  
3501 s. 499.012(3) ~~s. 499.01(4)~~, including requirements for  
3502 prescriptions or orders.

3503 ~~(m)(12) The department may adopt rules governing~~ The  
3504 recordkeeping, storage, and handling with respect to each of the  
3505 distributions of prescription drugs specified in s.  
3506 499.003(53)(a)-(d) subparagraphs (1)(a)1-4.

3507 (n) Alternatives to compliance with s. 499.01212 for a  
3508 prescription drug in the inventory of a permitted prescription  
3509 drug wholesale distributor as of June 30, 2006, and the return of  
3510 a prescription drug purchased prior to July 1, 2006. The  
3511 department may specify time limits for such alternatives.



836536

3512 (2) With respect to products in interstate commerce, those  
3513 rules must not be inconsistent with rules and regulations of  
3514 federal agencies unless specifically otherwise directed by the  
3515 Legislature.

3516 (3) The department shall adopt rules regulating  
3517 recordkeeping for and the storage, handling, and distribution of  
3518 medical devices and over-the-counter drugs to protect the public  
3519 from adulterated products.

3520 Section 29. Section 499.051, Florida Statutes, is amended  
3521 to read:

3522 499.051 Inspections and investigations.--

3523 (1) The agents of the department ~~of Health~~ and of the  
3524 Department of Law Enforcement, after they present proper  
3525 identification, may inspect, monitor, and investigate any  
3526 establishment permitted pursuant to this part ~~ss. 499.001-499.081~~  
3527 during business hours for the purpose of enforcing this part ~~ss.~~  
3528 ~~499.001-499.081~~, chapters 465, 501, and 893, and the rules of the  
3529 department that protect the public health, safety, and welfare.

3530 (2) In addition to the authority set forth in subsection  
3531 (1), the department and any duly designated officer or employee  
3532 of the department may enter and inspect any other establishment  
3533 for the purpose of determining compliance with this part ~~ss.~~  
3534 ~~499.001-499.081~~ and rules adopted under this part ~~those sections~~  
3535 regarding any drug, device, or cosmetic product.

3536 (3) Any application for a permit or product registration or  
3537 for renewal of such permit or registration made pursuant to this  
3538 part ~~ss. 499.001-499.081~~ and rules adopted under this part ~~those~~  
3539 ~~sections~~ constitutes permission for any entry or inspection of  
3540 the premises in order to verify compliance with this part ~~those~~  
3541 ~~sections~~ and rules; to discover, investigate, and determine the





836536

3542 | existence of compliance; or to elicit, receive, respond to, and  
3543 | resolve complaints and violations.

3544 |       (4) Any application for a permit made pursuant to s.  
3545 | 499.012 ~~ss. 499.01 and 499.012~~ and rules adopted under that  
3546 | section ~~those sections~~ constitutes permission for agents of the  
3547 | department ~~of Health~~ and the Department of Law Enforcement, after  
3548 | presenting proper identification, to inspect, review, and copy  
3549 | any financial document or record related to the manufacture,  
3550 | repackaging, or distribution of a drug as is necessary to verify  
3551 | compliance with this part ~~ss. 499.001-499.081~~ and the rules  
3552 | adopted by the department to administer this part ~~those sections~~,  
3553 | in order to discover, investigate, and determine the existence of  
3554 | compliance, or to elicit, receive, respond to, and resolve  
3555 | complaints and violations.

3556 |       (5) The authority to inspect under this section includes  
3557 | the authority to access, review, and copy any and all financial  
3558 | documents related to the activity of manufacturing, repackaging,  
3559 | or distributing prescription drugs.

3560 |       (6) The authority to inspect under this section includes  
3561 | the authority to secure:

3562 |       (a) Samples or specimens of any drug, device, or cosmetic;  
3563 | or

3564 |       (b) Such other evidence as is needed for any action to  
3565 | enforce this part ~~ss. 499.001-499.081~~ and the rules adopted under  
3566 | this part ~~those sections~~.

3567 |       (7) The complaint and all information obtained pursuant to  
3568 | the investigation by the department are confidential and exempt  
3569 | from the provisions of s. 119.07(1) and s. 24(a), Art. I of the  
3570 | State Constitution until the investigation and the enforcement  
3571 | action are completed. However, trade secret information contained



836536

3572 therein as defined by s. 812.081(1)(c) shall remain confidential  
3573 and exempt from the provisions of s. 119.07(1) and s. 24(a), Art.  
3574 I of the State Constitution, as long as the information is  
3575 retained by the department. This subsection does not prohibit the  
3576 department from using such information for regulatory or  
3577 enforcement proceedings under this chapter or from providing such  
3578 information to any law enforcement agency or any other regulatory  
3579 agency. However, the receiving agency shall keep such records  
3580 confidential and exempt as provided in this subsection. In  
3581 addition, this subsection is not intended to prevent compliance  
3582 with the provisions of s. 499.01212 ~~s. 499.0121(6)(d)~~, and the  
3583 pedigree papers required in that section ~~subsection~~ shall not be  
3584 deemed a trade secret.

3585 Section 30. Section 499.052, Florida Statutes, is amended  
3586 to read:

3587 499.052 Records of interstate shipment.--For the purpose of  
3588 enforcing this part ~~ss. 499.001-499.081~~, carriers engaged in  
3589 interstate commerce and persons receiving drugs, devices, or  
3590 cosmetics in interstate commerce must, upon the request, in the  
3591 manner set out below, by an officer or employee duly designated  
3592 by the department, permit the officer or employee to have access  
3593 to and to copy all records showing the movement in interstate  
3594 commerce of any drug, device, or cosmetic, and the quantity,  
3595 shipper, and consignee thereof.

3596 Section 31. Subsection (4) of section 499.055, Florida  
3597 Statutes, is amended to read:

3598 499.055 Reports and dissemination of information by  
3599 department.--

3600 (4) The department shall publish on the department's  
3601 website and update at least monthly:



836536

3602 (a) A list of the prescription drug wholesale distributors  
3603 ~~wholesalers~~, out-of-state prescription drug wholesale  
3604 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
3605 distributors ~~wholesalers~~ against whom the department has  
3606 initiated enforcement action pursuant to this part ~~ss. 499.001-~~  
3607 ~~499.081~~ to suspend or revoke a permit, seek an injunction, or  
3608 otherwise file an administrative complaint and the permit number  
3609 of each such wholesale distributor ~~wholesaler~~.

3610 (b) A list of the prescription drug wholesale distributors  
3611 ~~wholesalers~~, out-of-state prescription drug wholesale  
3612 distributors ~~wholesalers~~, and retail pharmacy drug wholesale  
3613 distributors ~~wholesalers~~ to which the department has issued a  
3614 permit, including the date on which each permit will expire.

3615 (c) A list of the prescription drug wholesale distributor  
3616 ~~wholesalers~~, out-of-state prescription drug wholesale distributor  
3617 ~~wholesalers~~, and retail pharmacy drug wholesale distributor  
3618 ~~wholesalers~~' permits that have been returned to the department,  
3619 were suspended, were revoked, have expired, or were not renewed  
3620 in the previous year.

3621 Section 32. Subsections (1) and (3) of section 499.06,  
3622 Florida Statutes, are amended to read:

3623 499.06 Embargoing, detaining, or destroying article or  
3624 processing equipment which is in violation of law or rule.--

3625 (1) When a duly authorized agent of the department finds,  
3626 or has probable cause to believe, that any drug, device, or  
3627 cosmetic is in violation of any provision of this part ~~ss.~~  
3628 ~~499.001-499.081~~ or any rule adopted under this part ~~such sections~~  
3629 so as to be dangerous, unwholesome, or fraudulent within the  
3630 meaning of this part ~~ss. 499.001-499.081~~, she or he may issue and  
3631 enforce a stop-sale, stop-use, removal, or hold order, which



836536

3632 | order gives notice that such article or processing equipment is,  
3633 | or is suspected of being, in violation and has been detained or  
3634 | embargoed, and which order warns all persons not to remove, use,  
3635 | or dispose of such article or processing equipment by sale or  
3636 | otherwise until permission for removal, use, or disposal is given  
3637 | by such agent or the court. It is unlawful for any person to  
3638 | remove, use, or dispose of such detained or embargoed article or  
3639 | processing equipment by sale or otherwise without such  
3640 | permission; and such act is a felony of the second degree,  
3641 | punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3642 |         (3) If the court finds that the detained or embargoed  
3643 | article or processing equipment is in violation, such article or  
3644 | processing equipment shall, after entry of the court order, be  
3645 | destroyed or made sanitary at the expense of the claimant  
3646 | thereof, under the supervision of such agent; and all court  
3647 | costs, fees, and storage and other proper expenses shall be taxed  
3648 | against the claimant of such article or processing equipment or  
3649 | her or his agent. However, when the violation can be corrected by  
3650 | proper labeling of the article or sanitizing of the processing  
3651 | equipment, and after such costs, fees, and expenses have been  
3652 | paid and a good and sufficient bond, conditioned that such  
3653 | article be so labeled or processed or such processing equipment  
3654 | be so sanitized, has been executed, the court may by order direct  
3655 | that such article or processing equipment be delivered to the  
3656 | claimant thereof for such labeling, processing, or sanitizing,  
3657 | under the supervision of an agent of the department. The expense  
3658 | of such supervision shall be paid by the claimant. Such bond  
3659 | shall be returned to the claimant of the article or processing  
3660 | equipment upon representation to the court by the department that  
3661 | the article or processing equipment is no longer in violation of



836536

3662 this part ss. ~~499.001-499.081~~ and that the expenses of such  
3663 supervision have been paid.

3664 Section 33. Section 499.062, Florida Statutes, is amended;  
3665 section 499.063, Florida Statutes, is redesignated as section (2)  
3666 of that section and amended; and section 499.064, Florida  
3667 Statutes, is redesignated as paragraphs (a) and (b) of subsection  
3668 (2) of that section and amended, to read:

3669 499.062 ~~Cause for~~ Seizure and condemnation of drugs,  
3670 devices, or cosmetics.--

3671 (1) Any article of any drug, device, or cosmetic that is  
3672 adulterated or misbranded under this part ss. ~~499.001-499.081~~ is  
3673 subject to seizure and condemnation by the department or by its  
3674 duly authorized agents designated for that purpose in regard to  
3675 drugs, devices, or cosmetics.

3676 (2) ~~499.063 Seizure; procedure; prohibition on sale or~~  
3677 ~~disposal of article; penalty.--~~Whenever a duly authorized officer  
3678 or employee of the department finds cause, or has probable cause  
3679 to believe that cause exists, for the seizure of any drug,  
3680 device, or cosmetic, as set out in this part ss. ~~499.001-499.081~~,  
3681 he or she shall affix to the article a tag, stamp, or other  
3682 appropriate marking, giving notice that the article is, or is  
3683 suspected of being, subject to seizure under this part ss.  
3684 ~~499.001-499.081~~ and that the article has been detained and seized  
3685 by the department. Such officer or employee shall also warn all  
3686 persons not to remove or dispose of the article, by sale or  
3687 otherwise, until permission is given by the department or the  
3688 court. Any person who violates this subsection ~~section~~ is guilty  
3689 of a felony of the second degree, punishable as provided in s.  
3690 775.082, s. 775.083, or s. 775.084.



836536

3691            ~~(a) 499.064~~ ~~Condemnation and sale; release of seized~~  
3692 ~~article.~~ ~~(1)~~ When any article detained or seized under this  
3693 subsection ~~s. 499.063~~ has been found by the department to be  
3694 subject to seizure and condemnation ~~under s. 499.063~~, the  
3695 department shall petition the court for an order of condemnation  
3696 or sale, as the court directs. The proceeds of the sale of drugs,  
3697 devices, and cosmetics, less the legal costs and charges, shall  
3698 be deposited into the Florida Drug, Device, and Cosmetic Trust  
3699 Fund.

3700            ~~(b) (2)~~ If the department finds that any article seized  
3701 under this subsection ~~s. 499.063~~ was not subject to seizure ~~under~~  
3702 ~~that section~~, the department or the designated officer or  
3703 employee shall remove the tag or marking.

3704            Section 34. Section 499.065, Florida Statutes, is amended  
3705 to read:

3706            499.065 Inspections; imminent danger.--

3707            (1) Notwithstanding s. 499.051, the department shall  
3708 inspect each prescription drug wholesale distributor  
3709 establishment, prescription drug repackager establishment,  
3710 veterinary prescription drug wholesale distributor establishment,  
3711 limited prescription drug veterinary wholesale distributor  
3712 ~~wholesaler~~ establishment, and retail pharmacy drug wholesale  
3713 distributor ~~wholesaler~~ establishment that is required to be  
3714 permitted under this part ~~chapter~~ as often as necessary to ensure  
3715 compliance with applicable laws and rules. The department shall  
3716 have the right of entry and access to these facilities at any  
3717 reasonable time.

3718            (2) To protect the public from prescription drugs that are  
3719 adulterated or otherwise unfit for human or animal consumption,  
3720 the department may examine, sample, seize, and stop the sale or



836536

3721 use of prescription drugs to determine the condition of those  
3722 drugs. The department may immediately seize and remove any  
3723 prescription drugs if the State Surgeon General or his or her  
3724 designee determines that the prescription drugs represent a  
3725 threat to the public health. The owner of any property seized  
3726 under this section may, within 10 days after the seizure, apply  
3727 to a court of competent jurisdiction for whatever relief is  
3728 appropriate. At any time after 10 days, the department may  
3729 destroy the drugs as contraband.

3730 (3) The department may determine that a prescription drug  
3731 wholesale distributor establishment, prescription drug repackager  
3732 establishment, veterinary prescription drug wholesale distributor  
3733 establishment, limited prescription drug veterinary wholesale  
3734 distributor ~~wholesaler~~ establishment, or retail pharmacy drug  
3735 wholesale distributor ~~wholesaler~~ establishment that is required  
3736 to be permitted under this part ~~chapter~~ is an imminent danger to  
3737 the public health and shall require its immediate closure if the  
3738 establishment fails to comply with applicable laws and rules and,  
3739 because of the failure, presents an imminent threat to the  
3740 public's health, safety, or welfare. Any establishment so deemed  
3741 and closed shall remain closed until allowed by the department or  
3742 by judicial order to reopen.

3743 (4) For purposes of this section, a refusal to allow entry  
3744 to the department for inspection at reasonable times, or a  
3745 failure or refusal to provide the department with required  
3746 documentation for purposes of inspection, constitutes an imminent  
3747 danger to the public health.

3748 Section 35. Subsections (1) through (4) of section 499.066,  
3749 Florida Statutes, are amended to read:



836536

3750 499.066 Penalties; remedies.--In addition to other  
3751 penalties and other enforcement provisions:

3752 (1) The department may institute such suits or other legal  
3753 proceedings as are required to enforce any provision of this part  
3754 ~~ss. 499.001-499.081~~. If it appears that a person has violated any  
3755 provision of this part ~~ss. 499.001-499.081~~ for which criminal  
3756 prosecution is provided, the department may provide the  
3757 appropriate state attorney or other prosecuting agency having  
3758 jurisdiction with respect to such prosecution with the relevant  
3759 information in the department's possession.

3760 (2) If any person engaged in any activity covered by this  
3761 part ~~ss. 499.001-499.081~~ violates any provision of this part  
3762 ~~those sections~~, any rule adopted under this part ~~those sections~~,  
3763 or a cease and desist order as provided by this part ~~those~~  
3764 ~~sections~~, the department may obtain an injunction in the circuit  
3765 court of the county in which the violation occurred or in which  
3766 the person resides or has its principal place of business, and  
3767 may apply in that court for such temporary and permanent orders  
3768 as the department considers necessary to restrain the person from  
3769 engaging in any such activities until the person complies with  
3770 this part ~~ss. 499.001-499.081~~, the rules adopted under this part  
3771 ~~those sections~~, and the orders of the department authorized by  
3772 this part ~~those sections~~ or to mandate compliance with this part  
3773 ~~ss. 499.001-499.081~~, the rules adopted under this part ~~those~~  
3774 ~~sections~~, and any order or permit issued by the department under  
3775 this part ~~those sections~~.

3776 (3) The department may impose an administrative fine, not  
3777 to exceed \$5,000 per violation per day, for the violation of any  
3778 provision of this part ~~ss. 499.001-499.081~~ or rules adopted under  
3779 this part ~~those sections~~. Each day a violation continues





836536

3780 | constitutes a separate violation, and each separate violation is  
3781 | subject to a separate fine. All amounts collected pursuant to  
3782 | this section shall be deposited into the Florida Drug, Device,  
3783 | and Cosmetic Trust Fund and are appropriated for the use of the  
3784 | department in administering this part ~~ss. 499.001-499.081~~. In  
3785 | determining the amount of the fine to be levied for a violation,  
3786 | the department shall consider:

3787 |       (a) The severity of the violation;

3788 |       (b) Any actions taken by the person to correct the  
3789 | violation or to remedy complaints; and

3790 |       (c) Any previous violations.

3791 |       (4) The department shall deposit any rewards, fines, or  
3792 | collections that are due the department and which derive from  
3793 | joint enforcement activities with other state and federal  
3794 | agencies which relate to this part ~~ss. 499.001-499.081~~, chapter  
3795 | 893, or the federal act, into the Florida Drug, Device, and  
3796 | Cosmetic Trust Fund. The proceeds of those rewards, fines, and  
3797 | collections are appropriated for the use of the department in  
3798 | administering this part ~~ss. 499.001-499.081~~.

3799 |       Section 36. Section 499.0661, Florida Statutes, is amended  
3800 | to read:

3801 |       499.0661 Cease and desist orders; removal of certain  
3802 | persons.--

3803 |       (1)~~(2)~~ CEASE AND DESIST ORDERS.--

3804 |       (a) In addition to any authority otherwise provided in this  
3805 | chapter, the department may issue and serve a complaint stating  
3806 | charges upon any permittee or upon any affiliated party, whenever  
3807 | the department has reasonable cause to believe that the person or  
3808 | individual named therein is engaging in or has engaged in conduct  
3809 | that is:



836536

3810 | 1. An act that demonstrates a lack of fitness or  
3811 | trustworthiness to engage in the business authorized under the  
3812 | permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
3813 | hazardous to the public health, or constitutes business  
3814 | operations that are a detriment to the public health;

3815 | 2. A violation of any provision of this part ~~ss. 499.001-~~  
3816 | ~~499.081~~;

3817 | 3. A violation of any rule of the department;

3818 | 4. A violation of any order of the department; or

3819 | 5. A breach of any written agreement with the department.

3820 | (b) The complaint must contain a statement of facts and  
3821 | notice of opportunity for a hearing pursuant to ss. 120.569 and  
3822 | 120.57.

3823 | (c) If a hearing is not requested within the time allowed  
3824 | by ss. 120.569 and 120.57, or if a hearing is held and the  
3825 | department finds that any of the charges are proven, the  
3826 | department may enter an order directing the permittee or the  
3827 | affiliated party named in the complaint to cease and desist from  
3828 | engaging in the conduct complained of and take corrective action  
3829 | to remedy the effects of past improper conduct and assure future  
3830 | compliance.

3831 | (d) A contested or default cease and desist order is  
3832 | effective when reduced to writing and served upon the permittee  
3833 | or affiliated party named therein. An uncontested cease and  
3834 | desist order is effective as agreed.

3835 | (e) Whenever the department finds that conduct described in  
3836 | paragraph (a) is likely to cause an immediate threat to the  
3837 | public health, it may issue an emergency cease and desist order  
3838 | requiring the permittee or any affiliated party to immediately  
3839 | cease and desist from engaging in the conduct complained of and



836536

3840 to take corrective and remedial action. The emergency order is  
3841 effective immediately upon service of a copy of the order upon  
3842 the permittee or affiliated party named therein and remains  
3843 effective for 90 days. If the department begins nonemergency  
3844 cease and desist proceedings under this subsection, the emergency  
3845 order remains effective until the conclusion of the proceedings  
3846 under ss. 120.569 and 120.57.

3847 (2)~~(3)~~ REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

3848 (a) The department may issue and serve a complaint stating  
3849 charges upon any affiliated party and upon the permittee involved  
3850 whenever the department has reason to believe that an affiliated  
3851 party is engaging in or has engaged in conduct that constitutes:

3852 1. An act that demonstrates a lack of fitness or  
3853 trustworthiness to engage in the business authorized under the  
3854 permit issued pursuant to this part ~~ss. 499.001-499.081~~, is  
3855 hazardous to the public health, or constitutes business  
3856 operations that are a detriment to the public health;

3857 2. A willful violation of this part ~~ss. 499.001-499.081~~;  
3858 however, if the violation constitutes a misdemeanor, a complaint  
3859 may not be served as provided in this section until the  
3860 affiliated party is notified in writing of the matter of the  
3861 violation and has been afforded a reasonable period of time, as  
3862 set forth in the notice, to correct the violation and has failed  
3863 to do so;

3864 3. A violation of any other law involving fraud or moral  
3865 turpitude which constitutes a felony;

3866 4. A willful violation of any rule of the department;

3867 5. A willful violation of any order of the department; or



836536

3868 |           6. A material misrepresentation of fact, made knowingly and  
3869 | willfully or made with reckless disregard for the truth of the  
3870 | matter.

3871 |           (b) The complaint must contain a statement of facts and  
3872 | notice of opportunity for a hearing pursuant to ss. 120.569 and  
3873 | 120.57.

3874 |           (c) If a hearing is not requested within the time allotted  
3875 | by ss. 120.569 and 120.57, or if a hearing is held and the  
3876 | department finds that any of the charges in the complaint are  
3877 | proven true, the department may enter an order removing the  
3878 | affiliated party or restricting or prohibiting participation by  
3879 | the person in the affairs of that permittee or of any other  
3880 | permittee.

3881 |           (d) A contested or default order of removal, restriction,  
3882 | or prohibition is effective when reduced to writing and served on  
3883 | the permittee and the affiliated party. An uncontested order of  
3884 | removal, restriction, or prohibition is effective as agreed.

3885 |           (e)1. The chief executive officer, designated  
3886 | representative, or the person holding the equivalent office, of a  
3887 | permittee shall promptly notify the department if she or he has  
3888 | actual knowledge that any affiliated party is charged with a  
3889 | felony in a state or federal court.

3890 |           2. Whenever any affiliated party is charged with a felony  
3891 | in a state or federal court or with the equivalent of a felony in  
3892 | the courts of any foreign country with which the United States  
3893 | maintains diplomatic relations, and the charge alleges violation  
3894 | of any law involving prescription drugs, pharmaceuticals, fraud,  
3895 | theft, or moral turpitude, the department may enter an emergency  
3896 | order suspending the affiliated party or restricting or  
3897 | prohibiting participation by the affiliated party in the affairs



836536

3898 | of the particular permittee or of any other permittee upon  
3899 | service of the order upon the permittee and the affiliated party  
3900 | charged. The order must contain notice of opportunity for a  
3901 | hearing pursuant to ss. 120.569 and 120.57, where the affiliated  
3902 | party may request a postsuspension hearing to show that continued  
3903 | service to or participation in the affairs of the permittee does  
3904 | not pose a threat to the public health or the interests of the  
3905 | permittee and does not threaten to impair public confidence in  
3906 | the permittee. In accordance with applicable departmental rules,  
3907 | the department shall notify the affiliated party whether the  
3908 | order suspending or prohibiting the person from participation in  
3909 | the affairs of a permittee will be rescinded or otherwise  
3910 | modified. The emergency order remains in effect, unless otherwise  
3911 | modified by the department, until the criminal charge is disposed  
3912 | of. The acquittal of the person charged, or the final, unappealed  
3913 | dismissal of all charges against the person, dissolves the  
3914 | emergency order but does not prohibit the department from  
3915 | instituting proceedings under paragraph (a). If the person  
3916 | charged is convicted or pleads guilty or nolo contendere, whether  
3917 | or not an adjudication of guilt is entered by the court, the  
3918 | emergency order shall become final.

3919 |       (f) Any affiliated party removed pursuant to this section  
3920 | is not eligible for reemployment by the permittee or to be an  
3921 | affiliated party of any permittee except upon the written consent  
3922 | of the department. Any affiliated party who is removed,  
3923 | restricted, or prohibited from participating in the affairs of a  
3924 | permittee pursuant to this section may petition the department  
3925 | for modification or termination of the removal, restriction, or  
3926 | prohibition.



836536

3927 Section 37. Section 499.067, Florida Statutes, is amended  
3928 to read:

3929 499.067 Denial, suspension, or revocation of permit,  
3930 certification, or registration.--

3931 (1)(a) The department may deny, suspend, or revoke a permit  
3932 if it finds that there has been a substantial failure to comply  
3933 with this part ~~ss. 499.001-499.081~~ or chapter 465, chapter 501,  
3934 or chapter 893, the rules adopted under this part ~~any of these~~  
3935 ~~sections~~ or those chapters, any final order of the department, or  
3936 applicable federal laws or regulations or other state laws or  
3937 rules governing drugs, devices, or cosmetics.

3938 (b) The department may deny an application for a permit or  
3939 certification, or suspend or revoke a permit or certification, if  
3940 the department finds that:

3941 1. The applicant is not of good moral character or that it  
3942 would be a danger or not in the best interest of the public  
3943 health, safety, and welfare if the applicant were issued a permit  
3944 or certification.

3945 2. The applicant has not met the requirements for the  
3946 permit or certification.

3947 3. The applicant is not eligible for a permit or  
3948 certification for any of the reasons enumerated in s. 499.012 ~~s.~~  
3949 ~~499.01~~ or ~~s. 499.012(5)~~.

3950 4. The applicant, permittee, or person certified under s.  
3951 499.012(16) ~~s. 499.012(11)~~ demonstrates any of the conditions  
3952 enumerated in s. 499.012 ~~s. 499.01~~ or ~~s. 499.012(5)~~.

3953 5. The applicant, permittee, or person certified under s.  
3954 499.012(16) ~~s. 499.012(11)~~ has committed any violation of ~~ss.~~  
3955 ~~499.005-499.0054~~.



836536

3956 (2) The department may deny, suspend, or revoke any  
3957 registration required by the provisions of this part ~~ss. 499.001-~~  
3958 ~~499.081~~ for the violation of any provision of this part ~~ss.~~  
3959 ~~499.001-499.081~~ or of any rules adopted under this part ~~these~~  
3960 ~~sections.~~

3961 (3) The department may revoke or suspend a permit:

3962 (a) If the permit was obtained by misrepresentation or  
3963 fraud or through a mistake of the department;

3964 (b) If the permit was procured, or attempted to be  
3965 procured, for any other person by making or causing to be made  
3966 any false representation; or

3967 (c) If the permittee has violated any provision of this  
3968 part ~~ss. 499.001-499.081~~ or rules adopted under this part ~~these~~  
3969 ~~sections.~~

3970 (4) If any permit issued under this part ~~ss. 499.001-~~  
3971 ~~499.081~~ is revoked or suspended, the owner, manager, operator, or  
3972 proprietor of the establishment shall cease to operate as the  
3973 permit authorized, from the effective date of the suspension or  
3974 revocation until the person is again registered with the  
3975 department and possesses the required permit. If a permit is  
3976 revoked or suspended, the owner, manager, or proprietor shall  
3977 remove all signs and symbols that identify the operation as  
3978 premises permitted as a drug wholesaling establishment; drug,  
3979 device, or cosmetic manufacturing establishment; or retail  
3980 establishment. The department shall determine the length of time  
3981 for which the permit is to be suspended. If a permit is revoked,  
3982 the person that owns or operates the establishment may not apply  
3983 for any permit under this part ~~ss. 499.001-499.081~~ for a period  
3984 of 1 year after the date of the revocation. A revocation of a



836536

3985 permit may be permanent if the department considers that to be in  
3986 the best interest of the public health.

3987 (5) The department may deny, suspend, or revoke a permit  
3988 issued under this part ~~ss. 499.001-499.081~~ which authorizes the  
3989 permittee to purchase prescription drugs, if any owner, officer,  
3990 employee, or other person who participates in administering or  
3991 operating the establishment has been found guilty of any  
3992 violation of this part ~~ss. 499.001-499.081~~ or chapter 465,  
3993 chapter 501, or chapter 893, any rules adopted under this part  
3994 ~~any of those sections~~ or those chapters, or any federal or state  
3995 drug law, regardless of whether the person has been pardoned, had  
3996 her or his civil rights restored, or had adjudication withheld.

3997 (6) The department shall deny, suspend, or revoke the  
3998 permit of any person or establishment if the assignment, sale,  
3999 transfer, or lease of an establishment permitted under this part  
4000 ~~ss. 499.001-499.081~~ will avoid an administrative penalty, civil  
4001 action, or criminal prosecution.

4002 (7) Notwithstanding s. 120.60(5), if a permittee fails to  
4003 comply with s. 499.012(6) ~~s. 499.01(7)~~, the department may revoke  
4004 the permit of the permittee and shall provide notice of the  
4005 intended agency action by posting a notice at the department's  
4006 headquarters and by mailing a copy of the notice of intended  
4007 agency action by certified mail to the most recent mailing  
4008 address on record with the department and, if the permittee is  
4009 not a natural person, to the permittee's registered agent on file  
4010 with the Department of State.

4011 Section 38. Paragraph (a) of subsection (1) of section  
4012 409.9201, Florida Statutes, is amended to read:

4013 409.9201 Medicaid fraud.--

4014 (1) As used in this section, the term:





836536

4015 (a) "Prescription Legend drug" means any drug, including,  
4016 but not limited to, finished dosage forms or active ingredients  
4017 that are subject to, defined by, or described by s. 503(b) of the  
4018 Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s.  
4019 499.007(13) ~~s. 499.007(12)~~, or s. 499.003(45) or (52) ~~s.~~  
4020 ~~499.0122(1)(b) or (c)~~.

4021  
4022 The value of individual items of the legend drugs or goods or  
4023 services involved in distinct transactions committed during a  
4024 single scheme or course of conduct, whether involving a single  
4025 person or several persons, may be aggregated when determining the  
4026 punishment for the offense.

4027 Section 39. Paragraph (c) of subsection (9) of section  
4028 460.403, Florida Statutes, is amended to read:

4029 460.403 Definitions.--As used in this chapter, the term:  
4030 (9)

4031 (c)1. Chiropractic physicians may adjust, manipulate, or  
4032 treat the human body by manual, mechanical, electrical, or  
4033 natural methods; by the use of physical means or physiotherapy,  
4034 including light, heat, water, or exercise; by the use of  
4035 acupuncture; or by the administration of foods, food  
4036 concentrates, food extracts, and items for which a prescription  
4037 is not required and may apply first aid and hygiene, but  
4038 chiropractic physicians are expressly prohibited from prescribing  
4039 or administering to any person any legend drug except as  
4040 authorized under subparagraph 2., from performing any surgery  
4041 except as stated herein, or from practicing obstetrics.

4042 2. Notwithstanding the prohibition against prescribing and  
4043 administering legend drugs under subparagraph 1. ~~7~~ or s.  
4044 499.01(2)(m) ~~s. 499.0122~~, pursuant to board rule chiropractic



836536

4045 physicians may order, store, and administer, for emergency  
4046 purposes only at the chiropractic physician's office or place of  
4047 business, prescription medical oxygen and may also order, store,  
4048 and administer the following topical anesthetics in aerosol form:

4049 a. Any solution consisting of 25 percent ethylchloride and  
4050 75 percent dichlorodifluoromethane.

4051 b. Any solution consisting of 15 percent  
4052 dichlorodifluoromethane and 85 percent  
4053 trichloromonofluoromethane.

4054  
4055 However, this paragraph does not authorize a chiropractic  
4056 physician to prescribe medical oxygen as defined in chapter 499.

4057 Section 40. Subsection (3) of section 465.0265, Florida  
4058 Statutes, is amended to read:

4059 465.0265 Centralized prescription filling.--

4060 (3) The filling, delivery, and return of a prescription by  
4061 one pharmacy for another pursuant to this section shall not be  
4062 construed as the filling of a transferred prescription as set  
4063 forth in s. 465.026 or as a wholesale distribution as set forth  
4064 in s. 499.003(53) ~~s. 499.012(1)(a)~~.

4065 Section 41. Section 794.075, Florida Statutes, is amended  
4066 to read:

4067 794.075 Sexual predators; erectile dysfunction drugs.--

4068 (1) A person may not possess a prescription drug, as  
4069 defined in s. 499.003(42) ~~s. 499.003(25)~~, for the purpose of  
4070 treating erectile dysfunction if the person is designated as a  
4071 sexual predator under s. 775.21.

4072 (2) A person who violates a provision of this section for  
4073 the first time commits a misdemeanor of the second degree,  
4074 punishable as provided in s. 775.082 or s. 775.083. A person who



836536

4075 violates a provision of this section a second or subsequent time  
4076 commits a misdemeanor of the first degree, punishable as provided  
4077 in s. 775.082 or s. 775.083.

4078 Section 42. Paragraph (a) of subsection (1) of section  
4079 895.02, Florida Statutes, is amended to read:

4080 895.02 Definitions.--As used in ss. 895.01-895.08, the  
4081 term:

4082 (1) "Racketeering activity" means to commit, to attempt to  
4083 commit, to conspire to commit, or to solicit, coerce, or  
4084 intimidate another person to commit:

4085 (a) Any crime that is chargeable by indictment or  
4086 information under the following provisions of the Florida  
4087 Statutes:

4088 1. Section 210.18, relating to evasion of payment of  
4089 cigarette taxes.

4090 2. Section 403.727(3)(b), relating to environmental  
4091 control.

4092 3. Section 409.920 or s. 409.9201, relating to Medicaid  
4093 fraud.

4094 4. Section 414.39, relating to public assistance fraud.

4095 5. Section 440.105 or s. 440.106, relating to workers'  
4096 compensation.

4097 6. Section 443.071(4), relating to creation of a fictitious  
4098 employer scheme to commit unemployment compensation fraud.

4099 7. Section 465.0161, relating to distribution of medicinal  
4100 drugs without a permit as an Internet pharmacy.

4101 8. Section 499.0051 ~~Sections 499.0051, 499.0052, 499.00535,~~  
4102 ~~499.00545, and 499.0691,~~ relating to crimes involving contraband  
4103 and adulterated drugs.

4104 9. Part IV of chapter 501, relating to telemarketing.



836536

- 4105 | 10. Chapter 517, relating to sale of securities and  
4106 | investor protection.
- 4107 | 11. Section 550.235, s. 550.3551, or s. 550.3605, relating  
4108 | to dogracing and horseracing.
- 4109 | 12. Chapter 550, relating to jai alai frontons.
- 4110 | 13. Section 551.109, relating to slot machine gaming.
- 4111 | 14. Chapter 552, relating to the manufacture, distribution,  
4112 | and use of explosives.
- 4113 | 15. Chapter 560, relating to money transmitters, if the  
4114 | violation is punishable as a felony.
- 4115 | 16. Chapter 562, relating to beverage law enforcement.
- 4116 | 17. Section 624.401, relating to transacting insurance  
4117 | without a certificate of authority, s. 624.437(4)(c)1., relating  
4118 | to operating an unauthorized multiple-employer welfare  
4119 | arrangement, or s. 626.902(1)(b), relating to representing or  
4120 | aiding an unauthorized insurer.
- 4121 | 18. Section 655.50, relating to reports of currency  
4122 | transactions, when such violation is punishable as a felony.
- 4123 | 19. Chapter 687, relating to interest and usurious  
4124 | practices.
- 4125 | 20. Section 721.08, s. 721.09, or s. 721.13, relating to  
4126 | real estate timeshare plans.
- 4127 | 21. Chapter 782, relating to homicide.
- 4128 | 22. Chapter 784, relating to assault and battery.
- 4129 | 23. Chapter 787, relating to kidnapping or human  
4130 | trafficking.
- 4131 | 24. Chapter 790, relating to weapons and firearms.
- 4132 | 25. Section 796.03, s. 796.035, s. 796.04, s. 796.045, s.  
4133 | 796.05, or s. 796.07, relating to prostitution and sex  
4134 | trafficking.



836536

- 4135 |           26. Chapter 806, relating to arson.
- 4136 |           27. Section 810.02(2)(c), relating to specified burglary of
- 4137 | a dwelling or structure.
- 4138 |           28. Chapter 812, relating to theft, robbery, and related
- 4139 | crimes.
- 4140 |           29. Chapter 815, relating to computer-related crimes.
- 4141 |           30. Chapter 817, relating to fraudulent practices, false
- 4142 | pretenses, fraud generally, and credit card crimes.
- 4143 |           31. Chapter 825, relating to abuse, neglect, or
- 4144 | exploitation of an elderly person or disabled adult.
- 4145 |           32. Section 827.071, relating to commercial sexual
- 4146 | exploitation of children.
- 4147 |           33. Chapter 831, relating to forgery and counterfeiting.
- 4148 |           34. Chapter 832, relating to issuance of worthless checks
- 4149 | and drafts.
- 4150 |           35. Section 836.05, relating to extortion.
- 4151 |           36. Chapter 837, relating to perjury.
- 4152 |           37. Chapter 838, relating to bribery and misuse of public
- 4153 | office.
- 4154 |           38. Chapter 843, relating to obstruction of justice.
- 4155 |           39. Section 847.011, s. 847.012, s. 847.013, s. 847.06, or
- 4156 | s. 847.07, relating to obscene literature and profanity.
- 4157 |           40. Section 849.09, s. 849.14, s. 849.15, s. 849.23, or s.
- 4158 | 849.25, relating to gambling.
- 4159 |           41. Chapter 874, relating to criminal street gangs.
- 4160 |           42. Chapter 893, relating to drug abuse prevention and
- 4161 | control.
- 4162 |           43. Chapter 896, relating to offenses related to financial
- 4163 | transactions.



836536

4164 44. Sections 914.22 and 914.23, relating to tampering with  
4165 a witness, victim, or informant, and retaliation against a  
4166 witness, victim, or informant.

4167 45. Sections 918.12 and 918.13, relating to tampering with  
4168 jurors and evidence.

4169 Section 43. Paragraphs (d), (f), (h), (i), and (j) of  
4170 subsection (3) of section 921.0022, Florida Statutes, are amended  
4171 to read:

4172 921.0022 Criminal Punishment Code; offense severity ranking  
4173 chart.--

4174 (3) OFFENSE SEVERITY RANKING CHART

4175 (d) LEVEL 4  
4176

Florida Statute	Felony Degree	Description
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4177

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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4178

499.0051(1)	3rd	Failure to maintain or deliver pedigree papers.
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4179

499.0051(2)	3rd	Failure to authenticate pedigree papers.
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4180

499.0051(6)	2nd	<u>Knowing</u> sale or delivery, or possession with intent to sell, contraband
-------------	-----	--



836536

prescription ~~legend~~ drugs.

- 4181 784.07(2) (b) 3rd Battery of law enforcement officer,  
firefighter, intake officer, etc.
- 4182 784.074(1) (c) 3rd Battery of sexually violent predators  
facility staff.
- 4183 784.075 3rd Battery on detention or commitment  
facility staff.
- 4184 784.078 3rd Battery of facility employee by  
throwing, tossing, or expelling certain  
fluids or materials.
- 4185 784.08(2) (c) 3rd Battery on a person 65 years of age or  
older.
- 4186 784.081(3) 3rd Battery on specified official or  
employee.
- 4187 784.082(3) 3rd Battery by detained person on visitor  
or other detainee.
- 4188 784.083(3) 3rd Battery on code inspector.
- 4189 784.085 3rd Battery of child by throwing, tossing,  
projecting, or expelling certain fluids  
or materials.

4190



836536

4191	787.03 (1)	3rd	Interference with custody; wrongly takes minor from appointed guardian.
4192	787.04 (2)	3rd	Take, entice, or remove child beyond state limits with criminal intent pending custody proceedings.
4193	787.04 (3)	3rd	Carrying child beyond state lines with criminal intent to avoid producing child at custody hearing or delivering to designated person.
4194	790.115 (1)	3rd	Exhibiting firearm or weapon within 1,000 feet of a school.
4195	790.115 (2) (b)	3rd	Possessing electric weapon or device, destructive device, or other weapon on school property.
4196	790.115 (2) (c)	3rd	Possessing firearm on school property.
4197	800.04 (7) (d)	3rd	Lewd or lascivious exhibition; offender less than 18 years.
4198	810.02 (4) (a)	3rd	Burglary, or attempted burglary, of an unoccupied structure; unarmed; no assault or battery.
	810.02 (4) (b)	3rd	Burglary, or attempted burglary, of an unoccupied conveyance; unarmed; no





836536

4199			assault or battery.
4200	810.06	3rd	Burglary; possession of tools.
4201	810.08 (2) (c)	3rd	Trespass on property, armed with firearm or dangerous weapon.
4202	812.014 (2) (c) 3.	3rd	Grand theft, 3rd degree \$10,000 or more but less than \$20,000.
4203	812.014 (2) (c) 4.- 10.	3rd	Grand theft, 3rd degree, a will, firearm, motor vehicle, livestock, etc.
4204	812.0195 (2)	3rd	Dealing in stolen property by use of the Internet; property stolen \$300 or more.
4205	817.563 (1)	3rd	Sell or deliver substance other than controlled substance agreed upon, excluding s. 893.03 (5) drugs.
4206	817.568 (2) (a)	3rd	Fraudulent use of personal identification information.
4207	817.625 (2) (a)	3rd	Fraudulent use of scanning device or reencoder.
	828.125 (1)	2nd	Kill, maim, or cause great bodily harm or permanent breeding disability to any registered horse or cattle.



836536

4208	837.02 (1)	3rd	Perjury in official proceedings.
4209	837.021 (1)	3rd	Make contradictory statements in official proceedings.
4210	838.022	3rd	Official misconduct.
4211	839.13 (2) (a)	3rd	Falsifying records of an individual in the care and custody of a state agency.
4212	839.13 (2) (c)	3rd	Falsifying records of the Department of Children and Family Services.
4213	843.021	3rd	Possession of a concealed handcuff key by a person in custody.
4214	843.025	3rd	Deprive law enforcement, correctional, or correctional probation officer of means of protection or communication.
4215	843.15 (1) (a)	3rd	Failure to appear while on bail for felony (bond estreature or bond jumping).
4216	874.05 (1)	3rd	Encouraging or recruiting another to join a criminal street gang.
4217	893.13 (2) (a) 1.	2nd	Purchase of cocaine (or other s. 893.03 (1) (a), (b), or (d), (2) (a),



836536

4218			(2) (b), or (2) (c) 4. drugs).
4219	914.14 (2)	3rd	Witnesses accepting bribes.
4220	914.22 (1)	3rd	Force, threaten, etc., witness, victim, or informant.
4221	914.23 (2)	3rd	Retaliation against a witness, victim, or informant, no bodily injury.
4222	918.12	3rd	Tampering with jurors.
4223	934.215	3rd	Use of two-way communications device to facilitate commission of a crime.
4224	(f) LEVEL 6		
4225	Florida Statute	Felony Degree	Description
4226	316.193 (2) (b)	3rd	Felony DUI, 4th or subsequent conviction.
4227	499.0051 (3)	2nd	<u>Knowing</u> forgery of pedigree papers.
4228	499.0051 (4)	2nd	<u>Knowing</u> purchase or receipt of <u>prescription</u> <del>legend</del> drug from unauthorized person.
4229	499.0051 (5)	2nd	<u>Knowing</u> sale <u>or transfer</u> of <u>prescription</u>



836536

~~legend~~ drug to unauthorized person.

4230

775.0875(1) 3rd Taking firearm from law enforcement officer.

4231

784.021(1)(a) 3rd Aggravated assault; deadly weapon without intent to kill.

4232

784.021(1)(b) 3rd Aggravated assault; intent to commit felony.

4233

784.041 3rd Felony battery; domestic battery by strangulation.

4234

784.048(3) 3rd Aggravated stalking; credible threat.

4235

784.048(5) 3rd Aggravated stalking of person under 16.

4236

784.07(2)(c) 2nd Aggravated assault on law enforcement officer.

4237

784.074(1)(b) 2nd Aggravated assault on sexually violent predators facility staff.

4238

784.08(2)(b) 2nd Aggravated assault on a person 65 years of age or older.

4239

784.081(2) 2nd Aggravated assault on specified official or employee.

4240



836536

4241	784.082 (2)	2nd	Aggravated assault by detained person on visitor or other detainee.
4242	784.083 (2)	2nd	Aggravated assault on code inspector.
4243	787.02 (2)	3rd	False imprisonment; restraining with purpose other than those in s. 787.01.
4244	790.115 (2) (d)	2nd	Discharging firearm or weapon on school property.
4245	790.161 (2)	2nd	Make, possess, or throw destructive device with intent to do bodily harm or damage property.
4246	790.164 (1)	2nd	False report of deadly explosive, weapon of mass destruction, or act of arson or violence to state property.
4247	790.19	2nd	Shooting or throwing deadly missiles into dwellings, vessels, or vehicles.
4248	794.011 (8) (a)	3rd	Solicitation of minor to participate in sexual activity by custodial adult.
4249	794.05 (1)	2nd	Unlawful sexual activity with specified minor.
	800.04 (5) (d)	3rd	Lewd or lascivious molestation; victim 12 years of age or older but less than



836536

16 years; offender less than 18 years.

4250

800.04(6)(b) 2nd Lewd or lascivious conduct; offender 18 years of age or older.

4251

806.031(2) 2nd Arson resulting in great bodily harm to firefighter or any other person.

4252

810.02(3)(c) 2nd Burglary of occupied structure; unarmed; no assault or battery.

4253

812.014(2)(b)1. 2nd Property stolen \$20,000 or more, but less than \$100,000, grand theft in 2nd degree.

4254

812.014(6) 2nd Theft; property stolen \$3,000 or more; coordination of others.

4255

812.015(9)(a) 2nd Retail theft; property stolen \$300 or more; second or subsequent conviction.

4256

812.015(9)(b) 2nd Retail theft; property stolen \$3,000 or more; coordination of others.

4257

812.13(2)(c) 2nd Robbery, no firearm or other weapon (strong-arm robbery).

4258

817.034(4)(a)1. 1st Communications fraud, value greater than \$50,000.

4259



836536

4260	817.4821(5)	2nd	Possess cloning paraphernalia with intent to create cloned cellular telephones.
4261	825.102(1)	3rd	Abuse of an elderly person or disabled adult.
4262	825.102(3)(c)	3rd	Neglect of an elderly person or disabled adult.
4263	825.1025(3)	3rd	Lewd or lascivious molestation of an elderly person or disabled adult.
4264	825.103(2)(c)	3rd	Exploiting an elderly person or disabled adult and property is valued at less than \$20,000.
4265	827.03(1)	3rd	Abuse of a child.
4266	827.03(3)(c)	3rd	Neglect of a child.
4267	827.071(2)&(3)	2nd	Use or induce a child in a sexual performance, or promote or direct such performance.
4268	836.05	2nd	Threats; extortion.
4269	836.10	2nd	Written threats to kill or do bodily injury.



836536

4270	843.12	3rd	Aids or assists person to escape.
4271	847.0135(2)	3rd	Facilitates sexual conduct of or with a minor or the visual depiction of such conduct.
4272	914.23	2nd	Retaliation against a witness, victim, or informant, with bodily injury.
4273	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.
4274	944.40	2nd	Escapes.
4275	944.46	3rd	Harboring, concealing, aiding escaped prisoners.
4276	944.47(1)(a)5.	2nd	Introduction of contraband (firearm, weapon, or explosive) into correctional facility.
4277	951.22(1)	3rd	Intoxicating drug, firearm, or weapon introduced into county facility.
4278	(h)	LEVEL 8	
4279			

Florida                      Felony      Description





836536

	Statute	Degree	
4280	316.193 (3) (c) 3.a.	2nd	DUI manslaughter.
4281	316.1935 (4) (b)	1st	Aggravated fleeing or attempted eluding with serious bodily injury or death.
4282	327.35 (3) (c) 3.	2nd	Vessel BUI manslaughter.
4283	<u>499.0051 (8)</u> <del>499.0051 (7)</del>	1st	<u>Knowing</u> forgery of prescription labels or <u>prescription legend</u> drug labels.
4284	<u>499.0051 (7)</u> <del>499.0052</del>	1st	<u>Knowing</u> trafficking in contraband <u>prescription legend</u> drugs.
4285	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.
4286	560.125 (5) (b)	2nd	Money transmitter business by unauthorized person, currency or payment instruments totaling or exceeding \$20,000, but less than \$100,000.
4287	655.50 (10) (b) 2.	2nd	Failure to report financial transactions totaling or exceeding



836536

4288			\$20,000, but less than \$100,000 by financial institutions.
	777.03 (2) (a)	1st	Accessory after the fact, capital felony.
4289			
	782.04 (4)	2nd	Killing of human without design when engaged in act or attempt of any felony other than arson, sexual battery, robbery, burglary, kidnapping, aircraft piracy, or unlawfully discharging bomb.
4290			
	782.051 (2)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony not enumerated in s. 782.04 (3).
4291			
	782.071 (1) (b)	1st	Committing vehicular homicide and failing to render aid or give information.
4292			
	782.072 (2)	1st	Committing vessel homicide and failing to render aid or give information.
4293			
	790.161 (3)	1st	Discharging a destructive device which results in bodily harm or property damage.
4294			



836536

4295	794.011(5)	2nd	Sexual battery, victim 12 years or over, offender does not use physical force likely to cause serious injury.
4296	794.08(3)	2nd	Female genital mutilation, removal of a victim younger than 18 years of age from this state.
4297	800.04(4)	2nd	Lewd or lascivious battery.
4298	806.01(1)	1st	Maliciously damage dwelling or structure by fire or explosive, believing person in structure.
4299	810.02(2)(a)	1st,PBL	Burglary with assault or battery.
4300	810.02(2)(b)	1st,PBL	Burglary; armed with explosives or dangerous weapon.
4301	810.02(2)(c)	1st	Burglary of a dwelling or structure causing structural damage or \$1,000 or more property damage.
4302	812.014(2)(a)2.	1st	Property stolen; cargo valued at \$50,000 or more, grand theft in 1st degree.
4303	812.13(2)(b)	1st	Robbery with a weapon.
	812.135(2)(c)	1st	Home-invasion robbery, no firearm,



836536

4304			deadly weapon, or other weapon.
	817.568 (6)	2nd	Fraudulent use of personal identification information of an individual under the age of 18.
4305			
	825.102 (2)	2nd	Aggravated abuse of an elderly person or disabled adult.
4306			
	825.1025 (2)	2nd	Lewd or lascivious battery upon an elderly person or disabled adult.
4307			
	825.103 (2) (a)	1st	Exploiting an elderly person or disabled adult and property is valued at \$100,000 or more.
4308			
	837.02 (2)	2nd	Perjury in official proceedings relating to prosecution of a capital felony.
4309			
	837.021 (2)	2nd	Making contradictory statements in official proceedings relating to prosecution of a capital felony.
4310			
	860.121 (2) (c)	1st	Shooting at or throwing any object in path of railroad vehicle resulting in great bodily harm.
4311			
	860.16	1st	Aircraft piracy.
4312			



836536

4313	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).
4314	893.13(2)(b)	1st	Purchase in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4315	893.13(6)(c)	1st	Possess in excess of 10 grams of any substance specified in s. 893.03(1)(a) or (b).
4316	893.135(1)(a)2.	1st	Trafficking in cannabis, more than 2,000 lbs., less than 10,000 lbs.
4317	893.135(1)(b)1.b.	1st	Trafficking in cocaine, more than 200 grams, less than 400 grams.
4318	893.135(1)(c)1.b.	1st	Trafficking in illegal drugs, more than 14 grams, less than 28 grams.
4319	893.135(1)(d)1.b.	1st	Trafficking in phencyclidine, more than 200 grams, less than 400 grams.
4320	893.135(1)(e)1.b.	1st	Trafficking in methaqualone, more than 5 kilograms, less than 25 kilograms.
	893.135(1)(f)1.b.	1st	Trafficking in amphetamine, more than 28 grams, less than 200 grams.



836536

4321	893.135(1)(g)1.b.	1st	Trafficking in flunitrazepam, 14 grams or more, less than 28 grams.
4322	893.135(1)(h)1.b.	1st	Trafficking in gamma-hydroxybutyric acid (GHB), 5 kilograms or more, less than 10 kilograms.
4323	893.135(1)(j)1.b.	1st	Trafficking in 1,4-Butanediol, 5 kilograms or more, less than 10 kilograms.
4324	893.135(1)(k)2.b.	1st	Trafficking in Phenethylamines, 200 grams or more, less than 400 grams.
4325	895.03(1)	1st	Use or invest proceeds derived from pattern of racketeering activity.
4326	895.03(2)	1st	Acquire or maintain through racketeering activity any interest in or control of any enterprise or real property.
4327	895.03(3)	1st	Conduct or participate in any enterprise through pattern of racketeering activity.
4328	896.101(5)(b)	2nd	Money laundering, financial transactions totaling or exceeding \$20,000, but less than \$100,000.



836536

4329

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.

4330

4331            (i)    LEVEL 9

4332

Florida Statute	Felony Degree	Description
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4333

316.193 (3) (c) 3.b.	1st	DUI manslaughter; failing to render aid or give information.
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4334

327.35 (3) (c) 3.b.	1st	BUI manslaughter; failing to render aid or give information.
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4335

<u>499.0051 (9)</u> <del>499.00535</del>	1st	<u>Knowing</u> sale or purchase of contraband <u>prescription</u> <del>legend</del> drugs resulting in great bodily harm.
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4336

560.123 (8) (b) 3.	1st	Failure to report currency or payment instruments totaling or exceeding \$100,000 by money transmitter.
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4337

560.125 (5) (c)	1st	Money transmitter business by unauthorized person, currency, or payment instruments totaling or exceeding \$100,000.
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836536

4338	655.50(10)(b)3.	1st	Failure to report financial transactions totaling or exceeding \$100,000 by financial institution.
4339	775.0844	1st	Aggravated white collar crime.
4340	782.04(1)	1st	Attempt, conspire, or solicit to commit premeditated murder.
4341	782.04(3)	1st,PBL	Accomplice to murder in connection with arson, sexual battery, robbery, burglary, and other specified felonies.
4342	782.051(1)	1st	Attempted felony murder while perpetrating or attempting to perpetrate a felony enumerated in s. 782.04(3).
4343	782.07(2)	1st	Aggravated manslaughter of an elderly person or disabled adult.
4344	787.01(1)(a)1.	1st,PBL	Kidnapping; hold for ransom or reward or as a shield or hostage.
4345	787.01(1)(a)2.	1st,PBL	Kidnapping with intent to commit or facilitate commission of any felony.
4346	787.01(1)(a)4.	1st,PBL	Kidnapping with intent to interfere





836536

4347			with performance of any governmental or political function.
	787.02 (3) (a)	1st	False imprisonment; child under age 13; perpetrator also commits aggravated child abuse, sexual battery, or lewd or lascivious battery, molestation, conduct, or exhibition.
4348			
	790.161	1st	Attempted capital destructive device offense.
4349			
	790.166 (2)	1st, PBL	Possessing, selling, using, or attempting to use a weapon of mass destruction.
4350			
	794.011 (2)	1st	Attempted sexual battery; victim less than 12 years of age.
4351			
	794.011 (2)	Life	Sexual battery; offender younger than 18 years and commits sexual battery on a person less than 12 years.
4352			
	794.011 (4)	1st	Sexual battery; victim 12 years or older, certain circumstances.
4353			
	794.011 (8) (b)	1st	Sexual battery; engage in sexual conduct with minor 12 to 18 years by person in familial or custodial



836536

4354			authority.
	794.08 (2)	1st	Female genital mutilation; victim younger than 18 years of age.
4355			
	800.04 (5) (b)	Life	Lewd or lascivious molestation; victim less than 12 years; offender 18 years or older.
4356			
	812.13 (2) (a)	1st, PBL	Robbery with firearm or other deadly weapon.
4357			
	812.133 (2) (a)	1st, PBL	Carjacking; firearm or other deadly weapon.
4358			
	812.135 (2) (b)	1st	Home-invasion robbery with weapon.
4359			
	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.
4360			
	827.03 (2)	1st	Aggravated child abuse.
4361			
	847.0145 (1)	1st	Selling, or otherwise transferring custody or control, of a minor.
4362			
	847.0145 (2)	1st	Purchasing, or otherwise obtaining



836536

4363			custody or control, of a minor.
	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.
4364			
	893.135	1st	Attempted capital trafficking offense.
4365			
	893.135 (1) (a) 3.	1st	Trafficking in cannabis, more than 10,000 lbs.
4366			
	893.135 (1) (b) 1.c.	1st	Trafficking in cocaine, more than 400 grams, less than 150 kilograms.
4367			
	893.135 (1) (c) 1.c.	1st	Trafficking in illegal drugs, more than 28 grams, less than 30 kilograms.
4368			
	893.135 (1) (d) 1.c.	1st	Trafficking in phencyclidine, more than 400 grams.
4369			
	893.135 (1) (e) 1.c.	1st	Trafficking in methaqualone, more than 25 kilograms.
4370			
	893.135 (1) (f) 1.c.	1st	Trafficking in amphetamine, more than 200 grams.
4371			



836536

4372 893.135(1)(h)1.c. 1st Trafficking in gamma-hydroxybutyric acid (GHB), 10 kilograms or more.

4373 893.135(1)(j)1.c. 1st Trafficking in 1,4-Butanediol, 10 kilograms or more.

4374 893.135(1)(k)2.c. 1st Trafficking in Phenethylamines, 400 grams or more.

4375 896.101(5)(c) 1st Money laundering, financial instruments totaling or exceeding \$100,000.

4376 896.104(4)(a)3. 1st Structuring transactions to evade reporting or registration requirements, financial transactions totaling or exceeding \$100,000.

4377 (j) LEVEL 10

4378

Florida Statute	Felony Degree	Description
<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.
782.04(2)	1st,PBL	Unlawful killing of human; act is homicide, unpremeditated.

4381



836536

4382

787.01(1)(a)3. 1st,PBL Kidnapping; inflict bodily harm upon or  
terrorize victim.

4383

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.

4384

782.07(3) 1st Aggravated manslaughter of a child.

4385

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.

4386

812.135(2)(a) 1st,PBL Home-invasion robbery with firearm or  
other deadly weapon.

4387

876.32 1st Treason against the state.

4388

Section 44. This act shall take effect July 1, 2008.

4389

4390

===== T I T L E A M E N D M E N T =====

4391

And the title is amended as follows:

4392

Delete everything before the enacting clause

4393

and insert:

4394

A bill to be entitled

4395

An act relating to drugs, devices, and cosmetics; amending

4396

and reorganizing provisions in part I of ch. 499, F.S.;



836536

4397 | amending s. 499.002, F.S.; expanding the provisions of the  
4398 | section to include administration and enforcement of,  
4399 | exemptions from, and purpose of the part; amending and  
4400 | redesignating ss. 499.004, 499.0053, 499.07, 499.071, and  
4401 | 499.081, F.S., as provisions in that section relating to  
4402 | such functions to conform; amending s. 499.003, F.S.;  
4403 | revising and providing definitions; amending and  
4404 | redesignating provisions in ss. 499.012, 499.029, and  
4405 | 499.0661, F.S., relating to definitions, as provisions of  
4406 | that section; amending s. 499.005, F.S.; conforming  
4407 | provisions to changes made by the act, including the  
4408 | substitution of the term "prescription drug" for the term  
4409 | "legend drug"; amending s. 499.0051, F.S.; substituting  
4410 | the term "prescription drug" for the term "legend drug"  
4411 | with regard to criminal acts; consolidating criminal act  
4412 | provisions of part I of ch. 499, F.S.; amending and  
4413 | redesignating ss. 499.0052, 499.00535, 499.00545, 499.069,  
4414 | and 499.0691, F.S., as criminal offense provisions in that  
4415 | section; providing penalties; conforming provisions to  
4416 | changes made by the act; amending s. 499.0054, F.S.,  
4417 | relating to advertising and labeling of drugs, devices,  
4418 | and cosmetics to include certain exemptions; amending and  
4419 | redesignating ss. 499.0055 and 499.0057, F.S., as  
4420 | provisions relating to those functions in that section;  
4421 | amending s. 499.006, F.S.; conforming provisions to  
4422 | changes made by the act; amending s. 499.007, F.S.;  
4423 | conforming provisions to changes made by the act;  
4424 | providing that a drug or device is misbranded if it is an  
4425 | active pharmaceutical ingredient in bulk form and does not  
4426 | bear a label containing certain information; amending ss.



836536

4427 | 499.008 and 499.009, F.S.; conforming provisions to  
4428 | changes made by the act; amending s. 499.01, F.S.;  
4429 | providing that the section relates only to permits;  
4430 | requiring a permit to operate as a third party logistics  
4431 | provider and a health care clinic establishment; providing  
4432 | requirements for obtaining a permit to operate in certain  
4433 | capacities; deleting certain permit requirements;  
4434 | providing an exemption for a nonresident prescription drug  
4435 | manufacturer permit; providing requirements for such  
4436 | exemption; providing requirements for a third party  
4437 | logistics provider permit and a health care clinic  
4438 | establishment permit; amending and redesignating  
4439 | provisions of ss. 499.013, and 499.014, F.S., relating to  
4440 | such functions as provisions of that section; conforming  
4441 | provisions and cross-references to changes made by the  
4442 | act; amending s. 499.012, F.S.; providing that the section  
4443 | relates to permit application requirements; providing that  
4444 | a separate establishment permit is not required when a  
4445 | permitted prescription drug wholesale distributor operates  
4446 | temporary transit storage facilities for the sole purpose  
4447 | of storage; amending the provisions to conform; amending  
4448 | and redesignating provisions of s. 499.01, F.S., relating  
4449 | to such functions as provisions of that section;  
4450 | conforming provisions and cross-references to changes made  
4451 | by the act; amending s. 499.01201, F.S.; conforming  
4452 | provisions to changes made by the act; amending s.  
4453 | 499.0121, F.S., relating to storage and handling of  
4454 | prescription drugs and recordkeeping; directing the  
4455 | department to adopt rules requiring a wholesale  
4456 | distributor to maintain pedigree papers separate and



836536

4457 distinct from other required records; deleting a  
4458 requirement that a person who is engaged in the wholesale  
4459 distribution of a prescription drug and who is not the  
4460 manufacturer of that drug provide a pedigree paper to the  
4461 person who receives the drug; deleting the department's  
4462 requirement to adopt rules with regard to recordkeeping by  
4463 affiliated groups; conforming provisions and cross-  
4464 references to changes made by the act; amending and  
4465 redesignating a provision of s. 499.013, F.S., relating to  
4466 such functions as a provision of that section; amending s.  
4467 499.01211, F.S.; conforming provisions and cross-  
4468 references to changes made by the act; creating s.  
4469 499.01212, F.S.; requiring a person who is engaged in the  
4470 wholesale distribution of a prescription drug to provide a  
4471 pedigree paper to the person who receives the drug;  
4472 requiring certain information in a pedigree paper;  
4473 requiring a wholesale distributor to maintain and make  
4474 available to the department certain information; providing  
4475 exceptions to the requirement of a pedigree paper;  
4476 repealing s. 499.0122, F.S., relating to medical oxygen  
4477 and veterinary legend drug retail establishments;  
4478 repealing s. 499.013, F.S., relating to manufacturers and  
4479 repackagers of drugs, devices, and cosmetics; amending ss.  
4480 499.015, 499.024, 499.028, 499.029, and 499.03, F.S.;  
4481 conforming provisions and cross-references to changes made  
4482 by the act; amending ss. 499.032 and 499.033, F.S.;  
4483 conforming terminology to changes made by the act;  
4484 amending s. 499.039, F.S.; conforming a provision and  
4485 cross-reference; amending ss. 499.04, F.S.; conforming  
4486 provisions to changes made by the act; amending s.





836536

4487 | 499.041, F.S.; conforming provisions to changes made by  
4488 | the act; requiring the department to assess an annual fee  
4489 | for a third part logistic provider permit and a health  
4490 | care clinic establishment permit; amending s. 499.05,  
4491 | F.S.; conforming provisions to changes made by the act;  
4492 | requiring the department to adopt rules with regard to  
4493 | procedures and forms relating to pedigree paper  
4494 | requirements, alternatives to compliance with the  
4495 | requirement of certain pedigree papers, and the return of  
4496 | prescription drugs purchased before a specified date;  
4497 | amending and redesignating provisions of ss. 499.013 and  
4498 | 499.0122, F.S., as provisions relating to rulemaking  
4499 | functions of that section; amending ss. 499.051, 499.052,  
4500 | 499.055, and 499.06, F.S.; conforming provisions to  
4501 | changes made by the act; amending s. 499.062, F.S.;  
4502 | providing that the section relates to seizure and  
4503 | condemnation of drugs, devices, or cosmetics; conforming a  
4504 | provision to changes made by the act; amending and  
4505 | redesignating ss. 499.063 and 499.064, F.S., as provisions  
4506 | relating to such functions in that section; amending ss.  
4507 | 499.065, 499.066, 499.0661, and 499.067, F.S.; conforming  
4508 | provisions and cross-references to changes made by the  
4509 | act; amending ss. 409.9201, 460.403, 465.0265, 794.075,  
4510 | 895.02, and 921.0022, F.S.; conforming provisions to  
4511 | changes made by the act; conforming cross-references to  
4512 | changes made by the act; providing an effective date.